Matériel orthopédique en Belgique
Health Technology Assessment

KCE reports vol. 56B

Federaal Kenniscentrum voor de Gezondheidszorg
Centre fédéral d'expertise des soins de santé
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Titre : Matériel orthopédique en Belgique: Health Technology Assessment

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PREFACE

Les coûts à charge de l'assurance maladie en matière de matériel orthopédique dans les soins ambulatoires sont relativement peu importants. Néanmoins, un examen approfondi de ce marché s'avérait utile compte tenu du peu de transparence qui caractérise ce secteur. Cette étude, demandée par l'INAMI, s'inscrit dans la lignée d'autres projets réalisés par le KCE dans le domaine du Health Technology Assessment, comme ceux sur le matériel de stomie ou sur la procédure d'évaluation des dispositifs médicaux émergents.

Même si l'analyse contenue dans ce rapport est restée limitée aux produits préfabriqués pour le cou, le genou et le poignet, elle débouche sur des résultats intéressants.

Tout d'abord, la vérification de l'utilité de ce type de matériel à partir de données probantes issues d'une revue systématique de la littérature, constitue un travail de pionnier étant donné le nombre limité d'études comparatives dans ce domaine.

Ensuite, l'étude comparative des législations et des prix pratiqués dans d'autres pays fait apparaître des différences considérables. On découvre ainsi que les entreprises belges, abritées par une politique qui laisse peu de place aux mécanismes de marché, bénéficient d'avantages sans doute anormaux.

Enfin, comme dans des études précédentes du KCE, l'étude compare les prix observés aux prix qui découlent d'un modèle de coût de production pour deux produits spécifiques pour lesquels il existe des indications cliniques.

Chaque dépense imputée au budget de l'assurance maladie qui n'est pas justifiée, d'un point de vue médical ou économique, a des conséquences possibles sur l'introduction de nouveaux produits innovateurs et les petits ruisseaux font les grandes rivières. Nous avons l'impression que le secteur du matériel orthopédique en Belgique – et notre pays n'est d'ailleurs pas le seul concerné – reste encore une boîte noire. Nous espérons que ce rapport puisse aider à lever le voile et permette ainsi des choix plus appropriés.

Jean-Pierre CLOSON
Directeur général adjoint

Dirk RAMAEKERS
Directeur général

RÉSUMÉ

OBJECTIF DE L'ETUDE

Ce rapport est une étude de type Health Technology Assessessment dont l'objet est l'efficacité et le coût-efficacité des orthèses ainsi que les aspects organisationnels apparentés, examiné du point de vue de l'assurance maladie belge. Notre champ d'investigation s'est limité aux orthèses préfabriquées utilisées dans le secteur ambulatoire pour le cou, le poignet et le genou. Cette limitation aux dispositifs médicaux préfabriqués s'explique par deux facteurs (1) le choix de produits homogènes caractérisés par des échelles de production importantes et largement standardisées autorise des analyses comparatives et (2) pour les trois catégories de dispositifs médicaux considérés, la grande majorité des dépenses facturées à l'assurance maladie est attribuée aux produits préfabriqués.

Le remboursement par l'assurance-maladie dans le secteur des soins orthopédiques ambulatoires se chiffrait à environ 95 millions Euro en 2005 (environ 0,5% du budget soins de santé de l'INAMI). Le marché des produits préfabriqués représentait environ ¼ de ces dépenses et il est dominé principalement par les orthèses préfabriquées du genou (environ 10 millions Euro). Les dépenses de l'assurance maladie pour les orthèses du cou et du poignet étaient respectivement de 0,8 million Euro et de 0,6 million Euro.

Même si ce secteur de l'assurance maladie est relativement moins important en termes de dépenses que d'autres, une analyse détaillée du fonctionnement du marché des dispositifs médicaux, restreinte à trois catégories spécifiques d'orthèses seulement, semble être nécessaire pour différentes raisons. Tout d'abord, le marché des orthèses souffre de plusieurs défauts tels le manque de transparence et l'influence limitée des mécanismes de marché dans la fixation des prix pour les produits vendus en Belgique. De plus, le remboursement appliqué découle de la nomenclature basée sur une description technique/typologique établie en 1992. Enfin, le droit au remboursement de certains produits n'est pas soumis à des conditions limitatives comme le respect d'indications cliniques ou la justification préalable d'une étude coût efficacité.

QUESTIONS DE RECHERCHE

Les questions de recherche abordées dans ce rapport sont :

- Quelles sont les données scientifiques sur l'efficacité et le rapport coût-efficacité des orthèses du cou, du poignet et du genou ?
- Quelle est la structure de prix de ces trois types d'orthèses sur le marché belge ?
- Comment peut-on analyser empiriquement le fonctionnement du marché dans ses aspects institutionnels (réglementaires), économiques et organisationnels ?

METHODOLOGIE

La méthodologie utilisée dans ce rapport suit les étapes classiques d'un Health Technology Assessment.

- La revue systématique de littérature s'est focalisée sur les coûts, l'efficacité et le rapport coût-efficacité des trois groupes de produits sélectionnés. Il existe une littérature médicale considérable qui est disponible sur ces sujets mais relativement peu d'analyses de coût et d'analyses de coût efficacité. La littérature médicale tente de trouver réponse à deux questions :
  - Quelles sont les indications cliniques (contre-indications) pour chaque groupe de produits qui sont dérivées des études cliniques comparant un dispositif médical avec une alternative «de ne rien faire » ?
  - Quelle est l'efficacité relative des différents types de produits appartenant à une même catégorie d'orthèses qui découle des études cliniques comparant différents produits ?

Une information complémentaire concernant les éventuelles études cliniques en cours a été demandée aux producteurs les plus importants.

- Une analyse institutionnelle du marché des orthèses décrit les aspects réglementaires (fixation des prix, remboursement, fourniture et canaux de distribution ainsi que le comportement de prescription des orthèses) en Belgique et dans cinq autres pays (Angleterre (Royaume-Uni), France, Pays-Bas, Ontario (Canada) et Suède). Comme la revue de littérature fournissait insuffisamment de publications sur le cadre réglementaire, cette information provient d'une analyse des textes légaux et de l'interprétation des résultats d'une enquête.
- Le marché belge des orthèses a été examiné en détail et un aperçu général des marchés mondiaux et européens est également esquissé. Comme les chiffres sur le marché belge des orthèses manquent en l'absence d'un enregistrement officiel, le marché belge a été analysé via différentes approches, avec la collaboration des associations professionnelles :
  - une enquête a été envoyée aux orthopédistes afin de lister les produits spécifiques représentatifs du marché belge ;
  - une enquête a été envoyée aux distributeurs principaux afin d'obtenir les chiffres relatifs aux volumes de vente par produit ventilés selon les codes nomenclature distincts ;
  - une analyse des dépenses comptabilisées par l'INAMI par code nomenclature a été effectuée afin d'évaluer le profil des patients (selon l'âge et le sexe) et la répartition géographique de l'utilisation des orthèses ;
  - des interviews des distributeurs principaux ont été effectués afin d'avoir une meilleure compréhension des aspects organisationnels pertinents.
- Une comparaison internationale des prix a été réalisée dans les mêmes pays que ceux discutés dans l'analyse institutionnelle afin d'avoir une meilleure compréhension des coûts supportés par l'assurance maladie et des prix payés par le patient pour les

orthèses vendues sur le marché belge et définies dans notre projet. La Suède n'a pas été reprise dans cette analyse en raison d'un manque de données pertinentes. L'objectif était de collecter les prix du marché pratiqués à l'étranger pour chaque fois trois produits (ou marques) par code nomenclature sélectionné afin de permettre une comparaison avec les prix belges. Le prix de marché est défini comme le total du remboursement par des tiers et de la contribution personnelle du patient, y compris d'éventuelles taxes.

- Sur base des résultats recueillis grâce à la revue de littérature scientifique, un modèle de coût de production a été développé pour les classes de produits des orthèses rigides du genou et des orthèses rigides du cou, à savoir respectivement le Donjoy 4 titude et le Jerome Miami J. collar.
- Les conclusions de tous les chapitres ont été résumées dans une synthèse en mettant en perspective les différents résultats de ce rapport. La discussion qui en découle souligne les points principaux d'amélioration du système belge actuel.
- En fin de compte, toutes les analyses précédentes ont été combinées afin de formuler les recommandations aux décideurs.

RESULTATS

CONNAISSANCES SCIENTIFIQUES

La revue de la littérature scientifique sur l'efficacité, les coûts et le rapport coût-efficacité des orthèses du poignet, du cou et du genou fournit les indications suivantes pour l'utilisation adéquate de ces dispositifs médicaux.

- Les indications cliniques pour l'utilisation des orthèses du poignet sont : le syndrome du tunnel carpien, l'arthrite rhumatoïde et l'ostéoarthrite débutante. Pour les autres pathologies, l'utilisation d'une orthèse n'est pas recommandée puisqu'il n'y a pas de valeur thérapeutique ajoutée ou que les preuves cliniques disponibles sont insuffisantes.
- Il existe deux types de dispositifs médicaux pour le cou et le genou: les orthèses souples et rigides. Sur base de la littérature fondée sur les données probantes, seule l'utilisation des orthèses rigides est indiquée dans des cas spécifiques.
- L'utilisation d'une orthèse rigide du cou est indiquée dans le traitement de la fracture cervicale et lors de l'immobilisation de la colonne vertébrale pour les patients traumatisés.
- Les orthèses rigides du genou sont recommandées pour le traitement de l'ostéoarthrite du compartiment médian du genou et les lésions touchant les ligaments collatéraux médians du genou. Une orthèse fonctionnelle du genou peut être indiquée pour les blessures au ligament croisé antérieur du genou qui sont traitées sans intervention chirurgicale.

LE CONTEXTE INSTITUTIONNEL

La comparaison de la Belgique avec les autres pays (Pays-Bas, France, Royaume-Uni (Angleterre), Suède et Canada (Ontario) illustre la place particulière qu'occupe la Belgique sur le marché international.

- Contrairement aux autres pays, un produit qui est introduit sur le marché belge n'est soumis à aucune condition pour être remboursé, à part son enregistrement auprès de l'Agence Fédérale des Médicaments et des Produits de Santé.
- Les prix belges pour les orthèses sont élevés par rapport à ceux des autres pays bien qu'ils soient fixés librement par le marché comme en France, en Angleterre et aux Pays-Bas. En Belgique, il n'existe pas de mécanismes de marché comme des procédures publiques d'achat et des avis de marché public (c'est le cas respectivement en Suède et en Angleterre). Les assureurs n'opèrent pas non plus dans un environnement compétitif de marché comme aux Pays-Bas. En France, les tarifs de remboursement sont considérablement inférieurs aux prix du marché des produits les plus chers étudiés dans notre projet. L'Ontario présente un exemple de fonctionnement complètement libre du marché étant donné qu'il n'y a pas de règle de remboursement pour les orthèses préfabriquées. Il faut sans doute voir dans les tarifs de remboursement belges relativement élevés l'explication des niveaux de prix observés dans notre pays.
- Contrairement aux procédures en place pour le remboursement des médicaments en Belgique, l'introduction d'un dispositif médical sur le marché belge n'est pas soumise à des critères comme la justification du rapport coût-efficacité.. En Angleterre, en France et aux Pays-Bas, le remboursement est dépendant des résultats d'une analyse d'efficacité, de coût ou de coût-efficacité.
- En Belgique, tout comme en Angleterre, le remboursement du matériel orthopédique n'est pas lié à des critères médicaux stricts concernant le patient (comme par exemple une limitation aux patients chroniques). Jusqu'à présent, l'utilisation d'une liste limitative d'orthèses spécifiques par classe distincte de produits n'est pas envisagée.

ANALYSE DE MARCHE ET COMPARAISON DES PRIX

L'analyse du marché belge et la comparaison internationale des prix est basée sur une sélection de 6 codes nomenclature : l'orthèse préfabriquée rigide du genou (code 647592), la genouillère, en tissu souple, en néoprène ou non, renforcée de baleines (code 647555), la genouillère en tissu ou tissu élastique ou en néoprène, renforcée par du métal (code 647533), l'orthèse préfabriquée rigide du cou (code 645212) , l'orthèse préfabriquée souple du cou (code 645175) et le bandage préfabriqué du poignet (code 649434). Les différents produits qui sont comptabilisés sous ces codes, ont été recherchés et comparés sur le marché belge et sur le marché international. En ce qui concerne le marché belge, l'analyse s'est focalisée sur les fabricants, les distributeurs principaux, les orthopédistes, les volumes de vente, les prix du marché et les tarifs de remboursement ainsi que le profil des patients.

En général, la Belgique est caractérisée par des prix de marché qui sont plus élevés que les prix trouvés à l'étranger pour les mêmes produits. Pour illustrer cette différence, les coûts totaux ont été recalculés en appliquant aux volumes de marché en Belgique les prix de marché pratiqués à l'étranger. On observe alors que le coût total du groupe des produits comparés diminuerait de 25% si on appliquait en Belgique les prix hollandais et de 44% si on appliquait les prix canadiens.

LE MODELE DES COÛTS DE PRODUCTION

Un modèle des coûts de production a été développé pour deux produits qui appartiennent à la catégorie des orthèses rigides du genou et des orthèses rigides du cou, à savoir respectivement le Donjoy 4 titude et le Jerome Miami J. collar. Le prix estimé de marché pour l'orthèse rigide du genou serait compris entre 331€ et 523€; ce prix estimé est sensiblement inférieur au prix observé sur le marché belge (environ 950 €) et au tarif de remboursement (817€ et 580€ respectivement pour le tarif préférentiel et le tarif ordinaire). Le prix de marché le plus bas trouvé pour ce produit se montait environ à 550€ (Royaume-Uni).

Le prix estimé de marché pour l'orthèse rigide du cou est compris entre 55€ et 113€; sensiblement inférieur au prix observé sur le marché belge (environ 240€) et au tarif de remboursement (260€ et 194€ respectivement pour le tarif préférentiel et le tarif ordinaire). Le prix de marché le plus bas trouvé pour ce produit se montait environ à environ 100€ aux Pays-Bas et au Canada.

CONCLUSION ET RECOMMANDATIONS

Le présent rapport met en lumière l'absence de fondements scientifiques au rapport coût-efficacité de la majorité des orthèses vendues en Belgique et remboursées par l'assurance maladie. Les mécanismes de marché ne semblent pas jouer leur rôle. Les prix observés en Belgique sont sensiblement supérieurs à ceux que l'on rencontre à l'étranger pour les mêmes produits. Sur base de ces constatations, le Centre Fédéral d'Expertise des Soins de Santé formule les recommandations suivantes pour le remboursement des orthèses préfabriquées dans le secteur ambulant :

- Afin de promouvoir une transparence plus grande des prix et l'impartialité des orthopédistes dans le choix du produit, les tarifs actuels de remboursement devraient être scindés en deux tarifs forfaitaires :
  - un tarif forfaitaire qui couvre l'acte intellectuel de l'orthopédiste relatif au choix judicieux du produit, à l'avis donné au patient et au suivi de celui-ci. Il pourrait être envisagé que ce forfait soit identique pour tous les dispositifs médicaux préfabriqués.
  - Un tarif forfaitaire qui couvre le coût directement lié à l'orthèse fournie. Ce remboursement peut être identique dans le groupe de dispositifs médicaux qui sont semblables en termes d'indications cliniques, de matériel etc,… comme c'est le cas actuellement dans le cadre de la nomenclature.

  Cette nouvelle procédure aurait pour conséquence que le coefficient Walkiers utilisé actuellement afin de déterminer les tarifs de remboursement, ne serait plus d'application.
- En vue de garantir que le remboursement forfaitaire des produits ne diverge pas substantiellement (à la hausse ou à la baisse) du prix de marché attendu dans un environnement compétitif, deux options politiques possibles sont proposées et elles peuvent être directement appliquées dans le contexte belge : (1) l'utilisation d'une comparaison internationale des prix des produits impliqués qui serait réalisée de manière périodique et (2) un avis de marché public organisé par l'INAMI.
  - Proposition 1 : une comparaison internationale des prix

    Une comparaison internationale, telle que celle contenue dans ce rapport, des prix des différents produits qui entrent dans une même catégorie pourrait être réalisée périodiquement. Les dispositifs médicaux préfabriqués vendus le plus souvent (et faisant l'objet d'un remboursement public), ventilés par catégorie, doivent être listés dans un groupe représentatif de produits afin de servir de base de comparaison. Les tarifs de remboursement appliqués seraient par conséquent revus en fonction de cette comparaison de prix. Les tarifs de remboursement des groupes de produits pour lesquels les prix moyens de marché trouvés dans les autres pays divergent sensiblement des tarifs appliqués en Belgique doivent être adaptés. Si des variations importantes de prix du marché sont observées entre les pays étrangers pour des produits appartenant au même groupe, ceci peut indiquer que plusieurs tarifs spécifiques sont nécessaires pour des sous-groupes à l'intérieur de la catégorie comparée en question. En correspondance avec la

comparaison des prix présentée dans notre rapport, une révision des tarifs actuels de remboursement devrait être considérée pour les dispositifs médicaux étudiés dans ce projet suivant la procédure esquissée ci-dessus.

- Proposition 2 : l'avis de marché public

  Un avis de marché public peut être organisé par l'INAMI pour tous les produits momentanément remboursés selon la nomenclature et pour les autres produits à condition qu'ils satisfassent certains critères. L'INAMI spécifierait les caractéristiques techniques et médicales pour toutes les catégories distinctes d'orthèses. Comme condition prérequise, chaque code nomenclature doit être constitué de produits comparables. A l'intérieur de chaque catégorie de produit, le tarif de remboursement serait déterminé par le prix offert par la firme qui remporterait le marché public. Les autres produits appartenant à cette même catégorie d'orthèses ne bénéficieraient plus de remboursement ou seraient remboursés à un tarif inférieur à celui de la firme qui a emporté le marché.

- Aucune procédure n'est prévue pour évaluer les indications cliniques des orthèses, et du matériel orthopédique en général, dans le secteur ambulatoire qui entrent en ligne de compte pour le remboursement public. Ce rapport montre que la législation actuelle est, à cet égard, quelque peu défaillante puisque la revue de littérature clinique a mis en évidence certaines indications (contre indications) pour l'utilisation des orthèses du poignet, du cou et du genou. De plus, la plupart des autres pays prennent en considération l'efficacité clinique et le rapport coût-efficacité comme condition au remboursement public. La nomenclature devrait être révisée afin d'intégrer des critères transparents et objectifs ayant trait à l'efficacité et au rapport coût-efficacité.

- Jusqu'à présent, les produits vendus en Belgique ne font pas l'objet d'une garantie légale. La seule certitude que le patient puisse avoir en ce qui concerne la sécurité du produit est son enregistrement en tant que matériel médical auprès de l'Agence Fédérale pour les Médicaments et les Produits de Santé. La nouvelle procédure qui est développée ici sur base des recommandations devrait s'accompagner de mesures strictes afin de garantir la qualité des orthèses comme c'est le cas pour n'importe quel autre bien de consommation.

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1 INTRODUCTION

1.1 GENERAL SCOPE

1.1.1 Outline

The present report focuses on the cost-effectiveness of orthotic devices as well as on related aspects of healthcare delivery from a Belgian public payer standpoint.

Orthotic devices can be defined as "appliances or apparatus' used to support, align, prevent, or correct deformities or to improve the function of movable parts of the body". We will refer to recognized[1] health professionals involved in the selection, measurement, manufacturing and delivery of orthotic products as "orthotists". Specialist physicians in the field of orthopaedics will be referred to as "orthopaedicians".

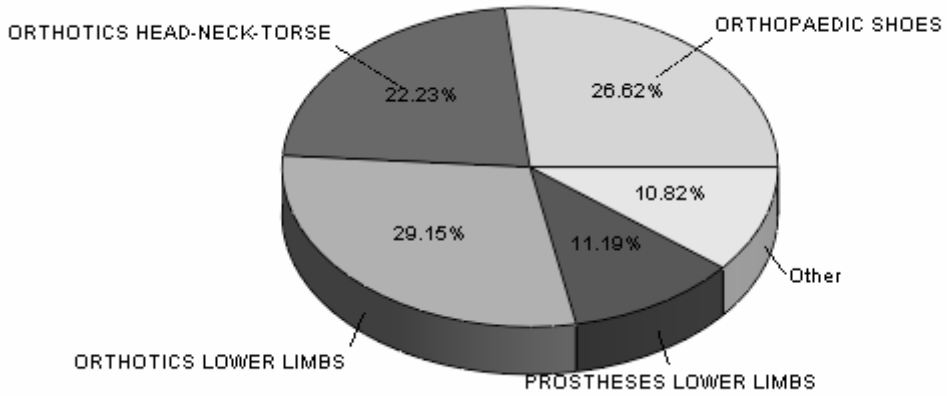
The use of knee braces, wrist braces and neck braces in publicly reimbursed outpatient care will be addressed. Lists of billing codes delimiting the report's general scope are included in appendix I.

1.1.2 Background

1.1.2.1 Outpatient orthopaedic devices: general overview

The overall RIZIV/INAMI[2] budget for outpatient orthopaedic devices added up to around 95.000.000€ in 2005 (or around 0,5% of all publicly reimbursed health care).The break-down in percentages of this amount by main device categories is depicted in Figure 1, orthotic devices account for the largest part of overall expenses, followed by orthopaedic shoes and prostheses[3]

Figure 1 : Percentage of booked expenses (reimbursements, 2005 €)



Source: Billing Data "N-Codes" RIZIV/INAMI

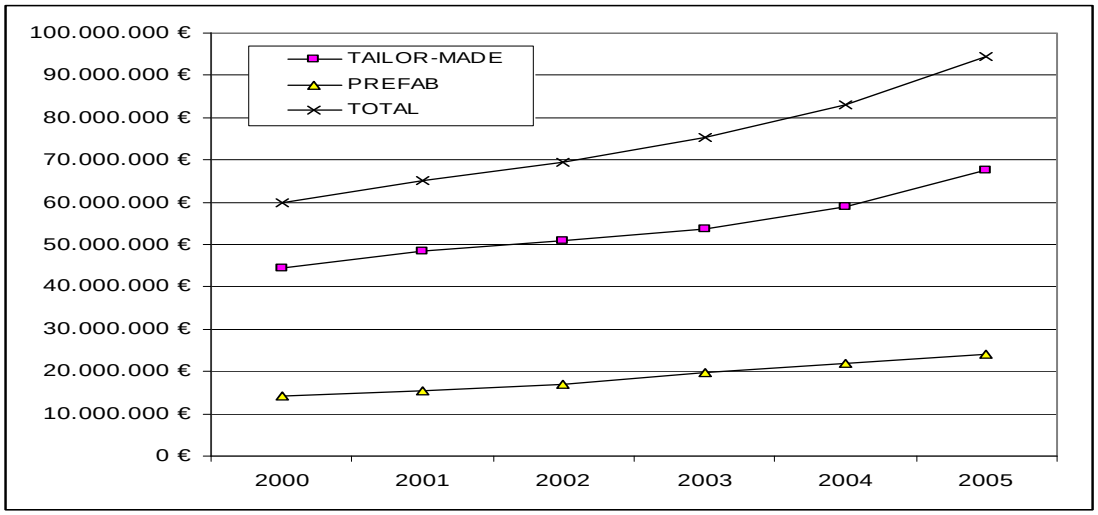
In all, some 26% of booked public reimbursements of outpatient orthopaedic devices in 2005 pertain to prefabricated devices (as indicated in the related billing fee description). A further 71% relate to (partially) tailor-made devices with 3% of public expenses booked by billing fee codes not distinguishing between prefab/tailor-made.

As shown by Figure 2, the stake held by prefab devices in the overall budget over the period 2000-2005 remains more or less stable at 25%.

---

1 Recognized as entitled to provide RIZIV/INAMI reimbursed care
2 Belgian public payer (third party)
3 artificial devices used to replace a missing body part

Figure 2 : Evolution of RIZIV-INAMI budget (€) for outpatient orthopaedic devices, broken down by distinction prefab / tailor-made.

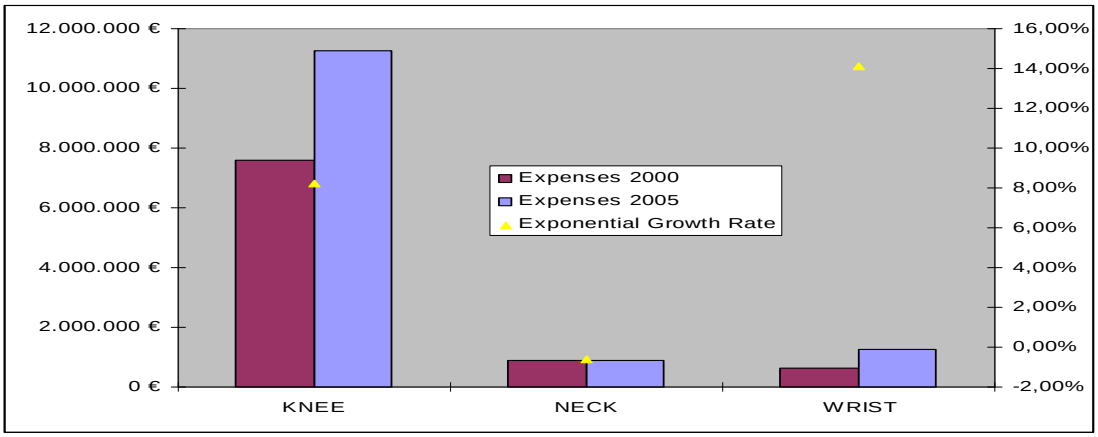


Source: Billing Data "N-Codes" RIZIV/INAMI

1.1.2.2 Outpatient orthopaedic devices: scope

Figure 3 applies to the public expenses for all orthotic devices in the respective categories of knee, neck and wrist braces. It can be observed that knee orthoses are the most prominent category among these categories from a budgetary viewpoint. As such, these devices account for around 12% of the overall outpatient budget for orthopaedic devices both in 2000 and 2005. The share represented by neck braces has declined[4] over the same period whilst the budgetary impact of wrist braces and neck braces has increased dramatically.

Figure 3 : Expenses by type of orthotic device



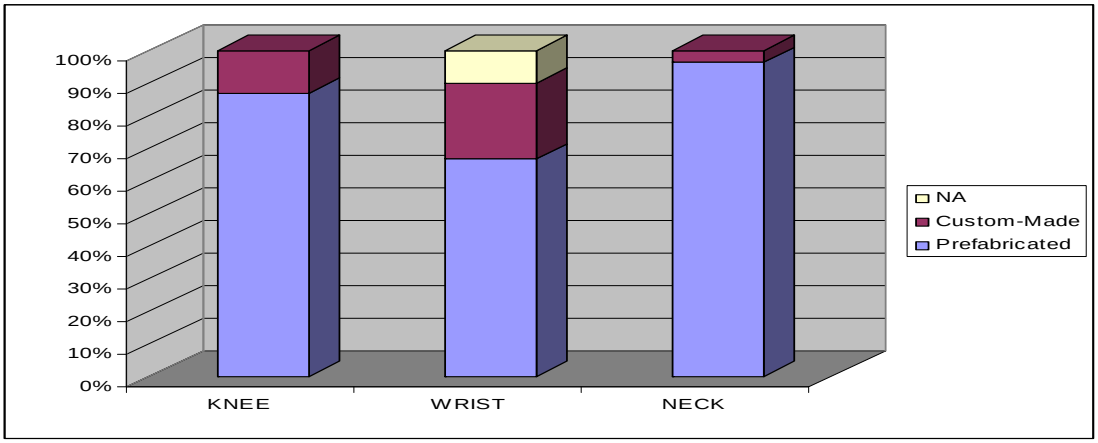
Source: Billing Data "N-Codes" RIZIV/INAMI

Within the three selected device categories prefabricated or "off-the-shelve" products as compared to custom-made products make up the vast majority of booked expenses (cf. figure 4).

---

4 The reimbursement for billing code 645175 (flexible neck braces) has been cut with over 50% as of September 1st 2004.

Figure 4 : Expenses (2005) for orthotic device categories by type of product as identified billing code label.



Source: Billing Data "N-Codes" RIZIV/INAMI

The report's more detailed analyses at the specific product level will be limited to prefabricated devices as these allow more readily for international comparisons and a straightforward description of devices' production cycles. A list of billing codes delimiting the report's specified scope is included in the appendix to this chapter.

1.2 GENERAL METHODOLOGY

This research follows a Health Technology Assessment (HTA) approach. The purpose is to support the process of decision making in health care at policy level by providing reliable information. A HTA collects and analyzes evidence in a systematic and reproducible way (and organizes it in an accessible and usable way for the decision makers). The principles of gathering, analyzing and using information are identical to the principles of Evidence Based Medicine (EBM) and Clinical Practice guidelines (GCP), but the purpose is different. EBM and GCP aim to support decision making at individual clinical or patient group level. In contrast, HTA aims to support decision making at policy level, leading to a different kind of recommendations and answers.

1.3 OBJECTIVES AND METHODS

The main objectives of this health technology assessment are:

- To assess the scientifically established cost-effectiveness of the selected orthotic device categories. This will be done through a critical appraisal of the clinical and economic literature on the subject.
- To assess the price structure for prefabricated orthotic devices and their utilisation on the Belgian market. This will be done through:
    - An international price comparison of selected devices. Furthermore, a production cost analysis will be performed for two particular devices, allowing then to estimate the value chain applying to Belgium.
    - An international comparison of the main institutional factors driving the market for orthopaedic devices.

1.4 FURTHER STRUCTURE OF THE REPORT

The next chapters are structured as follows:

- Chapter II contains a critical appraisal of the scientific literature on (cost-)effectiveness.
- Chapter III deals with an international comparison of policy regulations on orthopaedic devices.
- Chapter IV offers a market analysis for orthoses in Belgium and clarifies the set-up of the final product scope.
- Chapter V contains an international price comparison for the selected orthotic devices in the final product scope.
- Chapter VI offers an analysis of the production cycle for two selected orthotic devices, chosen from the product scope.
- Chapter VII contains a general discussion combining findings from preceding chapters.
- Chapter VIII contains policy recommendations.
- Chapter IX lists the scientific publications referenced in Chapter II.

Key points

- **The present report focuses on the cost-effectiveness of prefabricated knee braces, wrist braces and neck braces in publicly reimbursed outpatient care, as well as on related aspects of healthcare delivery in the Belgian context.**
- **The three selected categories of orthotic devices account for approximately 12% of a total budget for outpatient orthopaedic devices of around 95 million euro in 2005.**
- **Prefabricated ("off-the-shelve") devices hold a stake of around 25% in overall expenses for outpatient orthopaedic devices. For the three selected device categories they make up approximately 80% of expenses. The analyses at the specific product level will be limited to prefabricated devices as this allows for a more straightforward international price comparison and production cost estimation.**
- **The cost-effectiveness of the selected orthotic device categories will be assessed through a critical appraisal of the clinical and economic literature on the subject.**
- **The price structure and value chain for prefabricated orthotic devices on the Belgian market will be evaluated through an international price comparison and production cost analysis for selected devices.**
- **An international comparison of the main institutional factors driving the market for orthopaedic devices will further complement the above analyses and help to inspire policy recommendations.**

2 SCIENTIFIC BACKGROUND

2.1 INTRODUCTION

The previous chapter introduced readers to the various topics that this study addresses. Furthermore, the scope of the report was set and priorities were elucidated. The types of orthotic devices that were selected for further review, are now submitted to an exhaustive analysis of available scientific literature.

There is an extensive medical literature evaluating orthotic devices. The medical literature focuses on the biomechanical properties of devices, the use of devices in specific pathologies, and the comparison of devices with other treatment approaches (e.g. patient education, physical therapy and exercise, drug treatment, surgical treatment, alternative treatment). Studies exploring the biomechanical properties of devices and studies comparing devices with other treatment approaches fall outside the scope of this report and are not considered. There are few cost and cost-effectiveness analyses.

The aim of this chapter is to report scientific evidence on the costs, effectiveness and cost-effectiveness of cervical, wrist and knee braces. The small literature on costs and cost-effectiveness of orthotic devices is summarized. With respect to the effectiveness literature, two research questions are posed. First, what are the clinical indications for each device category (cervical / wrist / knee braces)? The answer to this question is derived from clinical studies that compare a device with a 'do nothing' alternative. Second, what is the relative effectiveness of various types of devices within each device category? This is based on clinical studies that contrast clinical outcomes of different types of devices.

Key points

- **This chapter summarizes and appraises evidence on the effectiveness of cervical, wrist and knee braces by examining:**
  - **what are the clinical indications for each device**
  - **category as derived from clinical studies comparing a device**
  - **with a 'do nothing' alternative;**
  - **what is the relative effectiveness of various types of a device**
  - **category as derived from clinical studies comparing different**
  - **types of devices.**
- **The chapter also reports scientific evidence on the costs and cost-effectiveness of cervical, wrist and knee braces.**

2.2 METHODOLOGY

2.2.1 Effectiveness literature

The following databases were searched:

- Ovid -Medline & PubMed Clinical Queries
- Ovid-CRCT - Cochrane Central Register of Controlled Trials
- Ovid-CDSR - Cochrane Database of Systematic Reviews
- Ovid-CRD - Database of Abstracts of Reviews of Effectiveness (DARE)
- Ovid-Cinahl (Cumulative Index to Nursing & Allied Health Literature)
- Ovid-BNI (British Nursing Index)
- Embase
- PEDro database (Centre for Evidence-Based Physiotherapy - CEBP)[5]
- CIRRIE database (Center for International Rehabilitation Research Information and Exchange)[6]
- REHABDATA database (National Rehabilitation Information Center)[7]
- CRD - Health Technology Assessment database (HTA)
- CRD - NHS Economic Evaluation database (NHS EED)
- Econlit.

Search terms varied following localisation ("knee*"; "wrist*"; "cervic*"). With Ovid and Embase searches for each of these body parts focus was directed to search terms "brace*" OR "bracing*" for the knee, "splint*" OR "brace*" OR "bracing*" for the wrist and "collar*" OR "splint*" for the neck respectively. These terms were entered with appropriate wildcard characters (* with Ovid or $ with Embase) and looked up for as "subject heading word" and as "text word" in publication title(s), abstract and/or full text.

MESH terms concerning orthopaedics are listed in Table 1 in Appendix II II.

The PEDro, CIRRIE and REHABDATA databases each have there own thesaurus, using field keywords (PEDro), title keywords and subject headings (CIRRIE) or main index terms (REHABDATA):

- PEDro:
  - therapy field: "orthoses, taping, splinting";
  - body part field: "hand or wrist", "lower limb or knee" and "head and neck" respectively and
  - method field: "practice guideline, systematic review or clinical trial".
- CIRRIE:
  - title keywords: "knee", "wrist" or "collar" respectively and
  - "Orthotics" as subject heading
- REHABDATA: main index terms: "knee brace", "wrist bace" or "cervical collar".

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5 http://www.pedro.fhs.usyd.edu.au/

6 http://cirrie.buffalo.edu/search/index.php

7 http://www.naric.com/research/rehab/default.cfm

The following inclusion criteria were used:

For primary research studies "clinical trial" or "controlled clinical trial" or "multicenter study" or "randomized controlled trial", but, failing these, consideration was also made of study designs with lower levels of evidence to reflect the "best evidence" available on the subjects. Those studies were mainly observational studies or biomechanical investigation reports.

Secondary research studies reporting systematic reviews or meta-analyses of RCTs were included provided they contained a methods section describing how the relevant studies were identified.

Practice guidelines were included.

No limits were applied as to publication date and all searches were ended on 2007, Febr. 1st.

The following exclusion criteria were used:

Correspondence, editorials, expert opinion articles, comments, articles published in abstract form only or conference proceedings.

Exclusively animal studies.

Studies merely discussing or comparing non-orthotic treatments such as surgical technique(s), anaesthesiology related topics (neck problems with laryngoscopy & intubation), tempormandibular disorders, pharmaceutical and/or behavioural treatment(s), alternative medicine, etc.

Any other study judged not to be relevant on reading of title and/or abstract, e.g. "knee-ankle-foot orthosis" for searches on the knee, specific medical niches such as cerebral palsy or myo-inflammatory or -dystrophic disorders.

Languages other than English, Dutch, French or German (if filter provided).

Overall, and after discarding duplicate references, 765 citations were retrieved for further study. No relevant references were found in CRD - Health Technology Assessment database (HTA), CRD - NHS Economic Evaluation database (NHS EED) nor Econlit. Detailed reporting of our other searches is summarized in Tables 2 to 12 in the Appendix II.

The methodological quality of clinical evidence was assessed according to the system proposed by Guyatt et al. 2006[1]. This system considers the level of evidence and the grade of recommendation. The level of evidence can be:

- High: further research is very unlikely to change our confidence in the estimate of effect;

- Moderate: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate;

- Low: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate;

- Very low: any estimate of effect is very uncertain.

The grade of recommendation takes into account: quality of evidence, importance of the outcome, magnitude of the treatment effect, precision of the estimate, risks and burden of therapy, risk for target event, costs and patient values.

The level of evidence and the grade of recommendation are combined to generate the following system of the methodological quality of the evidence:

- 1A: strong recommendation, high quality evidence;

- 1B: strong recommendation, moderate quality evidence;

- 1C: strong recommendation, low or very low quality evidence;

- 2A: weak recommendation, high quality evidence;

- 2B: weak recommendation, moderate quality evidence;

- 2C: weak recommendation, low or very low quality evidence;

This system assessing the methodological quality of the evidence was not applied to individual studies, but to the body of evidence relating to a specific pathology. A priori, no restrictions were placed on the design of clinical studies.

2.2.2 Cost and cost-effectiveness literature

Cost and cost-effectiveness analyses were identified by searching the following electronic databases up to December 2006: PubMed, EMBASE, CINAHL, Social Science and Citation Index, Cochrane Library, National Health Service Economic Evaluation Database and EconLit.

Search terms included 'brace', 'splint', 'wrist', 'neck/collar/cervical', 'knee', 'orthotic', 'cost', 'cost analysis', 'cost-effectiveness', 'cost-utility', 'economic evaluation' alone and in combination with each other. Additionally, the bibliography of included studies was checked for other relevant studies.

2.3 WRIST BRACES

2.3.1 Terminology

The terminology used to describe wrist orthoses is often complicated and confusing. To date, no single system has been adopted universally. Several ways of classifying wrist splints have been introduced: namely, by eponym (deriving from the name of the inventor or the place of origin), by acronym (based on the major joints encompassed), descriptive classification and the classification system proposed by the American Society of Hand Therapists[2]. Besides having taxonomic problems, some of the splinting terminology also causes confusion. For example, it is hard to distinguish between "splint", "orthosis" or "brace". In agreement with the American Society of Hand Therapists, the terms are used interchangeably in this chapter (Wong 2002)[2].

2.3.2 Effectiveness

In this section the evidence on the effectiveness of wrist "splints", "orthoses", "braces" as outlined in selected guidelines, systematic reviews and randomized controlled trials (RCTs) is summarized and categorised according to different indications. Also, the relative effectiveness of various types of devices within the same indication is compared where available. Following indications for which wrist braces are often used in daily practice are summarized below: carpal tunnel syndrome, rheumatoid arthritis, hand osteoarthritis, De Quervain's tenosynovitis, wrist/hand spasticity after stroke, uncomplicated wrist fractures, prevention of sport injuries and flexor tendon injuries.

2.3.2.1 Carpal tunnel syndrome

Carpal tunnel syndrome (CTS) is a condition in which the median nerve at the level of the carpal tunnel undergoes irritation, often attributed to compression.

It is common in people who perform repetitive motions of the hand and wrist, such as typing. Symptoms of CTS include pain in the wrist and hand which can radiate to the forearm and paraesthesiae in the thumb, index, middle and radial half of the ring finger. Advanced stages of median nerve compression can result in muscle weakness of the hand and fingers (O'Connor 2003)[3].

Several guidelines concerning diagnoses and treatment of carpal tunnel syndrome were available on the NGC (National Guideline Clearinghouse) website. A first guideline on "Acute and chronic CTS" recommended initial conservative treatment by night and possible day splinting of the wrist in mild to moderate CTS[4]. A second guideline on "Work-related CTS" also recommended conservative care by splinting of the wrist[5]. Furthermore, a guideline on "Upper extremity musculoskeletal disorders" recommended a light-weight wrist splint, either prefabricated or custom-made, designed to maintain the wrist in a neutral position for night-time use in the treatment of CTS[6].

Further evidence-based guidelines concerning CTS were obtained from the Dutch Institute for Healthcare Improvement (CBO 2005)[7]. They emphasise the seriousness of the complaints as an important driver of therapy choice. If the patient can still function in daily activities and work, it is recommended to take ergonomic measurements when necessary and wait and/or propose a conservative treatment (i.e. splinting or corticosteroid injections). Splint-wear treatment is also proposed for pregnant women or patients awaiting surgical treatment. The splint has to be worn at least during night-time, but day-time use can also be called for when patients have moderate complaints. If wearing a splint is effective, reduction of complaints will appear within two weeks. If no impact has been reached after six weeks, it makes no sense to continue carrying the splint (Burke 1994[8], Walker 2000[9]). It should be noted that the impact of so-called conservative treatments is generally temporary. When patients, who are not pregnant, experience serious restrictions on their daily activities and/or work, a surgical intervention is recommended. Furthermore, when patients are suffering from rheumatoid arthritis or an underlying endocrine disorder, it is better to await the impact of treating these disorders before treating CTS.

The Cochrane Library provides a systematic review on "Non-surgical treatment (other than steroid injection) for carpal tunnel syndrome" (O'Connor 2003[3]). Three of the included trials dealt with splinting (Burke et al. 1994[8]; Walker 2000[9]; Manente et al. 2001[10]). Data could not be pooled due to clinical heterogeneity in type and duration of intervention. The trials all received a high bias rating since they were unable to blind treatment providers and subjects to the treatment.

Manente et al. (2001)[10] (n = 80) evaluated the short-term effects of a nocturnal hand brace on symptoms, hand function, patient-reported change and nerve conduction. A significant clinical effect in favour of nocturnal hand brace use for CTS was demonstrated. The weighted mean difference for improvement in symptoms following two weeks and four weeks of use was -1.03 (95% CI -1.31 to -0.75) and -1.07 (95% CI -1.29 to -0.85), respectively using the Boston Carpal Tunnel Questionnaire[11-13] for symptoms (a 1 to 5 point scale in which 5 points is the worst score and 1 point is the best score). The weighted mean difference for improvement in hand function following two to four weeks of use was -0.52 (95% CI -0.79 to -0.25) and -0.55 (95% CI -0.82 to -0.28) respectively. The subjects' global impression of change documented an improvement in all treated subjects ($p = 0.006$). No significant difference was found in electrophysiological measurements, but overall neurophysiological classification shifted to less severe classes in the treated group ($p<0.05$). Important to notice is that the used brace (cf. Manu hand brace) in this study is conceptually very different from the currently available types of splint that work by immobilizing the wrist. The functioning of this brace relies mainly on widening the carpal tunnel.

One trial (Walker 2000[9]) (n = 24) compared the short-term effects (six weeks) of full-time use versus nocturnal use of a wrist splint (thermoplastic, custom-made, neutral wrist splint) on symptoms, hand function and nerve conduction. No significant

difference in symptom or hand function improvement was demonstrated between both groups over the six-week period. Physiological improvement, measured by median nerve sensory and motor distal latency, shows better results after full-time splint wear. Results of the combined sample, by demonstrating improved symptoms, functional deficits, and distal latencies, provides added scientific evidence for the efficacy of neutral wrist splints in CTS.

Burke et al. (1994[8]) (n = 90 hands) examined the short-term effects (two weeks) of wrist splinting in neutral position with splinting in an extended wrist position (20 degrees) on overall, nocturnal and day-time symptoms. A significant effect was demonstrated in favour of the neutral position for wrist splinting in CTS. The relative risk for improvement in overall and nocturnal symptoms at two weeks following fabrication of the neutral wrist splint was 2.43 (95% CI 1.12 to 5.28) and 2.14 (95% CI 0.99 to 4.65) respectively. No effect of wrist position was found for daytime symptoms at two weeks following splint use. However, interpretation of these findings should be done with caution because of the low methodological quality of the study.

A recent case-control study by Premoselli et al. (2006[14]) (n = 50) evaluated the long-term efficacy (three and six month follow-up) of night-time splint wear therapy (neutral custom-made thermoplastic resin wrist splint) for patients with recent symptoms of CTS. After a six month follow-up, improvements in symptom scale scores (p = 0.001) and function scores (p = 0.0004) in the case group were significantly larger as compared with the control group. These findings are in agreement with the neurophysiological data showing statistically significant modifications in distal latency, although the changes in motor scores at six-month follow-up visit were not statistically significant. These results suggest that long-term splint-wear treatment may be effective in early CTS care.

Finally, we report the study of Gerritsen et al. (2003[15]). Since this study was conducted within the framework of a trial on the efficacy of splinting and surgery for CTS, details of this study fall beyond the scope of our study. However, important to notice is that they could identify two prognostic indicators for the long-term success of night-time splinting in patients with electrophysiologically confirmed idiopathic CTS. For patients with a short duration of CTS complaints (one year or less) and a score of six or less for severity of paraesthesia at night (0-10 scale, with 0 equalling "no symptoms" and 10 equalling "very severe symptoms"), the predicted probability of treatment success was the largest.

In general, we can conclude from the above RCTs that there is a ***strong recommendation with moderate quality evidence*** (grade 1B, according to Guyatt et al. 2006[1]) ***to use a splint*** in patients with carpal tunnel syndrome. Although the included RCTs contain important methodological limitations (small studies, unable to blind treatment, short duration), the results of the studies clearly indicate that benefits outweigh risk and burdens.

Key points

- **Splinting in the neutral position is recommended in order to maintain the wrist in a position that has the lowest intra-canal pressure and therefore the least pressure on the median nerve.**
- **The splint has to be worn at least during night-time, but also day-time use can be considered if normal activities of daily living are not restricted.**
- **If wearing a splint is effective, reduction of complaints will appear within two weeks. If after six weeks no impact has been reached, it makes no sense to continue carrying the splint.**

2.3.2.2 Rheumatoid arthritis

In children as well as in adults, the wrist is frequently involved in rheumatic arthritic processes. With persistent activity of rheumatoid arthritis (RA), the adult wrist joint will become affected bilaterally in 95% of the patients, while in children the wrist is affected in approximately 60% of the cases.

One of the interventions aiming to preserve function is splinting of the affected wrist joint. The rationale for this intervention is to balance rest and activity, thereby preserving wrist function. However, the evidence base to support this rationale is scarce (Helders 2002[16]).

The Scottish Intercollegiate Guidelines Network (SIGN) provided a national guideline concerning "The management of early rheumatoid arthritis" (SIGN 2000)[17]. They reported that good evidence to support the use of *resting hand splinting* is sparse although two studies [Callinan 1996[18], Feinberg 1992[19] (not included in this report because of inadequate methodology)] did show a significant reduction in pain when splints were applied. *Wrist working splints* have been shown to decrease pain on activity, but do not improve function, grip strength or dexterity. There is no good evidence to support the use of splints to correct ulnar[8] deviation or any other deformity.

A systematic review about "Splints and orthoses for treating rheumatoid arthritis" is published in the Cochrane Library (Egan 2003[20]). This review included seven studies examining the effects of working splints, resting hand and wrist splints in people with rheumatoid arthritis. Unfortunately none of these studies were similar enough to allow pooling of the results. A distinction was made between *working splints*, recommended in order to limit circumduction and reduce torque during heavy wrist activities, and *resting wrist and hand splints*, designed to provide pain relief through immobilization of actively inflamed joints.

Three studies examined the effects of wearing ***working splints*** versus no splint. Anderson et al. (1987)[21] (n = 92) measured grip strength immediately after the splint was donned when four different types of splints (dorsal custom-made low temperature thermoplastic splint, palmar custom-made low temperature thermoplastic splint, palmar plastazote and polythene custom-made gauntlet splint, and ready-made elastic splint) were applied to the dominant or non-dominant hand. The only significant differences were in lower grip strength of the non-dominant hand, with both the palmar custom-made and the elastic ready-made splints as compared with no splint. In a cross-over trial by Pagnotta et al.[22] (1998) (n = 40), a ready-made elastic splint (Futuro Kendall #33) showed a highly task-specific effect after one week of use on work performance measured by various tasks like using a screwdriver and wielding shears. These results suggest that the ergonomic demands of the individual's daily life must be considered if a splint is to provide maximum effectiveness. Finally, in the study by Kjeken et al. (1995)[23] (n = 69), participants who wore a ready-made elastic splint (Rehband) for six months demonstrated smaller losses in passive dorsal-volar range of motion (ROM) compared with those who did not wear the splint. There were no differences in pain (at rest or in motion), non-splinted grip strength, morning stiffness, pinch grip, forearm joint circumference, or quality of life after six months.

In head-to-head studies of two ***working wrist splints*** [a ready-made elastic gauntlet (Futuro) or a custom-made medium temperature thermoplastic splint (ThermoLyn)], patients (n = 10) tended to favour the futuro wrist orthosis with respect to pain relief, handling the orthosis, swelling of the wrist and finger joints and movements of the wrist after two weeks. However, the differences in clinical effectiveness between the start and the end of each treatment period, as well as the differences between the two orthoses, were not statistically significant. Arguments in favour of the ThermoLyn orthosis were better hygiene, stability, and no need to remove the orthosis during dirty and wet conditions (Tijhuis 1998[24]). Stern et al. (1996) investigated the immediate and short-term (after one week) effects of three different types of ready-made elastic splints (Alimed Freedom Long, Kendall-Futuro #33, Smith and Nephew Rolyan D-Ring) on dexterity measured with or without the splint (Stern 1996a[25]) (n = 42), or grip strength with the splint removed (Stern 1996b[26]) (n = 36). Finger dexterity and hand function were reduced significantly and similarly with the three commercial wrist orthoses studied. The belief that orthotic use increases grip strength, either immediately or after one week, is not supported by this study.

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8 The larger of the two long bones within the forearm (on the little finger side of the forearm) that serves as a pivot in rotation of the hand.

Callinan et al. (1996)[18] investigated the effects of two types of ***resting orthoses*** (soft fabric and hard thermoplastic) on pain and hand function in 39 persons with RA. Arthritis pain was considerably less when these orthoses were worn at night-time for one month. There were no significant differences among conditions on hand function measures. Splint preference was 57% for the soft splint, 33% for the hard splint, and 10% for no splint. In the small study by Janssen et al. (1990) (n = 29) mentioned in the Cochrane review by Egan et al. (2001), application of resting splints on alternate hands every night for one year tended to improve deformity score, number of swollen joints and Ritchie index (joint tenderness) without a negative effect on grip strength. However, none of these results were statistically significant as compared with the results of the no-treatment group.

In general the authors of the Cochrane review report that there is insufficient evidence to make firm conclusions about the effectiveness of working wrist splints in decreasing pain or increasing function for people with RA (Egan 2003). Potential adverse effects, such as decreased range of motion, do not seem to be an issue although some of these splints decrease grip strength and dexterity. Similarly, preliminary evidence suggests that resting hand and wrist splints do not seem to affect range of motion or pain, although participants preferred wearing a resting splint to not wearing one.

Another systematic review of occupational therapy interventions for RA, including splints, concluded there were "indicative findings" that the use of wrist splints reduces pain and improves grip strength, but also decreases dexterity (Steultjens 2002[27]).

A recent study of Haskett et al. (2004)[28] (n = 45) compared the effect of three wrist splints [two prefabricated commercial splints (Rolyan wrist extensor orthosis and the Anatomical technologies elastic wrist support) and one custom-made leather wrist splint] on perceived wrist pain, hand function, and perceived upper-extremity function in adults with inflammatory arthritis in a 3-phase crossover trial. Wrist splints significantly reduced pain (p = 0.0007) after four weeks as compared with baseline. All splints improved hand strength and, in contrast to previous studies, the splints did not compromise dexterity. Similar improvements were achieved with the custom leather splint and Rolyan commercial splint, which were superior to the Anatech commercial splint.

Although the styles of splints differed across studies, as did the rigour of the research designs, the results collectively suggest that at least some splints reduce pain and improve grip strength, but they may reduce dexterity and performance of some functional tasks. More rigorous studies over a longer period with the most commonly prescribed orthoses are needed to draw firm conclusions about the efficacy of wrist splints in RA and to recommend which type of splint is designated for which patient. Since we believe that the best action may differ on patient's circumstances (cf. daily activities) and that clinical evidence on wrist orthoses is limited, we report ***a weak recommendation*** (grade 2B, according to Guyatt et al. 2006[1]) ***to use wrist orthoses in people with rheumatoid arthritis***.

Key points

- **At least some studies suggest working splints reduce pain and increase hand function during daily activities. Potential adverse effects, such as decreased grip strength and dexterity do not seem to be an important issue.**
- **Similarly, clinical evidence on resting wrist orthoses is limited, but at least some studies suggest pain relief and most of the people preferred wearing a resting splint to not wearing one.**
- **Similar improvements were achieved with commercial and custom-made wrist orthoses.**
- **More rigorous studies over a longer period investigating the most commonly used splints are needed to draw firm conclusions.**

2.3.2.3 Hand osteoarthritis

Symptomatic hand osteoarthritis (OA) affects 20% of people over 55 years of age. Despite this high prevalence, there are surprisingly few published RCTs for hand OA. Compared with knee and hip OA, it is a complex area to evaluate therapy. RCTs are weakened by a lack of consistent case definition and by a lack of standardized outcome assessments. Furthermore the number and location of symptomatic hand joints per treatment group at baseline was usually not stated and it is believed that the natural history of hand OA, in contrast to knee and hip, tends to be more variable with spontaneous intermittent exacerbations and improvements. To date, there are no RCTs comparing splinting with 'do nothing' to support the use of splinting in hand OA. Only a few head-to-head RCTs, described in the next paragraph, conclude that there is at least some evidence for the efficacy of using splints for first carpometacarpal OA (thumb base) (Towheed 2005[29]).

The EULAR (European League Against Rheumatism) (Zhang 2006[30]) task force issued 11 key evidence-based recommendations for treatment of hand osteoarthritis. One of these recommendations is the use of splints for thumb base OA and the use of orthoses to prevent or correct lateral angulation and flexion deformity with wrist protection. However, this recommendation was not based on research evidence comparing splinting with 'do nothing', but on clinical expertise or data derived from osteoarthritis studies of joints other than the hand. Two small (n = 26, n = 21) head-to-head RCTs with a cross-over design compared the treatment effects of a full splint (covering both thumb base and wrist) versus a half splint (only protecting the thumb base) in patients with first carpometacarpal OA. The results showed more pain relief (measured on a visual analogue scale) from the full splint as compared with the half splint (pooled effect size of 0.64, corresponding with a moderate clinical effect) after one week. The pooled NNT (number needed to treat) to obtain moderate to excellent (more than 50%) pain relief or symptomatic relief was 4. Unfortunately, the studies did not examine the effects of the splints on lateral angulation and flexion deformity (Weiss 2000[31], Weiss 2004[32]).

Based on the information we found in the literature, we report a ***very weak recommendation*** (grade 2C, according to Guyatt et al. 2006[1]) ***to use splints in treating first carpometacarpal osteoarthritis (thumb base)***.

Key points

- **To date, there are no RCTs comparing splinting with 'do nothing' to support or refute the use of splinting in hand OA.**
- **Two small head-to-head studies suggest that there is some evidence supporting the use of wrist splints in patients with first carpometacarpal OA.**

2.3.2.4 De Quervain's tenosynovitis

De Quervain's tenosynovitis is a disorder characterized by pain on the radial (thumb) size of the wrist, impairment of thumb function and thickening of the ligamentous structure covering the tendons in the first dorsal compartment of the wrist. It is a painful and often disabling condition that is mainly observed in workers who perform repetitive manual tasks, wrestlers, and bowlers.

In the literature we found two guidelines concerning splinting in the treatment of de Quervain's tenosynovitis. In the California guidelines (1997) for "Problems of the hand & wrist"[33] the authors recommend that immobilization of the wrist and thumb interphalangeal joint with a spice thumb splint or other similar device can be considered for up to 3 or 4 weeks in severe de Quervain's tenosynovitis. Splinting may not be necessary in milder cases and the authors warn that the functional restriction on thumb and hand use imposed by spica splinting is considerable. This is in agreement with the National Guideline Clearinghouse guidelines (2007) for "Upper extremity musculoskeletal disorders"[6]. In these guidelines splinting of the affected thumb is also recommended in patients with de Quervain's tenosynovitis. If symptoms persist for

more than 6 weeks patients should be referred for specialty evaluation and possible corticosteroid injection. However, at this moment no randomized clinical trials are available comparing the clinical efficacy of thumb splinting against 'do nothing' in the treatment of de Quervain's tenosynovitis. The only studies we found compared the use of splinting in combination with a corticosteroid injection.

Kosuwon (1996)[34] (n = 140) reported a prospective randomized controlled study comparing the results of steroid injection with and without immobilization in a splint. The authors of this study reported no difference in the results of treatments whether or not the patients were immobilized in a splint or not. On the contrary, the number of days lost from work in the group of non-immobilization is less than in the group of immobilization. So, the recommendation of immobilization after steroid injection in de Quervain's tenosynovitis is not supported by these results.

Weiss et al. (1994)[35] compared the use of a mixed steroid/lidocaine injection alone, an immobilization splint alone (custom-molded plastic thumb spica splint), and the simultaneous use of both in improving symptoms in de Quervain's disease. 93 wrists were included with an average follow-up examination after 13 months. Complete relief of symptoms was noted in 28 of 42 wrists receiving an injection alone, 8 of 14 wrists receiving both an injection and splint, and 7 of 37 wrists receiving a splint alone. The addition of a splint to this particular regimen does not improve any significant benefit to its success on a short or long term basis using either symptom improvement or the need for surgery as determinants of success.

More recently Richie et al. (2003)[36] conducted a pooled quantitative literature evaluation to review the different treatment options in de Quervain's tenosynovitis. The review included seven descriptive, non comparative, studies. In other words, each study reported the proportion of successful outcomes with different treatment, without a comparison to a specified control group. 459 wrists were subjected to one of several therapeutic modalities. The results of this study show that corticosteroid injection, with an 83% cure rate, was the most effective non-operative treatment for de Quervain's tenosynovitis. This rate was much higher than any other therapeutic modality (61% for injection and splint, 14% for splint alone, and 0% for rest or non-steroidal anti-inflammatory drugs).

Although some guidelines recommend the use of a wrist splint in the initial treatment of de Quervain's tenosynovitis, we found no RCTs confirming this indication. So we conclude that to date the ***available evidence does not support the use of an immobilization splint in the treatment of de Quervain's tenosynovitis*** (***weak recommendation***, grade 2C according to Guyatt et al. 2006[1]).

Key points

- **To date, no RCTs are available supporting any therapeutic advantage of a spica immobilization splint, with or without the combination of a corticosteroid injection, in the treatment of de Quervain's tenosynovitis.**

2.3.2.5 Wrist/hand spasticity after stroke

Despite the widespread use of hand and wrist splints for adult stroke patients, surprisingly few studies, and even fewer RCTs, have examined the effect of splinting in this population (Lannin 2003)[37]. At this moment, there are no RCTs available, comparing the clinical effects of wrist splinting with a no-treatment group which does not receive rehabilitation exercises.

This lack of evidence to either support or refute the effectiveness of wrist splinting in patients following stroke, makes ***it impossible to draw any conclusion or make a recommendation.***

Key points

- **There is insufficient evidence to either support or refute the effectiveness of wrist splinting for adults following stroke who are not receiving an upper limb stretching programme. There is no evidence of long-term benefits or adverse effects.**
- **Limited research and lack of a no-treatment group limit the usefulness of the results.**

2.3.2.6 Uncomplicated wrist fractures

Although fractures of the distal radius are a common clinical problem in adults, there is limited knowledge about the best method of treatment. Trials testing conservative interventions usually involved closed minimally to moderately displaced distal radius fractures (cf. the commonly referred 'Colles' fracture).

The Cochrane Library published a systematic review concerning "Conservative interventions for treating distal radial fractures in adults" (Handoll 2003)[38]. This review included several trials comparing the efficacy of application of an external support (plaster cast or brace) and fracture manipulation. Although quantitative data from some trials are presented, poor quality and heterogeneity, in terms of patient characteristics, interventions compared and outcome measurement, of the included trials meant that no meta-analyses were undertaken.

There remains insufficient evidence from randomised controlled trials to determine which methods of conservative treatment are the most appropriate for the more common types of distal radial fractures in adults. Further research is necessary to determine the clinical evidence of wearing wrist orthoses in common types of distal fractures. At this moment, ***no*** conclusions or ***recommendations*** can be made concerning this type of immobilization in the treatment of uncomplicated wrist fractures.

Key points

- **There is insufficient evidence from randomized controlled trials to determine which method of conservative treatment is the most appropriate for the more common types of distal radius fracture in adults. Patient preferences and circumstances, and the risk of complications should be considered.**
- **Further research is necessary to determine the clinical evidence of orthoses for uncomplicated wrist fractures.**

2.3.2.7 Prevention of sport injuries

Wrist injuries are common among snowboarders and in-line skaters. While some older studies (retrospective studies, case reports etc.) support the use of wrist protectors to protect against injury, others emphasize the fact that wrist protectors may transfer the injury to other locations of the forearm (Schieber 1996[39], Cheng 1995[40]). One prospective, randomized, clinical study of 5,029 snowboarders compared the effect of a wrist brace (D-ring wrist with a deformable aluminium support located on the volar side of the wrist) with a control group wearing no brace. The primary endpoint was fracture or sprain of the wrist with loss of range and motion and pain of at least 3-day duration. Significantly more injuries occurred in the control group compared to the braced group ($p = 0.001$). No injuries could be related to the use of the wrist brace. The study also indicated that the design and material properties in the brace are important factors for how much energy the brace can absorb. Indeed, a brace system that is too rigid will generate high-stress forces at the proximal and distal ends of the brace and in this way may produce a fracture below or above the brace. The ideal

stiffness of the brace is difficult to determine in advance because of individual differences in muscle support of the wrist (Ronning 2001[41]).

A recent literature review examined the effectiveness of wrist braces in preventing wrist injuries among snowboarders, Russell 2007[42]. The review included two randomised controlled trials (including the Ronning 2001 study described above), two prospective cohort studies and two case-control studies. The authors found that the risk of wrist injury, wrist fracture and wrist sprain was significantly reduced with the use of wrist braces. It was not possible to determine whether a particular type of wrist brace is more effective. Non-experimental data raised the possibility that wrist braces may increase the risk of finger and elbow-shoulder injuries, although this needs to be confirmed by future research.

Although the prevention of sport injuries is out of scope of this project, this paragraph is included for the completeness of the report. As prevention of sport injuries is ineligible for reimbursement, ***no recommendations*** are made.

Key points

- **Limited evidence is available pointing to a benefit of using wrist protectors in preventing snowboard and in-line skating injuries.**
- **More rigorous, prospective studies, comparing several splinting materials, are needed to confirm these results.**

2.3.2.8 Flexor tendon injuries

Splinting flexor tendon injuries is dependent on many variables, including injury-specific factors such as site, type and extent of injury; patient-specific variables such as age, health, intelligence, motivation and vocation; facility-specific factors such as the availability of surgical and rehabilitation personnel; surgeon-specific philosophy; and technical ability. With so many variables involved cookbook approaches to splinting flexor tendon injuries is neither reasonable nor possible. Furthermore the used splints are often custom-made and sophisticated, so they fall beyond the scope of this study (Fess 2002[43]). ***No recommendations*** are made in this report.

Key points

- **Splinting flexor tendon injuries is a very complicated matter, depending on many variables. Each situation must be carefully appraised and careful communication between surgeon, therapist and patient is critical.**
- **Custom-made, sophisticated splints are often recommended.**

2.3.2.9 Conclusions

Based on the guidelines, reviews and RCTs summarized in this section, Table 1 presents an overview of the clinical evidence for wrist braces. The last column contains the level of evidence and grade recommendations according to Guyatt et al. (2006)[1].

Table 1 : Clinical evidence for wrist braces and the grade of recommendation.

Pathology	Conclusion	Grade of recommendation
Carpal tunnel syndrome	Moderate quality evidence for use of brace for this indication	Strong recommendation, (grade 1B)
Rheumatoid arthritis	Moderate quality evidence for use of brace for this indication	Weak recommendation, (grade 2B)
First carpometacarpal (thumb base) osteoarthritis	(Very) low quality evidence for use of brace for this indication	Weak recommendation, (grade 2C)
De Quervain's tenosynovitis	(Very) low quality evidence of no use of brace for this indication	Weak recommendation, I (grade 2C)
Hand/wrist spasticity after stroke	Insufficient evidence	No recommendation
Uncomplicated wrist fractures	Insufficient evidence	No recommendation
Prevention of sport injuries	Out of scope	No recommendation
Flexor tendon injuries	Out of scope	No recommendation

2.3.3 Costs

Two cost analyses examined the cost of wrist braces in the treatment of distal radius fractures. First, a British study (n = 100) computed costs of treatment of distal radial fractures from admission of the patient to the Accident & Emergency department to discharge from the fracture clinic (Kakarlapudi et al. 2000)[44]. Costs of plaster casts and splints per patient amounted to £4.3 out of a total healthcare cost per patient of £320 (1.3%). Second, a British study compared the costs of a "Futura-type" wrist splint (n = 98) and a traditional forearm plaster-of-Paris cast (n = 81) for the treatment of torus fractures of the distal radius in children (Davidson et al. 2001)[45]. All patients were treated for a period of three weeks. Healthcare costs amounted to £116.98 with a cast and £65.75 with a splint. However, the costs were not derived from the patient sample, but were based on the authors' estimates of the expected use of resources in routine practice. No statistical or sensitivity analysis was carried out, thus limiting the interpretation of the findings. No studies were identified that compared the costs of different types of wrist braces for a specific clinical indication.

2.3.4 Cost-effectiveness

The review generated one cost-effectiveness analysis of wrist braces. A Dutch economic evaluation alongside a RCT assessed the cost-effectiveness and cost-utility of splinting (n = 89) as compared with surgery (n = 87) for patients with CTS (Korthals-de Bos et al. 2006)[46]. Patients randomized to the splint group received either a prefabricated splint or a custom-made splint (made of soft-cast) that immobilized the wrist in neutral position. Patients were instructed to wear the splint during the night for at least six weeks and during the day only if they wished to. Alternatively, patients received outpatient standard open carpal tunnel release surgery. After one year, the success rate (i.e. the proportion of patients who had completely recovered or had much improved) was significantly higher in the surgery group (92%, 67 out of 73 patients) than in the splint group (72%, 60 out of 83 patients). Surgery was also significantly superior to splinting with respect to severity of the main complaint and paraesthesia during the day. There were no differences between the surgery and splint

group in terms of utility (as based on quality of life measured by means of the EuroQol). Mean total costs per patient amounted to 2,126 € in the surgery group and 2,111 € in the splint group. There was a 90% probability that surgery is 2,500 € per patient cheaper in achieving one time less waking up at night than splinting. The authors concluded that surgery is more cost-effective than splinting given its higher effectiveness at equal cost. This does not correspond with the recommendation of the American Academy of Neurology (1993)[47] which advises initial treatment of CTS with a splint and open carpal tunnel release surgery only if splinting proves to be ineffective. Also, cost results may not be generalisable to other countries because costs of surgery in the Netherlands are lower than costs of a wrist splint. The authors argued that the costs of surgery are higher in other countries.

2.4 NECK BRACES

2.4.1 Effectiveness

In this section, the clinical evidence of neck braces in treating whiplash injuries, cervical osteoarthritis, cervical brachialgia, cervical fractures and spinal immobilization for trauma patients is summarized based on available guidelines, systematic reviews and randomized clinical trials.

According to the "Medical Treatment Guidelines of Cervical Spine Injury" (State of Colorado, Department of Labor and Employment Division of Workers' Compensation, 2007[48]) the primary principles and objectives of the application of cervical orthosis include : (1) control of the position through the use of control forces; (2) application of corrective forces to abnormal curvatures; (3) aid in spinal stability when soft tissues or osteoligamenteous structures cannot sufficiently perform their role as spinal stabilizers; and (4) restrict spinal segment movement after acute trauma or surgical procedure. There exist many cervical collars, ranging from soft collars to rigid collars. ***Soft collars*** are well tolerated by most patients but may not significantly restrict motion in any plane and are associated with delayed recovery. There is no evidence that their use promotes recovery from cervical sprain. ***Rigid collars*** are useful post-operative or in emergency situations. These collars restrict flexion and extension motion, and to a lesser degree, lateral bending and rotation.

2.4.1.1 Whiplash injury

Whiplash can be defined as an acceleration-deceleration mechanism of energy transfer to the neck.

It may result from rear end or side-impact motor vehicle collisions, but can also occur during diving or other mishaps. The impact may result in bony or soft-tissue injuries (whiplash injury), which in turn may lead to a variety of clinical manifestations called "whiplash-associated disorders" (WAD). By using the WAD definitions (by the Quebec Task Force[49, 50]), patients can be classified by the severity of their signs and symptoms. WAD Grade 0 indicates no complaints or physical signs, WAD Grade 1 indicates neck complaints (such as pain, tenderness and stiffness) but no physical signs, WAD Grade 2 indicates neck complaints and musculoskeletal signs (such as decreased range of motion or muscle weakness), WAD Grades 3 and 4 indicate neck complaints and neurological signs (such as sensory deficit) and fracture or dislocation, respectively (Verhagen 2004)[51, 52]. Next to this clinical anatomical classification, the Quebec Task Force also uses a time classification with six phases. Phase 1 covers the period up to four days after the whiplash; phase 2 lasts from four days to three weeks after; phase 3 from three to six weeks; phase 4 from six weeks to three months; and phase 5 and 6 cover the period of more than three months after the whiplash. This classification is based on the physiological tissue recovery process (Bekkering 2005)[53].

Several guidelines for treatment of whiplash-associated disorders have been reported. As an interim measure, the Quebec Task Force guidelines were updated by the New South Wales Motor Accidents Authority (MAA) in 2001[54]. These guidelines cover the management of WAD Grades I to III in the acute and sub-acute phases, up to around three months from injury. They concluded that the use of a collar is not recommended for WAD Grade I and if prescribed for WAD Grades 2 and 3, a collar should not be

used for more than three days as it may slow the recovery (Motor Accidents Authority 2001[54]). These guidelines are, to a large extent, in agreement with those of Leigh et al. (2004)[55], developed according to the method for physiotherapy guidelines issued by the Canadian Physiotherapy Association and the Scottish Intercollegiate Guideline Network. Advice to rest or wear a soft collar is not recommended by these authors for WAD Grades II and I, but rest or collar may be prescribed for no greater than 4 days for WAD Grade III. Furthermore, a recent guideline was obtained from KNGF (Koninklijk Nederlands Genootschap voor Fysiotherapie) (Bekkering 2005[53]). On the basis of the results of two RCTs [Borchgrevink 1998[56] and Rosenfeld 2000[57] (not included in this report because of the used study design)] the authors of these guidelines recommended not wearing a collar in WAD Grades I and II. Patients who are wearing collars on referral for physical therapy should be advised to reduce their use.

A recent review concerning "Conservative treatments for whiplash" is published in the Cochrane Library (Verhagen 2004[51]). This review focuses on what types of conservative treatments are effective in patients with WAD Grades I and II regarding pain, global perceived effect or participation in daily activities. Most of the trials compared "active" versus "passive" treatments and are beyond the scope of this report. One study of low methodological quality (Gennis 1996)[58] compared the degree of pain at ≥ 6 weeks postinjury in a group of whiplash victims (n = 196) treated with rest, analgesia, and a soft collar (a foam-rubber soft cervical collar with a Velcro fastener permitting 1 size to fit all adults) with that in a control group treated with rest and analgesia alone. The collars were worn within 24 hours after the whiplash trauma and for a median period of 14 days (median use of 6 hours a day). After 6 weeks follow-up pain persisted in 62% of the patients. There was no significant difference between the 2 groups in complete recovery ($p = 0.34$), improvement ($p = 0.34$), or deterioration ($p = 0.60$) of pain. However, 83% of the patients who used the soft collar reported feeling more comfortable wearing them while they had pain. Borchgrevink et al. (1998)[56] (n = 201) studied the long-term effects (at six months) of two different treatments, provided during the first 14 days after a car crash. Patients in the first group were encouraged to act as usual, whereas patients in the second group where given time off work and had their necks immobilized with a soft collar. All patients received instructions for self-training of the neck (to avoid complications with complete immobilization) and a prescription for non steroidal anti-inflammatory. At six months, there was a significant reduction of symptoms in both groups, but little or no differences were observed between both groups. There was a significantly better outcome (however not clinically relevant) for the act-as-usual group in terms of subjective symptoms, including pain localization, pain during daily activities, neck stiffness, memory, and concentration, and in terms of visual analogue scale measurements of neck pain and headache, whereas for variables of objective data such as neck mobility and duration of sick leave no significant differences were observed. These findings suggest that the differences in outcome may result from psychological factors. Immobilization treatment with a neck collar and sick leave may cause the patient to focus more attention on the accident and the resulting symptoms and therefore may cause the patient to worry about long-lasting problems.

A very recent study (Dehner 2006[59]) (n = 70) investigated the effects of 2-day versus 10-day immobilization of the cervical spine on pain, range of motion (ROM), and disability in patients with QTF Grade II whiplash injuries. All patients received non steroidal anti-inflammatory drugs and after seven days all patients started a standardized physiotherapy program. Patients' pain and disability scores were assessed using visual analogue scales and range of motion was assessed using a goniometer. No statistically significant differences could be identified between the two treatment groups after 2 or 6 months. After six months, persistent pain was reported by 4 patients in each group (12.5%). The authors of the study concluded that if a cervical collar is used in the acute treatment phase of whiplash trauma of the cervical spine, it is possible to offer the collar to the patient for a period of up to 10 days without any detrimental effect (cf. possible atrophy-related secondary damage after a long period of neck muscle immobilization).

Although several studies applied soft cervical collars as part of their therapy concept, very little concrete data could be extracted that relate to their use. In many studies, one group underwent immobilization with a cervical collar for periods up to two weeks while, in a comparison group, treatment did not include this measure but involved active physiotherapy instead.

The available evidence does not support the use of a soft cervical collar in patients with ***whiplash-associated disorders grade I and II.*** (***strong recommendation*** with moderate quality evidence, grade 1B according to Guyatt et al. 2006[1]). If people prefer to wear a soft collar in the initial phase (3 – 14 days) of whiplash-associated disorders this is mostly due to a subjective feeling of comfort while having pain.

Key points

- **To date, the available evidence does not support an evidence-based beneficial effect for soft cervical collars in whiplash associated disorders compared to no treatment (other than reassurance of the patient).**
- **If patients prefer to wear a soft collar (cf. feeling more comfortable while having pain), their use should be restricted to a short period. The optimal period (cf. 3 – 14 days) still needs to be determined.**

2.4.1.2 Cervical osteoarthritis (cervical spondylosis)

Cervical spondylosis is a chronic degeneration of the bones (vertebrae) of the cervical spine and the cushions between the vertebrae (disks), also known as cervical osteoarthritis.

The changes that accompany the degeneration, such as developing abnormal growths (bone spurs) on the spine, can lead to pressure on the spinal nerves and, sometimes, the spinal cord itself. Mild cases of cervical spondylosis often require no treatment or may respond to conservative treatment, including neck immobilization, pharmacologic treatments, lifestyle modification, and physical modalities (e.g. traction, manipulation, exercises) (MedlinePlus Medical Encyclopedia 2006[60]). No randomized controlled trials have compared these modalities, so these therapies often are initiated based on the clinician's preference or specialty. Also trials, comparing the efficacy of wearing a soft collar against no treatment are not available to date.

Despite their widespread use, soft collars largely are believed to work by placebo effect, since they do not appreciably limit motion of the cervical spine. They have not been demonstrated to change long-term outcomes in patients with cervical osteoarthritis. If worn properly, a soft collar maintains relative flexion. The collar should be worn as long as possible during the day. However, patient comfort is key. As symptoms improve, it can be worn only during strenuous activities. More rigid collars and devices may better limit motion of the cervical spine but may reduce muscle tone and cause neck stiffness from disuse. It is recommended to implement a daily cervical exercise program to limit loss of muscle tone (eMedicine 2006).

The available evidence does not support the use of a soft cervical collar in the treatment of cervical osteoarthritis (***weak recommendation*** with low quality or very low quality evidence level, grade 2C according to Guyatt et al. 2006[1]).

Key point

- **Despite the widespread use of soft cervical collars in cervical osteoarthritis, the available evidence does not support the use of soft cervical collars in the treatment of cervical osteoarthritis.**

2.4.1.3 Cervical brachialgia (cervical radiculopathy)

Cervical radiculopathy is a neurological condition characterized by dysfunction of a cervical spinal nerve, the roots of the nerve, or both. The seventh and sixth cervical nerve roots are the most commonly affected. It usually presents with pain in the neck and one arm, with a combination of sensory loss, loss of motor function, or reflex changes in the affected nerve-root distribution. In the younger population, cervical radiculopathy is often a result of a disk herniation or an acute injury causing foraminal impingement of an exiting nerve. In the older patient, cervical radiculopathy often is a result of foraminal narrowing from osteophyte formation. Factors associated with increased risk include heavy manual labour requiring lifting of more than 25 pounds,

smoking, and driving or operating vibrating equipment. The main objectives of treatment are to relieve pain, improve neurological function, and prevent recurrences.

In their guideline concerning "Upper extremity musculoskeletal disorders", the National Guideline Clearinghouse (2003)[6] reported that initial treatment of cervical radiculopathy (symptoms less than six weeks) usually consists of rest, a soft cervical collar and non steroidal anti-inflammatory medication. To the best of our knowledge, none of the commonly recommended non-surgical therapies for cervical radiculopathy have been tested in RCTs comparing non-surgical therapies with 'do nothing'. Thus, recommendations derive largely from case series and anecdotal experience. The preferences of patients should be taken into account in decision making (Carette 2005[61]).

One randomized, prospective study by Persson et al. (1997)[62] compared surgical versus non-surgical treatments in patients with cervical radiculopathy present for at least three months. 81 patients were randomly allocated to any of three treatments : surgery, physiotherapy or a cervical collar over a 3 –month period [rigid shoulder resting collar during daytime (Lundakrage, Miami Collar, Necky rigid Collar, Ortho-Collar, Philadelphia collar) and an additional soft collar (Adam, Camp, Necky soft) during night-time]. After three months, the patients in the surgical and the physiotherapy group reported less pain than the patients in the cervical collar group (reductions in visual analogue scores for pain : 42%, 18%, and 2%, respectively). However, at one year, there was no difference among the three treatment groups in any of the outcomes measured, included pain, function and mood.

The above data do not support the use of a cervical collar in the treatment of cervical brachialgia (***weak recommendation*** with low quality or very low quality evidence level, grade 2C according to Guyatt et al. 2006[1]).

Key points

- **Data are needed from well-designed RCTs to guide non-surgical management and decisions regarding whether and when to perform surgery in patients with cervical radiculopathy.**
- **Wearing a cervical collar to limit motion and decrease pain can be considered in the initial treatment but the available evidence does not support the efficacy of cervical collars.**

2.4.1.4 Cervical fracture/Cervical dislocation

A cervical fracture means that a bone is broken in the cervical region of the spine. A cervical dislocation means that a ligament injury in the neck has occurred, and two or more of the adjoining spine bones have become abnormally separated from each other, causing instability. The most common causes are motor vehicle accidents, violence and sports activities. The abrupt impact and/or twisting of the neck that occurs during the trauma can cause the spine bones to crack or the ligaments to rupture, or both. The overall goals of treatment are to preserve or improve neurologic function, provide stability, and increase pain. If these goals can be accomplished by conservative treatments, then that is generally preferred. However, because many cervical fractures and dislocations are highly unstable and will not adequately heal on their own, surgical stabilization is routinely performed[63].

Cervical fractures and dislocations are typically classified according to their region/location and injury/fracture pattern. According to the "American Association of Neurological Surgeons Guidelines for Management of Acute Cervical Spinal Injuries"[64] (2001), cervical orthoses are an option in the treatment of following types of cervical injuries;

- Occipital Condyle Fractures type I,II, type III without atlanto-occipital instability (cervical orthosis for 6-8 weeks)

- Atlas (C1) Fracture, bilateral posterior arch fx and Burst/lat mass with < 2 mm displ (cervical orthosis for 10-12 weeks)

- Odontoid (C2) Fracture type I

- Traumatic Spondylolisthesis of the Axis (C2) type I (cervical orthosis for 3 months)

- Subaxial (C3-C7) Fractures, compression flexion – stable with min kyphosis, stable posterior ligaments (cervical orthosis for 6-10 weeks)

- Subaxial (C3-C7) Fractures, vertical compression – stable with min kyphosis, no canal comp (cervical orthosis for 6-10 weeks)

The scientific foundation for these treatment options is described in detail in the original guidelines[64] and is often based on results of available case series and case reports, classified as class III data (American Medical Association data classification). Furthermore, in spite of these treatment options, the authors agree that the specific treatment of cervical fracture and/or dislocation ultimately depends on a number of factors (type and location of fracture, severity of fracture and amount of displacement, presence of spinal cord/nerve compression, patient's age, medical condition and associated injuries). The clinician should carefully evaluate a patient's injury, and with the general management guidelines for cervical fractures in mind, individualize the treatment.

A systematic review concerning the management of odontoid fractures is published by Julien et al. (2000)[65]. For Type I and Type III odontoid fractures the available evidence suggests that cervical immobilization for 6–8 weeks appeared to be an adequate treatment. Unfortunately, there were limited numbers of reported cases, and all data obtained were classified as class III (American Medical Association data classification). For type II fractures, analysis of results reported in the literature suggests that both operative and non-operative management remain treatment options.

Based on the above data we can conclude there is clinical evidence (strong recommendation with low quality or very low quality evidence level, grade 1C according to Guyatt et al. 2006[1]) to use rigid cervical orthoses in the treatment of several specific cervical fractures. However, treatment options are based on a variety of parameters (type and location of fracture, severity of fracture and amount of displacement, presence of spinal cord/nerve compression, patient's age, medical condition and associated injuries).

Key points

- **Treatment of cervical fractures and/or dislocations is a very complicated matter, depending on many variables. Each situation must be carefully appraised and careful communication between surgeon, orthotist and patient is critical.**
- **Results of case reports and case series suggest that several specific cervical fractures and/or dislocations can be treated effectively with a rigid cervical collar.**

2.4.1.5 Spinal immobilization for trauma patients

Spine immobilization can reduce untoward movement of the cervical spine and can reduce the likelihood of neurological deterioration in patients with unstable cervical spine injuries after trauma. Immobilization of the entire spinal column is necessary in these patients until a spinal column injury or a spinal cord injury has been excluded, or until appropriate treatment has been initiated.

Spinal immobilization is now routinely practised in the pre-hospital care of trauma patients and is widely recommended by emergency medical services programs and by a range of resuscitation guidelines (Advanced Paediatric Life Support, Pre-hospital Trauma Life Support, Advanced Life Support Group, Advanced Trauma Life Support Program for Doctors). The variety of techniques used and the lack of definitive evidence to advocate a uniform device for spine immobilization make it difficult to formulate recommendations for immobilization techniques and devices. To date, The American College of Surgeons recommends a combination of a rigid cervical collar and supportive blocks on a blackboard with straps to achieve safe, effective spine immobilization for transport.

Although anatomic and biomechanical evidence demonstrates that spine immobilization limits pathological motion of the injured spinal column, there are no case-control or randomized trials available supporting the clinical evidence of immobilization strategies in trauma patients. For a variety of both practical and ethical reasons, it may be impossible to obtain this information (Hadley 2002[66], Kwan 2001[67]).

Several studies compared different spinal immobilization strategies in healthy volunteers. Podolsky et al (1983)[68] (n = 25) investigated the efficacy of several collars and bilateral sandbags on controlled cervical spine motion in three axes (flexion, extension, rotation, and lateral bending while lying supine). Control measurements were made with no device and measurements were repeated following immobilization with: soft collar, hard collar, extrication collar, Philadelphia collar, bilateral sandbags jointed with cloth tape across the forehead, and the combination of sandbags, tape, and the Philadelphia collar. Hard foam and hard plastic collars were better at limiting cervical spine motion than soft foam collars. The Philadelphia collar was not significantly better than the other two types of hard collars, except in limiting extension. Neither collars alone nor sandbags and tape provided satisfactory restriction of cervical spine motion. Sandbag immobilization was significantly better than any of the other four methods used alone. The authors found that sandbags and tape combined with a rigid cervical collar were the best means of those evaluated to limit cervical motion. Chandler et al. (1992)[69] (n = 20) compared a rigid cervical extrication collar with the Ammerman halo orthosis in 20 men. Both orthoses significantly reduced motion in all planes ($p<0.001$) with the Ammerman halo orthosis reducing these motions significantly more ($p<0.001$). With the use of a spine board these motions were restricted even more ($p<0.001$). The Ammerman halo orthosis with a spine board provided the greatest immobilization, equivalent to that provided by an halo-vest.

Despite their widespread use in the pre-hospital setting, the use of rigid cervical collars can be associated with possible complications (Hadley 2002[66], Webber-Jones 2002[70], Plaisier 1994[71]). A possible elevation of intracranial pressure (ICP) was reported by Kolb et al. (1999)[72]. They examined changes in intracranial pressure after the application of a rigid Philadelphia collar in 20 adult patients. ICP averaged 176.8 mm H_2O initially and increased to an average of 201.5 mm H_2O after collar placement. Although the difference in ICP of 24.7 mm H_2O was statistically significant ($p=0.001$), it remains uncertain that it has clinical relevance. Nonetheless, this modest increase in pressure may be important in patients who already have elevated ICP. Cervical collars also may increase the risk of skin damage. Pressure exerted by a rigid collar is a possible cause of pressure ulcers. Specific areas of concern are occiput, chin and mandible. Other possible side-effects correlated with the use of rigid collars are limitations in swallowing, coughing, breathing and vomiting, leading to an increased risk of aspiration. Additional injuries to the spinal cord can also occur. In general, the rigid cervical collar restricts 30 – 83% of neck motion, but these collars have somehow erroneously developed a reputation for 100% motion restriction and therefore inadvertently provide a false sense of security for full neck immobilization.

In general, there is a ***strong recommendation*** (grade 1B, according to Guyatt et al. 2006[1]) ***to use a rigid cervical collar in combination with other immobilization devices*** in trauma patients with possible cervical spine injuries. To avoid possible harms the immobilization devices should be removed as soon as definitive evaluation is accomplished and/or definitive management is initiated.

Key points

- **A combination of a rigid cervical collar and supportive blocks on a blackboard with straps is effective in limiting motion of the cervical spine in trauma patients with potential cervical spine injuries. These spine immobilization devices should be used to achieve the goals of spinal stability for safe extrication and transport. They should be removed as soon as definitive evaluation is accomplished and/or definitive management is initiated. It is unclear whether the spines of all trauma patients must be immobilized during preadmission transport. The development of specific selection criteria for those patients for whom immobilization is indicated remains an area of investigation.**
- **Despite the widespread use of rigid cervical collars in trauma patients, there are no RCTs available supporting their clinical evidence in trauma patients. Studies on healthy persons suggest they contribute to spinal immobilization.**
- **Observational studies show that the use of rigid collars may be associated with possible harms (cf. increased intracranial pressure, airway difficulties, skin ulceration). Their use should be limited in time.**

2.4.1.6 Conclusions

Based on the guidelines, reviews and RCTs summarized in this section, Table 2 presents an overview of the clinical evidence for the use of neck braces. The last column contains the level of evidence and grade recommendations according to Guyatt et al. (2006)[1].

Table 2 : Clinical evidence for use of neck braces and the grade of recommendation.

Pathology	Conclusion	Grade of recommendation
Whiplash injury	Moderate quality evidence of no use of brace for this indication	Strong recommendation, (grade 1B)
Cervical osteoarthritis	(Very) low quality evidence of no use of brace for this indication	Weak recommendation (grade 2C)
Cervical brachialgia (cervical radiculopathy)	(Very) low quality evidence of no use of brace for this indication	Weak recommendation (grade 2C)
Cervical fracture/ Cervical dislocation	(Very) low quality evidence for use of brace for this indication	Strong recommendation (grade 1C)
Spinal immobilization for trauma patients	Moderate quality evidence for use of brace for this indication	Strong recommendation (grade 1B)

2.4.2 Costs

No cost studies of neck braces were identified.

2.4.3 Cost-effectiveness

No economic evaluations of neck braces were identified.

2.5 KNEE BRACES

2.5.1 Effectiveness

Through the American Academy of Orthopaedic Surgeons (AAOS) knee braces are currently classified into four categories based on their intented use (AAOS 2003[73], BlueCross of California 2006[74]):

- *Prophylactic knee braces*, intended to prevent or reduce the severity of knee ligament injuries in contact sports.
- *Rehabilitative knee braces,* designed to allow protected and controlled motion during the rehabilitation of injured knees.
- *Functional knee braces,* designed to provide stability for unstable knees during activities of daily living or sports.
- *Unloader/offloader braces,* which are designed to provide pain relief in arthritic knees.

2.5.1.1 Osteoarthritis (OA) of the knee

Osteoarthritis can occur in different areas of the knee or the whole knee. Depending on the area, OA can change the alignment of joints.

Patients with osteoarthritis of the medial compartment often have a varus (towards the midline of the body) alignment, and the mechanical axis and load bearing pass through the medial compartment. Patients with osteoarthritis of the lateral compartment generally have a valgus alignment (towards the lateral side of the body), and the mechanical axis and load bearing pass through the lateral compartment.

To date, only knee braces for ***medial compartment osteoarthritis*** were studied. Compared with lateral compartment osteoarthritis, medial compartment osteoarthritis has a much higher prevalence. Furthermore, bracing for lateral osteoarthritis is probably less effective. In general osteoarthritis of the knee, there is no compartment to unload and perhaps a sleeve or a neutral brace will benefit, but further research is necessary to confirm this. In OA of the medial compartment, knee braces may fix or correct the alignment, provide support and help weak muscles. It is thought that by providing support, braces may decrease pain, improve physical function and slow the progress of OA (Brouwer 2005[75]).

In the literature, several recommendations for the medical management of osteoarthritis of the knee can be found. The American College of Rheumatology (1995[76], update 2000) was the first to outline the use of non-pharmacologic modalities, including the use of braces, in patients with OA of the knee. However, these guidelines were not evidence based. An evidence-based approach was made by the EULAR (European League Against Rheumatism) task force (2003)[77]. Based on the study of Kirkley (1999)[78] (described further in this report) they recommended the use of knee bracing for reduction in pain and improvement in function in patients with osteoarthritis of the knee. Other guidelines concerning the 'Diagnosis and treatment of adult degenerative joint disease of the knee' were published by the Institute for Clinical Systems Improvement (ICSI) (2004)[79]. They mentioned that knee sleeves and unloader braces can reduce pain in osteoarthritic patients with varus deformities. Those patients can be referred to an orthotist or a physiotherapist to assist in fitting the brace. Finally, we report the guidelines made by the American Academy of Orthopaedic Surgeons (AAOS) (2003, 2004)[73]. The AAOS believes that some unloader braces may provide significant reduction in pain when properly fitted in selected patients with osteoarthritis of the knee. Patients with OA of the knee and varus or valgus deformity often develop increased pain in the affected compartment due to increased mechanical loading. Unloader/offloader braces are designed to reduce asymmetric loading of such knees. There is strong biomechanical data demonstrating reduction in adduction movement in varus knees when the appropriate unloader brace is used. Clinical studies have shown improved pain and function in patients with medial compartment osteoarthritis using

some unloader braces. Patients with advanced osteoarthritis or severe varus or valgus malalignment would not likely benefit from bracing. In addition, patient compliance is an important consideration according to the authors.

A recent review about 'Braces and orthoses for treating osteoarthritis of the knee' has been published in the Cochrane Library (Brouwer 2007[80]). Only one RCT study (Kirkley 1999)[78] (n = 119) of low methodological quality was included, comparing the clinical effectiveness of a custom-made valgus-producing unloader knee brace (generation II custom-made brace consisting of a polyethylene thigh shell connected to a polyethylene calf shell through a polyaxial hinge on the medial side, which allows application of four degrees valgus), a neoprene sleeve, and medical treatment only (control group) in patients with medial compartment osteoarthritis. At the six-month follow-up evaluation, the osteoarthritis specific quality of life score (WOMAC) in the brace group showed greater improvement compared with the sleeve group, which showed greater improvement compared with the control group. Also function tests (pain on the 6-minute walk test, pain on the 30-seconds stair-climbing test) showed greater improvement in the brace group compared with the sleeve group, which showed greater improvement compared with the control group. In general, the authors conclude that there is limited evidence that an unloader knee brace has additional beneficial effects in terms of pain and function for medial knee OA compared with medical treatment alone. This effect is probably due through an improvement in joint-position sense (proprioception) combined with a biomechanical unloading effect. However, long term implications (both for clinical evidence and possible side effects) are lacking.

In an early cross-over study Horlick et al. (1993)[81] (n = 39) evaluated the efficacy of the same valgus-producing GII brace (consisting of fairly rigid plastic thigh and calf sockets and a polyaxial hinge on the medial side) in relatively young athletic patients with medial gonarthrosis. Each patient was evaluated for 6 weeks under three conditions : no brace, the brace in neutral alignment, and the brace in valgus alignment. Assessment of pain using a visual analogue scale during activities of daily living demonstrated a reduction in pain only during the interval with brace in valgus alignment ($p< 0.0001$). Draper et al. (2000)[82, 83] correlated subjective and objective outcome measures by using the Hospital for Special Surgery knee score (HSS) and instrumented gait symmetry in their study of 30 patients treated with the same valgus-producing GII brace (consisting of two semi-rigid plastic shells for the thigh and calf, linked by a polyaxial medial hinge set at 4° of valgus) for medial compartment OA. At three months, all patients reported subjective improvements in their symptoms, with less pain on walking on the treadmill with the brace fitted. This was confirmed by a significant improvement in objective knee scores ($p<0.001$) and gait symmetry ($p<0.05$). However, this study did not contain a real control group since the patients served as their own control. Two additional small studies without a control group [Hewett 1998 (n = 18, using a commercially available valgus brace with a dual-hinged adjustable strut fixed to the brace shell at the calf and thigh to decrease the loads on the medial tibiofemoral compartment) and Lindenfeld 1997[84] (n = 11, using a valgus brace designed to unload the medial knee compartment with an adjustable tension strap that crossed the lateral aspect of the knee joint, while fixed to the brace shell at the calf and the thigh)] confirmed significant improvements in pain and knee function when patients wore valgus braces to treat medial osteoarthritis of the knee.

In a very recent study Draganich et al. (2006)[85] compared the effectiveness of a custom and off-the-shelf patient-adjustable valgus-producing knee brace in relieving pain, reducing stiffness, and improving function in 11 patients with varus gonarthrosis of the knee. Patients served as their own controls and wore each of the two braces for 4 to 5 weeks with a wash-out period of 2 weeks. Both braces significantly reduced pain and stiffness compared to baseline values. However, the custom brace was more effective than the off-the shelf brace in improving pain, stiffness and function. The results of this study strongly suggest that the closeness of fit of a certain brace on the limb is important for the clinical effectiveness. More studies comparing the clinical efficacy of different types of unloader braces are necessary in the future.

In general we can conclude that in the above studies bracing has been studied in patients with concomitant use of NSAIDS or analgesics, so it is difficult to assess what benefits

bracing alone may have. Larger prospective clinical studies should address this issue. Currently, there is no firm guideline regarding how much coronal angulation (cf. alignment of the knee joint towards the midline of the body) can be treated with a valgus-producing brace, but manufacturers recommend a varus angulation ≤ 10°. The duration of brace use may vary from patient to patient. Patients with milder degrees of arthritic change may need to wear the brace only during high-impact activities, such as sports, walking long distances, or standing for long periods. However, patients with more advanced stages of OA may need to wear the brace all day. Possible contraindications for unloading knee bracing are patients with medial compartment arthritis who have injury or chronic stretch of the medial collateral ligament or anteromedial structures of the knee, because these patients may be susceptible to further damage of those structures with the continued stress applied by the brace. Furthermore, one should be careful in treating patients with risk factors for deep-vein thrombosis, since tight bracing of the knee can cause venous stasis in the limb and lead to deep-vein thrombosis and pulmonary embolus (Pollo 2006[86], Giori 2004[87]).

Based on the above study results, ***a strong recommendation*** (grade 1B, according to Guyatt et al. 2006) for use of ***valgus producing unloader knee braces in the treatment of medial compartment osteoarthritis of the knee*** (varus angulation ≤ 10°) can be made. The duration of brace use may vary from the degree of osteoarthritis.

Key points

- **Results of several studies show an improvement in pain and function when patients with medial compartment osteoarthritis are splinted with a valgus-producing unloader knee brace. However, RCTs without the concomitant use of pain killers are necessary to confirm these results.**
- **Manufacturers recommend varus angulations ≤ 10° can be treated with valgus-producing knee braces. The duration of brace use may depend on the degree of osteoarthritis.**

2.5.1.2 Patellofemoral pain syndrome (PFPS)

Patellofemoral pain syndrome can be defined as retropatellar or peripatellar pain resulting from physical and biochemical changes in the patellofemoral joint.

It should be distinguished from chrondromalacia, which is actual fraying and damage to the underlying patellar cartilage. Patients with patellofemoral pain syndrome have anterior knee pain that typically occurs with activity and often worsens when they are descending steps or hills. It can also be triggered by prolonged sitting. One or both knees can be affected (Juhn 1999[88]). Patellofemoral braces are introduced to resist lateral displacement of the patella, maintain patellar alignment and, theoretically, decrease knee pain (Paluska 2000)[89, 90].

According to the American Academy of Family Physicians (Juhn 1999[88], Paluska 2000[89, 90]) the use of knee sleeves and braces is controversial in patients with patellofemoral pain. This lack of consensus stems from the absence of well-controlled studies addressing their efficacy. Nonetheless, patients appear to welcome patellofemoral braces and report significant subjective improvements in pain and disability with brace wear. Overall, the authors conclude that patellofemoral braces should be used in conjunction with a comprehensive knee rehabilitation program that includes strengthening, flexibility and technique improvements. These guidelines are in agreement with the more recent APA (Australian Physiotherapy Association) recommendations concerning "The physiotherapy treatments for patellofemoral pain" (2005)[91]. They report that there is insufficient evidence to support or refute the use of patellar bracing or taping. These interventions may be used, provided there is evidence of improvement in subjective and objective outcomes. A large number of within-subject design studies have identified an immediate reduction in pain in response to patellar bracing or taping, but the mechanism behind the pain relief is unclear. However, evidence from systematic reviews of RCTs is inconclusive. Further investigation on taping and patellar bracing is required.

A systematic review concerning "Orthotic devices for treating patellofemoral pain syndrome" was published by D'hondt et al. (2002)[92]. This review included only one study (cf. Timm 1998[93]) (n = 100) comparing the effect of a Protonics orthosis versus no treatment for treating PFPS. The use of a Protonics orthosis is based on a theory that a high volume of submaximal concentric contractions of the quadriceps and hamstring muscle groups will facilitate an appropriate alignment of the patella in the femoral groove and reduce the patellofemoral pain and the abnormal patellofemoral congruence. After a 4 week follow-up, the Protonics orthosis was significantly more effective for decrease in pain on a visual analogue scale [weighted mean difference (WMD) between groups 3.2; 95% CI 2.8 – 3.6], functional improvement on the Kujala scale (WMD 45.6; 95% CI 43.4 – 47.7) and change in patellofemoral congruence angle (WMD 17.2; 95% 14.1 – 20.3) when compared with no treatment. Miller et al. (1997)[94] compared the efficacy of a Palumbo brace (consisting of a mechanism wherein a lateral pad 'floats' over the patella, helping it to maintain the most effective position during knee motion) with the Cho-Pat knee strap (designed to improve patellar tracking and to spread pressure uniformly over the knee surface as the knee bends and straightens) in a prospective, randomized study on 59 basic cadets who represented with anterior knee pain during the initial phases of basic cadet training. Group 1 received no brace, group 2 was issued a Palumbo 'Dynamic patellar brace', and group 3 was issued a Cho-Pat knee strap. All patients were started on physical therapy with "closed chain" rehabilitation and given non-steroidal anti-inflammatory medication. Although the study describes a follow-up period of eight weeks, only data from two to three weeks were presented. After that period, no significant difference between the groups regarding change in pain and motivation (both assessed on a VAS scale) was observed. In general, the authors of the review conclude that the evidence from RCTs is too limited to draw definitive conclusions about the use of knee orthotics for the treatment of patellofemoral pain syndrome. The follow-up period used in these trials might not be sufficient to detect clinically relevant changes. Based on their own clinical experience they suggest that the short-term follow-up period should involve at least eight weeks. Furthermore, they mention that it would be interesting to see if a positive effect is maintained for a longer period after treatment.

In a recent prospective, randomized single-blinded study, Lun et al. (2005)[95] (n = 136) investigated the effectiveness of patellar bracing on patients with patellofemoral pain syndrome. Subjects were randomly assigned to 1 of 4 treatment groups : home exercise program, patellar bracing (special FX brace; generation II orthotics with a Y-shaped inferior patellar buttress pad and an external stabilization strap to help control the patella), home exercise with patellar bracing, and home exercise program with knee sleeve (same sleeve material as the patella, no hole was made in the sleeve over the patella). There was no difference in the 95% confidence intervals in change of knee function and visual analogue scale pain ratings among the 4 treatment groups over 12 weeks. Symptoms of PFPS improved over time in terms of pain (during sport activity, 1 hour after sport activity, and after sitting with knees bent for 30 minutes) and knee function regardless of the treatment group. Patellar bracing did not improve the symptoms of PFPS more quickly when added to a home program of leg strengthening. However, patellar bracing alone can improve the symptoms of PFPS. Denton et al. (2005)[96] (n = 34) examined the clinical efficacy of the addition of the Protonics orthosis to a standard-based patellofemoral rehabilitation protocol. After 6 weeks, patients in both groups demonstrated significant improvements in knee function ($p<0.001$), performance on the lateral step-up test ($p<0.001$) and pain during the step-up test ($p<0.001$). However, there was no significant difference between groups with respect to those three outcomes after 6 weeks. Patients using the Protonics system demonstrated a shift in increased hip rotation and reported less pain with step-up testing, however these changes were not outside the bounds of potential measurement error and did not translate into significant differences. So, the authors of the study conclude that there is no clinical benefit when bracing is used in addition to physical therapy.

The above data do not support the use of patellar bracing in the treatment of patellofemoral pain syndrome. Other alternatives like physical therapy may be equally reasonable (***weak recommendation***, grade 2C according to Guyatt et al. 2006[1]).

Key points

- **Although patellar bracing alone may provide some symptomatic relief, the evidence did not show a significant benefit when a patellar brace was used in addition to physical therapy.**
- **More rigorous studies comparing bracing with 'do nothing' over a longer period are needed to draw firm conclusions.**

2.5.1.3 Anterior cruciate ligament injuries (ACL injuries)

An anterior cruciate ligament injury is extreme stretching or tearing of the anterior cruciate ligament in the knee. It can be caused by abnormal rotational stress placed on the knee. In general, the incidence of ACL injures is higher in people who participate in high-risk sports such as basketball, football, skiing, and soccer.

The American Academy of Orthopaedic Surgeons (AAOS) "Position Statement regarding the Use of Knee Braces" (2003)[73] states that whereas functional knee braces offer limited control of functional instability symptoms in patients with anterior cruciate ligament injuries, they have not been shown to prevent the development of meniscal tears and articular cartilage wear. Studies have shown that some of the currently available braces are very effective in controlling abnormal motions under low loading conditions but not under high loading conditions that occur during many athletic activities. Most studies designed to test whether functional knee braces protect against the knee "giving way" have demonstrated some beneficial effect of the brace. However, the patient and the physician must guard against a false sense of security evoked by the use of such a brace; biomechanical studies show that functional knee braces do not restore normal knee stability under high forces related to certain activities. Furthermore, some studies suggest that functional braces negatively affect some aspects of athletic performance.

According to the National Guideline Clearinghouse guidelines on "Diagnosis and management of soft tissue knee injuries : internal derangements" (2006)[97] bracing is generally not required for the conservative management of soft tissue knee injuries. Bracing may be indicated in selected cases where recurrent instability exists, but concurrent medical conditions or other factors preclude surgery. Furthermore, bracing may be indicated in selected cases where there is a psychological benefit associated with wearing a brace which enhances a person's ability to undertake tasks in work and sport. This is in agreement with the National Guideline Clearinghouse guidelines on "Lower extremity musculoskeletal disorders" (2006) stating ACL injuries in older patients, who are often less affected by knee instability due to decreased activity levels, may be managed conservatively with hamstring and quadriceps strengthening exercises and bracing for vigorous activity. Surgery is sometimes indicated for more active patients.

In a recent prospective randomized trial Swirtun et al. (2005)[98] evaluated the effect of a functional knee brace during early treatment of patients with a nonoperated acute ACL tear. 95 patients (18–50 years old) were randomized to either a brace group, treated with functional bracing (from < 5 weeks postinjury to 12 weeks postinjury) or a control group, treated without bracing. 42 patients completed the trial and were followed for six months. Patients in the brace group experienced less ($p = 0.047$) sense of instability, evaluated with a visual analogue scale, than the control group. Subjectively, they experienced a positive effect of the brace on rehabilitation. However, these findings were not supported by objective outcomes (cf. the Knee Osteoarthritis Outcome Score or the Cincinnati Score).

Barrack et al. (1990)[99] evaluated the results of a conservative treatment (early rehabilitation and bracing) in 72 patients with complete ACL tears. At an average follow-up of 38 months, overall results of symptoms and knee function were excellent in 11%, good in 20%, fair in 15% and poor in 54% of the patients. 35% of the patients had ACL reconstruction during the follow-up period. These results indicate that young adults who return to a vocation requiring strenuous physical activity frequently can expect unsatisfactory results after nonoperative treatment of an acute complete tear of the ACL.

In their study Fujimoto et al. (2002)[100] examined the healing capacities of ACL injuries in 31 patients with low athletic demands treated with an extension block soft brace without anterior stabilization for 2-3 months. After a follow up of 6-36 months 74% of the knees revealed to be stable. The authors of the study conclude that conservative management of the acute ACL injury can yield satisfactory results in a group of individuals who have low athletic demands, provided the patients are willing to accept the slight risk of late ACL reconstruction and meniscal injury.

Overall, the results of the above studies show some weak clinical evidence (weak recommendation, grade 2C according to Guyatt et al. 2006[1]) for using functional knee braces in the treatment of ACL injuries in patients with low athletic activities. However, orthotists must guard patients against a false sense of security evoked by the use of such a brace.

Key points

- **Functional knee bracing in patients with ACL injuries can give acceptable recovery results in patients with low athletic demands. However these subjective findings are not supported by objective outcomes.**
- **Orthotists must guard against a false sense of security evoked by the use of a functional knee brace in patients with ACL injuries.**

2.5.1.4 Bracing after anterior cruciate ligament (ACL) reconstruction

Bracing in the immediate post-operative period following ACL reconstruction was standard practice for many years. Braces were designed to allow protected motion to prevent excessive loading on the graft. With improved operative techniques in ACL reconstruction, the need for bracing to protect the graft in the immediate post-operative period has been questioned. Recent surveys show that about 50% of surgeons still use bracing in the early post-operative period following ACL reconstruction in the UK, Canada, Australia, and the USA, suggesting that this aspect of management is still controversial. However, the evidence base to support this rationale has not been convincingly demonstrated (New Zealand Guidelines Group 2003[101]).

According to the National Guideline Clearinghouse recommendations (2006) concerning "The diagnosis and management of soft tissue knee injuries"[101], bracing of the knee in the immediate post-operative period following anterior cruciate ligament reconstruction is not recommended. In their "Position Statement on Knee Braces", the American Academy of Orthopaedic Surgeons (AAOS) (2003)[102] believes that after ACL reconstruction, there may be a role for rehabilitation braces used in the early post-surgical phase, but functional braces used later during recovery appear to provide no added protection on the knee following a well performed reconstruction. Some evidence is reported that the use of rehabilitation braces in the initial post-surgical period may improve early functional outcomes. However, the majority of scientific studies show no difference in final outcomes of anterior cruciate reconstructed knees, whether a brace is worn or not. The overall long-term outcomes in all studies reviewed was good. Thus, it does not appear that a brace is needed to support or protect a reconstruction in a well done surgical procedure. Questions remain as to whether a brace would be useful to support the knee in patients with ACL reconstructions in special cases (e.g. weakened tissue, collagen disorders, suboptimal fixation). Since these braces neither improve nor degrade the long-term results of ACL surgery, they should remain in the armamentarium of the orthopaedic surgeon for discretionary use.

Wright et al. (2007)[103] published a very recent systematic review on "Bracing after ACL reconstruction". Below, you find a brief description of the several RCTs comparing the clinical effectiveness of rehabilitation and functional braces after ACL reconstruction.

Kartus et al. (1997)[104] evaluated the effect of a standard post-operative rehabilitation knee brace on function, stability and post-operative complications after an anterior cruciate ligament (ACL) reconstructive surgery in a retrospective study. Post-operatively, 87 patients were consecutively divided into a standard rehabilitation protocol with or without a knee brace (Genu Syncro Quick-lock S 2300) for 4 weeks. 2

years after the ACL reconstruction, knee function, stability and post-operative complications were comparable in both treatments groups. The brace did not influence the subjective results (pain, stability) or the functional performance, nor did it shorten the time of the sick leave period (median of 62 days with the brace vs. 59 days without the brace). However, this study did not verify the hypothesis that graft protection by using a knee brace improved stability and function in the early rehabilitation period after arthroscopic ACL reconstruction.

In their prospective study Brandsson et al. (2001)[105] examined the use of a knee brace (DonJoy, Smith & Nephew) after arthroscopic anterior cruciate ligament reconstruction. 50 patients were randomly allocated to a standard rehabilitation program with or without the use of a brace three weeks post-operatively. At the two year-follow-up, there were no significant differences between both study groups in terms of knee function, knee laxity and activity level. However, the braced group had less pain (1.0 vs. 2.3 on a visual analogue scale from 0-10, p=0.04) than the non-braced group during the first two post-operative weeks and displayed a tendency towards fewer early complications. Post-operative pain is an important factor after ACL reconstruction. Almost half of the patients in this study complained that post-operative pain had hampered their early rehabilitation. So lowering this pain might be important when it comes to reducing post-operative complications.

Risberg et al. (1999)[106] (n = 60) evaluated the use of a rehabilitative and functional brace for the first 12 weeks after ACL reconstruction. Patients randomized to the braced group, wore a rehabilitative brace (DonJoy rehabilitative range of motion brace) for two weeks, followed by a functional brace (DonJoy Gold Point) for 10 weeks, patients in the control group wore no brace and performed the same standard physical therapy. 6 weeks, and 3, 6, 12 and 24 months postoperatively, there were no significant differences between both groups with regard to knee joint laxity, range of motion, muscle strength, functional knee tests, or pain. However, the Cincinnati knee score (a patient- and physician-based knee outcome score) was significantly increased for the braced group at 3 months ($p<0.005$) compared with the non-braced group, even though the braced group showed significantly ($p<0.0001$) increased thigh atrophy compared with the non-braced group at 3 months.

Möller et al. (2001)[107] prospectively randomized 62 patients to rehabilitation programs either with or without post-operative bracing (DonJoy E.L.S rehabilitative brace) for 6 weeks following bone-tendon-bone ACL reconstruction. The non-braced group had a smaller knee circumference 2 weeks after surgery and a better Tegner knee activity score 6 months post-operatively, but a two years there was no difference between the groups. Furthermore, there were no differences between both groups in either subjective or objective knee stability at 2 or 6 weeks or at follow-up 3, 6, and 24 months after surgery.

Muellner et al. (1998)[108] (n = 40) evaluated a hinged brace (DonJoy; Smith & Nephew) versus a neoprene sleeve during 6 weeks after ACL reconstruction. All patients participated in identical postoperative rehabilitation protocols. The authors suggested the neoprene sleeve improved range of motion better during the first 12 weeks than the hinged brace, but provided no supportive data. After 24 weeks the function of the knee (cf. one-leg hop test) was better in the neoprene sleeve group compared to the braced group. After 1 year, no differences regarding the stability of the knee and subjective knee scores could be seen between both groups. Therefore the authors of the study concluded the use of a brace should be limited to patients with multiple ligamentous injuries and those who have to be restricted in their postoperative activities. However, further studies are mandatory to evaluate the effect of the bandage on the long-term follow-up after ACL reconstruction.

Mc Devitt et al. (2004)[109] reported the only prospective study evaluating the effectiveness of a functional brace after ACL reconstruction. In a multicenter, prospective study, 100 patients were randomized after ACL reconstruction into 2 groups. Group 1 wore a hinged knee brace (DonJoy IROM, locked in extension for 3 weeks and set to allow ROM from full extension to within 10° of the flexion achieved in therapy during weeks 3 to 6). Six weeks after surgery patients were fitted with an off-the-shelf function ACL brace and asked to wear it full-time for 6 months and during "rigorous" activities for at least 1 year. Group 2 wore a knee immobilizer for 3 weeks,

after that all bracing was stopped. After a 2-year follow up, no significant differences between both groups could be seen for a wide range of subjective and objective outcome measures, functional tests, stability assessments, and isokinetic strength measurements. There were no significant differences in injury and complication rates; however, with the small number of injuries and complications seen in this study, the population size was too small to conclude that functional bracing does not influence the reinjury or complication rates after ACL reconstruction in a young, active population.

All studies described in this review contain several potential biases (cf. failure to disclose randomisation methods, blinding, use of an independent examiner, small studies, problems with compliance). However, the authors of this review generally conclude there is no evidence supporting the routine use of functional or rehabilitative braces in patients with a reconstructed ACL. There was no study demonstrating a clinically important finding of improved range of motion, decreased pain, improved graft stability or decreased complications and reinjuries.

In a recent prospective 5-year follow-up study (Harilainen et al. 2006)[110] 60 patients were randomized to brace and non-braced groups after a bone-tendon-bone ACL reconstruction. The brace group wore a rehabilitation orthosis (DonJoy COOL IROM) for 12 weeks post-operatively, while the non-braced group was mobilized immediately, and crutches were discarded 2 weeks post-operatively. 5 years post-operatively, there were no differences between both groups in terms of knee score, activity level, degree of laxity or isokinetic peak muscle torque.

To date, hamstring tendons have gained popularity over the patellar tendon in ACL reconstruction. There should not be as much post-operative anterior knee pain as in BTB reconstruction. However, prospective randomized studies of post-operative rehabilitation after hamstring tendon reconstructions with or without braces have not been published to the best of our knowledge.

The above studies do not support the use of bracing of the knee in the post-operative period following a well done anterior cruciate ligament reconstruction (***weak recommendation***, grade 2C according to Guyatt et al. 2006). An accelerated rehabilitation program is currently suggested to offer a reasonable alternative with possible better functional outcomes and fewer complications.

Key points

- **The current post-operative management of ACL injuries is based on an 'accelerated rehabilitation program' which has been shown to produce better functional outcomes and fewer complications.**
- **To date, the available evidence does not demonstrate a clinically important finding of improved range of motion, decreased pain, improved graft stability or decreased complications and reinjuries for bracing in the immediate post-operative period following ACL reconstruction.**

2.5.1.5 Medial collateral ligament injuries

A medial collateral ligament injury is a stretch, partial tear, or complete tear of the ligament on the inside of the knee. The ligament is usually injured by pressure placed on the knee joint from the outside. The American Medical Association (1966) distinguishes between three grades of medial collateral ligament injuries. A grade I injury consists of a minimal number of torn fibres, localized tenderness, and no instability. A grade II injury involves a greater degree of ligamentous disruption with slight to moderate abnormal motion. Finally, a grade III injury refers to a complete tear of the ligament with disruption of fibers and demonstrable instability.

Several literature reviews have assessed the effectiveness of conservative approaches to medial collateral ligament injuries for the three grades of medial collateral ligament injuries (Kannus and Järvinen, 1990; Reider, 1996; Azar, 2006; Edson, 2006; Giannotti et al., 2006). With a grade I injury, the patient may not need a brace or, at most, be placed in a short-leg brace to enable early motion. Range of motion exercises and

strengthening exercises as tolerated are advised. With a grade II injury, a long-leg brace is recommended in combination with range of motion exercises and strengthening exercises. As an alternative to surgical management of a grade III injury, a brace is recommended in combination with range of motion exercises and strengthening exercises. Grade III injuries can be treated non-operatively, but only after exclusion of any associated injuries that may require surgical management. Finally, these reviews emphasized the need for a supervised, functional rehabilitation program in addition to bracing. Early activity has been advocated to avoid deleterious effects of immobilization on cartilage, bone, muscles, tendons and ligaments by improving cartilage nutrition and preventing scarring and adhesions.

Reider et al. (1994) carried out a prospective case series of 35 athletes suffering from isolated grade III sprains of the medial collateral ligament. Patients received a lateral hinged brace to provide valgus support without restricting flexion or extension of the knee. Additionally, they entered a programme of early functional rehabilitation consisting of range of motion exercises, quadriceps setting, leg raises and resistive exercises. Patients were followed up for five years. The mean score of patients on the 50-point Hospital for Special Surgery scale was 45.9 points (range 41-50 points), placing all of the knees in the good-to-excellent category of the scale. The authors argued that the results of bracing in combination with early functional rehabilitation were comparable with those achieved with surgery or immobilization, while minimizing treatment-related morbidity and enabling a more rapid return to sports participation.

A German retrospective study compared conservative options to treat a rupture of the medial collateral ligament of the knee joint (Pforringer et al., 1993). Patients were either partially immobilized with a brace (Texas or Donjoy brace) and engaged in early functional therapy (n=26); or were immobilized in a plaster cast for six weeks (n=36). Patients receiving a brace and early functional rehabilitation performed better in shorter rehabilitation and in all other treatment aspects. However, the study is likely to suffer from selection bias in that patients wearing a brace were highly-motivated athletes with a developed musculature, which may speed up recovery. The authors recommended that plaster casting for isolated ruptures of medial collateral ligaments should not be used.

Results of the above studies show ***a clinical indication*** for bracing of the knee in combination with functional rehabilitation to treat medial collateral ligament injuries (***strong recommendation***, grade 1C according to Guyatt et al. 2006). To date, no randomised controlled trial has been carried out examining the effectiveness of bracing in the field of medial collateral ligament injuries of the knee.

Key points

- **Isolated tears of the medial collateral ligament can be treated non-operatively by means of a brace in combination with a functional rehabilitation program.**
- **The evidence is derived from non-randomised studies and its value, therefore, is limited.**

2.5.1.6 Prevention of medial collateral ligament injuries in contact sports

Prophylactic knee braces have been intended to prevent injuries to the medial collateral ligaments in contact sports. The evidence base is limited and suffers from methodological shortcomings, including inadequate control groups, inconsistent methods of data collection, and biases. A review of the literature concluded that the effectiveness of braces to prevent medial collateral ligament injuries is uncertain (Reider, 1996). Some studies have found that prophylactic knee braces significantly reduce medial collateral ligament injuries (Albright et al., 1994a,b; Sitler et al., 1990), while others have detected few beneficial effects with regular use (Albright et al., 1995).

The American Academy of Orthopaedic Surgeons and the American Academy of Pediatrics have pointed to a lack of evidence of the efficacy of prophylactic knee braces in reducing the incidence and severity of ligamentous knee injuries (American Academy

of Pediatrics, 1990; American Academy of Orthopaedic Surgeons, 1999). The use of prophylactic knee braces seems to be less important in preventing medial collateral ligament injuries than strength training, conditioning, technique refinement and flexibility. Similarly, a literature review found that prophylactic bracing has not been conclusively shown to have the capacity to reduce injury to the knee (Baker, 1990).

A recent literature review found that braces may be effective in reducing the injury rate for braced athletes based on the results of two epidemiological studies (Najibi and Albright, 2005). There was no evidence that brace use is associated with increased frequency or severity of knee injury. However, preventive knee braces may negatively impact performance level of athletes, leg cramping and fatigue symptoms.

Although the prevention of medial collateral ligament injuries is out of scope of this project, this section is included for the completeness of the report. As prevention of sport injuries is ineligible for reimbursement, ***no recommendations*** are made.

Key points

- **Prophylactic knee braces lack sufficient evidence of efficacy in preventing medial collateral ligament injuries in contact sports.**
- **More well-designed, prospective studies, comparing different models of knee braces, are needed.**

2.5.1.7 Conclusions

Based on the guidelines, reviews and RCTs summarized in this section, Table 3 presents an overview of the clinical evidence for the use of knee braces. The last column contains the level of evidence and grade recommendations according to Guyatt et al. (2006)[1].

Table 3 : Clinical evidence for the use of knee braces and the grade of recommendation.

Pathology	Conclusion	Grade of recommendation
Medial compartment osteoarthritis of the knee (≤ 10° varus angulation)	Moderate quality evidence for use of brace for this indication	Strong recommendation, (grade 1B)
Patellofemoral pain syndrome	(Very) low quality evidence of no use of brace for this indication	Weak recommendation evidence (grade 2C)
Anterior cruciate ligament injury	(Very) low quality evidence for use of brace for this indication	Weak recommendation (grace 2C)
Bracing after anterior cruciate ligament reconstruction	(Very) low quality evidence of no use of brace for this indication	Weak recommendation (grade 2C)
Medial collateral ligament injuries	(Very) low quality evidence for use of brace for this indication	Strong recommendation (grade 1C)
Prevention of medial collateral ligament injuries in contact sports	Out of scope	No recommendation

2.5.2 Costs

No cost studies of knee braces were identified.

2.5.3 Cost-effectiveness

A US study compared the cost-utility of ligament reconstruction with a patellar tendon autograft to non-operative care consisting of rehabilitation, counseling and functional bracing in young adults suffering from acute anterior cruciate ligament tears (Gottlob et

al. 1999, 2000)[111, 112]. A decision model was constructed for the initial seven years following the injury with effectiveness data derived from the literature and cost data derived from the author's institution. As cost estimates originated from a local source, they are unlikely to be generalisable to other settings or countries. A questionnaire was administered to university students and elicited utility values related to various classes of functional activity. The incremental cost-utility of operative over non-operative treatment was $5,857 per quality-adjusted life year. The cost-utility ratio was not sensitive to changes in model parameters.

An Australian study contrasted the cost-utility of disparate interventions (surgery, NSAIDs, primary prevention, patient education, knee braces, exercise and strength training, and other pharmacotherapies) for the prevention and management of osteoarthritis (Segal et al., 2004). Effectiveness data were derived from the published literature. As various disease-specific and generic instruments were used in primary studies to report effectiveness, commonly used osteoarthritis outcome scales were converted into a utility-equivalent scale. Combining these utility values with time lived in particular health states allowed the authors to compute quality-adjusted life years. Costs were calculated by multiplying health care program inputs by Australian unit costs. The results indicated that specifically manufactured and fitted knee braces for patients with knee osteoarthritis had an incremental cost-utility of $4,000 (around 2,530€)-$12,000 (around 7,590€) per quality-adjusted life year depending on the length of time the brace was worn as compared with 'do nothing' or usual care. Given the favourable cost-utility ratios for knee braces, the authors concluded that providing knee braces to patients for whom the treatment is clinically appropriate would represent an efficient use of healthcare resources.

2.6 CONCLUSIONS

This section draws conclusions from the scientific literature on cervical, wrist and knee braces. Conclusions derived from the review of the effectiveness of braces inform the choice of braces for which production costs are estimated in the next chapter.

With respect to wrist braces, braces seem to be indicated for carpal tunnel syndrome, rheumatoid arthritis and hand osteoarthritis. The evidence does not support the use of braces for the treatment of de Quervain's tenosynovitis. Evidence is lacking to support or refute the use of braces in hand/wrist spasticity after stroke and uncomplicated wrist fractures.

Focusing on cervical braces, a distinction needs to be made between soft and rigid braces. The data do not support the use of cervical braces for whiplash injury or cervical osteoarthritis. A rigid cervical brace is indicated in the treatment cervical fracture and spinal immobilization for trauma patients. Based on this evidence, we suggest that the estimation of production costs is limited to rigid cervical braces.

The evidence does not support the use of a knee brace in patellofemoral pain syndrome or following anterior cruciate ligament reconstruction. A functional knee brace may be indicated for anterior cruciate ligament injuries that are treated non-operatively. Bracing in combination with a rehabilitation program appears to be effective in treating medial collateral ligament injuries to the knee. A valgus producing unloader (rigid) knee brace is indicated in the treatment of medial compartment osteoarthritis of the knee. Therefore, we recommend that production costs are estimated for rigid knee braces only.

Key points

- **Production costs need to be estimated for rigid cervical and knee braces as these braces have been shown to be effective in treating specific pathologies.**

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3 INSTITUTIONAL ANALYSIS OF ORTHOTIC DEVICE MARKETS: INTERNATIONAL PERSPECTIVE

3.1 INTRODUCTION

The comparison that will be made in the following chapters between estimated costs of production and distribution of orthotic devices, and reimbursement tariffs hints at the impact that domestic regulatory factors have on market prices. Therefore, a detailed analysis of regulatory traits of markets for orthotic devices in various countries seems to be a logical step in assessing the market for orthotic devices for Belgian patients and health insurance funds. In this chapter, the term 'orthotic devices' is used to refer specifically to neck braces, wrist splints and knee braces.

This chapter describes the regulatory traits of the orthotic device market in Belgium and in a number of other countries (England, France, the Netherlands, Ontario (Canada), Sweden). These countries were selected for their comparable living standards and – barring Ontario (Canada) - geographic proximity to Belgium. Furthermore, the chosen country panel provides insight into the variety of regulatory mechanisms that govern orthotic device markets. Finally, health expenditure is primarily financed by the public payer in each of these countries[9].

Key points

- **This chapter examines regulatory traits of orthotic device markets in a number of countries;**
- **Regulation of the Belgian market is compared with regulation governing the Dutch, English, French, Ontario and Swedish markets.**

3.2 METHODOLOGY

Orthotic device markets were investigated by examining the following regulatory traits: pricing, reimbursement, distribution, and the prescribing process of orthotic devices. Pricing issues related to whether a country has adopted a system of free or fixed pricing. The mechanism for reimbursing orthotic devices and whether orthotic devices are fully or partially reimbursed were also identified. Different actors can be involved in distributing orthotic devices. Some countries have certified 'orthotists', i.e. health care professionals who specialise in the fabrication and delivery of orthotic devices to patients. Orthotic devices can also be delivered by shops that sell medical equipment, by community pharmacies or through the internet. Additionally, the way in which these actors are paid for delivering orthotic devices was explored. The final regulatory trait examined was the way in which orthotic devices are prescribed.

The following electronic databases were searched up to April 2007 to identify published studies on the regulation of orthotic device markets: Pubmed, EMBASE, Social Science and Citation Index, Cochrane Library, National Health Service Economic Evaluation Database and EconLit. The review of the international literature confirmed the absence of research on the regulation of orthotic device markets. Therefore, information about regulatory traits of markets was gained by accessing documents setting out national legislation and local publications. Additionally, a qualitative questionnaire (see appendix III) was filled in by correspondents from governmental and regulatory agencies, major orthotic device manufacturers, patient organizations, health insurance funds and

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9 Organisation for Economic Co-operation and Development (OECD). Health data 2002. OECD: Paris, 2002.

INAHTA (International Network of Agencies for Health Technology Assessment)[10]. Each country-specific section of this chapter was validated by a national expert (see appendix III).

Key points

- **The institutional analysis focused on issues related to pricing, reimbursement, delivery channels and distribution margins, and the prescribing process of orthotic devices.**
- **Regulatory traits of domestic orthotic device markets were examined through the perusal of legal texts and the analysis of survey results.**

3.3 BELGIUM

3.3.1 Registration

Orthotic devices are registered as medical devices with the Ministry of Health, Food Chain Safety and Environment.

3.3.2 Pricing

Pricing of orthotic devices is free in Belgium. The public price of orthotic devices is made up of a number of components (see Figure 5). Manufacturers sell devices to distributors at the ex-factory price, i.e. a price covering costs of research and development, production, marketing, import and a profit margin. The distributor sells the device on to the dispenser (i.e. the orthotist, cfr. infra) at the price to dispenser.

When the 'nomenclature'[11] of orthotic devices was developed in 1992, the mean price to dispensers across similar products was multiplied by the so-called 'Walkiers coefficient' to obtain the reimbursement tariff of each category of orthotic devices (see Figure 5). The Walkiers coefficient covers a pay-off for general costs, wages, measurement and adaptation of orthotic devices, and costs of materials. In other words, the delivery margin is determined by the Walkiers coefficient, although this does not have a legal foundation. The Walkiers coefficient that is used now by the Commission of Orthotists and Health Insurance Funds to determine the reimbursement tariff of new nomenclature codes is currently set at 2.13 for prefabricated devices and at 4 for custom-made devices.

For dispensers who adhere to the national agreement between orthotists and health insurance funds, the public price needs to be equal to the tariff for custom-made devices[12], but can exceed the tariff for prefabricated devices[13](see Figure 5). Dispensers who do not adhere to the national agreement are free to set prices, but reimbursement is limited to 75% of the reimbursement tariff as compared with a dispenser who adheres to the national agreement.

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10 http://www.inahta.org/inahta_web/index.asp

11 Set of billing codes describing the public reimbursement applying to products and/or services in Belgian healthcare.

12 A custom-made device is a device that is manufactured from raw materials and/or loose parts and that is individually manufactured according to the specific needs of the patient.

13 A prefabricated device is any standard device that is manufactured in a series and that may undergo small individual modifications.

Figure 5 : Pricing and reimbursement of orthotic devices

Stakeholders		Prices		Reimbursement
Manufacturer				
		Ex-factory price		
Distributor				
		Price to dispenser		
Orthotist				
		Price to dispenser x Walkiers coefficient	=	Tariff
Health insurance fund				
		Public price	=	Tariff + possible patient co-payment
Patients				

3.3.3 Reimbursement

The reimbursement of orthotic devices is linked to a number of nomenclature codes in combination with a description of the product class for each code. The dispenser determines the nomenclature code to which the delivered orthotic device belongs. A system of a posteriori control is in place for selected cases, where the manufacturer/importer/distributor invoice and the certificate of delivery by the orthotist to the patient are checked by the health insurance funds with which the patient is affiliated.

In the case of knee braces, a royal decree has imposed a personal co-payment of the patient that is subtracted from the reimbursement tariff of the brace. For prefabricated devices, dispensers can but do not have to ask for a supplementary patient co-payment (i.e. the difference between the public price and the reimbursement tariff). The dispenser is required to inform the patient of the existence of such a supplementary co-payment. If a dispenser decides not to charge or partially charge patients, this corresponds to the dispenser receiving a lower margin. However, dispensers are not allowed to sell orthotic devices at a loss. Manufacturers/importers/distributors can offer discounts to dispensers, thus increasing the margin of the dispenser.

The nomenclature lists types of orthotic devices and their availability as a prefabricated device or a custom-made device. In contrast with for example wheelchairs or orthotic shoes, no prior approval by the advising physician is required for prefabricated devices. If prefabricated and custom-made versions of the same product exist and the orthotist delivers the custom-made version, the orthotist must submit a detailed motivation to the advising physician of the health insurance fund and await his/her approval before delivery of the orthotic device to the patient. If only a custom-made version exists, such a motivation is not required. Custom-made devices are fully reimbursed by the RIZIV/INAMI if the dispenser adheres to the national agreement between orthotists and health insurance funds.

If there is no risk of a budget deficit, the Commission of Orthotists and Health Insurance Funds can adjust the reimbursement tariffs on the 1st January of each year on

the basis of the evolution of the 'Health Index'[14] during the previous six months. Conversely, if there is a (risk of a) budget deficit, corrective measures can be taken that primarily target those product classes exhibiting a disproportionate increase or that reduce the reimbursement tariff of those classes.

The dispenser is compelled to apply third-party-payer regulation if the cost of the orthotic device exceeds 310 €. This means that the patient does not pay the full amount to the dispenser, but only his/her personal and supplementary co-payment, if there is one. Subsequently, the dispenser is reimbursed by the health insurance fund for the remainder or the total of the amount. If the reimbursable value is lower than 310 €, the dispenser can choose whether or not to apply third-party-payer regulation. If the dispenser opts not to apply this regulation, the patient has to pay the full amount to the dispenser and then seek reimbursement from the health insurance fund.

Maintenance of orthotic devices by the dispenser is not compulsory, but does attract a reimbursement. Limits have been set on the minimum length of time that must expire before the orthotic device can be renewed and benefit from reimbursement. In the case of prefabricated devices, if the patient is less than 21 years old, then the orthotic device can be renewed after one year. If the patient is 21 years or older, renewal is possible after a period of three years. In the case of custom-made devices, if the patient is less than 14 years old, then the orthotic device can be renewed after one year. If the patient is between 14 and 21 years old, renewal is possible after a period of two years. For patients older than 21 years, the renewal period is set at five years. The age that is used to determine the length of the renewal period is the age at date of the last delivery.

There is no specific procedure for reimbursing orthotic devices delivered in the hospital setting. In practice, either no reimbursement applies and the patient incurs the full cost of the device or reimbursement occurs as if the patient was treated in ambulatory care, thus implying that the officially indicated dispensing date does not match the actual one.

3.3.4 Distribution

In order to be reimbursed by the third-party payer, orthotic devices need to be delivered to ambulatory patients by an officially recognised orthotist (who works for a company or a medical device shop that is affiliated to a health insurance fund). This implies that orthotic devices delivered by a community pharmacist without the qualification of an orthotist or acquired through the internet do not qualify for reimbursement. In the hospital setting, orthotic devices need to be provided by an officially recognised orthotist. The margin of the dispenser is determined by the Walkiers coefficient and the possible difference between the public price and the reimbursement tariff (cfr. supra).

3.3.5 Prescribing process

Orthotic devices are reimbursed only if they have been prescribed by specific types of specialist physicians. There are few regulations as to how the orthotic device is identified on the prescription form. Present regulations state that the prescription form needs to provide an indication and a description of the type of orthotic device. In practice, the physician writes the nomenclature code, the description of the product or a specific brand name on the prescription form. Unless a particular brand name is specified, the orthotist in agreement with the patient decides which specific device within the product class is used. Renewal of the orthotic device also requires a prescription by a specialist physician.

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[14] The health index is obtained by removing a number of products from the consumption basket for the regular Belgian consumption price index: alcoholic drinks, tobacco products and fuel oils, with the exception of LPG.

Key points

- **Pricing of orthotic devices is free;**
- **The reimbursement tariff of orthotic devices is determined by adding a distribution mark-up to the price to dispensers. This mark-up varies between prefabricated and custom-made devices;**
- **Dispensers can, but do not have to, ask for a patient co-payment on prefabricated devices. Dispensers cannot ask for a co-payment on custom-made devices, which are fully reimbursed;**
- **Reimbursement is subject to prescription by a specific type of specialist physician and distribution by a recognized orthotist;**
- **There is little regulation governing the prescribing of orthotic devices.**

3.4 ENGLAND (UK)

In England, regulation governing soft cervical braces differs from regulation governing other orthotic devices. Regulation for each type of orthotic device is described in the following sections.

3.4.1 Registration

With respect to soft cervical braces, the Prescription Pricing Division of the National Health Service (NHS) Business Services Authority compiles a national list – 'Part IX A Appliances' of the 'Drug Tariff' – on behalf of the Secretary of State. This list enumerates the braces that benefit from NHS reimbursement in ambulatory care and that can be prescribed for any patient or condition for which the device is considered appropriate. The Department of Health grants approval for inclusion of soft cervical braces in Part IX A if the devices are safe and of good quality; if they are appropriate for general practitioners to prescribe; and if they are cost-effective. Soft cervical braces that carry a CE marking are generally considered safe and of acceptable quality by the Department of Health. Devices that can be administered by the patient, with or without the help of a health care professional, are considered appropriate for general practitioners to prescribe. In assessing the cost-effectiveness of a new soft cervical brace, two considerations play a role: first, whether the NHS should reimburse the device at all; and, second, what is the cost of the new device as compared with the cost of similar products and with the cost of the most effective alternative products or treatment regimes.

Other orthotic devices are normally provided in secondary care. As long as the orthotic device carries the CE mark, it can be purchased by any hospital. Some hospitals may wish to undertake their own testing in terms of product suitability, quality, competitor evaluation and costing with a view to determining which company to choose for their product selection.

3.4.2 Pricing

Prices are determined separately for soft cervical braces dispensed in ambulatory care and the other orthotic devices that are provided in hospital. With respect to soft cervical braces in ambulatory care, free pricing prevails and prices are negotiated between manufacturers and distributors.

With respect to orthotic devices provided in hospitals, devices are purchased by the NHS Supply Chain through a European tendering process. An advert is placed in the Official Journal of the European Union to notify suppliers from within Europe of the forthcoming contract. Suitable suppliers are shortlisted and tender documents issued. The completed tenders are then evaluated based on criteria as stated in the advert and tender documents, and the most economically advantageous award is made based on the results. If during the life of the contract a supplier applies for a price increase, the

supplier needs to submit a full reasoning for the request (i.e. an increase in utility bills or manufacturing costs). Acute and Community NHS Trusts can then use these National Framework Agreements to purchase orthotic devices directly from the manufacturer.

3.4.3 Reimbursement

Orthotic devices are fully reimbursed by the NHS. In ambulatory care, reimbursement of soft cervical braces is determined on the basis of the tariffs listed in Part IX A of the Drug Tariff. The entry tariff of soft cervical braces is determined as follows. If the brace is similar to products listed in Part IX A, the Prescription Pricing Division attempts to set a tariff around the same level of tariffs of listed products. Manufacturers have the opportunity to suggest which products they consider appropriate for comparison with their new soft cervical brace. Tariffs are therefore negotiated between the Prescription Pricing Division and the manufacturer, and each product is awarded its individual tariff. Additionally, manufacturers can request a different tariff from that of listed products if they can point to differences in the use and patient benefits between products that have a financial impact (e.g. differences in quantities required, comfort, ease of disposal). If the soft cervical brace is not similar to previously listed products, manufacturers need to demonstrate that the requested tariff is in line with the benefits to patients and the NHS.

As community pharmacies may be able to obtain discounts from manufacturers, tariffs of soft cervical braces are discounted using a sliding scale depending on the number of prescriptions. Unlike for pharmacies, reimbursement of soft cervical braces delivered by appliance contractors is fixed and does not take into account any discounts that appliance contractors may gain.

In hospital, orthotic devices are paid for by the Trust. Payment is made directly to manufacturers by Trusts or through the NHS Supply Chain.

3.4.4 Distribution

Soft cervical braces in ambulatory care are provided by community pharmacies or by appliance contractors. The remuneration of community pharmacies for delivering soft cervical braces consists of a fee per prescription. Pharmacies may receive additional fees depending on the number of prescriptions. Alternatively, soft cervical braces are delivered at home by appliance contractors. Their remuneration amounts to 15-25% of the reimbursement tariff of the brace, depending on the number of prescriptions. This implies that appliance contractors are generally paid more than community pharmacies, particularly on the more expensive braces.

In secondary care, orthotic devices are provided by orthotists. Orthotists can be contracted from a commercial supplier that holds a contract to supply these services to the NHS and orthotists receive an annual salary. Also, orthotists can be employed directly by the NHS to deliver an in-house service and are paid on the standard NHS terms. Finally, there are locum orthotists who supply services on an ad hoc basis and are paid according to the number of clinical sessions that they provide either through a commercial supplier or through the NHS.

3.4.5 Prescribing process

The initial prescription of an orthotic device in ambulatory care is issued by a general practitioner or a specialist physician. In secondary care, the physician will refer the patient to an orthotist. If the physician knows what type of orthotic device that the patient needs, the physician will state the type on the prescription form. Alternatively, the orthotist will be asked to undertake additional exams to determine the best orthotic device for that patient. The orthotic device is identified on the prescription form by its generic name or by its brand name.

Renewal of long-term braces depends on the type of orthotic device and the condition. Long-term conditions normally require a six-month review if the patient is wearing an orthotic device. A repeat prescription needs to be issued by a general practitioner or a specialist physician.

If the prescribed orthotic device does not fit, the patient switches to an alternative device and a corresponding prescription is written. Any additional expense caused by a switch to a more expensive orthotic device is incurred by the NHS.

Key points

- **Soft cervical braces are provided in ambulatory care. Other orthotic devices are normally provided in secondary care.**
- **Prices of orthotic devices are negotiated between manufacturers and distributors;**
- **The reimbursement tariff is negotiated between the Prescription Pricing Division and manufacturers;**
- **Orthotic devices are distributed by community pharmacists or appliance contractors;**
- **Community pharmacists receive a fee per prescription. Appliance contractors receive 15-25% of the reimbursement tariff.**
- **Orthotic devices are prescribed by a specialist physician or a general practitioner.**

3.5 FRANCE

3.5.1 Registration

Registration of orthotic devices is the responsibility of the Products and Services Assessment Committee of the French Agency for the Safety of Health Products. This committee examines the justification for registering, renewing the registration or changing the registration conditions of an orthotic device, and gives advice to the Minister of Health on the request for reimbursement of the orthotic device. Manufacturers need to submit a dossier that sets out product characteristics, clinical studies, the service rendered by the product (based on determination of the medical need addressed by the device, place of the device relative to current routine practice, benefits and risks of the device, and public health interests of the device), target population and sales volume forecasts of the orthotic device that is to be registered.

Devices are generally registered using a generic description. In exceptional cases, devices are registered by their brand name when, for instance, the impact on public expenditure, the interests of public health or the existence of minimal technical specifications require a specific follow-up of the device. The registration can be subject to technical specifications, therapeutic or diagnostic indications or specific conditions relating to the use and prescription of the device. Dossiers requesting a registration of an orthotic device need to be processed by the Products and Services Assessment Committee within a period of 180 days.

3.5.2 Pricing

In principle, manufacturers are free to set prices, although the Economic Committee for Health Products of the Ministry of Health has the right to set sales price limits by decree. Price fixing considers trends in charges, income and volume of activity of practitioners or companies involved. In specific cases, the price of the orthotic device may exceed the reimbursement tariff when the patient asks for an additional product characteristic for aesthetic or technical reasons. The difference between the price and the tariff is paid for by the patient. If no maximum price has been set, distributors may sell an orthotic device at a price higher than the reimbursement tariff, with the difference being paid for by the patient.

3.5.3 Reimbursement

The Economic Committee for Health Products of the Ministry of Health finalises conditions for reimbursement and determines the reimbursement tariff of orthotic devices in the List of Reimbursable Products and Services. Devices can only be reimbursed if they lead to an improvement in the service rendered or to cost savings. Reimbursement is withheld if it is likely to lead to unjustified public expenditure.

Tariffs are set taking into account (improvements in) the service rendered; tariffs and prices of comparable products on the list; sales volume forecasts; foreseeable and actual conditions of use, and health economic studies. For orthotic devices that do not generate an improvement in service rendered, the tariff is set at the same level as that applicable to comparable products already registered. A higher tariff can be granted for products with an improvement in service rendered, although regulation does not specify the size of the increase in tariff. Furthermore, improvement in service rendered does not necessarily lead to a higher tariff. Indeed, such orthotic devices can be reimbursed at a lower tariff than that of comparators. Additional conditions can be imposed on awarding a higher tariff to orthotic devices with an improvement in service rendered. Such conditions limit the use of the device to those groups of patients for which the service rendered by the device has been well established. Reimbursement in these cases is accompanied by restrictions on sales volume. Manufacturers can ask for a revision of the tariff to take account of the evolution of production costs of orthotic devices.

Generally, orthotic devices are fully reimbursed in ambulatory care by the French social insurance system as they qualify for recognition as a chronic condition, i.e. a condition lingering over more than six months. Patients whose conditions are deemed to be of a more temporary nature are entitled to a partial reimbursement amounting to 65% of listed tariffs. In the case of cervical braces, reimbursement is restricted to one brace per year. In hospital, orthotic devices are paid for by the institution.

3.5.4 Distribution

Orthotic devices are distributed by community pharmacies, medical equipment shops and orthotists. Distributors sell orthotic devices to patients at the tariff specified in the List of Reimbursable Products and Services. The distribution margin derives from the difference between the reimbursement tariff and the wholesale price that distributors are able to negotiate with manufacturers. The distributor does not need to maintain or repair orthotic devices.

3.5.5 Prescribing process

The first prescription of orthotic devices can be generated by a specialist physician or a general practitioner. Orthotic devices are referred to on the prescription by their generic name or brand name. Prescriptions are renewed by the specialist physician or the general practitioner as a function of the needs of the patient and the type of device involved. If the orthotic device does not fit, patients need to obtain a new prescription in order to switch to an alternative orthotic device.

Key points

- **Orthotic devices are registered using a generic description.**
- **Free pricing of orthotic devices prevails, although the Economic Committee for Health Products can set maximum prices.**
- **The reimbursement tariff is based on, among other things, the value added by the orthotic device. Orthotic devices for chronic conditions are fully reimbursed, devices for temporary conditions are partially reimbursed.**
- **Orthotic devices are distributed by community pharmacies, medical equipment shops and orthotists.**
- **The distribution margin is made up of the difference between the reimbursement tariff and the wholesale price.**
- **Orthotic devices are prescribed by a specialist physician or a general practitioner.**

3.6 THE NETHERLANDS

3.6.1 Registration

Except for the registration requirements stated in Directive 93/42/EEC (cfr. infra), there are no registration requirements that orthotic devices need to meet in order to be admitted to the Dutch market.

3.6.2 Pricing

Free pricing of orthotic devices prevails in the Netherlands. Prices are determined as a result of negotiations between health insurance funds and manufacturers or distributors. As health insurance funds are free to decide which orthotic devices to offer, they are able to exclude, for instance, expensive orthotic devices.

3.6.3 Reimbursement

As of January 2006, a new insurance system for curative health care came into force in the Netherlands. Under the new Health Insurance Act, all residents of the Netherlands are obliged to take out health insurance. Reimbursement of orthotic devices in ambulatory care is regulated in detail under the Health Care Insurance Decree and the Health Care Insurance Regulations. The Health Care Insurance Regulations specify a limitative list of the various classes of orthotic devices that are entitled to reimbursement using generic terminology. In other words, there is no specification of brand names. Any orthotic device that corresponds to the description of the class within the regulations in principle qualifies for full reimbursement.

In general, orthotic devices qualify for reimbursement if:

- they correspond to a clinical indication[15] or compensate for a handicap;
- the costs impose a substantial financial burden on the patient;
- they are not 'commonly used' by a significant part of the population;
- they have demonstrated their efficacy, safety and effectiveness;
- they have demonstrated their therapeutic value[16] and cost-effectiveness as compared to other interventions for the same indication.

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15 The list of clinical indications for which orthotic devices are reimbursed can be accessed at http://www.hulpmiddeleninformatiecentrum.nl

16 To date, no uniform guidelines or indicators exist to assess therapeutic value of orthotic devices.

In particular, reimbursement of orthotic devices is restricted to rigid orthotic devices for long-term use, whereby the strengthening is a functional part of the orthotic device and has a therapeutic added value as compared with a soft device. Additional criteria regarding medical indication apply to knee braces. Knee braces are reimbursed only for:

- a combined or not-combined injury of the knee, involving a rapture of the cruciate or collateral ligaments;
- one-sided gonarthrosis, involving a varus/valgus angulation exceeding 10°.

To qualify for reimbursement, health insurance funds can ask for further information about the condition for which the orthotic device will be used. Wrist and knee braces used to prevent sports injuries do not qualify for reimbursement. Orthotic devices for hospitalized patients are paid for by the institution.

In order to gain reimbursement, orthotic devices need to be delivered by a distributor who has a contract with a health insurance fund. Such contracts impose conditions on reimbursement and delivery of orthotic devices. Contract conditions may vary between health insurance funds, but in general tend to relate to preferred brands, qualifications, usage norms, minimum period of time to elapse before a device can be replaced, replacement or maintenance of an orthotic device. If the patient buys an orthotic device from a distributor who does not have a contract with a health insurance fund, reimbursement is typically limited to 85-90% of the reimbursement tariff.

3.6.4 Distribution

Orthotic devices are delivered in the Netherlands through either medical equipment shops or by orthotists. The remuneration for the services delivered by distributors depends on the agreement between the health insurance fund and the distributor. Often, there is a certain surcharge on the purchase price and a remuneration for the value added by the distributor. Also, health insurance funds may have fixed maximum prices for a specific type of orthotic devices, irrespective of their purchase price.

Whether the distributor needs to maintain or repair orthotic devices and the length of time during which the device benefits from a guarantee depends on the contract between the distributor and the health insurance fund.

3.6.5 Prescribing process

The first prescription of an orthotic device is issued by a specialist physician or a general practitioner. Orthotic devices are identified on the prescription form by their generic name. As far as it is deemed to be efficient, patients are allowed to switch between orthotic devices if the delivered orthotic device is not suitable. According to specific contract conditions, a device can be replaced (i.e. once a year for cervical braces, once every two years for wrist and knee braces). Replacement or repair of the orthotic device requires a repeat prescription by the physician.

Key points

- **Prices of orthotic devices are negotiated between health insurance funds and manufacturers or distributors;**
- **Health insurance funds are able to exclude expensive orthotic devices from reimbursement;**
- **There is a limitative list of the various classes of orthotic devices that qualify for full reimbursement;**
- **Reimbursement is limited to rigid orthotic devices for long-term use;**
- **Health insurance funds negotiate contracts with distributors that impose conditions on reimbursement and delivery of orthotic devices;**
- **The remuneration of distributors depends on the contract between health insurance funds and distributors. Often, there is a surcharge on the purchase price;**
- **Orthotic devices are prescribed by a specialist physician or a general practitioner.**

3.7 ONTARIO (CANADA)

The institutional setting of the orthotic device market varies between Canadian provinces/territories. After setting out national procedures governing registration of orthotic devices, the remainder of this section focuses on registration, pricing, reimbursement, distribution and prescribing of orthotic devices in Ontario.

3.7.1 Registration

In Canada, manufacturers of orthotic devices need to obtain an Establishment License from the Health Products and Food Branch of Health Canada. A license entails that the orthotic device meets safety, quality and effectiveness requirements and is appropriately labelled. Moreover, manufacturers need to have in place procedures for distribution records, complaint handling, mandatory problem reporting and recall. Establishment Licenses need to be renewed on an annual basis.

Ontario does not have any additional requirements regarding registration of orthotic devices. This means that the Assistive Devices Program of the Ontario Ministry of Health and Long-Term Care does not evaluate orthotic devices and does not maintain a list of manufacturers' devices.

3.7.2 Pricing

The Assistive Devices Program sets ceiling prices for orthotic devices and procedures that are eligible for reimbursement.

3.7.3 Reimbursement

The Assistive Devices Program reimburses orthotic devices for Ontario residents who have a chronic physical disability requiring the use of an orthotic device with a view to improving his/her function in a variety of activities of daily living for at least six months. Reimbursement covers specified orthotic devices that are custom-made and either molded to the patient or molded to a patient model. The Assistive Devices Program pays 75% of the ceiling price of orthotic devices, implying a patient co-payment amounting to 25%.

Orthotic devices that cost less than Can$ 100 (around 65 €) are not reimbursed. Also, reimbursement is not available for:

- Braces for less than six months use;

- Braces worn only at night or to rest a body part;
- Braces worn for only one daily activity (e.g. school, work or sports);
- Braces for acute conditions (e.g. fracture braces);
- Prefabricated orthotic devices;
- Centrally-fabricated orthotic devices[17];
- Repairs to orthotic devices.

If a patient needs a prefabricated orthotic device, but cannot afford the cost in the absence of reimbursement (cfr. supra), the patient can call his/her physician to ask if a custom-made device might meet his/her needs. If this is the case, the patient would seek a referral from the physician to be assessed by a Canadian Board-certified orthotist. However, the reader should note that prefabricated orthotic devices in some cases are substantially less costly than custom-made devices. One example is an over-the-counter wrist brace to be used for carpal tunnel syndrome. At a pharmacy, such a device would cost around Can$ 40 (around 26 €). A custom-made wrist brace would range in price from Can$ 500 (around 325 €) to over Can$ 1000 (around 650 €). Even if the Assistive Devices Program funds 75% of this cost, the patient co-payment is substantially higher for a custom-made wrist brace than for a prefabricated wrist brace.

3.7.4 Distribution

Patients must buy their orthotic device directly from a vendor who is registered with the Assistive Devices Program. The vendor must employ a Canadian Board-certified orthotist, who is also registered with the Assistive Devices Program. Vendors may not charge more, but can charge less than the ceiling price approved by the Assistive Devices Program. No additional labour costs or procedures may be billed for the devices funded by the Assistive Devices Program. If, however, services or items are provided that are not funded by the Assistive Devices Program, these are billed directly to the patient. The distribution margin of vendors is 25% of the ceiling price of the orthotic device.

3.7.5 Prescribing process

Orthotic devices are initially prescribed by a specialist physician or a general practitioner, depending on the complexity of the device. Orthotic devices are identified on the prescription form by their generic name. The patient is then referred to a so-called 'authorizer', i.e. a Canadian Board-certified orthotist. The authorizer assesses the patient and determines the details and type of orthosis that is required. Patients having a chronic physical disability requiring specified highly specialised orthotic devices must see both an authorizer and a rehabilitation assessor, i.e. an occupational therapist or physiotherapist who determines the need for occupational therapy or physiotherapy.

Replacement or modifications of an orthotic device requires a prescription by a specialist physician or general practitioner and/or an assessment by an authorizer and/or a rehabilitation assessor. These different requirements for assessment depend on the complexity of the device and the reason for replacement. Orthotic devices are not automatically replaced at expiry of the minimum replacement period, but only when the current device is no longer usable. Proven need for replacement must exist. Orthotic devices that jeopardize the patient's safety or that no longer meet the patient's needs due to physiological growth, atrophy, normal wear or change in medical condition are eligible for replacement. Devices are eligible for replacement after one year for orthotic devices molded to the patient and after two years for orthotic devices molded to a patient model from the date of the authorizer's assessment. Orthotic devices can be replaced during the minimum replacement period if the patient undergoes physiological growth, atrophy or change in medical condition that makes his/her current device no longer usable. During the minimum replacement period, an orthotic device can be replaced as a result of normal wear due to heavy use.

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17 An orthotic device is centrally fabricated when measurements or a cast is taken of the patient's body part and the orthosis is ordered from a central manufacturing facility.

The Assistive Devices Program pays up to 75% of the replacement cost if the patient's medical condition or size changes and a new orthotic device is required. The Program provides pro-rated funding of the replacement cost if the orthotic device is worn out due to regular use during the minimum replacement period. In this case, a written request for Special Approval is needed.

Key points

- **The Assistive Devices Program sets ceiling prices for orthotic devices that are eligible for reimbursement.**
- **Reimbursement is limited to 75% of the ceiling price of the orthotic device.**
- **Orthotic devices worn for less than six months and prefabricated devices are not reimbursed.**
- **Vendors must employ a Canadian Board-certified orthotist.**
- **The distribution margin is 25% of the ceiling price of the orthotic device.**
- **Determination of a patient's need for an orthotic device and eligibility for funding requires a prescription by a specialist physician or general practitioner and an assessment by a certified orthotist who is registered with the Assistive Devices Program. If a highly specialised device is needed, assessment by a rehabilitation assessor is also required.**

3.8 SWEDEN

In Sweden, the institutional framework surrounding orthotic devices is regulated by the Health and Medical Service Act. Under this Act, the main responsibility for orthotic devices provided in hospitals and primary health care centres lies with the 21 county councils at the regional level. Most councils have a Board for Assistive Devices that guides and supervises the provision and distribution of orthotic devices. The 290 municipalities are responsible for providing orthotic devices to the elderly, the disabled and nursing homes. As the Health and Medical Service Act is a framework law, the county councils and municipalities have considerable freedom to interpret the Act and issue additional detailed rules regarding the disabilities for which orthotic devices can be prescribed, which devices are covered, which staff is entitled to prescribe orthotic devices and the level of patient co-payment. Therefore, legislation surrounding orthotic devices varies from county council to council and from municipality to municipality.

3.8.1 Registration

Orthotic devices are registered as medical devices by the Swedish Handicap Institute. The Institute stimulates research and development of orthotic devices, is involved in testing devices, and provides quality assurance.

3.8.2 Pricing

Prices of orthotic devices are set freely in Sweden through a process of public procurement by the county councils and municipalities. This tendering process aims to enable county councils and municipalities to negotiate competitive prices for orthotic devices with orthopaedic workshops, of which there are 42 throughout Sweden. Of these workshops, 34 are run by private enterprise and 8 are run by the county council. The Swedish Handicap Institute also makes coordinated purchases of orthotic devices.

3.8.3 Reimbursement

New orthotic devices are paid for by county councils and municipalities, and are essentially free of charge (or are provided at a negligible cost to the patient) if there is a medical/functional need for the device. Repair and maintenance of devices are provided free of charge. Orthotic devices for hospitalized patients are paid for by the institution.

3.8.4 Distribution

Orthotic devices are delivered to patients by community pharmacies, medical equipment shops, orthotists and health authorities. The role of the orthotist is to ensure that the appropriate orthotic device is provided to patients. The remuneration of the orthotist depends on the contract with the county council or municipality. The orthotist also carries the responsibility to maintain or repair orthotic devices. The length of time during which the device benefits from a guarantee and the remuneration of the orthotist for providing a guarantee varies according to the specifications of the contract with the county council or municipality. Finally, health authorities may deliver orthotic devices directly to patients from their own stock.

3.8.5 Prescribing process

The responsibility for the prescription of orthotic devices lies with the county councils and municipalities. Orthotic devices are prescribed by specialist physicians. Prescriptions generally refer to orthotic devices by their generic name. The prescription process consists of the following phases:

- Assessing the need for assistance;
- Assessing, adapting and selecting an appropriate, specific product;
- If required, preparing instructions for special adaptation;
- Instructing, training and providing information;
- Following up and assessing the function and benefit of orthotic devices.

The prescription needs to be renewed by a specialist physician following a certain amount of time, the duration of which varies from county council to council and from municipality to municipality. Patients are allowed to switch from the prescribed orthotic device to another device if the prescribed device does not fit.

Key points

- **Prices of orthotic devices are set freely through a process of public procurement at regional level.**
- **Orthotic devices are fully reimbursed if there is a medical/functional need for the device.**
- **Orthotic devices are distributed by community pharmacies, medical equipment shops, orthotists, and health authorities.**
- **The distribution margin of the orthotist depends on the contract with the county council or municipality.**
- **Orthotic devices are prescribed by a specialist physician using the generic name of the device.**

3.9 COMPARATIVE INSTITUTIONAL ANALYSIS

Regulatory traits of the orthotic device market for outpatients in the six countries studied are presented in Table 4.

Table 4 : Regulation governing outpatient orthotic device markets

Features	Belgium	England	France	Netherlands	Ontario (Canada)	Sweden
PRICING						
Pricing system:						
- Free market	•	•	•	•		•
- Price fixing			•		•	
REIMBURSEMENT						
Reimbursement system:						
- National public procurement						
- Regional public procurement						•
- Tariff	•	•	•	•	•	
Reimbursement based on (cost-)effectiveness:						
- Yes		•	•	•		
- No	•				•	•
Reimbursement level:						
- Full reimbursement		•		•		•
- Full or partial reimbursement	•		•			
- Partial reimbursement					•	
Reimbursement linked to medical indication / chronic condition:						
- Yes			•	•	•	•
- No	•	•				
DISTRIBUTION						
Delivery channels:						
- Community pharmacies		•	•			•
- Medical equipment shops	•		•	•		•
- Orthotists	•		•	•	•	•
PRESCRIBING PROCESS						
First prescription by:						
- Specialist physician	•	•	•	•	•	•
- General practitioner		•	•	•	•	
Prescription by:						
- Brand name	•	•	•			
- Generic name	•	•	•	•	•	•
Repeat prescription by:						
- Specialist physician	•	•	•	•	•	•
- General practitioner		•	•	•	•	

In addition to national legislation, the registration of orthotic devices is governed by the Directive 93/42/EEC[18]. Orthotic devices are classified as class I (low risk) devices and, thus, require a minimum level of assessment by the notified bodies. Such devices must follow the essential principles of safety and performance in their design, construction and labeling requirements. Orthotic devices that meet the essential requirements and have undergone the appropriate conformity assessment procedures are CE marked by the notified body. Orthotic devices, other than custom-made devices, must bear the CE marking of conformity when they are placed on the market. In addition to this, the Directive requires the registration of persons responsible for placing orthotic devices on the market. The competent authorities of the member state in which the manufacturer has his registered place of business must be informed of the address of the registered place of business and the description of the devices concerned.

Registration of an orthotic device implies that it will be reimbursed in Belgium, France and England. In the Netherlands, health insurance funds can choose to exclude expensive orthotic devices from reimbursement. When a device is included in a list of orthotic devices, this automatically determines the reimbursement tariff in France and England as tariffs are set at the same level for comparable products.

Prices of orthotic devices are set freely in Belgium, France, England, the Netherlands and Sweden. In order to maximize price competition, prices in Sweden are determined by a system of public procurement at the regional level. In France, maximum prices can be fixed as a function of charges, income and volume of activity. Ontario (Canada) sets maximum prices for orthotic devices.

The relationship between prices and reimbursement tariffs tends to differ between countries. In Belgium, prices of orthotic devices tend to be higher than or equal to the reimbursement tariff. If the price of a device exceeds the tariff, the supplement is paid by the patient or by the dispenser. A similar system operates in France, although the fixing of maximum prices limits the difference between the price and the tariff of an orthotic device. This system is intended to create price competition between manufacturers, whilst restricting reimbursement borne by the French social insurance system. In the Netherlands, Ontario (Canada) and Sweden, the tariff is set as 100% or less of the price of orthotic devices. In England, reimbursement is based on a discounted tariff to take account of the fact that community pharmacies may be able to attain discounts from manufacturers.

To gain reimbursement, the (cost-)effectiveness of orthotic devices needs to be demonstrated in France, England and the Netherlands. Not all orthotic devices are fully reimbursed in all countries studied. Orthotic devices are fully reimbursed in England, the Netherlands and Sweden. Belgium and France operate a mixed system of full or partial reimbursement depending on the price of orthotic devices. In Ontario (Canada), patients incur a co-payment when purchasing an orthotic device. Some countries link reimbursement to the presence of a medical indication or chronic condition. In the Netherlands and Sweden, orthotic devices qualify for reimbursement if they correspond to a medical indication. Orthotic devices used in the treatment of a chronic condition are reimbursed in France and in Ontario (Canada). Devices used in the management of a temporary condition are partially reimbursed in France.

Orthotic devices are distributed by orthotists in ambulatory care in the countries studied except for England. Orthotic devices can also be distributed by community pharmacies in England, France and Sweden; and by medical equipment shops in Belgium, France, the Netherlands and Sweden. Various approaches are used to remunerate distributors. Distributors in Belgium and in Ontario (Canada) receive a proportion of the price of orthotic devices. In France, the distribution margin depends on the difference between the reimbursement tariff and the wholesale price negotiated between distributors and manufacturers. The remuneration of Dutch and Swedish distributors is determined by the agreement between the public payer and the distributor. Finally, community pharmacies in England are paid by means of a fee-for-service system.

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18 Council Directive of 93/42/EEC of 14 June 1993 concerning medical devices L 169 12 July 1993

Orthotic devices are initially prescribed by a specialist physician or a general practitioner in England, France, the Netherlands and Ontario (Canada). The initial prescription is the exclusive responsibility of the specialist physician in Belgium and Sweden. Orthotic devices are identified by their generic name in the six countries studied. In Belgium, England and France, orthotic devices can also be identified by their brand name. Replacement of the orthotic device requires a repeat prescription in the six countries studied. Conditions are imposed on the renewal of orthotic devices in England, France, the Netherlands, Ontario (Canada) and Sweden These conditions tend to relate to the type of device, the needs and condition of the patient, and the amount of time that has expired.

4 MARKET ANALYSIS

4.1 INTRODUCTION

In this chapter we give an overview of the results of our market analysis on orthoses. Our intent is to complement the institutional analysis for Belgium presented in the preceding chapter and to assess in detail the product scope in our report.

The first part gives an overview of the global and European medical devices market. Quantitative and qualitative information is given. This information is mainly based on secondary research.

The second part explains the methodology followed to determine the final project scope of this study. We describe the different steps taken and their intermediate results. Figures quoted in this part concern billing data for expenses reimbursed by RIZIV/INAMI. As such, they pertain to booked amounts and quantities for 2005.

The third part covers the market analysis for a limited number of prefabricated knee, neck and wrist orthoses. Qualitative information is given on the distribution chain, sales volumes, the RIZIV/INAMI reimbursement expenses, the market shares of manufacturers and the market shares of distributors. This part is mainly based on primary research

The fourth and final part covers the organisation of the Belgian market, focusing on the retailers, manufacturers and more in depth the distributors. This paragraph is mainly based on primary research and interviews executed with distributors active on the Belgian market.

4.2 THE GLOBAL AND EUROPEAN MARKET FOR MEDICAL DEVICES

In this part we give a brief overview of the global and European market for medical devices.

4.2.1 The global and European medical devices market in figures

The market for medical devices covers a large number of different kinds of products varying from very high tech products as MRI scanners or surgery robots, over middle tech products as pacemakers, electric wheelchairs and braces to low tech products as syringes, bandages or incontinence pads.

There is no homogeneous market for medical devices. Products are purchased by hospitals, professionals as well as by individual patients.

Few specific data on the medical devices industry are being published (see Table 5). For 2003 the worldwide global medical device market was valued at over 184 billion €. (Eucomed 2004) [19]

The US market is by far the most important world market representing between 38 and 43 % of the global market.[20] For 2005 the US market on medical devices is being valued at $75 billion growing annually with 8 to 10 %.[21]

The European market represents between 30 to 34 % of the world market and is the second largest market followed by Japan. The rest of the world market represents between 14 to 16 % of the global market. [22]

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19 Eucomed (European Medical Technology Industry Association) www.eucomed.be

20 Medical devices competitiveness and impact on Public health expenditure, Cerm Rome, University of Florence. Study for the Directorate Enterprise of the European Commission July 2005.

21 Forecast for the medical device outsourcing market; Frost & Sullivan Market insight 2006.

Table 5 : Shares of medical devices market 2002

	Eucomed		Datamonitor	
	Expenditure (bill €)	Share (%)	Expenditure (bill $)	Share (%)
Europe	55	30	63	34
Us	79	43	71	38
Japan	20	11	25	13
Rest	30	16	26	14
World	184	100	186	100

Source Datamonitor(2003a), Eucomed (2003)

The European market for medical devices is valued at 55 billion € in 2002 of which Germany represents 34,4 %, France 16,3 %, Italy 11,2 % and the UK 10,5 %. These 4 countries cover more than 70 % of the total European medical devices market. The Netherlands cover 4,5 % of the European market, Sweden 2 % and Belgium 1,5 %. Average expenditure per capita for the 17 Western European countries is 134 € with Germany on top with 230 € and Greece at the bottom with 49 €.

This percentage for Belgium is equivalent to a total of 820 million euro spent on medical devices in 2002. The combined public healthcare budget for medical devices sold in pharmacies, care by bandagers, orthotists and prosthetists, implants and implantable cardiac defibrillators adds up to about 427 million euro in 2002[23]. Assuming further reimbursed costs for dental implants, hearing aids and other devices were incurred, the above quoted estimate of 820 million euro (which includes all private expenditures, patient co-payments, etc.) appears to be realistic.

The European market on medical devices is a growing market. Growth varies substantially between the different sub markets. The orthopaedic sub-market (orthotic and prosthetic devices, mostly implants and orthopaedic materials) shows a substantial and constant growth over the years. A detailed overview is added in appendix IV.[24]

Key points

- **The medical devices industry covers a wide variety of products**
- **Potential buyers of medical devices range from individuals (patients) to institutions (hospitals) and public health authorities, resulting in a heterogeneous consuming market**
- **Few market data are published on the medical device industry**
- **The US represent between 38% and 43% of the global medical devices market, followed by Europe (30%–34%) and Japan (11%-13%)**
- **Germany, France, Italy, UK, have the highest expenditure for medical devices, covering more than 70 % of the European market**
- **Expenditures of medical devices / capita for Europe range between 230 € (Germany) and 49 € (Greece), with an average of 134 €.**
- **The medical devices market is a growing market. Growth in the orthopaedic sub-market is substantial and constant.**

22 Medical devices competitiveness and impact on Public health expenditure, o.c.
23 See "Statistieken van het RIZIV / Statistiques de l'INAMI" (www.riziv.fgov.be)
24 See appendix IV "European Medical device markets expenditure"

4.2.2 Specificities, Market drivers & barriers in the medical devices market

4.2.2.1 A relatively young industry

The medical devices industry is relatively young. Certainly when compared to the pharmaceutical industry one notices a great difference in historical background. Most of the companies are not only relatively young, but also mostly small ones. About 80% of the EU companies active in medical devices are small and medium-sized companies.

4.2.2.2 Fierce Competition in the Market

Continuous healthcare reforms put pressure on prices and calls for more cost efficiency. On the other hand patient demands increase. As a result, we observe increased competition, manufacturers compete with each other attempting to improve or maintain their competitive positioning on the market.

Next to quality and service delivery, price setting is seen as one of the most important competitive factors in the orthoses market. Improvement of existing products and development of new ones, addressing patients needs and expectations is judged as very important by manufacturers and highly affect their sales revenues and market shares.[25]

4.2.2.3 Short product lifecycle

The products are subject to continuous innovation and improvements making use of the newest scientific and technical evolution. Typical for medical devices is a relative short product lifecycle. In the US by some estimates, up to 80% of a medical device company's profit comes from products introduced in the last 5 years. Fifty to seventy percent of product portfolios consist of products launched in the last 3 years.[26]

4.2.2.4 Introduction of new products

As mentioned in chapter III, orthoses are classified as class I products that must bear the CE marking of conformity. [27] These products can be self certified by the manufacturer.

Introducing new products on the EU market is rather complicated due to the different procedures for reimbursement and registration of the products. It is common in EU Member States that an official or even government-appointed "Notified Body" or organization has to certify the conformity to the existing assessment procedures.

Considerable price differences exist across the member states as differences in value added tax (VAT) imposed on medical devices. Most old EU member states, including France, impose a reduced VAT rate on medical devices treating them as a 'social good'. In France the VAT tariff on medical devices is 5,5 %, in Belgium 6 %, in U.K the VAT tariff is set at 17,5 %.

4.2.2.5 Complex reimbursement systems affect sales

Public health systems in general and reimbursement systems in particular in the EU Member States vary considerably. The level of pricing, possible co-payments by patients and as well the conditions as the height of reimbursement set by National health authorities is very much differentiated. The conditions for selling, purchasing and using medical devices in the EU healthcare systems differ considerably.

These different reimbursement systems influence the medical device market and affect the type of products that qualify for commissioning by government bodies, sales volume, market growth, and profits.[28]

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25 Trends in European Orthopeadic braces and supports, Frost & Sullivan 2005/11

26 Forecast for the medical device outsourcing market, Frost & Sullivan Market insight, February 2006.

27 COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices

28 Health Governance in Europe; Bridging European and member state implementation; Christa Altenstetter, Routledge/ECPR Studies in European Political Science

The complexity of these different systems is an important factor that manufacturers and distributors of medical devices have to face. Knowledge of the specific regulations and purchase procedures is crucial to realize commercial success. This explains why products imported from the US but also from EU member States are distributed on the market by means of local distributors.

4.2.2.6 Market drivers sustaining market growth for the medical devices

The main factors driving market growth are:

- demographics, increasing average age of people affects the health care consumption and the demand for medical devices (for example orthopaedic implants, pacemakers...),
- more active lifestyles: Disabled people want to participate in society, patients want to have a better quality of life,
- advances & innovation in medical technology: Medical devices are subject to constant research and improvements affecting lifecycle of products,
- globalisation of the world economies: New markets are being created, mergers and acquisitions of medical devices companies are huge, manufacturing is shifting to low wages countries,
- income growth: Sustain increasing demand for high-tech health services,
- increasingly extensive health insurance systems facilitating access to expensive medical devices.

4.2.2.7 Market Barriers:

The most important market barriers for the medical devices market are the budget restraints of the Public Authorities. In the US and in Europe, measures are being taken to limit and control health expenditures.

In the US, the medical devices market has to deal with the restrictive impact of the expansion of managed care. Managed care providers make use of their important purchasing power to obtain discounts on prices of medical products.[29]

In Europe, the same tendency can be observed. The Health insurance companies in the Netherlands for instance contract directly with medical suppliers putting pressure on selling prices. In the UK the Department of Health installed the "Purchasing and Supply Agency (NHS PASA)", to optimise the NHS purchasing of goods and services.[30].

29 Frost & Sullivan Market Insight
30 www.pasa.nhs.uk

Key points

- **The medical devices market is a relatively young industry. The majority of companies are small and medium sized companies.**
- **The medical devices market is a very competitive market.**
- **Medical devices have a relatively short product cycle as a result of continuous innovation and product improvements.**
- **New products are difficult to introduce on the European market.**
- **Reimbursement systems and regulation differ substantially in Europe. Knowledge of local regulations is a key factor for success affecting the organization of the medical devices market and making the role of local distributors, very important.**
- **The most important market drivers for the medical devices market are the aging population, higher demand for "quality of life", constant innovation in medical technology, extension of potential markets, income growth and increasing health insurance systems**
- **The most important market barriers for the medical devices industry are the budget restraints of public authorities.**

4.3 FINAL PRODUCT SCOPE

The general introduction to (international) market trends for orthotic devices will now be followed by an in-depth elaboration of our final product scope. This scope will be used as our reference for the analyses in the following chapters.

The scope of the study was limited to the orthoses in Belgian Healthcare, and more specifically to knee braces, wrist braces and neck braces in publicly reimbursed outpatient care. In the following paragraphs we explain our project scoping approach. [31]

4.3.1 Step 1: Limitation of the scope to prefabricated orthoses

As one of the final objectives of the market study is to obtain an international price comparison of knee, neck and wrist orthoses, as well as a cost calculation of two representative orthoses, the scope has been limited to prefabricated devices, i.e. homogenous products that allow for straightforward comparisons across countries and for which standardized large scale production can be assumed.

The different types of orthoses are linked to a number of nomenclature codes in combination with a description of the product class for each code. The nomenclature lists the different types, their availability as a prefabricated or a custom-made device and the amount that is being reimbursed if prescription and delivery of the device comply with the RIZIV / INAMI regulation. [32] Table 6 gives an overview of the (booked) expenses of the RIZIV / INAMI for 2005 on all prefabricated orthoses and on the prefabricated neck, knee and wrist orthoses.

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31 This approach was presented to and discussed with the experts during the expert meeting (January 27, 2007)

32 See chapter III

Table 6 : RIZIV/ INAMI reimbursed expenses booked in 2005 for outpatient orthopaedic devices

			Reimbursement expenses 2005	Number of cases	Number of distinct nomenclature codes
Orthoses	Prefab	Knee orthoses	9.779.226 €	27.700	6
		Neck orthoses	841.592 €	9.939	8
		Wrist orthoses	583.095 €	12.549	2
		Other	12.844.586 €	73.203	53
	Other		33.885.466 €	228.075	299
	Subtotals		57.933.965 €	351.466	368
Other			36.536.566 €	421.349	213
Totals			94.470.532 €	772.815	581

Source: RIZIV / INAMI 2005 billing data

The expenses for prefabricated orthoses (24.133.351,30 €) represent more than one quarter of the overall RIZIV/INAMI expenditures for outpatient orthopaedic devices (94.470.532 €). Prefabricated orthoses are classified into 69 different nomenclature codes and in 2005 a total number of 123.391 products were reimbursed.

Limitation to prefabricated knee, neck and wrist orthoses:

- Prefabricated knee orthoses are classified into 6 nomenclature codes. Based on 2005 data, 27.700 cases were reimbursed representing 9.779.225,68 €.
- Prefabricated neck orthoses are classified into 8 nomenclature codes. Based on 2005 data, 9.939 cases were reimbursed representing 841.591,69 €.
- Prefabricated wrist orthoses are classified into 2 nomenclature codes. Based on 2005 data, 12.549 cases were reimbursed representing 583.095,25 €.

These three categories represent 11.203.912,62 € or 46,6 % of total reimbursement on prefabricated orthoses and 50.188 cases out of the total of 123.391 or an equivalent of 40,6 %.

4.3.2 Step 2: Limiting the number of nomenclature codes for prefabricated knee, neck and wrist orthoses

The objective of the second step was to reduce the scope to 6 out of the 16 different nomenclature codes.

Based on the input received during the expert meeting (external expert group associated to our research project) on proven clinical effectiveness of neck and wrist orthoses and the above mentioned data on expenses, the experts suggested to keep 3 nomenclature codes for prefabricated knee orthoses, 2 nomenclature codes for prefabricated neck orthoses and one nomenclature code for prefabricated wrist orthoses.

The selection process of the 6 nomenclature codes was based on:

- The respective importance in terms of expenses for the RIZIV/INAMI (reimbursement regulated in article 29 of the nomenclature code 33).
- Importance in terms of number of cases (number of products reimbursed by the RIZIV/INAMI)

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33 Nomenclatuur van de geneeskundige verstrekkingen - La nomenclature des prestations de santé RIZIV / INAMI; http://www.inami.fgov.be/care/fr/nomenclature/index.htm; A detailed description of all nomenclature codes is included in appendix I.

4.3.2.1 *Selection of 3 nomenclature codes for prefabricated knee orthoses.*

Table 7 shows the RIZIV/INAMI expenses (reimbursements) and the number of products reimbursed over 2005 for the different types of the prefabricated knee orthoses.

Based on the above mentioned criteria the first type of knee orthoses we selected is the hard knee brace (nomenclature code 647592) The amount of 6.678 hard knee braces reimbursed, represents over 24% of the total of 27.700 reimbursed prefabricated knee orthoses in 2005. The total amount of reimbursement for the hard knee braces in 2005 is around six million euro or well over 60 % of the total reimbursement for prefabricated knee orthoses.

The second type of knee orthoses we selected for the further market analysis is the soft elastic woven reinforced knee bandage (nomenclature code 647555). This type of orthoses has been reimbursed 12.727 times (around 46 % of the cases) representing 1.122.063,16 € or 11,47 % of the total amount of reimbursement by the RIZIV / INAMI on prefabricated knee orthoses in 2005.

The third type of knee orthoses that has been selected for the market analysis is the elastic woven reinforced with metal knee brace (nomenclature code 647533). In 2005 a total number of 4.834 of knee braces corresponding to this type of knee orthoses have been reimbursed, representing 17,45 % of the cases. The RIZIV/INAMI reimbursement expenditure on this type of braces counted for 986.463,89 € or 10,09 % of a total of 9.779.225,68 € of reimbursement expenses on prefabricated knee orthoses in 2005. The three selected nomenclature codes are indicated in the table below.

Table 7 : Prefabricated knee orthoses: reimbursed expenses and cases 2005

Prefabricated knee orthoses					
Nomen-clature code	**Description in the nomenclature**	**Reimburse-ment expenses 2005 RIZIV/ INAMI (€)**	**% expenses**	**Number of reimbursed cases 2005**	**% Number of cases 2005**
647533	Elastic woven brace, reinforced with metal	986.464 €	10,1%	4.834	17,5%
647555	Soft elastic woven brace, reinforced	1.122.063 €	11,5%	12.727	45,9%
647592	Hard knee brace	6.166.519 €	63,1%	6.678	24,1%
647570	Out of Scope	287.503 €	2,9%	789	2,8%
647614		720.185 €	7,4%	1.763	6,4%
655690		496.492 €	5,1%	909	3,3%
Totals		**9.779.226 €**	**100,0%**	**27.700**	**100,0%**

Source: RIZIV / INAMI 2005 billing data

In conclusion, the knee orthoses for the further market analysis are:

- The hard knee brace (nomencl. code 647592)
- The soft elastic woven reinforced knee bandage (nomencl. code 647555)
- The elastic woven reinforced with metal knee brace (nomencl. code 647533)

4.3.2.2 *Selection of 2 nomenclature codes for prefabricated neck orthoses.*

Table 8 shows the different types of orthoses within the category of the prefabricated neck orthoses. The total reimbursement for the neck orthoses for 2005 is of

841.591,69 € representing a total number of 9.939 cases (prefabricated neck orthoses delivered in 2005).

The first type of neck orthoses selected on the basis of RIZIV/INAMI reimbursement expenditure[34] and number of orthoses reimbursed is the soft neck collar (nomenclature code 645175). This type represents 6.939 of the total of 9.939 reimbursed prefabricated neck orthoses (69,82%). The reimbursed expenses only represent 99.819,37 € or 11,9 % of the total amount of 841.591,69 € reimbursed for prefabricated neck orthoses in 2005.

The second type of neck orthoses chosen for the further market analysis is the adjustable hard neck collar (nomenclature code 645212). This type has been reimbursed in 652 cases (6,6 % of prefabricated neck orthoses) and represents a public expenditure of 162.296,67 € or 19,3 % of the reimbursed subtotal of 841.591,69 € in 2005.

Table 8 : Prefabricated neck orthoses - reimbursed expenses and cases 2005

Nomen-clature code	Description in the nomenclature	Reimbursement expenses 2005 RIZIV/ INAMI (€)	% expenses	Number of reimbursed cases 2005	% Number of cases 2005
645175	Soft neck collar	99.819 €	11,9%	6.939	69,8%
645212	Adjustable hard neck collar	162.270 €	19,3%	652	6,6%
645234		51.732 €	6,1%	440	4,4%
645190		79.328 €	9,4%	1.351	13,6%
645256		63.362 €	7,5%	119	1,2%
645271		3.556 €	0,4%	10	0,1%
645293		350.624 €	41,7%	101	1,0%
645315	Out of Scope	30.901 €	3,7%	327	3,3%
Totals		841.592 €	100,0%	9.939	100,0%

Source: RIZIV/ INAMI 2005 billing data

Consequently, the neck orthoses chosen for further analysis are:

- The soft neck collar (nomenclature code 645175)
- The adjustable hard neck collar (nomenclature code 645212)

4.3.2.3 Selection of 1 nomenclature code for prefabricated wrist orthoses.

For the wrist orthoses, selection of the single type covered by in the market analysis was very obvious (see Table 9) since the type of soft wrist bandage stands for 12.376 or 98,62 % of the total of 12.549 cases and for 580.561,77 € or 99,57 % of the total of 583.095,25 € that was reimbursed for prefabricated wrist orthoses in 2005.

34 Public expenditure is measured as the amount being reimbursed by the RIZIV / INAMI.

Table 9 : Prefabricated wrist orthoses: reimbursement expenses and cases 2005

Prefabricated wrist orthoses					
Nomen-clature code	**Description in the nomenclature**	**Reimburse-ment expenses 2005 RIZIV/ INAMI (€)**	**% expenses**	**Number of reimbursed cases 2005**	**% Number of cases 2005**
649434	Soft wrist bandage	580.562 €	99,6%	12.376	98,6%
649412	Out of Scope	2.533 €	0,4%	173	1,4%
Totals		583.095 €	100,0%	12.549	100,0%

Source: RIZIV / INAMI 2005 billing data

The wrist orthosis selected for our final product scope is:

- the soft wrist bandage (nomenclature code nr. 649434)

4.3.3 Overview final selection of the product types and categories

An overview of the types of orthoses selected for our market analysis can be found in table 10.

Table 10 : Overview final selection nomenclature codes

Type of Brace	**Nomenclature**		**Reimbursement tariff 2007**		**Reimbursed expenses 2005**	**Cases 2005**	
	Code	**Description**	**Pref**	**Non Pref**		**Number**	**% cases**
Knee	647533	Elastic woven reinforced with metal knee brace	212,77	159,01	986.463,89	4.834	10,9%
	647555	Soft elastic woven reinforced knee bandage	91,72	65,11	1.122.063,16	12.727	28,8%
	647592	Hard knee brace	816,56	579,59	6.166.519,23	6.678	15,1%
Neck	645175	Soft neck collar	14,66	9,59	99.819,37	6.939	15,7%
	645212	Adjustable hard neck collar	258,77	194,08	162.269,67	652	1,5%
Wrist	649434	Soft wrist bandage	48,82	34,74	580.561,77	12.376	28,0%
Totals					**9.117.697,09**	**44.206**	**100,0%**

Source: RIZIV / INAMI 2005 billing data

The project expert committee (January 27, 2007) discussed the importance and relevance of the different types of orthoses and approved the proposed final selection for the Belgian market analysis and international price comparison.

The expert committee stated the two products in the cost analysis had to be chosen out of the products selected for the market analysis, had to be representative and should have preferably have an evidence based utility.

To assess the medical utility of the products, we refer to the literature review[35]. An additional assessment was made by members of the expert committee and C.T.O. [36] , an orthotic and prosthetic expert centre in Belgium which collaborates with the University hospitals of Leuven, Ghent and Antwerp. As a result of this exercise the hard knee brace and the adjustable hard neck collar were chosen for the cost model as these devices meet all three criteria for production cost analysis set forth by the expert committee.

4.4 THE BELGIAN MARKET FOR KNEE, NECK AND WRIST ORTHOSES

The elaboration of our final scope will be followed by an overview of available Belgian market data, with a particular emphasis on the scoped products

Figures on the Belgian market of orthoses are near to non-existent. As for the whole of the European market, the Belgian market on medical devices and particularly on orthoses is dominated by a number of small and medium sized enterprises.

Belgium has no important manufacturers of orthoses. Only in the market for bandages and some soft orthoses one Belgian manufacturer could be detected[37]. Further analysis showed the products fabricated by this manufacturer are not frequently used by the registered and recognised orthotists in Belgium and as such are out of scope for the purpose of this study.

4.4.1 The most representative products on the Belgian market

Aiming to produce a list of specific products that are representative for the market of the prefabricated orthoses as determined within the scope of the study[38], a survey to the orthotists, members of the BBOB-UPBOB and of UNAMEC was sent.[39]. Aiming to obtain detailed information on the numbers of products sold on the Belgian market, a second survey to the distributors of orthoses has been performed.

4.4.1.1 Survey to the orthotists:

The detailed scope of the products, the methodology and the questionnaire used for the survey are added in appendix IV.

The survey produced a list of specific products and brands for each type of orthoses within the scope sold by the orthotists. The results of the survey also showed all orthoses are being purchased via a limited number of distributors situated in Belgium or in The Netherlands. None of the orthotists buy the orthoses directly from manufacturers. The survey also resulted in a list of the distributors of these products. The list is added in appendix IV of the report.

Analysing the list of products used by the orthotists[40], one can conclude all of these are imported products. The number of different products mentioned is rather important. Since the survey did not provide usable information on the relative importance of the different products, the project team organised a second survey to the distributors.

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35 The selection of the two products for the cost analysis is commented in chapter II.
36 Centrum Technische Orthopedie, Biezeweg 13 9230 Wetteren - Belgium
37 Bota N.V. Stadionlaan 12-16 9800 Deinze, Belgium - www.bota.be
38 The scope as described in chapter I of this report.
39 Survey organised in December 2006.
40 Products reimbursed by the RIZIV/INAMI

4.4.1.2 Survey to the distributors:

The aim of this second survey was to obtain detailed figures on sales of the products classified per nomenclature code. This survey was organised in collaboration with the professional associations of the (wholesale) distributors[41].

The methodology and the questionnaire used for the survey[42] are added to the report in appendix IV.

Distributors were asked to provide the numbers of products (per product) sold in Belgium in 2006, the selling prices (to the orthotists), their cost prices (buying price from manufacturer), the identification of their providers and the cheapest product known to them.

Based on the answers to this survey and the additional information gathered, a list of the different products sold on the Belgian market (within the nomenclature codes of the scope) was drawn.

4.4.2 Products sold on the Belgian market on knee-, neck- and wrist orthoses

In the following paragraphs we give a detailed overview of the results of the survey to the distributors, following the nomenclature codes used for reimbursement by the RIZIV / INAMI. For each type of orthosis, the top 10 of products and their numbers sold on the Belgian market are mentioned (2006). The complete list of products sold is added in appendix IV. For each nomenclature code we also give an overview of the market share of manufacturers and distributors. These figures are based on the total number of products.

Market data for 2006 are compared to estimated numbers of reimbursements for 2006. These estimates for annual observations of time series data over the period 1995-2005 are based on ordinary least square (OLS, 95% CI) regressions of the number of booked devices on an intercept and booking year as regressors (see appendix IV)

Finally, we try to assess patient profiles (by age and sex) and geographic utilisation patterns for Belgium for each product type by presenting standardized per capita utilisation rates for all Belgian regions ("arrondissementen / arrondissements"). Standardization was based on utilisation rates per age group of five years / per sex / per region for all Belgian residents for the entire Belgian territory.

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41 BBOB-UPBOB and UNAMEC

42 The survey was organised in the period February -March 2007.

4.4.2.1 Knee orthoses

Prefab hard knee brace hinged (nomenclature code 647592)

Table 11 : Knee nomenclature code 647592: distributors / top 10 products sold in 2006

KNEE Nomenclature code 647592: Products Top 10 products	Distributor Belgium	Number of products sold/Year Belgium (2006)
Bledsoe Aligner ESE L/R	Ortho-Medico	988
Bledsoe Axiom L/R	Ortho Medico	948
Donjoy 4-titude	Sprofit	874
Donjoy grouped number	Dirame	660
Donjoy Legend Funct. brace ACL	Sprofit	642
C.Ti.2	Somas	350
Generation II unloader adj.	Ossur	350
Donjoy OAdjuster	Sprofit	344
Bauerfeind SecuTec® Genu LR	Bauerfeind	319
Bauerfeind MOS Genu® Short (court + long)	Bauerfeind	269
TOTAL top 10		5.744
Number of RIZIV/INAMI reimbursed cases (2006 forecast) = 6.878	TOTAL all products	6.481

Source: Survey to distributors

For the hard knee brace the survey to the distributors on the Belgian market provided a total sale of 6.481 products covering about 94 % of the forecasted number of 6.878 knee braces reimbursed in 2006. The top 10 of the products sold (5.744 units) mentioned in the table above cover about 88 % of the market.

Taking into account the fact the average price of these products is high (the selling price to the patient as recommended by the RIZIV / INAMI is of 947,91 €[43]) and reimbursement is of 579,59 € for non preferential beneficiaries and of 816,56 € for preferential beneficiaries, one can expect nearly all hard knee braces corresponding to this nomenclature code that are sold on the Belgian market will be included in the reimbursed products.

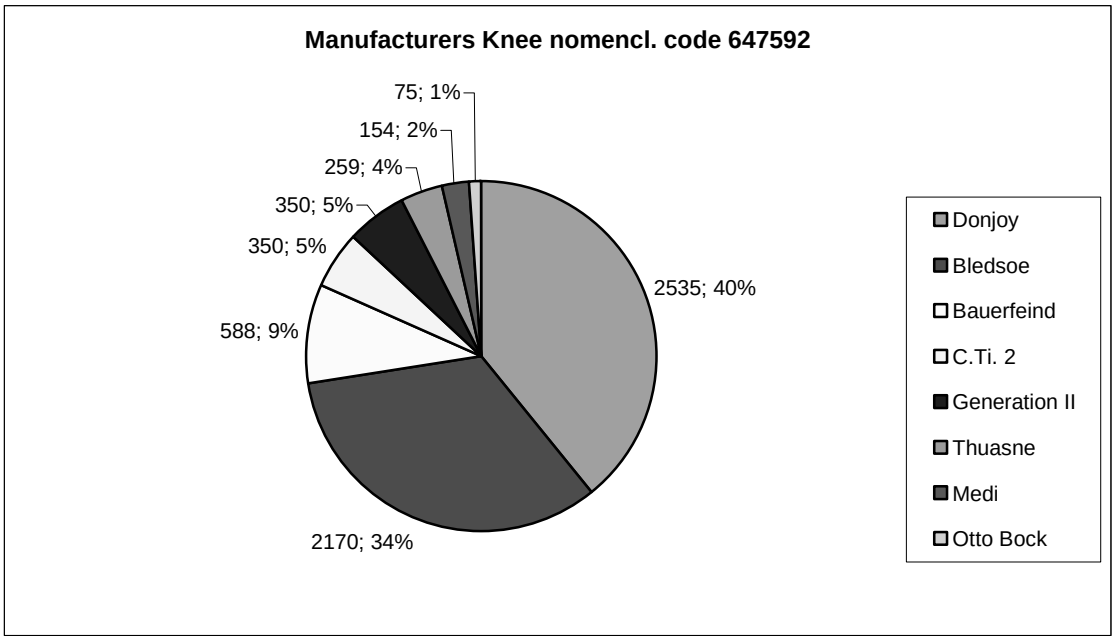
Market positioning manufacturers for prefab hard knee brace

Looking at the different manufacturers (Figure 6) the US based company Donjoy with 2.535 hard knee braces sold on the Belgian market is the market leader. Bledsoe (US based) with a total of 2.170 hard knee braces is to be ranked second. The third major brand is Bauerfeind (Germany) with a total of 588 hard knee braces.

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43 The nomenclature code of the RIZIV / INAMI defines the amount that is reimbursed to the patients. There are two different amounts defined, one for the preferential beneficiaries (widows, people with disabilities, people with low pension…) and another (lower) amount for the non preferential beneficiaries. The RIZIV / INAMI also defines a selling price for the devices. This selling price is however not binding for the orthotists. The amounts of reimbursement quoted in the report are those that apply to 2007.

Figure 6 : Manufacturers Knee nomenclature code 647592

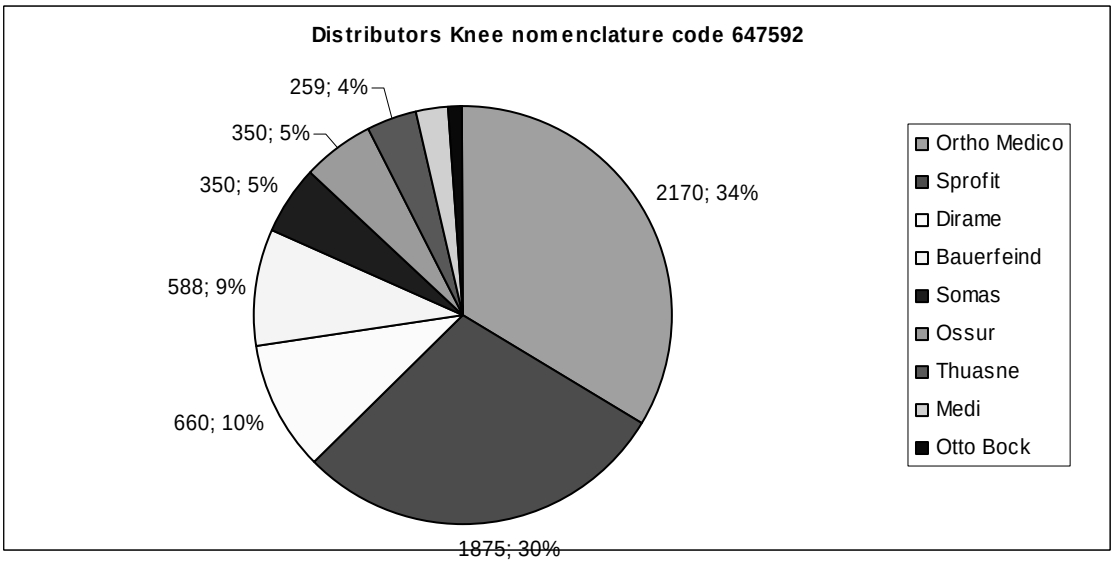


Source: Survey to distributors

Market positioning distributors for prefab hard knee brace

As shown in Figure 7 the most important distributors for the hard knee brace are Ortho Medico (distributor of Bledsoe), Sprofit (distributor of Donjoy in 2006), Dirame (co-distributor of Donjoy) and Bauerfeind Benelux (distributor of Bauerfeind)

Figure7 : Distributors knee nomenclature code 647592

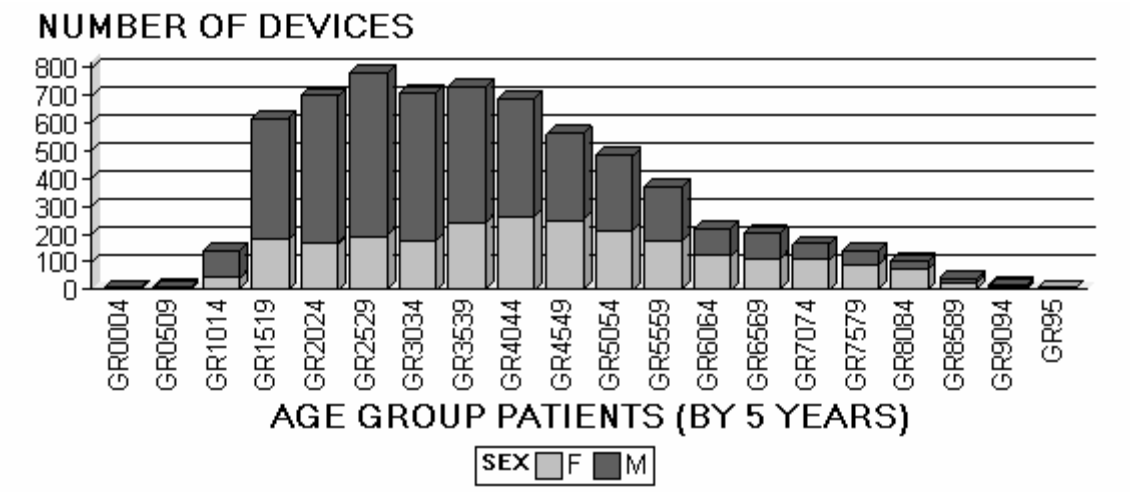


Source: Survey to distributors

Patient profile for prefab hard knee brace

Figure 8 depicts the number of RIZIV/INAMI reimbursed devices booked in 2005. The hard knee brace appears to be used more frequently by a male and younger population.

Figure 8 : Patient profile knee nomenclature code 647592

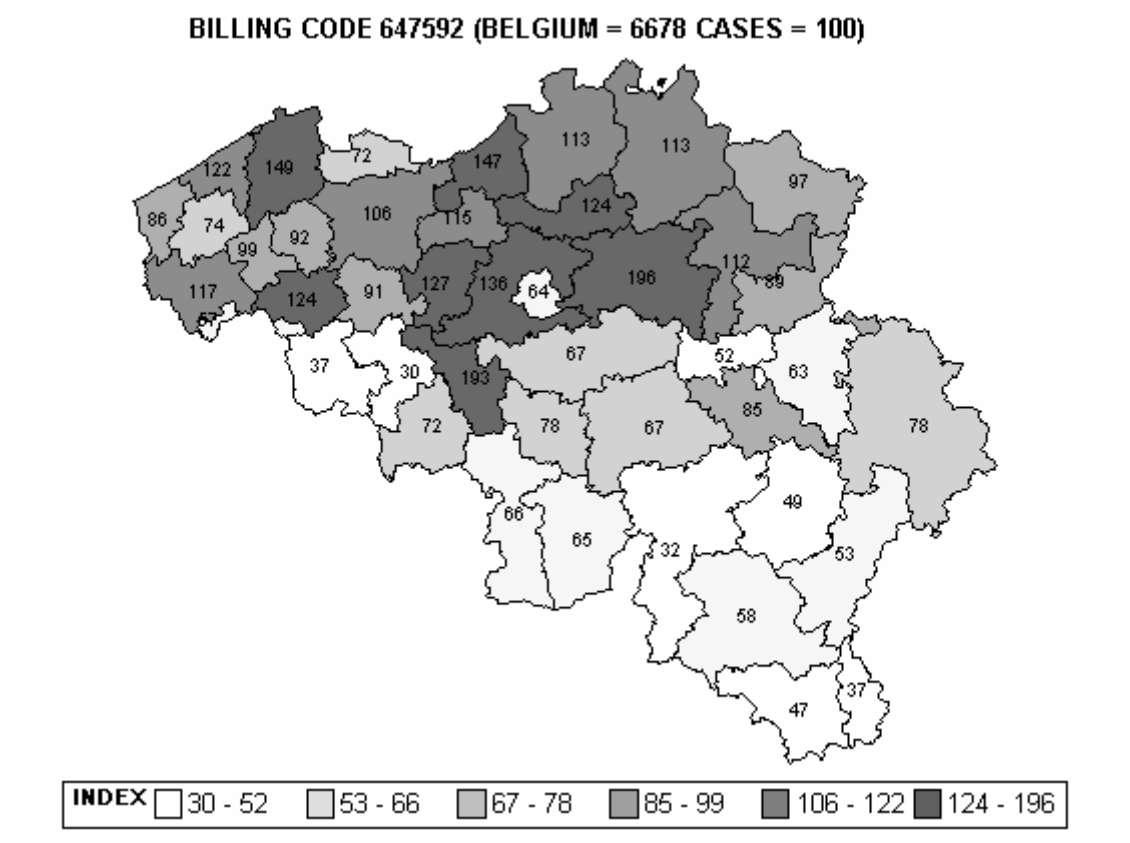


Source: RIZIV / INAMI 2005 billing data

Geographic distribution

The figure below plots the standardized utilisation rates for all 43 Belgian regions (arrondissementen / arrondissements) in 2005. The total number of devices for Belgium that would have been reimbursed if the whole of Belgium followed a utilisation pattern (by sex and age profile) similar to that of a particular region is calculated and indexed with the actual number of reimbursed devices for 2005 set to 100.

Figure 9 : Geographic distribution of prefab hard knee brace



Source: RIZIV / INAMI 2005 billing data and National Statistical Institute 2005 demographic data

We notice a concentration of the use of prefab hard knee braces in Flanders. There are wide differences in utilisation with a maximum factor of almost 7 between regions. The coefficient of variation[44] for the observations between regions equals 44%. A more detailed analysis of geographic utilisation patterns can be found in appendix IV.

[44] Standard deviation devided by mean

Key points

- **For the hard knee brace the match between the number of products sold and the number of reimbursed cases is high.**
- **The market for hard knee braces is characterized by concentration of the market.**
- **The three most important manufacturers are Donjoy, Bledsoe and Bauerfeind. The most important distributors are Ortho Medico, Sprofit, Dirame and Bauerfeind.**
- **Hard knee braces tend to be worn by a mostly younger, male and Flemish population.**

Prefab knee bandage woven reinforced (nomenclature code 647555)

The number of "knee bandages woven reinforced", sold on the Belgian market by the distributors that responded to the survey represents a total sale of 17.580 products (see Table 12). This number is substantially higher than the 2006 forecast of 13.446 cases reimbursed by the RIZIV/INAMI. One explanation for the gap between sold and reimbursed products in Belgium is the fact that the price of these products is much lower, compared with the category of hard knee brace. The selling price to patients as defined by the RIZIV / INAMI is of 106,46 € of which 91,72 € is reimbursed for the preferential beneficiaries and 65,11 € for the none preferential beneficiaries.

Table 12 : Knee nomenclature code 647555 distributors / top 10 products sold in 2006

KNEE Nomenclature code 647555: Products Top 10 products	**Distributor Belgium**	**Number of products sold/Year Belgium (2006)**
Bauerfeind Genutrain®	Bauerfeind	10.092
Bauerfeind Genutrain® P3	Bauerfeind	3.124
Bauerfeind Genutrain® A3	Bauerfeind	1.503
Push Med knee	Vitamed	605
Push Care knee	Vitamed	328
Thuasne Silistab Genu	Thuasne	261
Otto Bock Genu Sensa 50K15	Otto Bock	250
Medi.ortho Genumedi®	Medi	250
OM-IMMOB knee immobilizer	Ortho Medico	233
Medi.ortho elastic knee support 603	Medi	150
TOTAL		16.796
Number of RIZIV / INAMI reimbursed cases (2006 forecast) = 13.446	TOTAL all products	17.580

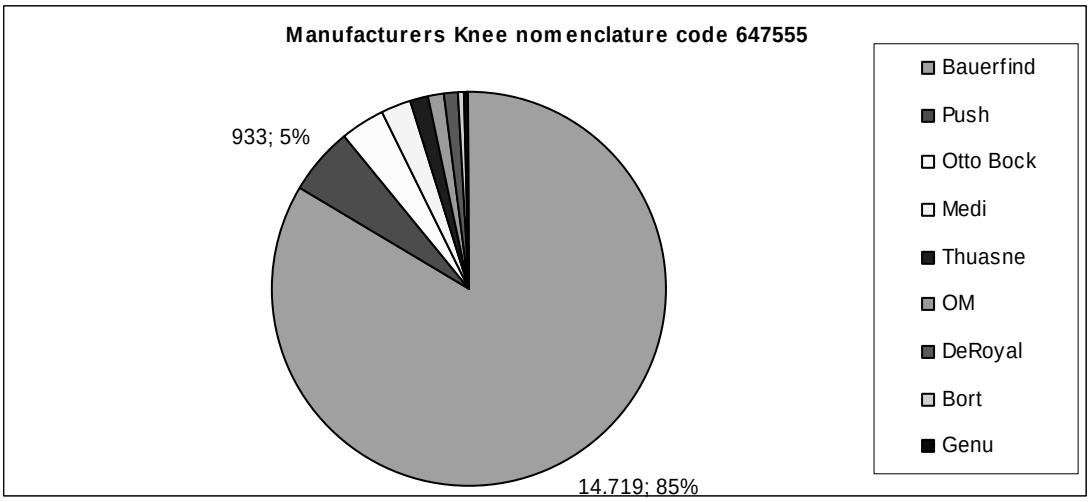
Source: survey to distributors

We assume that these products are also sold by the orthotists outside the reimbursed circuit (for instance without medical prescription, a necessary condition for reimbursement) and via the alternative distribution channel of "non registered retailers", pharmacies and the department stores. The top 10 of the products sold in 2006 covers more than 95 % of the market.

Market positioning manufacturers

Market leader for this type of knee orthoses is definitely Bauerfeind as indicated by Figure 10 (Germany) with their Genutrain® brand. Bauerfeind sold 14.719 pieces on the Belgian market in 2006. The Push brand (based in the Netherlands) distributed on the Belgian market by the distributor Vitamed holds a second position with a total number of 933 products sold. In third and fourth position we find Otto Bock (Germany) with 720 products and Medi (Germany) with about 450 units sold.

Figure10 : Manufacturers knee nomenclature code 647555

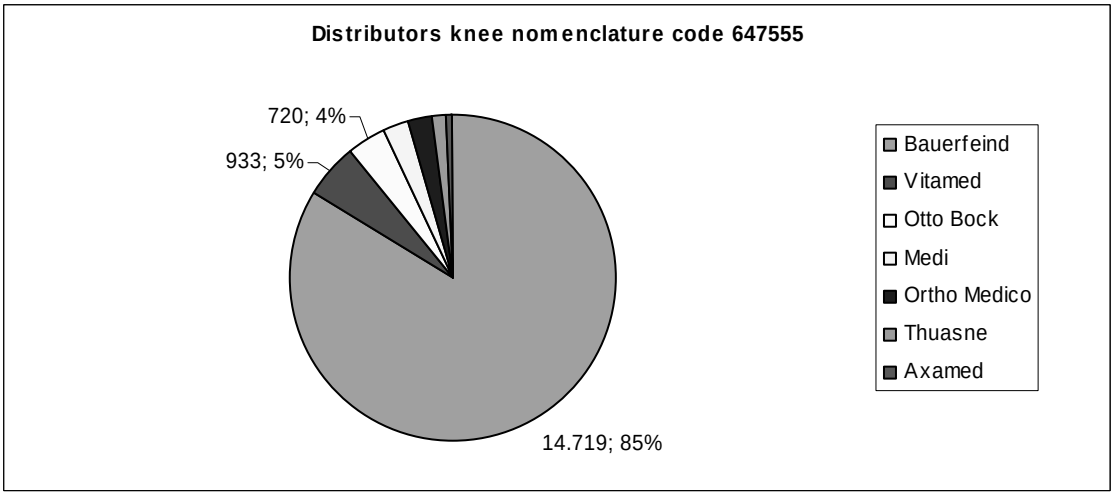


Source: Survey to distributors

Market positioning distributors

As Bauerfeind has its own distribution network there is a complete overlap between the Bauerfeind manufacturing data and distribution data. In second position we see (Figure 11) Vitamed (distributor of Push).

Figure 11 : Distributors knee nomenclature code 647555

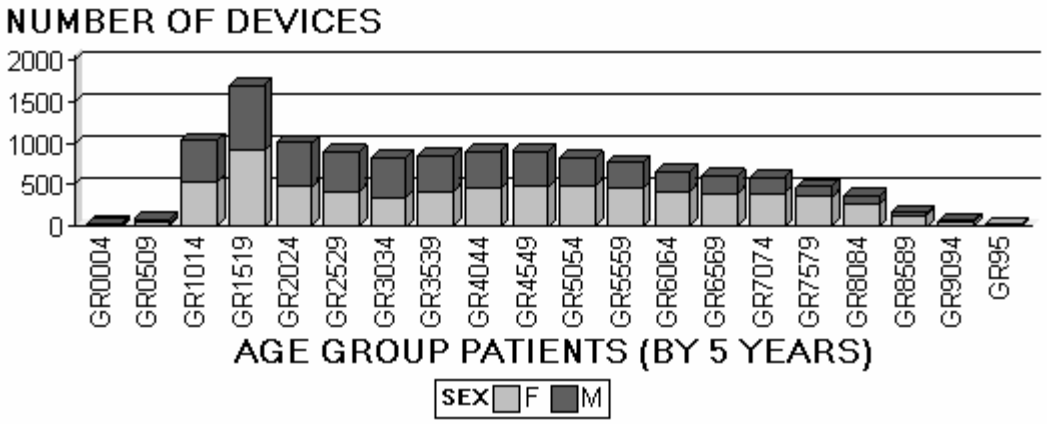


Source: Survey to distributors

Patient profile

Figure 12 indicates that this type device is mostly prescribed to women. The distribution of the number of devices by age group is bimodal with a salient hike in utilisation between the ages of 15 and 20.

Figure12 : Patient profile code 647555

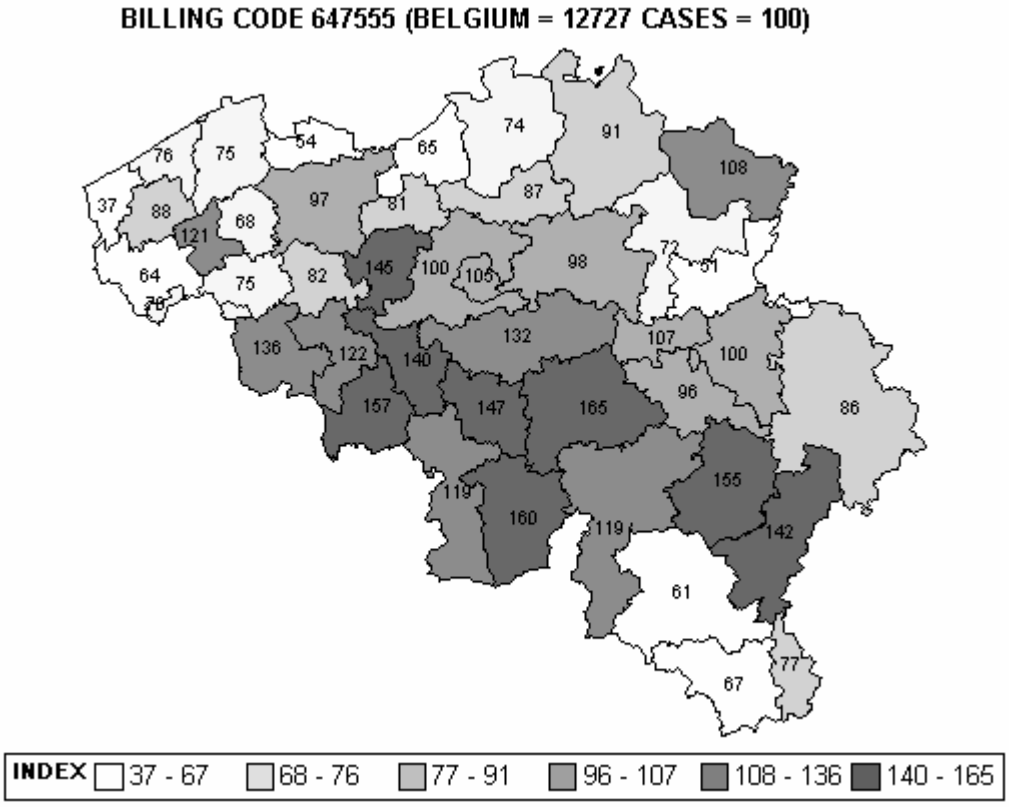


Source: RIZIV / INAMI 2005 billing data

Geographic distribution

Figure 13 indicates the highest (relative) utilisation of these devices is observed in the southwestern part of Belgium. Again, wide differences by region are observed. The coefficient of variation for the observations between regions equals 33%

Figure13 : Geographic distribution code 647555



Source: RIZIV / INAMI 2005 billing data and National Statistical Institute 2005 demographic data

Key points

- **For the category knee bandage woven reinforced the number of product sold is higher than the number of reimbursed cases by the RIZIV / INAMI.**
- **The market of knee bandage woven reinforced is dominated by one manufacturer (Bauerfeind).**
- **The modal patient profile for these devices concerns women between the ages of 40 and 60 in the South(west)ern part of Belgium.**

Prefab knee brace elastic tissue or neoprene reinforced with metal (nomenclature code 647533)

For the soft reinforced jointed knee braces the survey to the distributors (see Table 13) resulted in a total number of products sold on the Belgian market of 5.721 units. This number is slightly higher than the forecast of 5.026 products reimbursed by the Belgian public health system in 2006. In 2007, the advised selling price to patients used by the RIZIV / INAMI is of 223,05 € of which 212,77 € is reimbursed for the preferential beneficiaries and 157,01 € for the not preferential beneficiary patients. The top 10 products sold cover about 93 % of the market.

Table 13: Knee nomenclature code 647533 distributors / top 10 of the products sold 2006

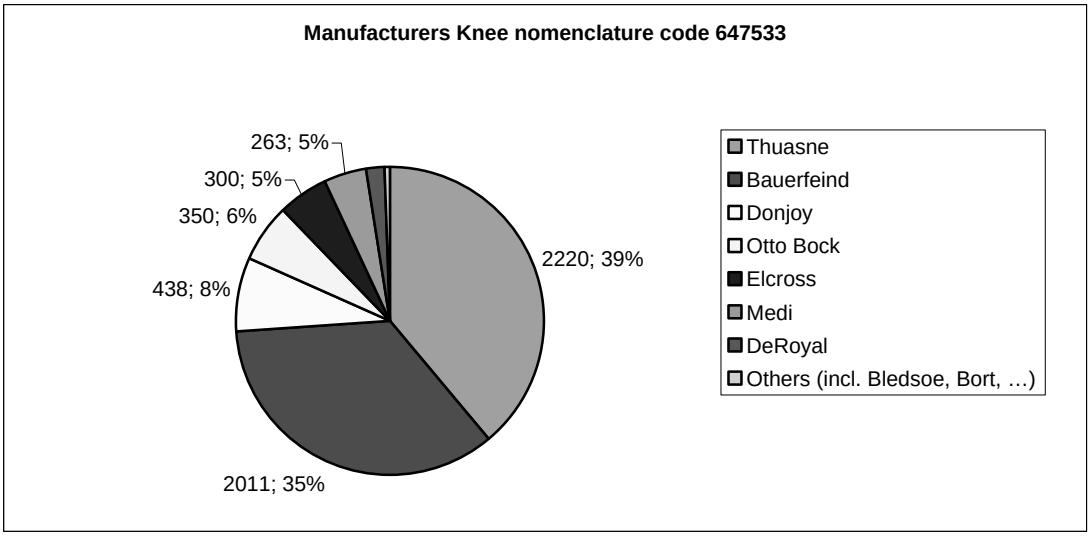
KNEE Nomenclature code 647533: Products Top 10 products	**Distributor Belgium**	**Number of products sold/Year Belgium (2006)**
Bauerfeind Genutrain® S	Bauerfeind	2.011
Thuasne Ligaflex Evolution	Thuasne	1.184
Thuasne Ligaflex 2370	Thuasne	1.036
Donjoy Drytec	Sprofit	342
Elcross réf. 124,126, 128 grouped number	Dirame	300
MEDI hinged knee PRO (airtex)	Medi	160
DeRoyal Genum Liga (T3) - ref EU 4112	Ortho Medico	115
Donjoy Tru-Pull hinged sleeve	Sprofit	96
Otto Bock Genu Track - 50K20	Otto Bock	60
Otto Bock Genu Direxa Stable Wraparound - 8367	Otto Bock	60
TOTAL		5.364
Number of RIZIV/INAMI reimbursed cases (2006 forecast) = 5.026	TOTAL all products	5.721

Source: Survey to distributors

Market positioning manufacturers

Figure 14 indicates that the market leader for this type of knee braces is the French manufacturer Thuasne with 2.220 units sold on the Belgian market in 2006, closely followed by the German manufacturer Bauerfeind with a total of 2.011 units sold in 2006. Donjoy (US) and Otto Bock (Germany) have more ore less the same market share with about 350 units sold. Elcross (Basko Camp-Germany) and Medi (Germany) follow with respectively 300 and 263 units sold in 2006.

Figure14 : Manufacturers knee nomenclature code 647533

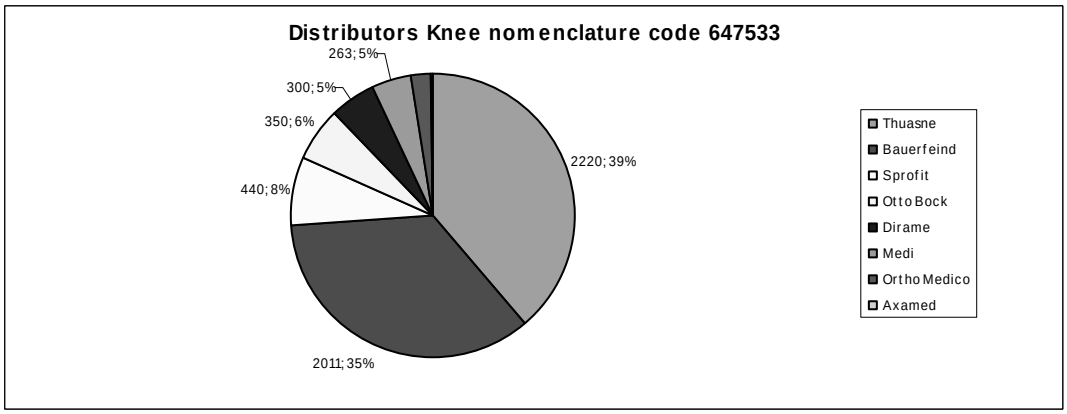


Source: Survey to distributors

Market positioning distributors

As shown in Figure 15 the main distributors for this nomenclature code are Thuasne and Bauerfeind itself as they have their own distribution network.

Figure 15 : Distributors knee nomenclature code 647533

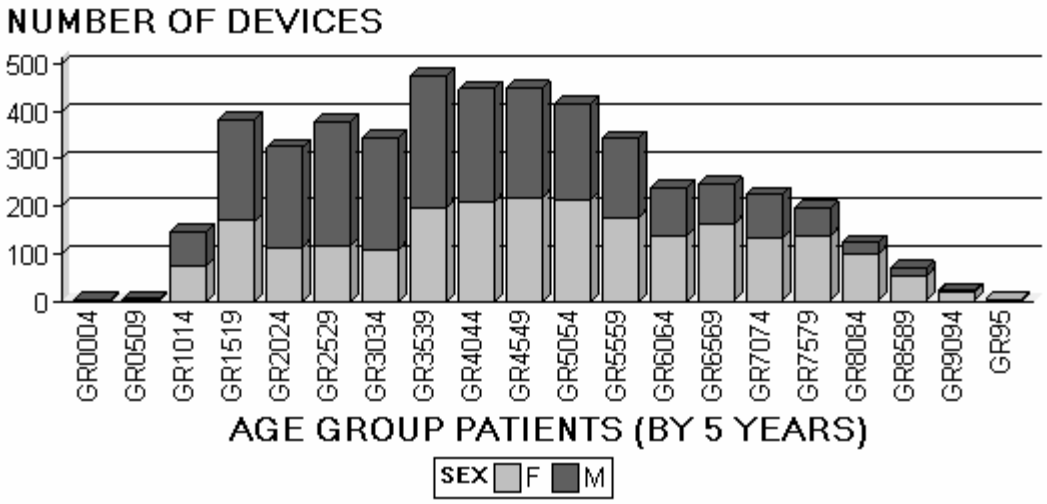


Source: Survey to distributors

Patient profile

As shown in Figure 16, the most representative patient profile is that of a person (no marked distinction according to sex) between the ages of 35 and 55

Figure 16 : Patient profile code 647533

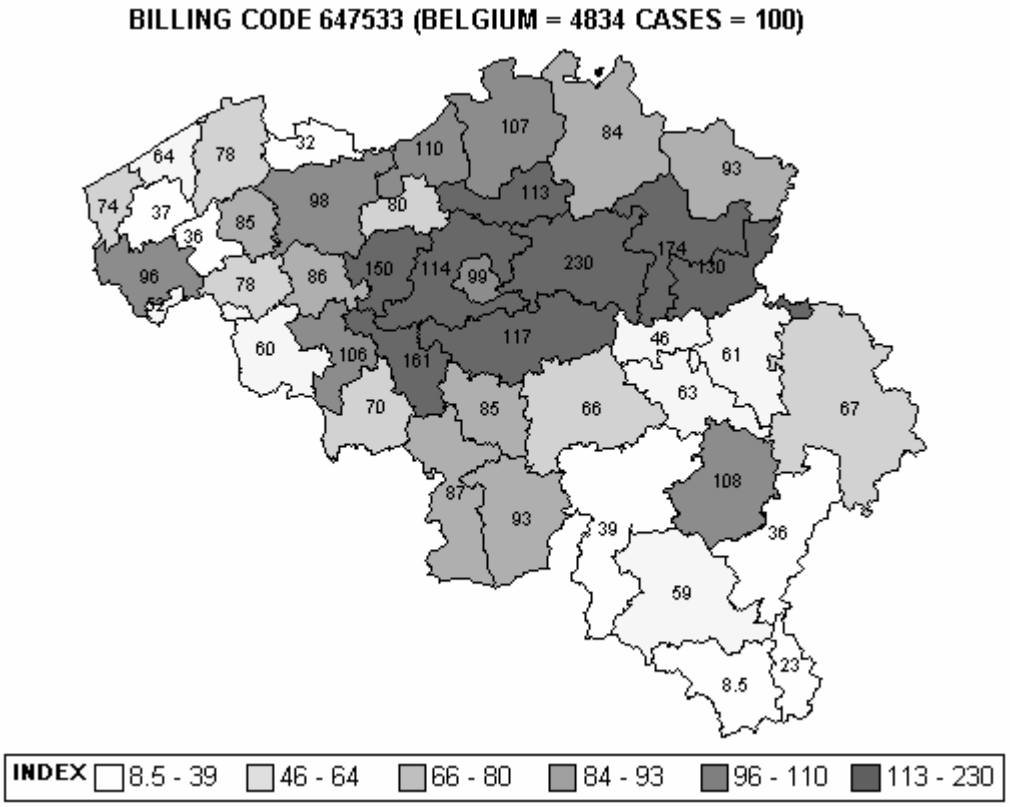


Source: RIZIV / INAMI 2005 billing data

Geographic distribution

Figure 17 depicts the geographic distribution for this type of device, showing a higher utilisation in the centre of Belgium (are surrounding Brussels). Wide differences are observed. The coefficient of variation for the observations between regions equals 50%

Figure 17 : Geographic distribution code 647533



Source: RIZIV / INAMI 2005 billing data and National Statistical Institute 2005 demographic data

Key points

- **For the category knee brace elastic tissue or neoprene reinforced with metal the Belgian market is dominated by two manufacturers being Thuasne and Bauerfeind.**
- **The manufacturers market share is almost a complete duplication of the distributors market share.**
- **The most representative patient profile is that of a person residing in the centre of the country (area surrounding the capital) between the ages of 35 and 55.**

4.4.2.2 Neck orthoses

The following tables give an overview of numbers of the collars sold on the Belgian market in 2006 classified following the nomenclature code used for reimbursement by the RIZIV / INAMI. As one can notice few distinct brands are sold.

Prefab hard neck collar with support chin and/or back of the head adjustable in height (nomenclature code 645212)

The survey to the distributors on the Belgian market resulted in a total of 827 hard neck collars sold (Table 14). In 2005 662 hard neck collars have been reimbursed by the RIZIV/INAMI (Belgian public health system).

Table 14 : Neck nomenclature code 645212 distributors / products sold 2006

Neck Nomenclature code 645212: Products	**Distributor Belgium**	**Number of products sold/Year Belgium (2006)**
Jerome Miami J.Collar	Ortho-Medico	477
Jerome Miami J. Collar	Distrac	150
Philadelphia neck collar	Distrac	75
Malibu neck collar 06/3020	Distrac	50
Philadelphia Cervical Orthosis - 50C40	Otto Bock	50
Somi brace	Distrac	25
TOTAL		827
Number of RIZIV/INAMI reimbursed cases (2005[45] booked number) = 662	TOTAL all products	827

Source: Survey to distributors

The selling price defined by the RIZIV / INAMY for this type of orthosis is of 258,77 €. The preferential beneficiary is entitled to a full reimbursement of this amount. The not preferential beneficiaries are entitled to a reimbursement of 194,08 €.

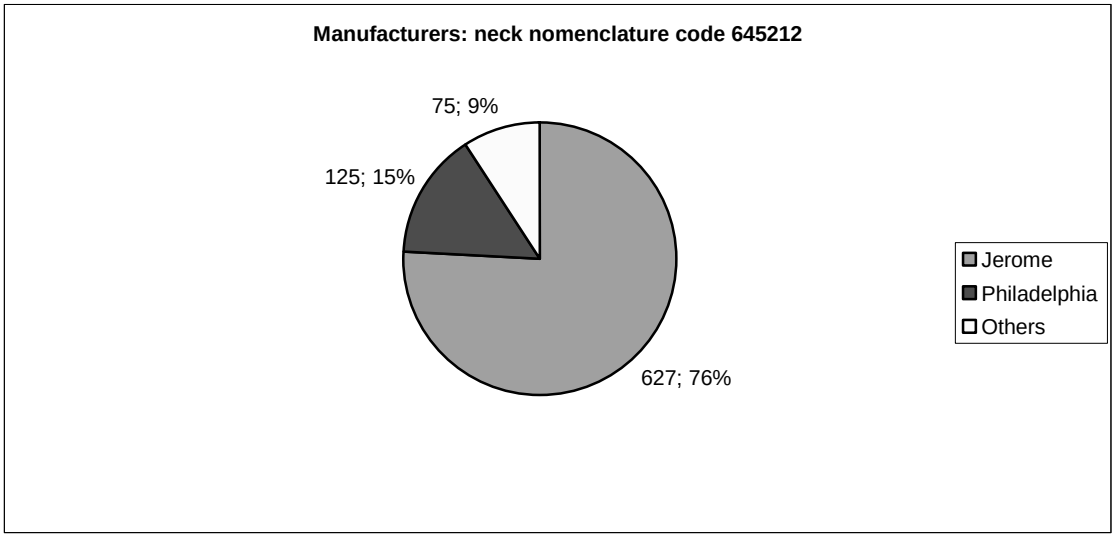
45 As no significant (95% confidence interval, OLS regression of booked numbers of devices on an intercept and booking year as regressors) time trend was established (see also appendix IV) no 2006 forecast was featured for the billing code 645212.

Market positioning manufacturers

Looking at the number of products sold by the different distributors on the Belgian Market (Figure 18), it is clear one product, the Jerome Miami J. collar is by far the sole market leader for this type of orthosis. Jerome Medical (US) and Philadelphia Collar Company (US) both have been acquired by the Iceland based Össur group.

Because of the importance of this product on the Belgian market, we decided to choose this product as the basis for the cost model on hard neck braces.

Figure 18 : Manufacturers neck nomenclature code 645212

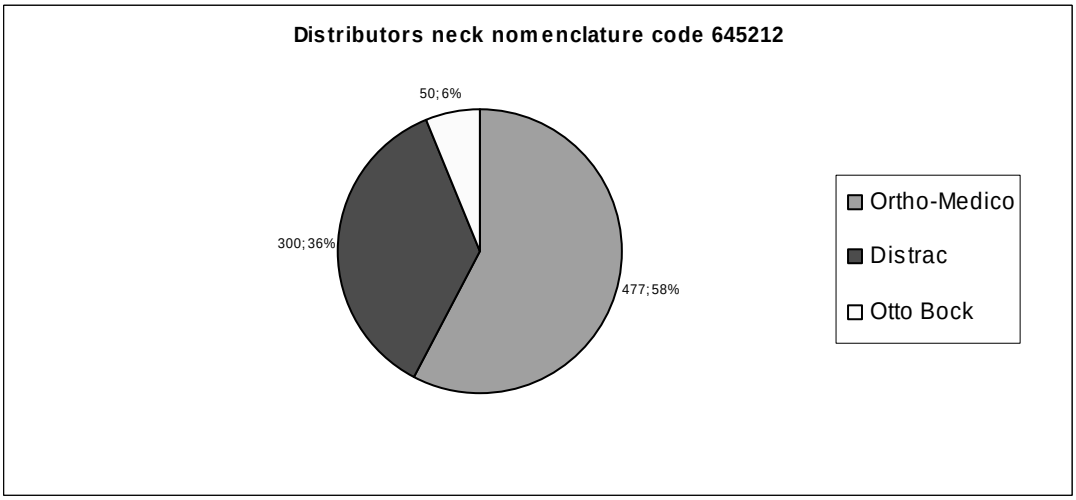


Source: Survey to distributors

Market positioning distributors

Ortho Medico (distributor of Jerome) is the most important distributor (Figure 19), followed by Distrac (also distributor for -among others- Miami J collar) and Otto Bock.

Figure 19 : Distributors neck nomenclature code 645212

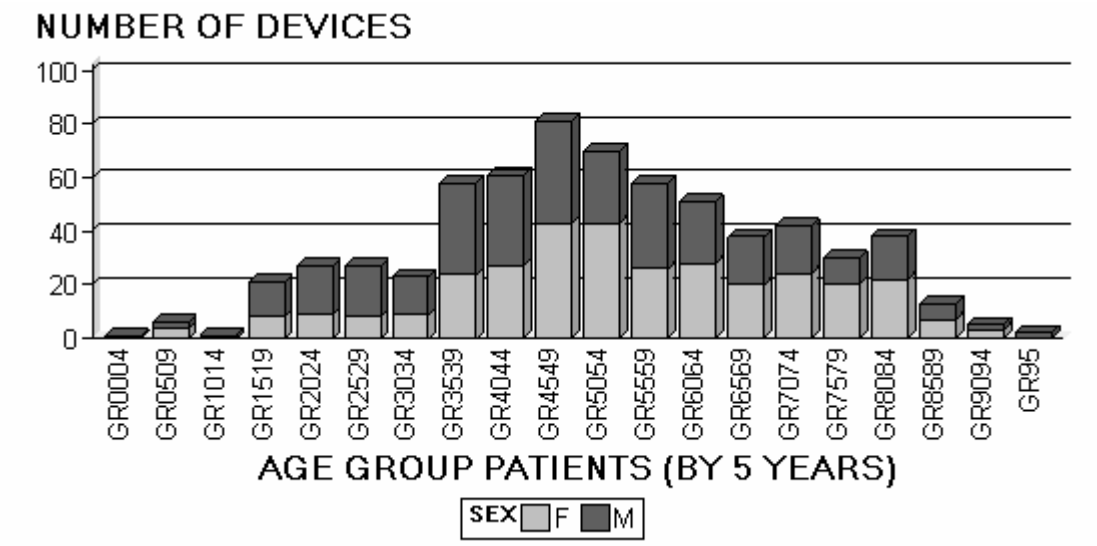


Source: Survey to distributors

Patient profile

Figure 20 indicates that the prefab hard neck braces are mostly worn by people between the ages of 35 and 65

Figure 20 : Patient profile code 645212

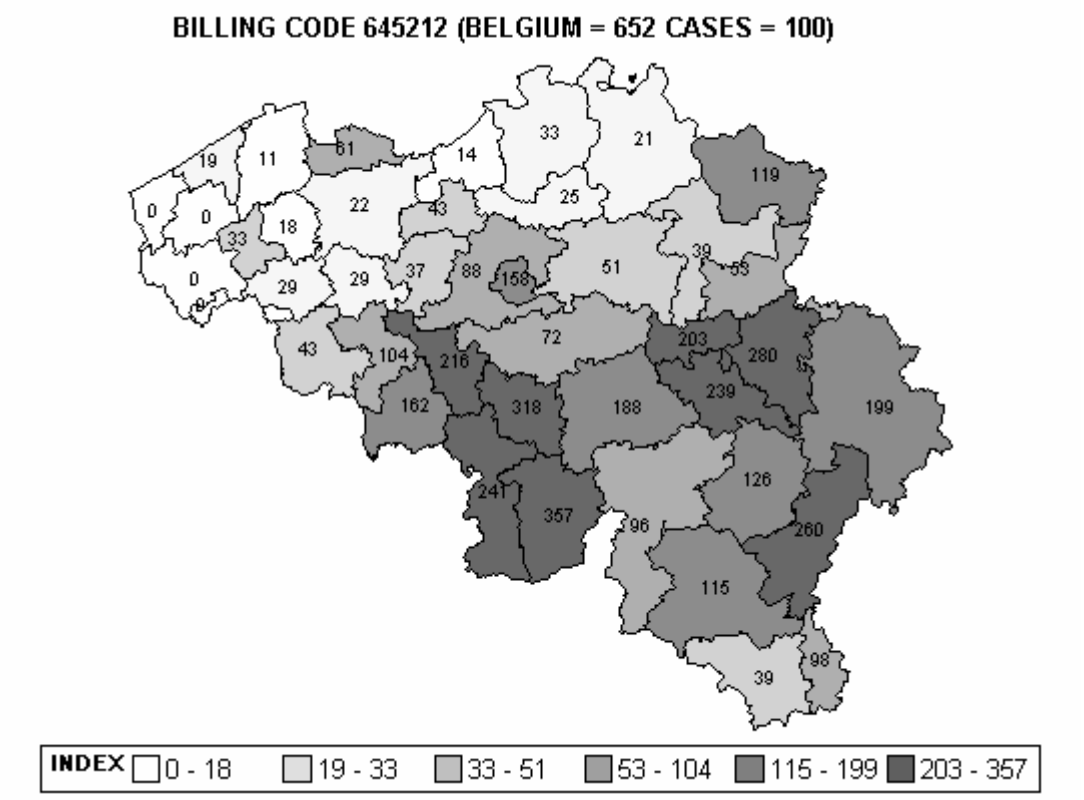


Source: RIZIV / INAMI billing data

Geographic distribution

Figure 21 shows that the use of prefab hard neck braces is concentrated in the southern part of the country. As is the case for the other devices, we find wide differences in utilisation by region. The coefficient of variation for the observations between regions equals 98%, the highest variance observed for our scope. It should, however, be observed that there are few observations for this device with some regions reporting not a single reimbursement in 2005.

Figure 21 : Geographic distribution code 6475212



Source: RIZIV / INAMI 2005 billing data and National Statistical Institute 2005 demographic data

Key points

- **The Belgian market for hard neck braces is dominated by one product, the Jerome Miami J Collar.**
- **The market for hard neck braces is caraterized by a limited number of products and as a consequence a limited number of distributors and manufacturers.**
- **These devices are mostly worn by people between the ages of 35 and 65 residing in the Southern part of Belgium.**

Prefab soft collar (nomenclature code 645175)

Although the proven clinical evidence for using soft neck braces is limited as stated in chapter II, the soft neck brace was included in the survey to the distributors. The number of sold soft neck collars covered by the survey counts for 11.152 pieces (Table 15), which is much higher than the 7.430 forecast for 2006. The top 10 products sold cover about 98 % of the sales detected through the survey.

Table 15 : Neck nomenclature code 645175 distributors / top 10 of the products sold 2006

Neck Nomenclature code 645175: Products Top 10 of products sols	**Distributor Belgium**	**Number of products sold/Year Belgium (2006)**
Thuasne Ortel (zacht)2390 ORTEL C1	Thuasne	2.118
GLOBOMEDIC Bauerfeind	Bauerfeind	1.719
Thämert 49/190	Axamed	1.691
Push Care 8 cm en 10 cm	Vitamed	1.288
Push nek Med 8 cm en 10 cm	Vitamed	1.274
Basco Camp grouped number	Dirame	950
DeRoyal Foam cervical collar 6/8/10/12cm ref EU 515	Ortho-Medico	837
Otto Bock Necky Color - 50C20	Otto Bock	685
Otto Bock Necky Anatomic - 103 - 104 - 105	Otto Bock	255
Bort Cervical Support beige 127 360	Axamed	112
TOTAL		10.929
Number of RIZIV / INAMI reimbursed cases (2006 forecast) = 7.430	TOTAL	11.152

Source: Survey to distributors

The average price of these soft neck collars is relatively low. The selling price as defined by the RIZIV / INAMI is of 20,28 € of which 14,66 € is reimbursed for the preferential beneficiaries and 9,59 € for the non-preferential ones.

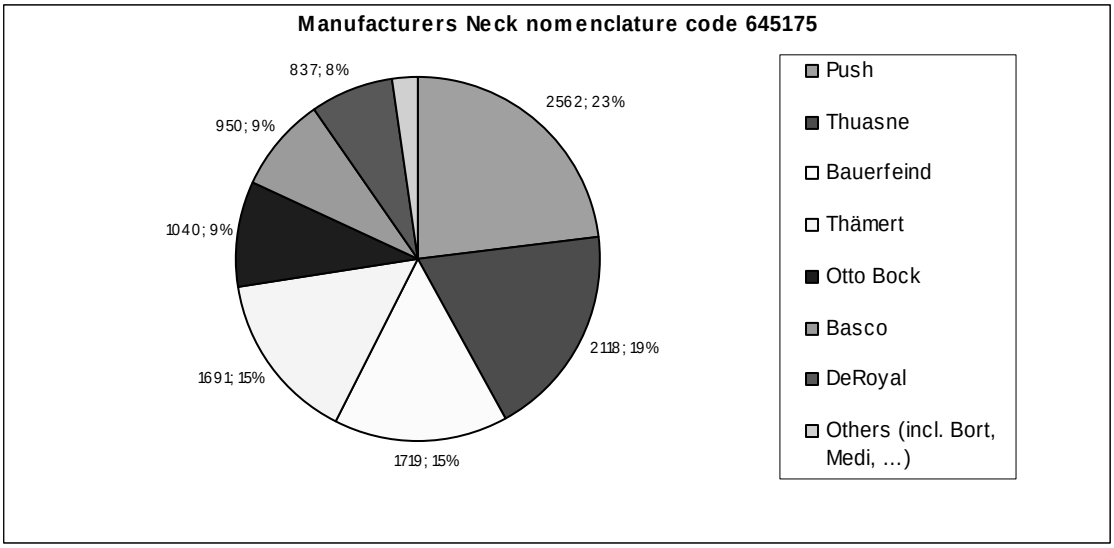
It is obvious that the soft neck collar is widely sold outside the circuit of the reimbursed products. This product can be purchased at local pharmacies and in department stores too. The brands that can be found at local pharmacies and in department stores are mostly other brands than these sold by the registered orthotists. One has to take into account that soft neck collars sold in pharmacies or in department stores do not qualify for reimbursement since they are not delivered by a registered orthotist.

The number of products sold by the (wholesale) distributors mentioned in the table merely concerns products sold to the orthopaedics. From our interviews with the distributors we noticed a market segmentation. Most of them focus on the registered orthotists and do not distribute directly to pharmacies or other vendors. The products sold in those premises are provided by wholesale dealers that specifically target them. Consequently one can assume an important number of soft neck collars must be sold by the orthotists without reimbursement. Since the price of the soft collar is low, one can assume not all collars are prescribed by medical specialist doctors (also a condition for reimbursement) and patients buy these collars without a specific prescription.

Market positioning manufacturers

For the products sold to the registered orthotists, the Push brand (based in the Netherlands) is clearly the market leader for soft neck collars with 2.562 units sold in 2006 (see Figure 22). Thuasne (France) holds a second position with 2.118 units preceding Bauerfeind (Germany) with 1.719 units sold on the Belgian market.

Figure 22 : Manufacturers neck nomenclature code 645175

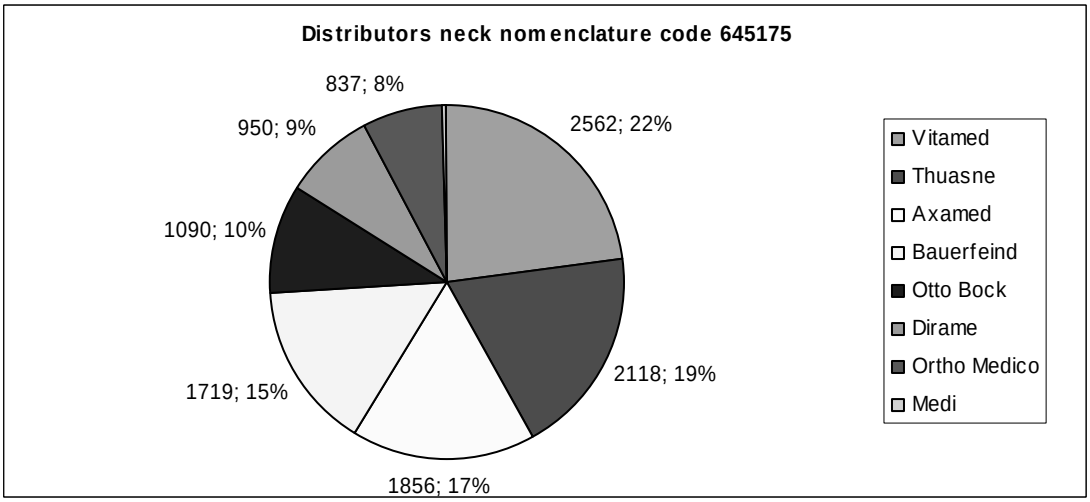


Source: Survey to distributors

Market positioning distributors

As indicated in Figure 23, different distributors play a role for the soft neck collar. This result was expected as this market is characterized by many different manufacturers.

Figure 23 : Distributors neck nomenclature code 645175

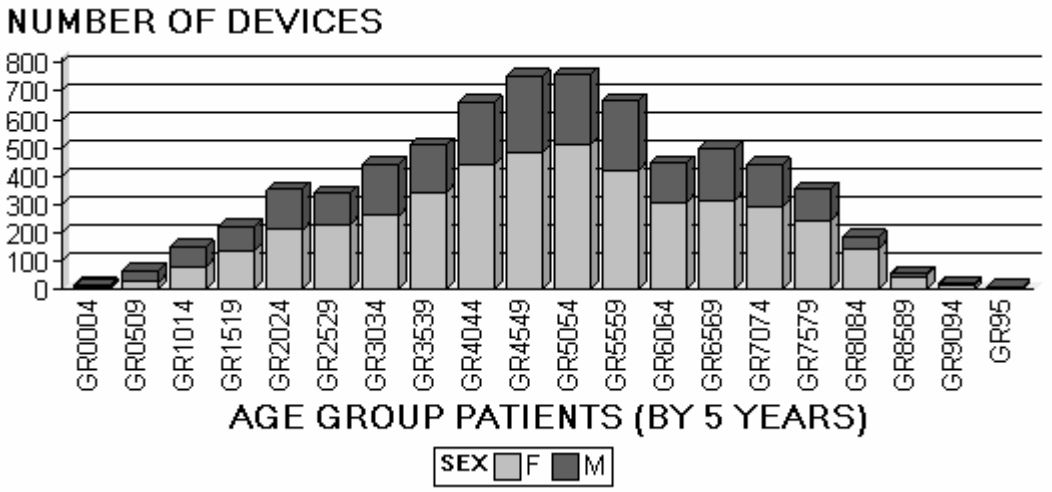


Source: Survey to distributors

Patient profile

As shown in Figure 24, the soft collars are mostly prescribed to women between the ages of 40 and 60.

Figure 24 : Patient profile code 645175

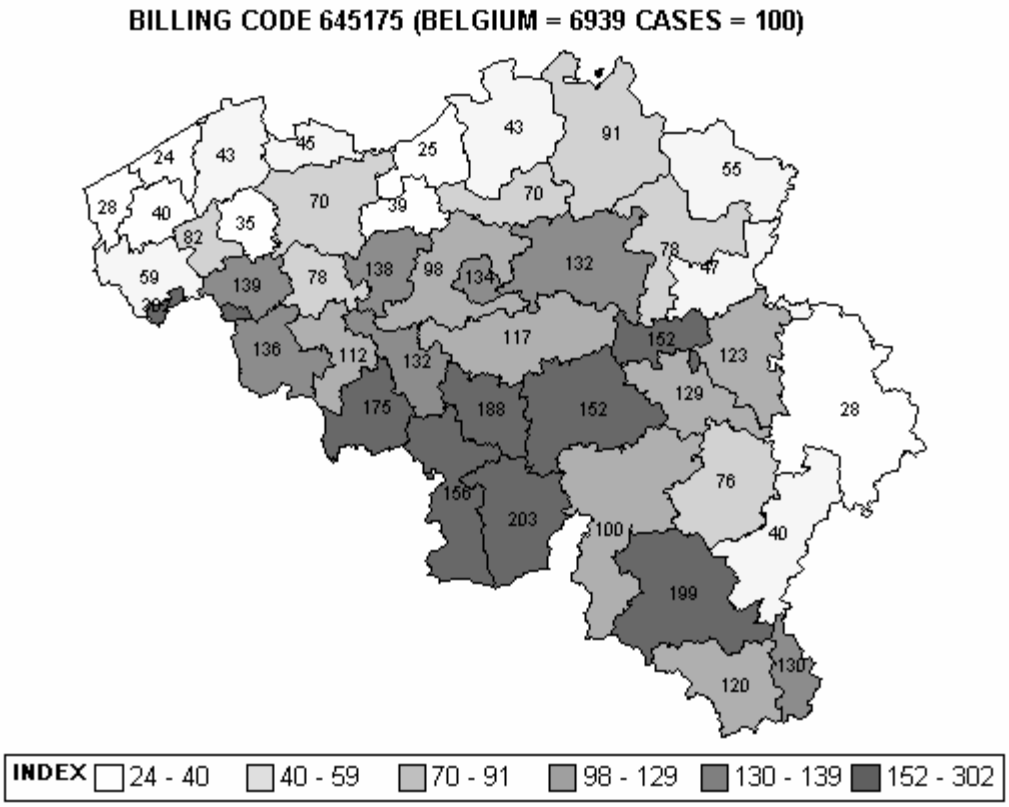


Source: RIZIV / INAMI 2005 billing data

Geographic distribution

Based on Figure 25, it can be observed soft neck collars are mostly worn in the southwestern part of Belgium. Once more, wide differences by region are found. The coefficient of variation for the observations between regions equals 59%.

Figure 25 : Geographic distribution code 645175



Source: RIZIV / INAMI 2005 billing data and National Statistical Institute 2005 demographic data

Key points

- **The market for soft neck braces is an important market in Belgium (in terms of sales volume) although there is little clinical evidence for this product.**
- **The number of products sold is much higher than the (forecasted) number of reimbursed cases. This gap can be explained by the fact that this product is often sold without compliance to RIZIV / INAMI regulation and is therefore not included in the reimbursement data.**
- **The market for soft neck braces is highly fragmented. Almost all manufacturers have products in this category.**
- **These products are distributed by almost all distributors active in the sector of prefabricated braces.**
- **Soft neck braces are often distributed trough alternative distribution channels such as pharmacies and department stores.**
- **The modal patient profile for these devices relates to women between the ages of 40 and 60 in the South(west)ern part of Belgium.**

4.4.2.3 Wrist orthoses

Prefab wrist bandage, reinforced limiting movement (nomenclature code nr. 649434)

Table 16 gives an overview of the numbers of reinforced wrist bandages sold on the Belgian market in 2006 .

The survey to the distributors provided a total sale of 19.831 units. The top 10 products cover about 83 % of these. The forecast for 2006 is 12.352 meaning this wrist bandage is obviously also largely sold outside the circuit of the registered orthopaedics. The same observations made for the soft neck collar are valid here. This product is largely sold in pharmacies and sport shops although the brands sold in these premises again mostly differ from the ones sold by the registered orthopaedics.

Table 16 : Wrist nomenclature code 649434 distributors / top 10 products sold 2006

Wrist Nomenclature code 649434: Products Top 10 of products sold	**Distributor Belgium**	**Number of products sold/Year Belgium (2006)**
Push Med wrist	Vitamed	5.820
Bort wrist support aluminium splint 103 300	Axamed	2.715
medi Wrist support	Medi	1.866
Elastic wrist brace Donjoy	Sprofit	1.690
Bauerfeind ManuTrain®	Bauerfeind	1.124
Manu Rheuma Flex - 4142	Otto Bock	810
Push Med Splint wrist	Vitamed	779
Basko Elcross grouped number	Dirame	730
DeRoyal - Manex Reuma Pollus - ref EU 2025	Ortho Medico	536
Bauerfeind ManuLoc®	Bauerfeind	474
TOTAL		16.544
Number of RIZIV/INAMI reimbursed cases (2006 forecast) = 12.352	TOTAL all products	19.831

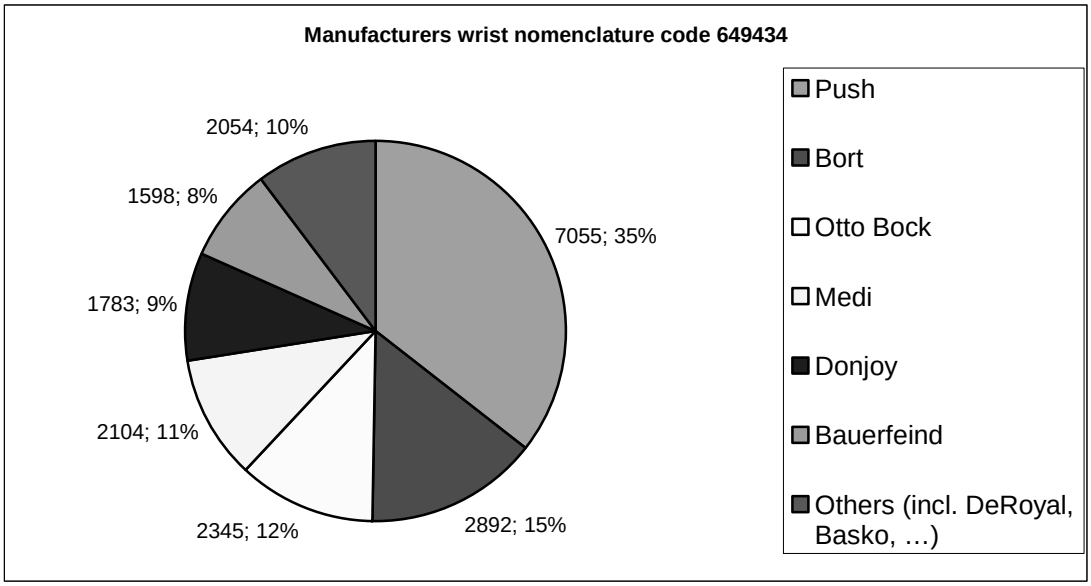
Source: Survey to distributors

The recommended selling price of these wrist bandages by the RIZIV / INAMI is of 56,32 € of which 48,82 € is being reimbursed for the preferential beneficiary patient and 34,74 € for the not preferential beneficiaries.

Market positioning manufacturers

The market leader for this type of orthoses clearly (Figure 26) is the Push brand (The Netherlands) distributed by Vitamed with a total of 7.055 units sold on the Belgian market in 2006. In second position one can see the Bort (Germany) brands with 2.892 products sold. Otto Bock (Germany) and Medi (Germany) count for respectively 2.345 and 2.104 units sold. Donjoy (US) and Bauerfeind (Germany) have a market share of about 10 % each.

Figure 26 : Manufacturers wrist nomenclature code 649434

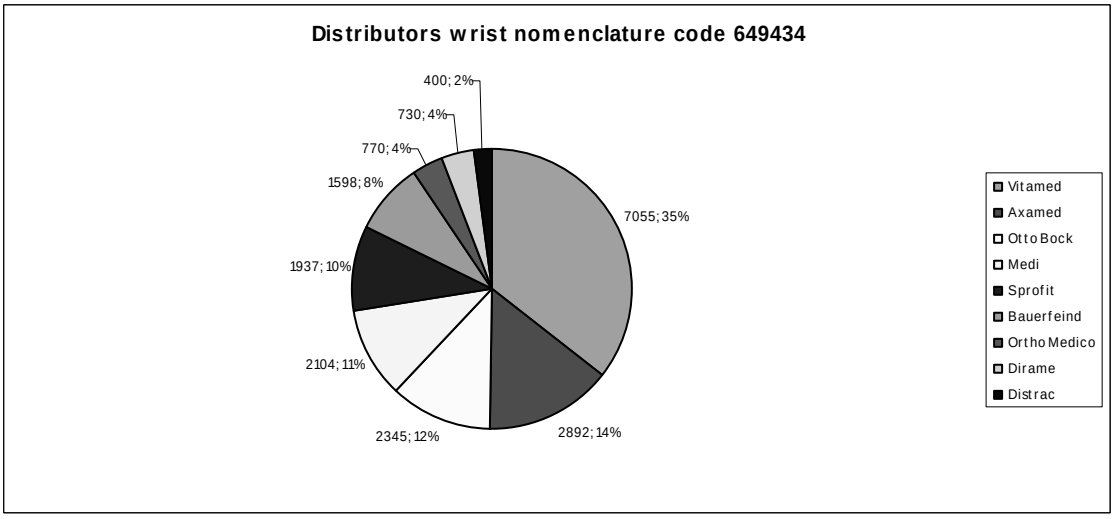


Source: Survey to distributors

Market positioning distributors

The diversity of manufacturers for this category of wrist braces is reflected in a diversity of distributors for these products. As shown in Figure 27, the main distributor is Vitamed (distributor of Push), followed by Axamed (distributor of Bort) and Otto Bock.

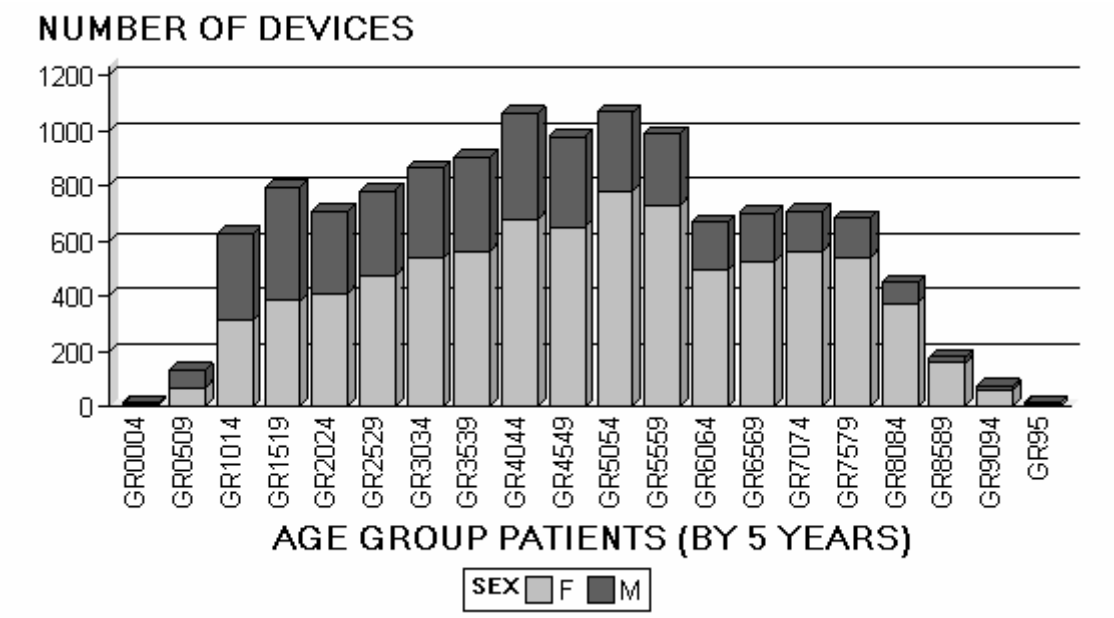
Figure 27 : Distributors wrist nomenclature code 649434



Patient profile

Figure 28 indicates that the prefab wrist barces in our scope are mostly prescribed to women between the ages of 40 and 60.

Figure 28 : Patient profile code 649434

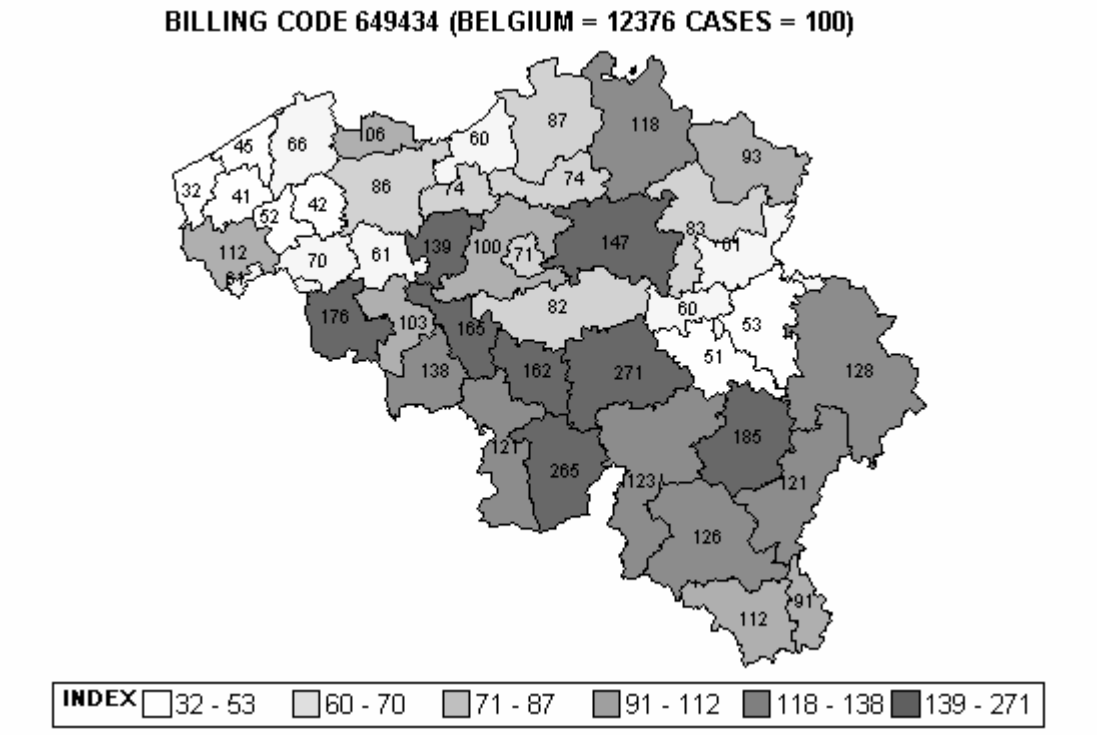


Source: RIZIV / INAMI 2005 billing data

Geographic distribution

As shown by Figure 29, these devices are used more widely in the southwestern part of Belgium. The coefficient of variation for the observations between regions equals 52%.

Figure 29 : Geographic distribution code 649434



Source: RIZIV / INAMI 2005 billing data and National Statistical Institute 2005 demographic data

Key points

- **The market of prefab wrist bandage, reinforced limiting movement is important in terms of number of products sold.**
- **The number of products sold is higher than the number of reimbursed cases. This gap can be explained by the fact that this product is often sold without compliance of RIZIV / INAMI regulation and is therefore not included in the reimbursement data.**
- **The manufacturers Push and Bort represent 50 % of the Belgian market.**
- **The other 50% of the market is divided between a lot of different manufacturers and distributors.**
- **The modal patient profile for these devices relates to women between the ages of 40 and 60 in the South(west)ern part of Belgium**

4.5 THE ORGANISATION OF THE BELGIAN MARKET FOR ORTHOSES

Functional aspects of the Belgian market for orthoses will be elucidated by highlighting the interacting roles held by various stakeholders. The major stakeholders on the market are the retailers of orthoses, the manufacturers and the distributors. Distributors influence the product range supplied on the Belgian market as they are the only channel used by orthotists to procure these goods. Further on, we will comment on the outcome of the interviews organised with a sample of distributors.

These stakeholders are organised in the professional associations: BBOB-UPBOB[46] and UNAMEC [47] . The BBOB-UPBBOB represents the orthotists/orthopaedists at RIZIV/INAMI level. Manufacturers of medical devices are represented by UNAMEC. Distributors of orthoses are represented both by UNAMEC and the BBOB-UPBOB.

Both organisations were deeply involved in this study and provided feedback on the most representative manufacturers, distributors and products on the Belgian market.

4.5.1 Retailers

The provision of orthoses to the patients and clients is rather fragmented. One can distinguish between orthoses that are eligible for reimbursement and orthoses delivered to patients or clients by retailers that do not meet the conditions stipulated by the RIZIV / INAMI.

As pointed out in chapter III, only the orthoses described in the nomenclature codes of art 29 of the RIZIV / INAMI code delivered by a recognised and registered orthopaedic, are reimbursed.

One can distinguish two types of retailers; the registered retailers (orthotists) and the other retailers.

- Registered orthotists

The orthotists are registered on an individual basis at the RIZIV/INAMI and have to meet certain requirements[48]. In 2004, 560 individual orthotists were registered but not all of them are active. For a substantial subset of orthotists (387 in total) RIZIV/INAMI data indicate 332 orthotists reported at least 100 reimbursed devices in 2005 (personal communication by A. Thijs and D. Bodart, RIZIV/INAMI) Consequently, one may assume around 85% of officially recognized orthotists are active, i.e. deliver at least 100 devices on an annual basis.

- Non registered retailers

Some orthoses, especially those in the lower price segment such as soft neck braces and wrist braces are sold in pharmacies, sports shops and department stores. Orthoses sold at the pharmacies are not registered. Consequently, there are no figures on their number.

As these distribution channels do not comply with the reimbursement regulation of the RIZIV / INAZMI, these products are out of scope of this study.

These purchases are not included in the RIZIV/INAMI data which leads to the conclusion that the RIZIV/INAMI data (number of products sold) are an underestimation of the market reality. This is confirmed in our data of the market analysis (cf. supra).

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46 Beroepsvereniging van bandagisten, orthesisten en prothesisten van België -
Union professionnelle des bandagistes, d'orthésistes et de prothésistes de Belgique.

47 Beroepsvereniging van fabrikanten, invoerders en verdelers van medische hulpmiddelen V.Z.W. – Association professionnelle des fabricants, importateurs et distributeurs de dispositifs médicaux A.S.B.L.

48 See chapter III

From the interviews with the distributors we understood they do not directly distribute their products to the pharmacies. A small number of their products are purchased by the pharmacies through intermediary channels (wholesalers). The orthoses sold in pharmacies mostly concern other brands as those delivered through of the registered orthotists. Three brands commonly found in pharmacies are Lohmann Rauscher, Bota and Beiersdorf.

Department stores and sports shops are other selling points for (also mostly soft and low segment) bandages and braces. Sports shops mostly sell protective bandages and braces for prophylactic use by healthy customers.

Key points

- **There are two types of retailers for orthoses: orthotists registered with the RIZIV/INAMI and non registered retailers.**
- **Delivery of orthoses by a recognised and registered orthotist is a condition for reimbursement by RIZIV/INAMI in Belgium (official circuit of orthoses in Belgium)**
- **The alternative circuit of orthoses through pharmacies, department stores and sport shops is out of scope for RIZIV/INAMI reimbursement**

4.5.2 Manufacturers

As mentioned earlier, a conclusion for the Belgian market for orthoses is there are no manufacturers covering the whole spectrum of orthoses, situated in Belgium. We only found one Belgian manufacturer that produces a limited range of soft orthoses. These products, manufactured by Bota NV mostly concern bandages that are not distributed by the registered orthotists. These products are often sold at pharmacies via wholesale stores [49] department stores and sport shops.

As a consequence, nearly all orthoses sold on the Belgian market are imported products. The worldwide manufacturers of orthoses are mainly situated in the EU and the US. Production itself, however, often takes place in low-wage countries (Poland, Eastern Europe, China, Malaysia, Mexico…) Some manufacturers are specialised in one specific type of orthosis. This is the case for Bledsoe, Donjoy and Generation II who are specialised in knee braces, and Jerome which mainly produces neck collars.

Other manufacturers cover the whole spectrum of orthopaedic devices including prosthetics, compression therapy products, implants and other materials for orthopaedic surgery. These manufacturers then mostly have a specific division for orthoses or specific factories to produce orthoses. Examples of these manufacturers active on the orthoses market segment are Bauerfeind, Otto Bock, Medi, Thuasne and Ossur.

Worldwide there is an important trend towards market concentration realised by mergers and acquisitions of companies with specific brands or market segments (by product or region). A good example of such a company is the Iceland based Össur, which acquired Generation II (Canada) in 2003, Royce Medical Holdings Inc. and by this the acquisition of Jerome Medical in 2005 (USA), Innovative Medical Products Holdings Ltd - IMP (UK) in 2005, Innovation Sports Inc in 2006 (USA) and the Groupe Gibaud (manufacturer and distributor in France) in 2006. Just a few months ago they acquired SOMAS Orthopedie, a Dutch distributor.

Another example is the German manufacturer Bauerfeind which was founded in 1978 by a take-over of the German manufacturer Diedrich and who acquired Heinrich Ad. Berkemann in 1994 and Globus in 1996, both German companies.

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49 We contacted Bota N.V. in Deinze but they were not willing to grant a interview.

Key points

- **Majority of orthoses on the Belgian market are imported from U.S. and other E.U countries**
- **There are two types of manufacturers: Some manufacturers focus on one specific type of orthoses. Others cover the whole spectrum of orthopaedic devices.**
- **The market of manufacturers is still very fragmented although we see a trend towards market concentration by mergers and acquisitions.**

4.5.3 Distributors on the Belgian market

Since no important manufacturing of orthoses takes place in Belgium, products sold on the Belgian market are imported from other EU countries and the US and distributed to the registered retailers (orthotists) by a limited number of local distributors.

The distributors identified on the Belgian market are can be found in

Table 17[50].

One can distinguish two types of distributors.

- Distributors directly linked to a specific manufacturer

Some manufacturers have set up their own subsidiaries for the distribution of their products on the Belgian market. Examples of these are Bauerfeind (operating via Bauerfeind Benelux b.v. with location in The Netherlands), Otto Bock (operating via Otto Bock b.v. and located in The Netherlands), Medi (operating via Medi Belgium bvba) and Thuasne (operating via Thuasne Belgilux NV).

- Autonomous distributors

Other foreign products are imported by autonomous Belgian distributors. They distribute different (non competitive) brands on the Belgian market. Examples of these are Vitamed (Push braces), Axamed (Bort) and Ortho Medico (Bledsoe and Jerome).

50 The list of the main distributors has been communicated to us by the BBOB-UPBOB and UNAMEC resulting from a survey to the orthopaedics as described further on in this chapter

Table 17 : Distributors of orthotic devices on the Belgian market

Distributor	Brands
Aircast Belgium Bvba	Subsidiary of DJO Incorporated (US) distributor for Donjoy
Axamed	Distributor for Bort
Bauerfeind Benelux b.v.	Subsidiary of Bauerfeind AG (Germany)
Dirame Orthopedie N.V.	Distributor for Donjoy and Basko Camp, Fillauer.
Distrac N.V.	Distributor for Philadelphia Malibu
Medi Belgium bvba	Subsidiary of medi GmbH & Co. KG (Germany)
Ortho-Medico (B&CO Inc N.V.)	Distributor for Bledsoe, DeRoyal, Jerome.
Ortimex N.V.	Distributor philadelphia
Ossur Europe b.v.	Distributor for GII (Subsidiary of Ossur hf (Iceland)
Otto Bock Benelux b.v.	Subsidiary of Otto Bock Holding GmbH & Co. KG (Germany)
Somas Orthopedie b.v.	Distributor for C.Ti2 (part of Ossur since 2007)
SproFit bvba	Distributor for Donjoy (till april 2007)
Thuasne Belgilux N.V.	Distributor for Thuasne
Vitamed N.V.	Distributor for Push

As mentioned in the previous description of the specificities of the market of orthoses for various reasons it is of utmost importance to have a good knowledge of the country markets and the specific regulations applying to reimbursement.

The fact a specific product is reimbursed and the level of reimbursement is seen as a very important aspect with high impact on sales. As the final decision on product selection is not made by consumers, the end-users or the patients, it is of vital interest to have good and direct access to the real decision makers: the orthotists, the medical doctors, the physiotherapists, the hospitals and the pharmacies.

This is one of the main reasons why foreign manufacturers resort to local distributors. They guarantee a direct contact between the company that puts the products on the market and the real decision makers. Orthotists and medical doctors are frequently contacted, informed, and much attention is given to a good follow)up system of feedback given by end customers.

Next to a close relation between the distributors and the decision makers, a profound knowledge on the reimbursement system and the specific regulation is vital. Direct presence on the market is essential to get this indispensable knowledge. Distributors organise themselves adhering to the professional organisations[51] that have access to the regulating authorities. For Belgium, the regulating authority is the RIZIV / INAMI, but in other EU countries there are different regulating bodies. In the Netherlands the Insurance companies[52] play a key role in reimbursement. Next to contact and access to the regulating authorities, it is also important to have close contacts with the Public Health authorities as well at the administration as at the political level.

51 For Belgium BBOB – UPBOB (with a separate division for the distributors) and UNAMEC

52 In 2006 there were 19 different groups of insurance companies involved in the care insurance

Key points

- **There are two categories of distributors: Subsidiaries of the manufacturers distributing their own brand and autonomous distributors distributing different (non competitive) brands on the Belgian market.**
- **Manufactures use local distributors as they have the best knowledge of the institutional context of the country**
- **Local distributors realise a more intensive relation with patients (feedback on products), orthopaedics and medical doctors (product choice), regulatory authorities (reimbursement systems) and political decision makers.**

4.5.4 Interviews with a sample of distributors

Describing the Belgian market on prefabricated orthoses, we thought it necessary to get direct input from the distributors and register their evaluation of the market.

From the list of distributors drawn from the results of the survey to the orthopaedics, we selected eight distributors to be interviewed.

Selection was based on the following criteria:

- Importance of the number of sales of the different distributors (product sales within the scope)
- Variety of products distributed
- Representation of Autonomous distributors as well as subsidiaries of foreign manufacturers

From the eight distributors selected, six agreed to participate in the interview. [53] The interviews have been organised in the period February – March 2007.

4.5.4.1 Size of the distributors

The size of the distributors interviewed varies from rather small companies to middle sized enterprises. Some of these companies are active on the Benelux market, others only on the Belgian market (mostly including Luxembourg also).

All the distributors interviewed also are active in other market segments than the market of the orthoses. They mostly distribute products in the related market segments of bandages, compression products, prostheses, anti-decubitus and wound care products. Some distributors also cover quite different market segments as wheelchairs, more technical assistive technology products, medical instruments or equipment for hospital care or home care products. These differences obviously affect the size and turnover figures of the respective distributors.

Total turnover for the Belgian market mentioned during the interviews varied between 300.000 € and 6 M €[54]. The segment of orthoses is important to very important varying from 10% to 80% of their global turnover, with an average of around 60 %.

Number of people employed varies according to the global turnover from 7 to 45. For the Belgian market including Luxembourg, all distributors have a specific sales team. The bigger companies diversify this team by market segment.

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53 The list of the distributors interviewed is added in annex 7 to the report. The distributors Aircast and Sprofit were also contacted but did not respond to our demand.

54 Disclosure of individual numbers was not allowed to us

4.5.4.2 *Margins - costs and price setting*

The average gross margin quoted by the distributors during the interviews is between 35% and 40%. Most of them stressed the minimal margin to guarantee long term sustainability and stability of business must be situated around 45 %.

The major costs are related to the wages of the sales teams, warehousing, transportation, marketing, public relations and administration. Transportation cost is mentioned as being rather high as distributors have to be able to provide orthoses to the orthotists at very short notice.

The cost of stockpiling varies since some distributors have the goods delivered directly from the manufacturer to their client and only keep a very small emergency stock themselves. All of the distributors, even those that have direct delivery from the manufacturing site to their clients, in terms of transactions buy the products from the manufacturer and resell them to the retailers.

Price setting to the orthotists seems to have changed over the last years. More and more the selling prices to the orthopaedics are being standardised. Discounts are given in relation to the volume purchased by the retailer and in relation to cash payment.

4.5.4.3 *View of the distributors on the Belgian market of orthoses*

In this part of the report, we reflect on the opinions and views of the distributors we interviewed regarding the Belgian orthoses market. We give their observations on developments of new products, their relation towards the orthopaedic and medical profession, pricing and reimbursement issues.

The market:

- Little knowledge of the Belgian market

Statistical market information for the orthoses market is very limited. Distributors have access to the official RIZIV / INAMI data on the reimbursement of the different types of products. Consequently, they only know the aggregated amounts and numbers of the reimbursed products at nomenclature code level. Contrary to the pharmaceutical market, there is no registration at product level in a database for the orthoses market. Other registration data, than aggregated ones on the types of product reimbursed do not exist.

For products sold outside the reimbursement system, no figures are registered at any level. The sales of orthoses in pharmacies are not registered in the databases of the pharmacies. This results in little knowledge on the orthoses market. Distributors keep track of their own data but information on a more global level is not at their disposal. They all stressed the importance of their own selling teams in the acquisition of market knowledge. The orthotists and visits to medical doctors are their most important information channels.

- The professional organisations for distributors

Asked what information the professional organisations provide to them, distributors told us it merely concerns information on reimbursement issues. They judge the contacts these organisations have with the RIZIV / INAMI and other public health authorities as very important, especially when changes in reimbursement regulation are at stake. The professional organisations do not provide market information on the market for orthoses itself.

- A growing market

Distributors describe the orthoses market as a growing market. This view corresponds with the findings as described in the previous part of this chapter. The distributors mentioned the aging population as a very important factor that underpins market growth as well in the bracing and supports market as in the market of prosthetic products. Changes in lifestyle are characterized by a more active living attitude and an increasing participation in sports, resulting in a higher demand of orthoses. For the sports segment increasing participation causes an increased number of sport related injuries but also an increased demand for preventive products.

- A very fragmented market

The market of orthoses is perceived as very fragmented. The orthotists are mostly small to very small sized companies. The distributors mentioned a certain expansion of scale over the last decade were orthopaedic shops are consolidated into larger entities, but in general the scale stays rather small. They notice a difference between the Flemish part of the country and the Brussels region where orthopaedics are more clustered versus Wallonia were most orthopaedists are organised in stand-alone settings.

Besides the fragmentation at client level, there is also an important fragmentation at manufacturers' level. We noticed differences in views depending of the fact the distributors are working as subsidiaries of manufacturing companies or as autonomous distributors. The autonomous distributors mostly work with different manufacturers in the different market segments they cover. In fact, those distributors are much depending on the manufacturers. The last few years multiple changes occurred. Mergers and acquisitions at manufacturers' level affect the distribution channels, sometimes resulting in a loss of distribution contracts. Due to the take-over of Aircast by Donjoy the distribution of Donjoy for Belgium shifted from an independent distributor to Aircast Belgium.

For the distributors acting as subsidiaries of the manufacturers, the situation is different. They only distribute the brands of their manufacturing company.

Fragmentation of the markets is most perceivable at country levels. Since the regulation on provision and financing (reimbursement) differ from one country to another, all countries are in fact different markets affecting the organisation of the distribution as well.

- The Belgian market is complex

The Belgian market is described as a complex market because this small market is divided in 3 sub markets (regions) with distinct main languages.

The aforementioned differences in the size of the orthopaedic shops between the different regions affect the marketing approach and numbers of products sold per contact point.

As a result of the different languages, catalogues, brochures, and other marketing material have to be provided in different languages too, affecting selling costs. Selling teams have to be differentiated in accordance to the part of the country they serve. A good knowledge of the specific language is indispensable for good sales.

The high population density typical of Belgium was not prompted as a possible facilitating factor (due to logistic advantages) by the interviewed distributors.

- Presence and knowledge of the market is most important.

Distributors are convinced it is very important to be located near the market that is targeted. Not only is it important to realise a good and frequent professional relationship with the orthotists and the prescribers of orthoses, it is imperative to know the specificities of the local market, its reimbursement system and to be able to detect and react to new tendencies. Direct interaction with public health authorities is judged as very important for a mutual good cooperation. To achieve these goals distributors are convinced they have to be located in Belgium or at least nearby in the Benelux.

- Internet shops are not seen as real competitors

Distributors do not see the internet brace shops as an important factor for the orthoses market. They certainly are not judged as a threat to the orthopaedic profession.

The fact products sold by internet shops are not personally delivered to the customer and thus customers have to take own responsibility for measurement and product selection is seen as an important and insuperable barrier to expansion of this market segment. Furthermore, products sold through the internet are nor eligible for reimbursement (as they are not delivered by a registered orthotist). For Belgium this restriction limits the market penetration of those internet shops.

Products and prices:

- Distributors find it difficult to introduce new products on the market.

They stated the development of new products requires important investments in research. Costly scientific studies are indispensable to a successful introduction of newly developed products. The launching of new products also demands important efforts at prescribers and retailers level. Both parties have to be informed on the advantages of the new product, its specificities and its pricing. Direct personal contact with them is perceived as vital to a successful introduction of new products.

- Sales prices are under pressure.

Reimbursement of orthoses is diminishing all over Europe. This reality puts selling prices under pressure since reimbursement largely affects the final profit of the retailers. Diminishing reimbursement levels results in demands for lower prices at distribution level since distributors notice the orthotists try to neutralise, or at least to limit the effects of diminishing reimbursement.

- Products have to be delivered in a very short time.

There is a clear tendency at retail level to minimise stocks. Consequently, the wholesale distributor has to have permanent stocks of a large number of products (and sizes) or at least be able to organise quick delivery directly from the manufacturing site to the orthotist. In both cases these requirements cause important costs (of stock piling or / and of transportation).

The decision making process on the choice of products:

- For orthoses, the orthotists exert a considerable influence on the final choice of the product the patient will make. The orthotist advises the patient on the different braces or bandages and thus greatly influences the patient's final decision.

The prescriber mostly determines the general product category. In Belgium, only specialist medical doctors can issue a prescription for reimbursed products. In The Netherlands since a few years, general practitioners can also prescribe certain type of orthoses that are reimbursed. In France, some paramedics are allowed to prescribe orthoses reimbursed by the Health insurance system.

Distributors see the specialist medical doctor as an important interlocutor in their sales strategy. Even if, as we mentioned above the orthotist decisively influences the final selection of the product, medical specialists are targeted by the distributors. They have to be informed on the different types of products, the new products, and the outcome of research on the functionality of the products.

Mostly there is a close collaboration between the orthotist and the prescribing medical specialists. The medical specialist has an important influence on the patients' choice on which orthotist he will appeal to. Most specialist doctors work together with one or in some cases a few orthotists. They mostly have a close cooperation sometime resulting in the actual presence of the orthotist at the specialists' consultation.

Reimbursement issues:

- Distributors find it difficult to fit newly developed products into a suitable prevailing Belgian billing code category.

Since the description of the products in the various nomenclature codes is a technical description, newly developed products involving new techniques do not always match with these existing descriptions. Distributors tend to advocate a different kind of nomenclature and would prefer the use of medical criteria to differentiate and classify the products in the nomenclature codes.

- The level of reimbursement co-determines the market penetration of products.

Distributors clearly see a link between the level of reimbursement of certain types of products and the sales of the products on the market. A product that is not reimbursed is more difficult to sell. This explains why certain products show differences in market

penetration between the EU Member States. Bracing in France is poorly reimbursed. In Portuguese public health system some orthoses are not reimbursed. In both cases distributors stated sales are much lower in these countries than in other Member States.

- The quality of orthoses is not assessed.

Quality is not a criterion for reimbursement nor for the level of reimbursement. Distributors see this as a potential risk. In combination with the tendency towards lower reimbursement, they fear competition of cheaper but less qualitative products might negatively affect the quality of the provision of orthoses to the patients.

- Reimbursement does not take into account the cost price of the orthoses.

The level of reimbursement is the same for a cheaper or a more expensive product. This fact might put pressure on some more financially driven orthotists to opt for the cheapest products instead of the more qualitative ones.

Key points

Characteristic of distributors of orthoses:

- **Distributors are mostly small to medium sized enterprises**
- **Average gross margin quoted by the distributors ranges between 35 and 40 %**
- **Price setting towards the retailers (orthotists) becomes more and more standardised.**
- **Price setting for retailers in the different EU countries is comparable to avoid parallel import.**

View of the distributors interviewed on the Belgian market:

- **Statistical information on the market of orthoses is very limited in Belgium as no registration at product level takes place.**
- **The market of orthoses is described as a growing market**
- **The orthoses market is very fragmented at retail level**
- **The orthoses market is fragmented at manufacturers' level although a consolidation trend exists.**
- **The Belgian market is a small and complex market as a result of the differences between the regions (language)**
- **Internet shops are not seen as a real competitor.**

Products

- **Introduction of new products is difficult**
- **Sales prices are under pressure**
- **Transportation and warehousing cost are high as product delivery towards the client needs to be realized fast.**

Decision making process

- **Orthotists and medical doctors are important in the selection of products. They often work in close cooperation**
- **Distributors approach orthotists and medical doctors for product information**

Reimbursement issues

- **Current nomenclature code classification is based on technical description which is no longer in keeping with market reality**
- **Quality is not assessed and as a consequence not used as a criterion for reimbursement**
- **The reimbursement level does not take into account the cost price of the different product.**

5 INTERNATIONAL PRICE COMPARISON FOR A SELECTION OF ORTHOSES

5.1 INTRODUCTION

To have a better view on the market price[55] (including cost for the patients and/or the health insurers) of the orthoses that are sold on the Belgian market, we performed an international price comparison in four different European countries and Ontario (Canada).

Price data for Belgium are taken as a baseline and compared to the corresponding data for France, the Netherlands, the United Kingdom and Ontario - Canada. Initially the aim was also to include Sweden. We received, however, insufficient relevant data to include Swedish prices in our analysis.

As indicated above, the country panel we selected is a subset of the countries discussed in our institutional analysis (chapter III). This will allow us to put local prices into their institutional perspective, which in turn may bring added value to our final policy recommendations.

For every country, a discussion on methodology describes the data used and how they should be interpreted. The international price comparison as presented here is related to the Belgian market.

Foreign prices are therefore always compared with Belgian prices for the same products. Accordingly, the price information for Belgium is presented as such.

[55] Also referred to as "public price" in chapter III

5.2 GENERAL METHODOLOGY

5.2.1 Information on prices

Sources on exact price levels are clearly identified for the different countries. The approach for obtaining relevant information on the market prices differs between the countries. As mentioned in Chapter III, regulations vary from one country to another, affecting how market prices (selling prices at end – user level, which cover both third party reimbursements and possible patient co-payments) are obtained. In some countries, market prices are free, in others the health authorities or the health insurance companies negotiate purchase prices with the distributors or manufacturers of orthoses. These differences influenced the methodology used to realise the price comparison and are further elucidated for each country in the remainder of this chapter..

In general, information on prices was acquired through direct contacts with health authorities, insurance companies, (wholesale) distributors and retailers of orthoses. Information was gathered through visits, by email and by phone. Limitations and interpretability of price data are commented. The summary tables show the average prices for each country.

The prices indicated in this chapter are:

- the market prices at which patients buy the orthoses (including reimbursement), or at which the health authorities or insurance companies contract. The market price is the total price including possible third party payments. If public health authorities or health insurance companies directly pay the cost of the product to the provider and no further cost is borne by patients, the market price (at end-user level) is set at the amount paid.
- Inclusive of VAT or other applicable taxes.
- calculated in EURO.

5.2.2 Price comparison between products

5.2.2.1 Price comparisons for the different products

Prices for selected foreign countries are compared with corresponding Belgian prices in the following way:

$$C_{1,FG} = \frac{(price_{BE} - price_{FG})}{price_{BE}}$$

where

price BE = the price of the product in Belgium incl VAT

price FG = the foreign price of the product

If the resulting figure is positive, the product is more expensive in Belgium and cheaper abroad. By contrast, if the resulting figure is negative (shaded areas in tables), the product is cheaper in Belgium and more expensive on the foreign market. The amount indicates how much the price abroad is different compared to the Belgian price, as a percentage.

Price correction based on Comparative Price Levels (CPL)

Next, the difference in overall price levels between the countries was corrected for in the second percent value comparison. Comparative price levels (CPL) published by the OECD for February 2007 were used for these calculations[56]. These comparative price levels are defined as the ratios of purchasing power parities to exchange rates.

$$C_{2,FG} = \frac{price_{BE} - \left[price_{FG} \cdot \left(\frac{CPL_{BE}}{CPL_{FG}} \right) \right]}{price_{BE}}$$

where

$price_{BE}$ = price of the product in Belgium

$Price_{FG}$ = foreign price of the product

CPL_{BE} = comparative price for Belgium (= 100, Belgium as basis)

CPL_{FG} = foreign comparative price level

Calculated price differentials $C_{1,FG}$ and $C_{2,FG}$ are shown as percentages, rounded down to integer values for the different countries compared to Belgium.

5.2.2.2 Comparative price levels (CPL) used

The CPL for the countries in the scope of the study, published by the OECD in February 2007 are:

- Belgium 100
- Netherlands 100
- France 102
- U.K. 101
- Canada 92

As the CPL is identical for the Netherlands and Belgium, there is no difference between the calculation of ratio C1 and C2.

5.2.3 Selected products (brands)

5.2.3.1 Step 1: Selection of the different types of orthoses for the price comparison based on the Belgian nomenclature codes

The selection of the types of orthoses, for which retail prices are inventoried, is completely in line with the nomenclature codes used for the market analysis[57]. We refer to chapter IV were we described the methodology and criteria used for this selection. This exercise resulted in the selection of three nomenclature codes for knee orthoses, two nomenclature codes for neck orthoses and one nomenclature code for wrist orthoses. These billing codes are shown below.

- The knee orthoses:

56 http://www.oecd.org

57 Chapter IV; 1.3.2. Step 2: Limiting the number of nomenclature codes for prefabricated knee, neck and wrist orthoses

  - Prefab knee brace elastic tissue or neoprene reinforced with metal (nomenclature code 647533)
  - Prefab knee bandage woven reinforced (nomenclature code 647555)
  - Prefab hard knee brace hinged (nomenclature code 647592)
- The neck orthoses:
  - Prefab soft collar (nomenclature code 645175)
  - Prefab stiff neck collar with support chin and/or back of the head adjustable in height (nomenclature code 645212)
- The wrist orthose:
  - Prefab wrist bandage, reinforced limiting movement (nomenclature code nr. 649434)

5.2.4 Step 2: Selection of the specific products (brands) for the price comparison

The final objective of the international price comparison exercise was to obtain maket prices in all countries for three products (brands) in each nomenclature code, resulting in 18 different products (brands).

To maximise our chances of finding these market prices in all countries we started our research on an extensive sample of more than 18 products. The overview of products included in this sample is added to the report in appendix V.

Composing the enlarged sample, we used the following criteria and rationale:

- Products must be included in the results of the survey sent to the distributors (see chapter IV).
- Differentiated prices at distributors' level: to diversify the sample portfolio we included a cheap, a mid-priced and an expensive product (at distributors' price level). To realize this selection we made an inventory of the distributor prices for all the products included in the survey results
- Products had to be representative for the Belgium market in term of market volume (number of sold items).
- Products needed to be on the market in different countries. Ideally, they would be on the market in all selected countries.
- Diversification of manufacturers involved

5.2.5 Further structure of chapter

The paragraphs below are structured as follows:

- Introduction to country-specific aspects, relevant for the price comparison
- For each nomenclature code in the scope
  - Data on the prices available in the country
  - Price comparison between Belgium and the foreign country based on the C1 and C2 ratio as explained before

5.3 PRICES FOR THE BELGIAN MARKET

For Belgium, we were able to collect (wholesale) distributor and market prices. As Belgium is the key country for this study, we decided to include both prices, to offer further insight in the Belgian market on orthoses.

- Distributor prices

The collection of distributor prices has been performed in collaboration with the BBOB-UPBOB and UNAMEC. The catalogues from the distributors have been used to compare, verify and complete the prices received as a result of the survey to the distributors.[58]

- Market prices

The market prices have been collected through a survey to the orthotists and through direct contacts with the orthotists. This survey covered the products of the expanded sample as described in the previous paragraph. The survey was organised in close collaboration with the BBOB-UPBOB, who distributed the questionnaire to a sample of 55 orthotists they selected. We only received nine responses provided to us on an anonymous basis. The response ratio of 16 % was perceived as rather low. Analysing the answers obtained, we could see that different important chains of orthotists were included representing a much higher number of selling points. The prices mentioned in one of the answers, for example, are applicable in 36 different orthopaedic shops. Nevertheless, we considered it necessary to complete the results of the survey with additional own research. Consequently, we directly visited or contacted orthotists that did not provide an answer to the survey. As such we were able to increase the results to twenty one respondents or 38,1% of the initial sample. For most of the knee braces and the hard neck collar, the selling prices correspond to the RIZIV/INAMI selling prices and price differentiation is very limited. Only for the soft neck collar and the wrist brace, we noticed more variety.

The tables below give an overview of the products, the number of products sold on the Belgian market in 2006, the distributor prices and the average end-user selling prices in 2007. Next to the RIZIV / INAMI nomenclature codes, the table indicates the amounts reimbursed and the RIZIV / INAMI selling price. As explained in the previous part, the amount reimbursed is different for the preferential beneficiary and the non-preferential beneficiary patients.

58 *The survey to the distributors as described in Chapter IV, 1.4.2.1. Survey to the distributors:*

5.3.1 The knee orthoses:

5.3.1.1 The prefab hard knee brace hinged (nomenclature code 647592):

This type of knee brace is reimbursed at 816,56 € for the preferential beneficiary patient and at 579,59 € for the non-preferential beneficiary.

Table 18 : Price information knee nomenclature code 647592 Belgium

RIZIV /INAMI Nomenclature code	Product	Distributor Belgium	# sold Belgium 2006	Distributor Selling Price excl VAT € 2007	Average market price Incl.VAT € 2007	Mark up (market price - distributor price) excl.VAT	Factor
Knee 647592	Bledsoe Aligner ESE L/R	Ortho - Medico	988	477,36 €	951,24 €	420,04 €	1,88
RIZIV/INAMI	Bledsoe Axiom Sport	Ortho Medico	948	402,90 €	947,91 €	491,35 €	2,22
Pref. 816,56 €	Bauerfeind SecuTec® Genu LR	Bauerfeind	319	299,50 €	947,91 €	594,75 €	2,99
Non Pref.579,59	Bauerfeind MOS Genu® long	Bauerfeind	see short	565,00 €	965,58 €	345,93 €	1,61
Selling price	Bauerfeind MOS Genu® Short	Bauerfeind	269	440,00 €	947,91 €	454,25 €	2,03
947,91 €	Donjoy Legend Funct. brace ACL	Sprofit	642	476,08 €	950,77 €	420,87 €	1,88
	Donjoy 4-titude	Sprofit	874	476,08 €	947,91 €	418,17 €	1,88
	THUASNE GENU PRO Control Clasic	Thuasne	259	485,00 €	947,91 €	409,25 €	1,84
	C.Ti.2 (OSSUR)	Somas	350	752,00 €	1.030,23 €	219,92 €	1,29
	Generation II unloader adj (OSSUR)	Ossur Europe	350	715,00 €	970,16 €	200,25 €	1,28
	Medi M.4® ACL orCI or PCL G021203	Medi	134	456,00 €	947,91 €	438,25 €	1,96
	Medi M.4 ® OA G045203	Medi	20	480,00 €	947,91 €	414,25 €	1,86
	Bort OTS Knee Brace 100600	Axamed	n.a.	425,12 €	947,91 €	469,13 €	2,10

Source: Combination of price information from survey to distributors, catalogues, survey to orthotists and RIZIV/INAMI data

The majority of selling prices mentioned in the survey correspond to the RIZIV / INAMI selling price of 947,91 €, which is not legally binding. For five products, the average selling price exceeds the RIZIV/INAMI price. The C.Ti.2 is the most expensive hard knee brace at end – user level with an average selling price of 1.030,23 €. The other knee braces exceeding the RIZIV/INAMI price are the Bledsoe Aligner, the Bauerfeind MOS Genu® long, the Donjoy Legend ACL and the Generation II unloader adj. For these products, the average selling prices are only slightly higher.

At the level of the distributor prices, there is a large difference. The most expensive one is the C.Ti.2 which is sold to the orthotists at 752,00 € (excl.VAT). The cheapest product is the Bauerfeind SecuTec®Genu which is sold at 299,50 €. The gross margin of the retailer varies considerably from 594,75 € (factor 2,99[59]) for the Bauerfeind SecuTec®Genu to 200,25 € for the Generation II unloader adj. (Factor 1,28)

5.3.1.2 The Prefab knee bandage woven reinforced (nomenclature code 647555)

This type of knee bandage is reimbursed at 91,72 € for the preferential beneficiary patient and at 65,11 € for the non-preferential beneficiary.

Table 19 : Price information knee nomenclature code 647555 Belgium

RIZIV /INAMI Nomenclature. code/	Product	Distributor Belgium	Number products sold/Year Belgium 2006	Distributor Selling Price excl VAT € 2007	Average market price Incl.VAT € 2007	Mark up (market price - distributor price) excl.VAT	Factor
Knee 647555	Bauerfeind Genutrain®	Bauerfeind	10.092	34,50 €	106,46 €	65,93 €	2,91
RIZIV/INAMI	Bauerfeind Genutrain® P3	Bauerfeind	3.124	53,50 €	114,29 €	54,32 €	2,02
Pref. 91,72 €	Bauerfeind Genutrain® A3	Bauerfeind	1.503	53,50 €	111,41 €	51,60 €	1,96
Non Pref.65,11 €	Push Care knee	Vitamed	328	39,62 €	102,81 €	57,37 €	2,45
Selling price	Push Med knee	Vitamed	605	72,74 €	128,43 €	48,42 €	1,67
106,46 €	Thuasne Silistab Genu	Thuasne	261	35,15 €	106,46 €	65,28 €	2,86
	Otto Bock Knee Support Basic	Otto Bock	140	10,00 €	106,46 €	90,43 €	10,04
	Otto Bock Genu Sensa	Otto Bock	250	30,70 €	106,46 €	69,73 €	3,27
	Medi.ortho Genumedi®	Medi	250	29,00 €	106,44 €	71,42 €	3,46
	Medi.ortho elastic knee support	Medi	150	17,00 €	106,46 €	83,43 €	5,91
	DeRoyal Sprt knbrace flex.springs	Ortho Medico	130	35,85 €	106,69 €	64,80 €	2,81
	DeRoyal Genum Stabiliser Lg Silicon	Ortho Medico	36	49,53 €	106,46 €	50,91 €	2,03
	Donjoy Patella Knee Support Lat.	Dirame	n.a.	52,75 €	106,46 €	47,68 €	1,90

Source: Combination of price information from survey to distributors, catalogues, survey to orthotists and RIZIV/INAMI data

The selling prices mentioned in the survey almost all correspond to the RIZIV / INAMI selling price of 106,46 €. The average selling price of the Push care knee (102,81 €) is slightly lower than the RIZIV / INAMI price. The Push Med knee is the most expensive one with an average selling price of 128,43 €. The selling price of the Bauerfeind Genutrain®P3 slightly exceeds the RIZIV / INAMI selling price.

Again, there are substantial differences at the level of the distributor prices. The cheapest product is the Otto Bock Knee support Basic 8953 being sold to the orthotists at 10,00 € (excl.VAT). The most expensive one is the Push Med Knee sold at 72,74 €. This product is not surprisingly also the most expensive one for the end-user with an average selling price of 128,43 €.

59 Factor = selling price (excl.VAT) / distributor price (excl.VAT)

If we calculate the gross margin for the cheapest and the most expensive product (distributor price), we notice a very important difference between the different products. The cheapest product that is purchased by the orthotists, the Otto Bock Knee support, shows a gross margin of 90,43 € (factor 10,04). The most expensive one, the Push Med Knee has a gross margin of only 48,42 € (factor 1,67).

5.3.1.3 Prefab knee brace elastic tissue or neoprene reinforced with metal (nomenclature code 647533)

This type of knee brace is reimbursed at 212,77 € for the preferential beneficiary patient and at 157,01 € for the non-preferential beneficiary.

Table 20 : Price information knee nomenclature code 647533 Belgium

RIZIV /INAMI Nomenclature. code/	Product	Distributor Belgium	Number products sold/Year Belgium 2006	Distributor Selling Price excl VAT € 2007	Average market price Incl.VAT € 2007	Mark up (market price - distributor price) excl.VAT	Factor
Knee 647533	Donjoy Drytec 11-0555	Bauerfeind	342	NA	223,05 €	NA	
RIZIV/INAMI	Bauerfeind Genutrain® S	Bauerfeind	2.011	79,50 €	223,17 €	131,04 €	2,65
Pref. 212,77 €	Thuasne Ligaflex Evolution	Thuasne	1.184	70,89 €	224,52 €	140,92 €	2,99
Non Pref.157,01 €	Thuasne Ligaflex 2370	Thuasne	1.036	45,11 €	215,94 €	158,61 €	4,52
Selling price	Otto Bock Genu Track	Otto Bock	60	133,70 €	237,13 €	90,00 €	1,67
223,05 €	Otto Bock Genu Direxa Stable Wrap	Otto Bock	60	105,00 €	226,07 €	108,27 €	2,03
	DeRoyal Genum Liga (T3)	Ortho Medico	115	63,04 €	223,05 €	147,39 €	3,34
	Donjoy Tru-Pull hinged sleeve	Sprofit	96	101,31 €	223,05 €	109,11 €	2,08
	MEDI hinged knee PRO (airtex)	Medi	160	47,00 €	223,05 €	163,42 €	4,48

Source: Combination of price information from survey to distributors, catalogues, survey to orthotists and RIZIV/INAMI data

The selling prices mentioned in the survey, mostly correspond to the RIZIV / INAMI selling price of 223,05 €. There are only slight differences. The most expensive product for the patient is the Otto Bock Genu Track which is sold at an average selling price of 237,13 €. The other differences are negligible.

As for the other types of knee orthoses, we also notice a large difference between the distributors' prices for the orthotists. The most expensive product is the Otto Bock Genu Track (also the most expensive to the end-user) at 133,70 € (excl.VAT); the less expensive is the Thuasne Ligaflex at 45,11 € (excl.VAT).

Consequently the gross margins differ considerably too. The gross margin for the Otto Bock Genu Track is of 90,00 € (factor 1,67) and for the Medi hinged knee of 163,42 € (factor 4,48).

5.3.2 The neck collars

5.3.2.1 Prefab stiff neck collar with support chin and/or back of the head - adjustable in height (nomenclature code 645212)

For the preferential beneficiary patient, this hard neck collar is totally reimbursed at 258,77 € which is the RIZIV / INAMI selling price. For the non-preferential beneficiary reimbursement is set at 194,08 €.

Table 21 : Price information neck nomenclature code 645212

RIZIV /INAMI Nomenclature. code/	Product	Distributor Belgium	Number products sold/Year Belgium 2006	Distributor Selling Price excl VAT € 2007	Average market price Incl.VAT € 2007	Mark up (market price - distributor price) excl.VAT	Factor
Neck 645212	Jerome Miami J.Collar	Ortho-Medico	477	67,92 €	240,62 €	159,08 €	3,34
RIZIV/INAMI Pref. 258,77 € Non Pref.194,08 € Selling price 258,77 €	Malibu halskraag	Distrac	50	92,00 €	258,77 €	152,12 €	2,65
	Fillauer/Basko Ortho-Collar	Dirame	n.a.	80,93 €	258,77 €	163,19 €	3,02

Source: Combination of price information from survey to distributors, catalogues, survey to orthotists and RIZIV/INAMI data

The number of different products found on the Belgian market is very limited. The retail selling prices correspond to the RIZIV/INAMI selling price of 258,77 €. Only for the Jerome Miami J. collar, is by far the most commonly sold product, we obtained an average selling price of 240,62 € which is lower than the RIZIV / INAMI price and the level of reimbursement for the preferential beneficiary. Analysing the different prices obtained for this product, we could see two orthotists classified this product under a different nomenclature number selling the product at 140,82 €.

Scrutinizing the prices at which retailers purchase the neck collars from distributors, we observe an important variation. The most expensive product is the Malibu collar (also the most expensive to the end-user) at 92,00 € (excl.VAT); the least expensive is the Jerome Miami J. collar at 67,92 € (excl.VAT).

The gross margins vary between 163,19 € for the Fillauer Basco ortho collar (factor 3,02) and 152,12 € for the Malibu collar (factor 2,65). For the most representative product, the Jerome Miami J. collar the gross margin is of 159,08 € (factor 3,34)

For this type of hard cervical collar, we conclude that the reimbursement level is high and clearly affects the average selling prices. The Jerome Miami J. collar is sold at over three times the purchase price.

5.3.2.2 Prefab soft collar (nomenclature code 645175)

This soft neck collar is reimbursed at 14,66 € for the preferential beneficiary patient and at 9,59 € for the non-preferential beneficiary. The amount of the reimbursement is low but, as we pointed out the number of products reimbursed is high (6.939)[60]

60 See Chapter IV, 1.4.2.2. Neck ortheses

Table 22 : Price information neck nomenclature code 645175 Belgium

RIZIV /INAMI Nomenclature. code/	Product	Distributor Belgium	Number products sold/Year Belgium 2006	Distributor Selling Price excl VAT € 2007	Average market price Incl.VAT € 2007	Mark up (market price - distributor price) excl.VAT	Factor
Neck 645175	Push Care 8 cm en 10 cm	Vitamed	1.288	27,74 €	47,03 €	16,63 €	1,60
RIZIV/INAMI	Push nek Med 8 cm en 10 cm	Vitamed	1.274	40,47 €	73,13 €	28,52 €	1,70
Pref. 14,66 €	Thuasne Ortel C1	Thuasne	2.118	4,98 €	28,43 €	21,84 €	5,39
Non Pref.9,59 €	GLOBOMEDIC Bauerfeind	Globus	1.719	14,50 €	47,83 €	30,62 €	3,11
Selling price	Basko Camp 5750	Dirame	950	11,10 €	37,04 €	23,84 €	3,15
20,28 €	Basko Camp 5620/21	Dirame	(grouped)	17,30 €	29,42 €	10,46 €	1,60
	Thamert 49/190		1.691	13,99 €	30,47 €	14,76 €	2,05
	Bort Cervical Support	Axamed	112	10,07 €	30,47 €	18,67 €	2,85
	DeRoyal Foam cervical collar	Ortho-Medico	837	9,43 €	28,28 €	17,25 €	2,83
	Otto Bock Necky Color	Otto Bock	685	15,10 €	40,81 €	23,40 €	2,55

Source: Combination of price information from survey to distributors, catalogues, survey to orthotists and RIZIV/INAMI data

Most of the soft neck collars are sold to the customers at a price that largely exceeds the RIZIV / INAMI price. The most expensive one for the patient is the Push Med collar which is sold at an average selling price of 73,13 €.

The differences between the purchase prices for the orthotists are very high. The Thuasne Ortel is purchased at a unit price of 4,98 € (excl. VAT). The most expensive product, the Push Med (also the highest market price) is purchased at 40,47 € (excl. VAT).

The gross margins differ considerably too. The gross margin for the Thuasne Ortel is of 21,84 € (factor 5,39) and for the Push Med of 28,52 € (factor 1,70).

5.3.3 The Wrist orthoses

5.3.3.1 Prefab wrist bandage, reinforced limiting movement (nomenclature code nr. 649434)

The wrist bandage is reimbursed at 48,82 € for the preferential beneficiary patient and at 34,74 € for the non-preferential beneficiary.

Table 23 : Price information wrist nomenclature code 649434 Belgium

RIZIV /INAMI Nomenclature. code/	Product	Distributor Belgium	Number products sold/Year Belgium 2006	Distributor Selling Price excl VAT € 2007	Average market price Incl. VAT € 2007	Mark up (selling price - distributor price) excl.VAT	Factor
Wrist 649434	Bauerfeind ManuLoc®	Bauerfeind	474	40,50 €	79,36 €	34,37 €	1,85
RIZIV/INAMI	Bauerfeind ManuTrain®	Bauerfeind	1.124	40,50 €	78,58 €	33,63 €	1,83
Pref. 48,82 €	Push Med wrist	Vitamed	5.820	41,04 €	73,39 €	28,20 €	1,69
Non Pref.34,74 €	Push Care wrist	Vitamed	456	20,66 €	56,84 €	32,96 €	2,60
Selling price	Donjoy Elastic Wrist Brace	Sprofit	1.690	21,38 €	57,75 €	33,10 €	2,55
56,32 €	medi Wrist support	Medi	1.866	19,00 €	56,32 €	34,13 €	2,80
	Bort wrist support with alusplint	Axamed	2.715	11,78 €	56,32 €	41,35 €	4,51
	DeRoyal - Manex Reuma Long	Ortho Medico	234	20,19 €	53,27 €	30,06 €	2,49
	DeRoyal - Manex Reuma Pollus	Ortho Medico	536	25,19 €	59,62 €	31,06 €	2,23
	Manu Rheuma Flex	Otto Bock	810	19,30 €	56,32 €	33,83 €	2,75

Source: Combination of price information from survey to distributors, catalogues, survey to orthotists and RIZIV/INAMI data

Most selling prices correspond to the RIZIV / INAMI selling price of 56,32 € with some slight differences. Only the Bauerfeind Manuloc®, the Bauerfeind Manu Train® and the Push Med wrist are sold at a considerably higher price. The purchase prices of these products are also much higher.

The highest average market price is found for the Bauerfeind Manuloc® at 79,36 €. The cheapest products are the Medi wrist support, the DeRoyal Manex Reuma long and the Manu Rheuma Flex at the RIZIV/INAM selling price of 56,32 €.

The differences between the prices at which the products are purchased by the orthotists are important varying from 11,78 € (excl.VAT) for the Bort Wrist support to 41,04 € (excl.VAT) for the Push Med.

The gross margins vary from 41,35 € for the Bort wrist support (factor 4,51) to 28,20 € for the Push Med wrist (factor 1,69)

Key points

- **The market prices at end – user level for the hard knee brace mostly correspond to the RIZIV / INAMI selling price. Differences are small and if so the market price is always higher.**
- **The market prices for the hard neck collar correspond almost entirely to the RIZIV / INAMI selling price. Differences are small.**
- **The market prices for the soft neck collars are considerably higher than the RIZIV / INAMI selling prices.**
- **The market prices of the wrist braces differ considerably from the RIZIV / INAMI selling price. The market prices are mostly higher. Differences are important.**
- **For all nomenclature codes, the prices at which the orthotists buy the different products, differs very considerably.**
- **Consequently the gross margin of the orthotists on the different products differs very much.**

5.4 PRICES FOR THE DUTCH MARKET

For the Dutch market, it is important to mention that the Public Health system is quite different from the Belgian system. We refer to the detailed description in the institutional analysis.[61]

In the Netherlands, there are about 19 different groups of insurance companies[62] that offer health insurance. These insurance companies operate in a competitive market. Every Dutch citizen is obliged to have a health indurance but he/she has a free choice as to which company to adhere to. These companies are bound to assure the minimal (medical and paramedical) acts, described in the Health Care Insurance decree and the Health insurance Regulations. The health insurance companies have to assure provision of adequate medical devices to their members[63]. The Dutch regulation stipulates the insurance companies are free to organise the provision of these devices, they have however to guarantee the availability of adequate devices to their members.

Health insurance companies negotiate contracts with providers of medical devices. For the orthoses, these contracts are negotiated with medical equipment shops and orthotists that deliver the orthoses to the patients.The contracts clearly stipulate the conditions for delivery to the patients (clients of the insurance company) as well as the prices paid directly to the provider.As the health insurance companies are free to choose the providers with whom they sign contracts, there is also real competition between the providers.

We mention these specificities because they highly influence price setting in The Netherlands.

The consequence for the collection of market prices was, we had to know the prices at which the insurance companies reimburse the providers. The end-user does not pay as it is the insurance company that directly reimburses the contracted price to the provider.

We contacted different insurance companies and different providers (mostly chains of providers). The contracts are not public which meant we relied on the concerned parties to provide us with the contracted prices. Since there is competition between the different health insurance companies this was not evident. We were able to collect contract prices for five of the most important health insurance companies. The prices

61 See Chapter III.
62 Situation January 2006
63 Hulpmiddelenregeling 1996, Ministerie van Volksgezondheid, Welzijn en Sport

were provided under the strict condition to keep them anonymous. In respect of this agreement, we calculated the average prices for the different products in our report.

We also collected prices for three web shops (www.sportbraces.nl, www.premed.nl, www.fysiosupplies.nl) were some types of orthoses can be purchased. The health insurance companies do not reimburse these purchases.

The table below displays in the third column the average web shop selling prices for three different shops.[64] In the fourth column, the market price is the average of prices reimbursed to the providers by four health insurance companies.

The last column represents the prices of VGZ Nederland, one of the most important health insurance companies. The providers who have a contract with VGZ charge the amounts mentioned in the third column to VGZ NL when they deliver an orthosis to a client of VGZ NL. VGZ NL is the only insurance company we are aware of that uses lump sum fees not related to specific products.

These prices include measurement, possible adjustments and delivery of the product. The provider has to evaluate the patient after 6 months. Possible maintenance and repair costs are included in the fixed price and the period of guarantee is 2 years (except for wrist othoses, where a one-year period is valid). An important remark is that the fixed amount for reimbursement to the provider is the same for prefabricated orthoses and for custom-made orthoses. It is the responsibility of the provider to decide which solution and which specific product will fit the patient's needs best.

VGZ NL wants to increase responsibility from the providers as much as possible. They claim their system (including maintenance and replacement of the devices) leads to the delivery of more appropriate orthoses and harder negotiation on prices between the retailer (provider) and the distributors[65]

As explained in the chapter III on the institutional analysis, the Dutch reimbursement system does not cover soft braces. The brace has to be strengthened and sport braces are totally excluded.[66]

At this moment, there is broad discussion on whether to include or not soft bandages and braces in the health insurance system. The health insurance companies tend to evolve towards reimbursement for treatments instead of reimbursement of products. The discussion is at yet still pending.[67]

64 Sportbraceshop.nl, Premed web shop and Fysiosupplies.

65 An interview was organised with VGZ Nederland on April 23rd 2007.

66 See Chapter III 1.6. Netherlands 1.6.3 Reimbursement

67 Monitor hulpmiddelen 2006, College voor zorgverzekeraars, Diemen; Hulpmiddelenzorg 2006-2010, visiedocument van Zorgverzekeraars Nederland; Signaleringsrapport hulpmiddelen 2006, College voor Zorgverzekeraars, Diemn.

5.4.1 The knee orthoses

5.4.1.1 The prefab hard knee brace hinged (nomenclature code 647592)

Table 24 : Price information knee nomenclature code 647592 The Netherlands

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	Average web shop prices	End-user price 2007 Netherlands (incl.VAT)	VGZ NL
Knee	**Bledsoe Aligner ESE L/R**		643,06 €	1.157,00 €
647592	**Bledsoe Axiom Sprt (new Knee Cage)**		662,45 €	1.157,00 €
	Bauerfeind SecuTec® Genu LR		557,79 €	1.157,00 €
	Bauerfeind MOS Genu® long		696,99 €	1.157,00 €
	Bauerfeind MOS Genu® Short		557,85 €	1.157,00 €
	Donjoy Legend Funct. brace ACL		614,89 €	1.157,00 €
	THUASNE GENU PRO Control Clasic		652,47 €	1.157,00 €
	C.Ti.2 (OSSUR)		1.116,74 €	1.157,00 €
	Generation II unloader adj (OSSUR)	NA	1.155,00 €	1.157,00 €
	Medi M.4 ® OA G045203	1.058,94 €	784,08 €	1.157,00 €

Source: Web shops, information from 5 health insurance companies

The market price (in this case the amount reimbursed to the provider by the insurance companies) varies depending from the product delivered to the patient. The most expensive product is the Generation II unloader adj. hard knee brace (distributed to the providers by the Össur Company).

The average price paid by the insurance companies for this product is 1.155,00 €. The lowest price is for the Bauerfeind SecuTec® Genu. This product is reimbursed at an average price of 557,79 €. The fixed amount reimbursed by the VGZ Insurance company (1.157,00 €) is also considerably higher than the reimbursement by the other insurance companies (except for the C.Ti.2 and the Generation II products).

The hard knee braces are difficult to find in web shop stores. The only one we found was the Medi M 4® AO at a price considerably higher than the amount paid by the health insurance companies to the providers. It is logic such type of product is not frequently bought through the web. Support from the provider (measurement and adjustment) is important and the price is very high if no reimbursement can be obtained.

Table 25 : Price comparison knee nomenclature code 647592 Belgium / The Netherlands

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	Average web shop prices	End-user price 2007 Netherlands (incl.VAT)	VGZ NL	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Knee	Bledsoe Aligner ESE L/R		643,06 €	1.157,00 €	951,24 €	0,32	0,32
647592	Bledsoe Axiom Sport (new Knee Cage) L/R		662,45 €	187,00 €	947,91 €	0,30	0,30
	Bledsoe Axiom Sport (new brand for Knee Cage) L/R		166,68 €	187,00 €	947,91 €	0,82	0,82
	Bauerfeind SecuTec® Genu LR		557,79 €	1.157,00 €	947,91 €	0,41	0,41
	Bauerfeind MOS Genu® long		696,99 €	1.157,00 €	965,58 €	0,28	0,28
	Bauerfeind MOS Genu® Short		557,85 €	1.157,00 €	947,91 €	0,41	0,41
	Donjoy Legend Funct. brace ACL		614,89 €	1.157,00 €	950,77 €	0,35	0,35
	THUASNE GENU PRO Control Clasic		652,47 €	1.157,00 €	947,91 €	0,31	0,31
	C.Ti.2 (OSSUR)		1.116,74 €	1.157,00 €	1.030,23 €	-0,08	-0,08
	Generation II unloader adj (OSSUR)	NA	1.155,00 €	1.157,00 €	970,16 €	-0,19	-0,19
	Medi M.4 ® OA G045203	1.058,94 €	784,08 €	1.157,00 €	947,91 €	0,17	0,17

In order to compare market prices between Belgium and The Netherlands we calculated the two ratio's described in the general methodology of this chapter. As shown in the table above, the market prices for all products, except the C.Ti.2 and the Generation II, are considerably higher in Belgium compared with the Netherlands. The C.Ti.2 and the Generation II are slightly more expensive in The Netherlands than in Belgium.

5.4.1.2 The Prefab knee bandage woven reinforced (nomenclature code 647555)

For this type of product prices reimbursed by the insurance companies vary between 63,18 € for the Bauerfeind Genutrain®, 134,34 € for the Push Med knee and 203,45 € for the Donjoy patella knee support. The fixed reimbursement price of VGZ for these type of products is 183,00 €.

Table 26 : Price information knee nomenclature code 647555 The Netherlands

Coresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	Average web shop prices	End-user price 2007 Netherlands (incl.VAT)	VGZ NL
Knee	**Bauerfeind Genutrain®**	61,73 €	63,18 €	183,00 €
647555	**Bauerfeind Genutrain® P3**	96,31 €	84,33 €	183,00 €
	Bauerfeind Genutrain® A3	97,25 €	84,33 €	183,00 €
	Push Care knee	63,22 €	105,15 €	183,00 €
	Push Med knee	104,35 €	134,34 €	183,00 €
	Thuasne Silistab Genu	43,25 €	91,66 €	183,00 €
	Otto Bock Genu Sensa 50K15	52,95 €		183,00 €
	Medi.ortho Genumedi®	58,00 €		183,00 €
	DeRoyal Knee brace flexible springs	55,95 €	NA	183,00 €
	Donjoy Patella Knee Support Lat.	107,95 €	203,45 €	183,00 €

Source: Web shops, information from 5 health insurance companies

The prices of the Internet shops vary widely. Differences with prices paid by the insurance companies can be considerable. The difference in service level to the customer is important. Postal delivery or personal measurement and adjustment by the orthopaedic are not comparable service levels.

Table 27 : Price comparison knee nomenclature code 647555 Belgium / The Netherlands

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	Average web shop prices	End-user price 2007 Netherlands (incl.VAT)	VGZ NL	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Knee	**Bauerfeind Genutrain®**	61,73 €	63,18 €	183,00 €	106,46 €	0,41	0,41
647555	**Bauerfeind Genutrain® P3**	96,31 €	84,33 €	183,00 €	114,29 €	0,26	0,26
	Bauerfeind Genutrain® A3	97,25 €	84,33 €	183,00 €	111,41 €	0,24	0,24
	Push Care knee	63,22 €	105,15 €	183,00 €	102,81 €	-0,02	-0,02
	Push Med knee	104,35 €	134,34 €	183,00 €	128,43 €	-0,05	-0,05
	Thuasne Silistab Genu	43,25 €	91,66 €	183,00 €	106,46 €	0,14	0,14
	Otto Bock Knee Support Basic-8953	19,95 €					
	Otto Bock Genu Sensa 50K15	52,95 €					
	Medi.ortho Genumedi® K100503	58,00 €					
	Medi.ortho elastic knee support 603 3290003	15,00 €					
	DeRoyal SPORT Knee brace with flexible springs ref 8052	55,95 €					
	DeRoyal Genum Stabiliser Long Silicon beige(T3) - ref EU 4332	NA	Na	Na	Na	Na	Na
	Donjoy Patella Knee Support Lateral J 11-0320	107,95 €	203,45 €	183,00 €	106,46 €	-0,91	-0,91

As shown in the table above, most price levels in The Netherlands are lower or comparable for the products belonging to this nomenclature code. The Donjoy Patella Knee Support Lateral however is much cheaper in Belgium than in the Netherlands.

5.4.1.3 Prefab knee brace elastic tissue or neoprene reinforced with metal (nomenclature code 647533)

Table 28 : Price information knee nomenclature code 647533 The Netherlands

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	Average web shop prices	End-user price 2007 Netherlands (incl.VAT)	VGZ NL
Knee 647533	Donjoy Drytec	NA	154,06 €	183,00 €
	Bauerfeind Genutrain® S	142,07 €	156,63 €	183,00 €
	Thuasne Ligaflex Evolution	NA	156,07 €	183,00 €
	Thuasne Ligaflex 2370		100,42 €	183,00 €
	Otto Bock Genu Track	252,00 €	216,95 €	183,00 €
	Otto Bock Genu Direxa Stable Wrap	206,98 €	NA	183,00 €
	MEDI hinged knee PRO (airtex)	99,00 €		183,00 €

Source: Web shops, information from 5 health insurance companies

The average contract prices of the insurance companies agreed with the orthopaedic retailers differ considerably. The contract price for the Thuasne Ligaflex is the lowest at 100,42 €. The highest price is for the Otto Bock Genu Track at 216,95 €. The fixed reimbursement amount of VGZ NL is 183,00 €

The prices from the web shops are more or less the same as the contract prices of the insurance companies.

Table 29 : Price comparison knee nomenclature code 647533 Belgium / The Netherlands

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	Average web shop prices	End-user price 2007 Netherlands (incl.VAT)	VGZ NL	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Knee 647533	Donjoy Drytec	NA	154,06 €	183,00 €	223,05 €	0,31	0,31
	Bauerfeind Genutrain® S	142,07 €	156,63 €	183,00 €	223,17 €	0,30	0,30
	Thuasne Ligaflex Evolution	NA	156,07 €	183,00 €	224,52 €	0,30	0,30
	Thuasne Ligaflex 2370		100,42 €	183,00 €	215,94 €	0,53	0,53
	Otto Bock Genu Track - 50K20	252,00 €	216,95 €	183,00 €	237,13 €	0,09	0,09

As shown in the table above, prices in Belgium are for all products considerably higher than in The Netherlands.

5.4.2 The neck collars

5.4.2.1 Prefab stiff neck collar with support chin and/or back of the head adjustable in height (nomenclature code 645212)

For the hard neck collar the contract prices vary from 102,64 € for the Jerome Miami J. collar to 189,20 € for the Fillauer Basko ortho collar. As shown in the table below, the health insurer VGZ differentiates its price for the Jerome Miami J. collar and the other neck collars. For Belgium, these products are classified in the same nomenclature code.

Table 30 : Price information neck nomenclature code 645212 The Netherlands

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	Average web shop prices	End-user price 2007 Netherlands (incl.VAT)	VGZ NL
Neck	**Jerome Miami J.Collar**		102,64 €	122,00 €
645212	**Malibu halskraag 06/3020**		152,78 €	163,00 €
	Fillauer/Basko Ortho-Collar	NA	189,20 €	163,00 €

Source: Web shops, information from 5 health insurance companies

We did not find the hard neck collar in web shops. This seems understandable since this type of orthoses all are prescribed by a medical doctor and suppose important medical follow up.

Table 31 : Price comparison neck nomenclature code 645212 Belgium / The Netherlands

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	Average web shop prices	End-user price 2007 Netherlands (incl.VAT)	VGZ NL	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Neck	**Jerome Miami J.Collar**		102,64 €	122,00 €	240,62 €	0,57	0,57
645212	**Malibu halskraag 06/3020**		152,78 €	163,00 €	258,77 €	0,41	0,41
	Fillauer/Basko Ortho-Collar 105320	NA	189,20 €	163,00 €	258,77 €	0,27	0,27

As shown in the table above, prices are higher for all products in Belgium. Difference in pricing for the Jerome Miami J. collar, the market leader in Belgium is very substantial.

5.4.2.2 Prefab soft collar (nomenclature code 645175)

Soft neck collars do not qualify for reimbursement in the Netherlands. The regulation on assistive devices excludes soft orthoses such as the soft woven neck collar. [68]Nevertheless, the Dutch health insurance companies have contracts with the medical shops that hold prices for this type of orthoses. The prices that are mentioned in the table below, are the prices used by the retailers and thus to be considered as market prices.

Table 32 : Price information neck nomenclature code 645175 The Netherlands

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	Average web shop prices	End-user price 2007 Netherlands (incl.VAT)	VGZ NL
Neck **645175**	**Push Care 8 cm en 10 cm**	41,99 €	50,39 €	
	Push nek Med 8 cm en 10 cm	61,42 €	63,70 €	
	Thuasne Ortel C1 2390	11,35 €	33,68 €	
	GLOBOMEDIC Bauerfeind	25,90 €	NA	
	Basco Camp grouped number		46,04 €	
	Basko Camp 5750		46,04 €	
	Basko Camp 5620		46,04 €	
	Thämert 49/190		68,73 €	
	DeRoyal Foam cervical collar	NA	37,11 €	
	Otto Bock Necky Color	29,95 €	NA	NA

Source: Web shops, information from 5 health insurance companies

As these products are not reimbursed by the Dutch health insurance, it is plausible they are largely purchased through alternative retail channels such as web shops, pharmacies, department stores. The prices on the web sites mostly are lower than the prices applied by the orthotists.

68 Regeling hulpmiddelen 1996 (version 2007) Ministerie van Volksgezondheid, Welzijn en Sport.

Table 33 : Price comparison neck nomenclature code 645175 Belgium / The Netherlands

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	Average web shop prices	End-user price 2007 Netherlands (incl.VAT)	VGZ NL	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Neck	**Push Care 8 cm en 10 cm**	41,99 €	50,39 €	122,00 €	47,03 €	-0,07	-0,07
645175	**Push nek Med 8 cm en 10 cm**	61,42 €	63,70 €	122,00 €	73,13 €	0,13	0,13
	Thuasne Ortel C1 2390	11,35 €	33,68 €	122,00 €	28,43 €	-0,18	-0,18
	Basko Camp 5750, 5700, 5800		46,04 €	122,00 €	37,04 €	-0,24	-0,24
	Basko Camp 5620/21, 5720/21, 5820/21		46,04 €	122,00 €	29,42 €	-0,56	-0,56
	Thämert 49/190		68,73 €	122,00 €	30,47 €	-1,26	-1,26
	DeRoyal Foam cervical collar ref EU 515	NA	37,11 €	122,00 €	28,28 €	-0,31	-0,31

As shown in the table above we have a complete different result for the products of the nomenclature code of soft neck collars. For five products the prices in Belgium are considerably lower than in the Netherlands. For one product, the price is nearly identical and for one product, the price is slightly higher.

5.4.3 The Wrist orthoses

5.4.3.1 Prefab wrist bandage, reinforced limiting movement (nomenclature code nr. 649434)

The average contract prices (market prices) for the reinforced wrist brace vary between 38,03 € for the Basko Elcross product to 69,86 € for the two Bauerfeind products. Once again, the fixed amount paid by VGZ NL is higher than the average contract prices of the other health insurance companies. As mentioned in the introduction of this chapter, the contacts of VGZ NL with the orthotists foresee a period of guarantee for one year. Consequently, the orthotists must replace the wrist orthosis during this period free of charges.

Table 34 : Price information wrist nomenclature code 649434 The Netherlands

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	Average web shop prices	End-user price 2007 Netherlands (incl.VAT)	VGZ NL
Wrist	**Bauerfeind ManuLoc®**	73,08 €	69,86 €	102,00 €
649434	**Bauerfeind ManuTrain®**	72,66 €	69,86 €	102,00 €
	Push Med wrist	62,69 €	64,56 €	102,00 €
	Push Care wrist	29,92 €	43,74 €	102,00 €
	Donjoy Elastic wrist brace	NA	59,44 €	102,00 €
	medi Wrist support 55G6023	33,19 €	NA	102,00 €
	DeRoyal - Manex Reuma Long		54,78 €	102,00 €
	DeRoyal - Manex Reuma Pollus		59,06 €	102,00 €
	Basko Elcross Carpus Midi		38,03 €	102,00 €
	Basko Elcross Carpus Flexi	NA	60,51 €	102,00 €
	Manu Rheuma Flex	33,95 €	NA	102,00 €

Source: Web shops, information from 5 health insurance companies

The prices of the wrist orthoses sold on the web shops are comparable with the prices agreed with the health insurance companies, except for the Push care wrist that is cheaper in the web shop.

Table 35 : Price comparison wrist nomenclature code 649434 Belgium / The Netherlands

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	Average web shop prices	End-user price 2007 Netherlands (incl.VAT)	VGZ NL	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Wrist	**Bauerfeind ManuLoc®**	73,08 €	69,86 €	102,00 €	79,36 €	0,12	0,12
649434	**Bauerfeind ManuTrain®**	72,66 €	69,86 €	102,00 €	78,58 €	0,11	0,11
	Push Med wrist	62,69 €	64,56 €	102,00 €	73,39 €	0,12	0,12
	Push Care wrist	29,92 €	43,74 €	102,00 €	56,84 €	0,23	0,23
	Donjoy Elastic wrist brace	NA	59,44 €	102,00 €	57,75 €	-0,03	-0,03
	medi Wrist support 55G6023	33,19 €	NA	NA	NA	NA	NA
	DeRoyal - Manex Reuma Long - ref EU2024		54,78 €	102,00 €	53,27 €	-0,03	-0,03
	DeRoyal - Manex Reuma Pollus - ref EU 2025	NA	59,06 €	102,00 €	59,62 €	0,01	0,01

As shown in the table above prices for wrist orthoses are more or less comparable between Belgium and the Netherlands. The difference is more substantial for the Push Care wrist bandage that is cheaper in The Netherlands.

Key points

- **Each of the Dutch health insurance companies and the orthotists negotiates market prices (contract prices) in The Netherlands.**
- **Compared with the Belgian market prices, the prices for the different types of knee braces are much lower in The Netherlands.**
- **Market prices (contract prices) for the hard neck collar are considerably lower in The Netherlands.**
- **Market prices (contract prices) for the soft neck collar are much higher in the Netherlands.**
- **For the wrist brace, market prices (contract prices) in The Netherlands are slightly lower than for Belgium.**

5.5 PRICES FOR THE FRENCH MARKET

Market prices for the products in France are hard to find. The prices at the level of the providers are free.[69] Pharmacies, medical equipment shops and orthotics deliver the orthoses. There is a difference between more sophisticated orthoses [70] (mostly tailor made) and more basic orthoses. Most orthotics concentrate on the tailored devices and the prosthetics. The prefabricated more basic products mostly are distributed by the pharmacies and the medical equipment shops.

5.5.1 Methodology

To collect price information, we contacted the different professional associations of orthothists.[71] They had no information on market prices. Next, we contacted 5 individual orthotists using the member lists of the professional organisations. This led to little information on market prices since most of them only provide tailor made orthoses and prostheses.

Subsequently, we contacted 32 local pharmacies and medical equipment shops by phone leading to poor results. The reluctance to give market prices was high and the assortment of products very restricted. We also visited 12 local pharmacies on the spot with similar results. Finally, information on prices was collected through 12 pharamacy visits, a major French orthotics chain Protea (36 sales points, employing 90 orthotists). Medi France, Ossur and Bauerfeind France also provided market prices. This information was complemented with a google-based grey search.

Information on market prices was collected in the period March- April 2007.

5.5.2 Reimbursement tariffs

Reimbursement varies depending on the situation of the patient (reimbursement to chronically ill patients is higher).

Compared to the Belgian reimbursement system, for most of the French patients the amounts reimbursed are low.

The table below indicates the respective tariffs for reimbursement in France and Belgium. Sometimes the classification does however not completely match. In that case, we mention the applicable different tariffs:

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69 See chapter III institutional analysis 1.5. France

70 "Grand appareillage" and "Petit appareillage".

71 Union Française des Ortho-Prothésistes and Syndicat National de l'Orthopédie Française.

Table 36 : Comparison between reimbursements tariffs in Belgium and France

Belgian nom. code	Description	France LPPR	Belgium (non prefer.)
647592	Prefab hard knee brace hinged	102,29 €	579,59 €
647555	Prefab knee bandage woven reinforced	24,46 €	65,11 €
647533	Prefab knee brace elastic tissue or neoprene reinforced with metal	102,29 €	223,05 €
645212	Prefab stiff neck collar with support chin and/or back of the head adjustable in height	15,71 € 18,77 €	194,08 €
645175	Prefab soft collar	9,25 €	9,59 €
649434	Prefab wrist bandage, reinforced limiting movement	36,71 €	34,74 €
(1) Liste der produits et prestations remboursables - art.L 165 -1 code de la sécurité sociale			

Source: RIZIV/ INAMI and liste des produits et prestations remboursables (LPPR)

As pricing of the prefabricated orthoses (within the scope of the study) at retailers' level is free, orthothists, pharmacies and medical equipment shops decide themselves the market prices.

As indicated in the table above, for most of the orthoses, especially the more expensive types, reimbursement is very low. Consequently, the patient has to pay a substantial part of the price himself.

Some of the pharmacists and the orthotics we spoke to, indicated that the low level of reimbursement affect sale volumes and puts certain limits on end user selling prices.

5.5.3 The knee orthoses

5.5.3.1 The prefab hard knee brace hinged (nomenclature code 647592)

For the hard knee brace, we found seven different products from the sample for which we were able to get market prices for France. As indicated in the table, the Bauerfeind Secutec is the cheapest product. The price difference between the products is very high. The most expensive knee braces are the C.Ti.2 and the Generation II unloader adj. braces.

Table 37 : Price comparison knee nomenclature code 647592 Belgium / France

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	End-user price 2007 France (incl.VAT)	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Knee 647592	**Bauerfeind SecuTec® Genu LR**	425,00 €	947,91 €	0,55	0,54
	Bauerfeind MOS Genu® long	850,00 €	965,58 €	0,12	0,10
	Bauerfeind MOS Genu® Short	690,00 €	947,91 €	0,27	0,26
	Donjoy Legend Funct. brace ACL	595,00 €	950,77 €	0,37	0,36
	Donjoy 4-titude	595,93 €	947,91 €	0,37	0,36
	C.Ti.2 (OSSUR)	947,28 €	1.030,23 €	0,08	0,06
	Generation II unloader adj (OSSUR)	947,00 €	970,16 €	0,02	0,00

As shown in the table above, the prices for the hard knee braces are much higher in Belgium than in France. Only for the Generation II, the difference in price between Belgium and France is small.

5.5.3.2 The Prefab knee bandage woven reinforced (nomenclature code 647555)

For the prefabricated woven bandage, we found market prices for seven products of the sample. The cheapest product is the Medi.ortho elastic knee support. The Genumedi® and the Thuasne Silistab Genu are mid priced products. Except the Bauerfeind Genutrain® P3, the other products are considerably more expensive. The Bauerfeind Genutrain®P3 is the most expensive product, costing more than four times the price of the Medi elastic knee support and nearly twice the price of the French Thuasne product.

Table 38 : Price comparison knee nomenclature code 647555 Belgium / France

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	End-user price 2007 France (incl.VAT)	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Knee 647555	**Bauerfeind Genutrain®**	66,00 €	106,46 €	0,38	0,37
	Bauerfeind Genutrain® P3	117,50 €	114,29 €	-0,03	-0,05
	Bauerfeind Genutrain® A3	86,00 €	111,41 €	0,23	0,21
	Thuasne Silistab Genu	59,44 €	106,46 €	0,44	0,43
	Medi.ortho Genumedi® K100503	57,06 €	106,44 €	0,46	0,45
	Medi.ortho elastic knee support 603 3290003	25,74 €	106,46 €	0,76	0,75
	Donjoy Patella Knee Support Lateral 11-0320	111,15 €	106,46 €	-0,04	-0,06

As shown in the table above prices are in general much higher in Belgium versus.

5.5.3.3 Prefab knee brace elastic tissue or neoprene reinforced with metal (nomenclature code 647533)

Market prices were found for four different products. The Thuasne Ligaflex 2370 is the by far cheapest product. All other products cost more than twice to four times the price of the Thuasne Ligaflex 2370 product.

Table 39 : Price comparison knee nomenclature code 647533 Belgium / France

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	End-user price 2007 France (incl.VAT)	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Knee 647533	**Donjoy Drytec**	102,29 €	223,05 €	0,54	0,53
	Bauerfeind Genutrain® S	155,50 €	223,17 €	0,30	0,29
	Thuasne Ligaflex Evolution	140,67 €	224,52 €	0,37	0,36
	Thuasne Ligaflex 2370	44,25 €	215,94 €	0,80	0,79

As shown in the table above all prices are much higher in Belgium for the products within the product scope of this nomenclature code.

5.5.4 The neck collars

5.5.4.1 Prefab stiff neck collar with support chin and/or back of the head adjustable in height (nomenclature code 645212)

We were unable to find prices in France for one of the three hard neck collars that are sold on the Belgian market. As we did not find the most representative product sold in Belgium, the Jerome Miami J. collar, at retailers' level, we contacted the European distributor Össur. They informed us the Jerome Miami J. collar is not exported to France at this time. Össur plans to put this collar on the French market in the near future.

5.5.4.2 Prefab soft collar (nomenclature code 645175)

For the prefabricated soft collar, we were able to collect market prices for four products included in the scope.

The Thuasne soft collar is the cheapest one. The DeRoyal foam cervical collar is more than 2,5 times more expensive than the French Thuasne collar. During our conversations with the pharmacies, they mentioned a lot of different other French brands that are being sold on this market segment. As for Belgium, this type of product is largely sold in department stores too.

Table 40 : Price comparison neck nomenclature code 645175 Belgium / France

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	End-user price 2007 France (incl.VAT)	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Neck 645175	**Thuasne Ortel C1**	15,59 €	28,43 €	0,45	0,44
	Thämert 49/190	22,00 €	30,47 €	0,28	0,26
	DeRoyal Foam cervical collar ref 515	40,50 €	28,28 €	-0,43	-0,46
	Otto Bock Necky Color - 50C20	30,00 €	40,71 €	0,26	0,25

As shown in the table above the prices for the Thuasne Ortel C1, the Thämert and for the Otto Bock necky color collar are lower in France versus in Belgium. The DeRoyal collar however is much more expensive in France.

5.5.5 The Wrist orthoses

5.5.5.1 Prefab wrist bandage, reinforced limiting movement (nomenclature code nr. 649434)

The market prices in France for the wrist bandages vary little. The sample of products did not include a Thuasne product for the wrist.

Table 41 : Price comparison wrist nomenclature code 649434 Belgium / France

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	End-user price 2007 France (incl.VAT)	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Wrist **649434**	**Bauerfeind ManuLoc®**	72,58 €	79,36 €	0,09	0,07
	Bauerfeind ManuTrain®	74,00 €	78,58 €	0,06	0,04
	Donjoy Elastic wrist brace	73,25 €	57,75 €	-0,27	-0,29

For the wrist orthoses prices are slightly higher in Belgium for the Bauerfeind Manuloc® and the Manutrain®. The Donjoy product is considerably cheaper in Belgium.

Key points

- **The market prices for France are free. Reimbursement in France is extremely lower than in Belgium.**
- **Market prices for the knee orthoses in France, compared with Belgium, are much lower.**
- **For the hard neck collar no product sold on the Belgian market was found.**
- **For the soft neck collar, most of the market prices in France are considerably lower than in Belgium.**
- **Market prices of the wrist brace are higher to equal versus the prices in Belgium.**

5.6 PRICES FOR THE UK MARKET (ENGLAND)

Market prices for medical devices in general and orthoses in particular in the UK are heavily impacted by the fact the NHS (the Public Health authority) since 2000 established the NHS PASA as an executive agency of the Department of Health. The prime objective of this agency is to make the most effective use of NHS resources by getting the best possible value for money when purchasing goods and services. Making use of the NHS PASA, through public tendering, the NHS organises competition between the providers of orthoses. Based on the results of the pulic tendering procedures, contracts on prices are drawn stipulating the specific orthoses to be purchased by all NHS services and their pricing.

5.6.1 Methodology

To collect price information, we contacted as well the UK Department of Health, the NHS Supply chain, the NHS PASA as the NHS Scotland and its NSS National Procurement service[72]. We asked to provide the prices they contracted with the providers and manufacturers of the products in the scope of this study. These organisations all denied access to this price information.

We consequently contacted the British association of prosthetists and orthotists (BAPO) who referred us back to the NHS. Since no prices could be obtained through these channels, we contacted the industry, the manufacturers and the distributors of orthoses to the NHS. We optained answers from Bauerfeind UK, Donjoy U.K., Push U.K., Otto Bock U.K., Ossur Europe, Medi U.K. and Thuasne.

For these companies, we obtained the prices used for the sales to the NHS, the pharmacies, the orthotists and the Public Hospitals. For some products however no prices were found, caused by the fact these products are not distributed in the UK. As described in the chapter on the Institutional analysis, orthoses are fully reimbursed or paid for by the NHS. In ambulatory care, the soft cervical collar is reimbursed based on the tariffs listed in the Drug tariff. Other orthoses are provided in secondary care through the orthotists and the hospitals. The orthoses are provided at the NHS contract prices. The orthotists are, or employees of the NHS, or contracted by the NHS who grants them a salary, or locum orthotists paid according to the number of clinical sessions.

Consequently, the prices for the UK of the orthoses do not include the actual services rendered by the orthotists.

Distributors however clearly mentioned their products are sold directly to the end – users at the same prices as the prices used for the NHS.

5.6.2 The knee orthoses:

5.6.2.1 The prefab hard knee brace hinged (nomenclature code 647592):

For the hard knee brace, we found eight different products from the sample for which we were able to get market prices[73]. Prices of the different products vary from 511,10 € for the Donjoy Legend and the Medi M.4®ACL to 884,69 € for the most expensive product, the C.Ti.2 from Össur. The price difference between the products is very high.

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72 NHS National Services Scotland

73 All prices are given in Euro.

Table 42 : Price comparison knee nomenclature code 647592 Belgium / UK

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	End-user price 2007 UK (incl.VAT)	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Knee 647592	**Bauerfeind SecuTec® Genu LR**	516,29 €	947,91 €	0,46	0,45
	Bauerfeind MOS Genu® long	848,94 €	965,58 €	0,12	0,11
	Bauerfeind MOS Genu® Short	641,03 €	947,91 €	0,32	0,32
	Donjoy Legend Funct. brace ACL	511,10 €	950,77 €	0,46	0,46
	Donjoy 4-titude	545,75 €	947,91 €	0,42	0,42
	C.Ti.2 (OSSUR)	884,69 €	1.030,23 €	0,14	0,13
	Medi M.4® ACL orCI or PCL G021203	511,10 €	947,91 €	0,46	0,46
	Medi M.4 ® OA G045203	632,38 €	947,91 €	0,33	0,33

As shown in the table, the prices we found for the hard knee braces are substantial lower in the UK than in Belgium.

5.6.2.2 The Prefab knee bandage woven reinforced (nomenclature code 647555)

On the prefabricated woven knee bandage, we found market prices for ten products of the sample. The cheapest product is the Medi.ortho elastic knee support. The Bauerfeind Genutrain®P3 and A3 are considerably more expensive. The Bauerfeind Genutrain®P3 is the most expensive one, costing more than five times the price of the Medi elastic knee support and twice the price of the French Thuasne product. As shown in the next table, prices are considerably higher in Belgium versus the UK for all but two products for which the prices are slightly higher in the UK.

Table 43 : Price comparison knee nomenclature code 647555 Belgium / UK

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	End-user price 2007 UK (incl.VAT)	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Knee 647555	**Bauerfeind Genutrain®**	83,16 €	106,46 €	0,22	0,21
	Bauerfeind Genutrain® P3	131,67 €	114,29 €	-0,15	-0,16
	Bauerfeind Genutrain® A3	131,67 €	111,41 €	-0,18	-0,19
	Push Care knee	58,19 €	102,81 €	0,43	0,43
	Push Med knee	103,78 €	128,43 €	0,19	0,18
	Thuasne Silistab Genu	67,55 €	106,46 €	0,37	0,36
	Otto Bock Genu Sensa 50K15	49,51 €	106,46 €	0,53	0,53
	Medi.ortho Genumedi® K100503	45,05 €	106,44 €	0,58	0,57
	Medi.ortho elastic knee support 603 3290003	24,26 €	106,46 €	0,77	0,77
	Donjoy Patella Knee Support Lateral11-0320	60,65 €	106,46 €	0,43	0,42

5.6.2.3 Prefab knee brace elastic tissue or neoprene reinforced with metal (nomenclature code 647533)

Market prices were found for six different products. The Medi Hinged pro is the by far the cheapest product at a price of 84,90 €. The most expensive is the Otto Bock Genu Track at 178,19 €.

Table 44 : Price comparison knee nomenclature code 647533 Belgium / UK

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	End-user price 2007 UK (incl.VAT)	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Knee 647533	**Bauerfeind Genutrain® S**	117,81 €	223,17 €	0,47	0,47
	Thuasne Ligaflex Evolution	135,49 €	224,52 €	0,40	0,39
	Otto Bock Genu Track - 50K20	178,19 €	237,13 €	0,25	0,24
	Otto Bock Genu Direxa Stable Wraparound 8367	111,38 €	226,07 €	0,51	0,50
	Donjoy Tru-Pull hinged sleeve	138,60 €	223,05 €	0,38	0,37
	MEDI hinged knee PRO (airtex) 55A2023	84,90 €	223,05 €	0,62	0,62

As shown in the table above all prices are considerably higher in Belgium for the products within the product scope of this nomenclature code.

5.6.3 The neck collars

5.6.3.1 Prefab stiff neck collar with support chin and/or back of the head adjustable in height (nomenclature code 645212)

The hard adjustable neck collars of the sample were hard to find in the UK. We only encountered the Jerome Miami J. collar who is being sold at 129,94 €. Different to the Belgian price the Jerome Miami collar however is sold with additional accessories (extra joints)

Table 45 : Price comparison neck nomenclature code 645212 Belgium / UK

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	End-user price 2007 UK (incl.VAT)	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Neck 645212	**Jerome Miami J.Collar**	129,94 €	240,62 €	0,46	0,45

As shown in the table above, the price we found is considerably lower than the equivalent average price on the Belgian market.

5.6.3.2 Prefab soft collar (nomenclature code 645175)

For the prefabricated soft collar, we were able to collect market prices for four products included in the scope.

The Otto Bock necky color collar is the cheapest one. The differences in prices between the different brands are rather substantial certainly for the Push Med that is three times as expensive as the cheapest product.

Table 46 : Price comparison neck nomenclature code 645175 Belgium / UK

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	End-user price 2007 UK (incl.VAT)	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Neck	Push Care 8 cm en 10 cm	50,39	47,03	-0,07	-0,08
645175	Push nek Med 8 cm en 10 cm	63,70	73,13	0,13	0,12
	Thuasne Ortel C1(zacht) 2390 ORTEL C1	33,68	28,43	-0,18	-0,20
	Otto Bock Necky Color - 50C20	21,66	40,81	0,47	0,46

Differences in prices are important for the Otto Bock necky collar. The other prices are more or less comparable.

5.6.4 The Wrist orthoses

5.6.4.1 Prefab wrist bandage, reinforced limiting movement (nomenclature code nr. 649434)

The market prices for the wrist bandages largely vary from 20,79 € for the Donjoy elastic wrist brace to 98,06 € for the most expensive product, the Bauerfeind ManuLoc®.

Table 47 : Price comparison wrist nomenclature code 649434 Belgium / UK

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	End-user price 2007 UK (incl.VAT)	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Wrist 649434	Bauerfeind ManuLoc®	98,06 €	79,36 €	-0,24	-0,25
	Bauerfeind ManuTrain®	83,16 €	78,58 €	-0,06	-0,07
	Push Med wrist	59,60 €	73,39 €	0,19	0,18
	Push Care wrist	30,07 €	56,84 €	0,47	0,47
	Donjoy Elastic wrist brace	20,79 €	57,75 €	0,64	0,64
	medi Wrist support 55G6023	22,53 €	56,32 €	0,60	0,60

For the wrist orthoses most prices are higher in Belgium. The Bauerfeind Manuloc®, and Manutrain are both more expensive in the UK.

Key points

- **Most orthoses are provided to the UK patients in secondary care settings.**
- **The prices of the different products are the outcome of public tendering procedures organized by the NHS agencies. The UK prices only cover the product price; they do not cover the salary of the orthotists for which the NHS pays separately.**
- **Market prices for knee braces and bandages are much lower than for Belgium.**
- **On the whole, market prices for the neck collars and the wrist brace are considerably lower in the UK.**

5.7 PRICES FOR THE CANADIAN MARKET (ONTARIO)

Market prices for prefabricated orthoses in Canada are free. As explained in the chapter on the Institutional analysis for Ontario they are not reimbursed by the Public health system. The Assistive devices programme reimburses only very specific orthoses for children.

5.7.1 Methodology

To collect price information, we contacted the professional association of orthothics.[74] They had no information on market prices. Further, we contacted the operational support branch of the Assistive Devices Program whom informed us prices were not catalogued and are completely free in Ontario. The assistive devices programme only provides custom-made orthoses and exceptionally, very specific prefabricated orthoses for children. Consequently, we contacted the different subsidiaries of manufacturers, distributors and retailers to obtain the end – user sale prices and search for prices on the internet. The companies who provided us with information on Canadian prices are distributors for Bauerfeind, Thuasne (Biomed Inc.), Otto Bock and Donjoy-Jerome.The prices obtained are the average end – user prices on the market.

5.7.2 The knee orthoses:

5.7.2.1 The prefab hard knee brace hinged (nomenclature code 647592):

For the hard knee brace, we found eight different products from the sample for which we were able to get market prices.

The cheapest product is the Bauerfeind Secutec® Genu at a retail price of 426,30 €. The most expensive product is the Thuasne Genu Pro Control C at 853,97 €. Prices of the different products of this nomenclature code vary rather substantial.

Table 48 : Price comparison knee nomenclature code 647592 Belgium / Canada

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	End-user price 2007 Canada (incl.VAT)	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Knee **647592**	**Bauerfeind SecuTec® Genu LR**	426,30 €	947,91 €	0,55	0,59
	Bauerfeind MOS Genu® long	699,39 €	965,58 €	0,28	0,33
	Bauerfeind MOS Genu® Short	566,18 €	947,91 €	0,40	0,45
	Donjoy Legend Funct. brace ACL	708,08 €	950,77 €	0,26	0,31
	Donjoy 4-titude	708,08 €	947,91 €	0,25	0,31
	THUASNE GENU PRO Control Clasic	853,97 €	947,91 €	0,10	0,17
	Generation II unloader adj (OSSUR)	476,88 €	970,16 €	0,51	0,55

As shown in the table below the market prices we found for the hard knee braces are substantial higher in Belgium than in Canada.

74 Canadian Association for Prosthetics and orthotics (CAPO).

5.7.2.2 The Prefab knee bandage woven reinforced (nomenclature code 647555)

On the prefabricated woven bandage, we found market prices for six products of the sample. The cheapest product is the Otto Bock Genu Sensa. The Genumedi® P3 and A3 and the Thuasne Silistab Genu are the most expensive products at end – user level.

Table 49 : Price comparison knee nomenclature code 647555 Belgium / Canada

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	End-user price 2007 Canada (incl.VAT)	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Knee 647555	**Bauerfeind Genutrain®**	48,84 €	106,46 €	0,54	0,58
	Bauerfeind Genutrain® P3	82,11 €	114,29 €	0,28	0,34
	Bauerfeind Genutrain® A3	82,11 €	111,41 €	0,26	0,32
	Thuasne Silistab Genu	83,56 €	106,46 €	0,22	0,28
	Otto Bock Genu Sensa 50K15	37,02 €	106,46 €	0,65	0,68
	Donjoy Patella Knee Support Lateral11-0320	76,46 €	106,46 €	0,28	0,34

As shown in the table above prices are considerably lower in Canada as in Belgium.

5.7.2.3 Prefab knee brace elastic tissue or neoprene reinforced with metal (nomenclature code 647533)

Market prices were found for four different products. The Thuasne Ligaflex 2370 is the by far the cheapest product. The Bauerfeind Genutrain is mid-priced; the two other products are much more expensive.

Table 50 : Price comparison knee nomenclature code 647533 Belgium / Canada

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	End-user price 2007 Canada (incl.VAT)	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Knee 647533	**Bauerfeind Genutrain® S**	114,71 €	223,17 €	0,49	0,53
	Thuasne Ligaflex Evolution	160,15 €	224,52 €	0,29	0,34
	Thuasne Ligaflex 2370	90,52 €	215,94 €	0,58	0,61
	Donjoy Tru-Pull hinged sleeve	175,41 €	223,05 €	0,21	0,28

As shown in the table above all prices for the products for this nomenclature code (within the product scope) are considerably higher in Belgium.

5.7.3 The neck collars

5.7.3.1 Prefab stiff neck collar with support chin and/or back of the head adjustable in height (nomenclature code 645212)

The hard adjustable neck collars of the sample were hard to find in Canada. We only encountered the Jerome Miami J. collar who is sold at an market price of 94,62 €.

Table 51 : Price comparison neck nomenclature code 645212 Belgium / Canada

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	End-user price 2007 Canada (incl.VAT)	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Neck					
645212	**Jerome Miami J.Collar**	94,62 €	240,62 €	0,61	0,64

As shown in the table above, the market prices for the Jerome Miami J. collar is much lower than the Belgian price.

5.7.3.2 Prefab soft collar (nomenclature code 645175)

For the prefabricated soft collar, we were able to collect market prices for two products included in the scope. The Otto Bock collar is the most expensive one.

Table 52 : Price comparison neck nomenclature code 645175 Belgium / Canada

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	End-user price 2007 Canada (incl.VAT)	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Neck	**Thuasne Ortel C1(zacht) 2390 ORTEL C1**	31,33 €	28,43 €	-0,10	-0,01
645175	**Otto Bock Necky Color - 50C20**	40,53 €	40,81 €	0,007	0,09

As shown in the table above the prices for the Thuasne Ortel C1 and for the Otto Bock necky color collars are nearly equal to the market price in Belgium.

5.7.4 The Wrist orthoses

5.7.4.1 Prefab wrist bandage, reinforced limiting movement (nomenclature code nr. 649434)

The market prices for the wrist bandages vary considerably from 26,47 € for the Donjoy elastic wrist brace to 66,25 € for the Bauerfeind Manuloc.

Table 53 : Price comparison wrist nomenclature code 649434 Belgium / Canada

Corresponding RIZIV / INAMI Nomencl.code BELGIUM	Product	End-user price 2007 Canada (incl.VAT)	End user price 2007 Belgium (incl.VAT)	C1, FG	C2, FG
Wrist **649434**	**Bauerfeind ManuLoc®**	66,25 €	79,36 €	0,17	0,23
	Bauerfeind ManuTrain®	48,10 €	78,58 €	0,39	0,44
	Donjoy Elastic wrist brace	26,47 €	57,75 €	0,54	0,58

For the wrist orthoses the market prices are relatively much higher in Belgium for the Donjoy elastic wrist brace (twice as high) and less high for the Bauerfeind Manuloc® and Manutrain.

Key points

- **Market prices in Canada are free. The prefabricated orthoses are not reimbursed except for some specific braces for children.**
- **All types of orthoses are cheaper in Canada than in Belgium excepted for one product.**
- **Differences in prices are very substantial in Canada.**

5.8 GLOBAL COMPARISON OF MARKET PRICES

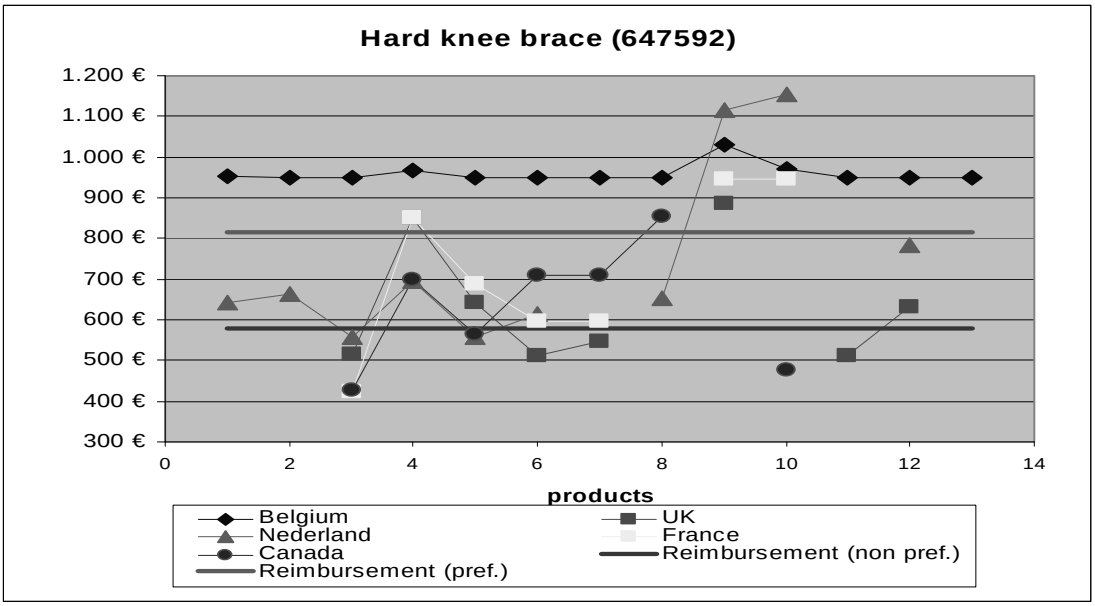
In the following paragraphs, we will give an overview of all prices collected for the different orthoses in the countries within the scope of the study. We do not repeat all individual prices for each country, but display price diagrams, grouping various products by nomenclature codes. The graphs give a good overview of how Belgian market prices an reimbursement tariffs compare to prices abroad.

5.8.1 The knee orthoses

5.8.1.1 The prefab hard knee brace hinged (nomenclature code 647592):

The graph in Figure 30 gives an overview of all prices for the different hard knee brace brands for all countries studied. Reimbursement tarifss for Belgium, both non-preferential and preferential are shown, respectively as the lower and upper straight line on the figure.

Figure 30 : Comparison prices knee nomenclature code 647592

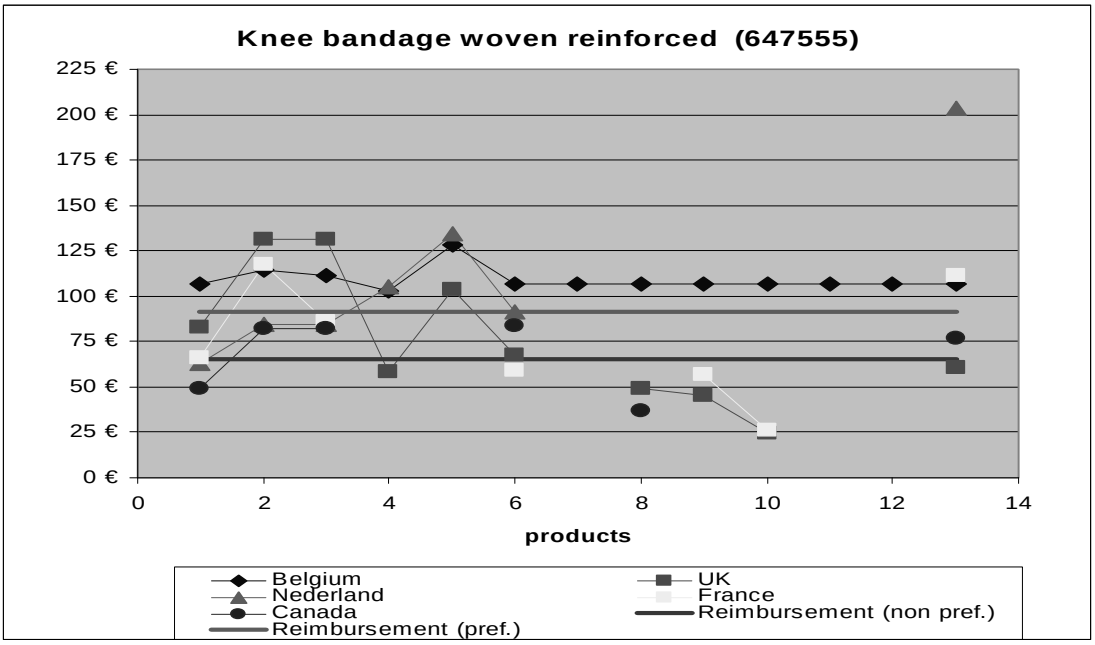


As is clear from the graphic, Belgian prices for the different products, when compared with the corresponding prices in the other countries, are much higher. Only in The Netherlands, for two specific products, the market price is higher than the Belgian one. There are different products in other countries that are sold at a lower price than the lowest reimbursement tariff in Belgium.

5.8.1.2 *The Prefab knee bandage woven reinforced (nomenclature code 647555)*

The graph shows the different prices for the reinforced knee bandage.

Figure 31 : Price Comparison knee nomenclature code 647555

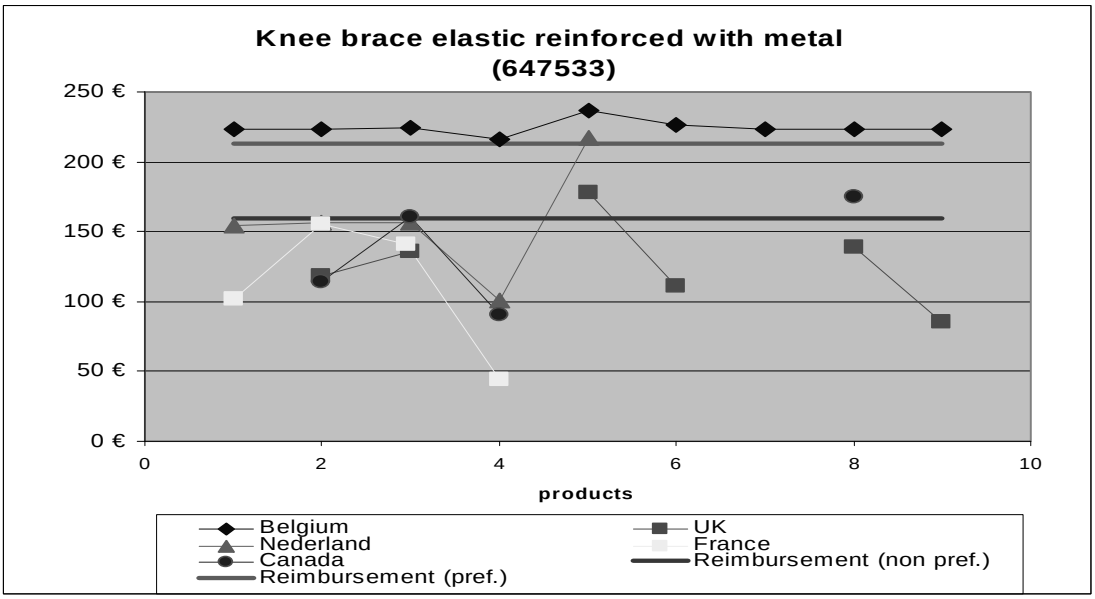


The market prices in Belgium are mostly higher than the prices in all other countries. For some specific products the prices in the UK, the Netherlands are higher. For the detailed information, we refer to the presentation of the results per country. There are different products that are sold at a lower price in the other countries than current reimbursement tariffs in Belgium.

5.8.1.3 *Prefab knee brace elastic tissue or neoprene reinforced with metal (nomenclature code 647533)*

The prices for the reinforced elastic knee brace are represented in the graph below.

Figure 32 : Price comparison knee nomenclature code 647533

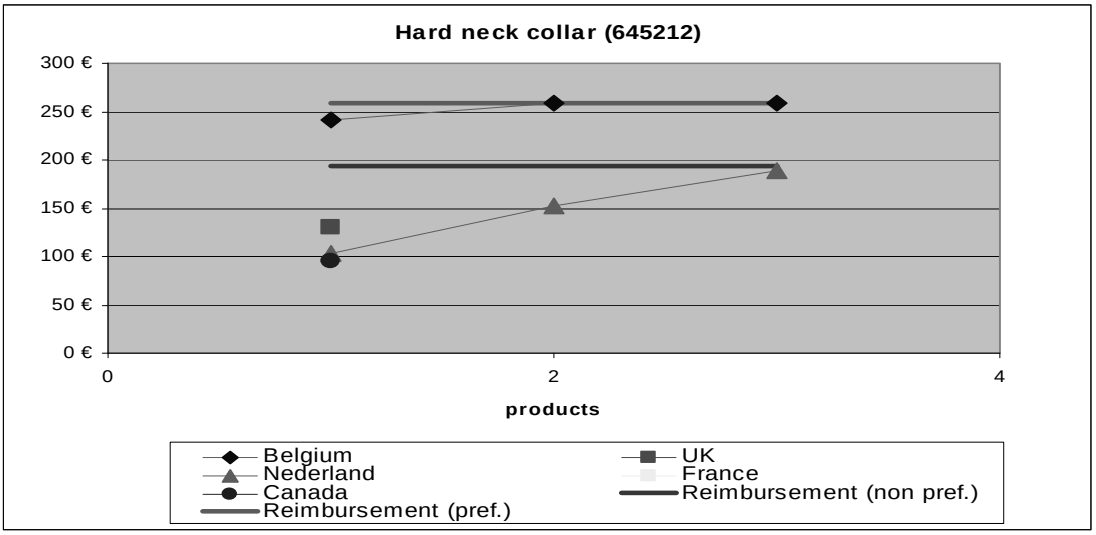


The Belgian prices all are much higher than those in the other countries. Strikingly, with the exception of one product found in the Netherlands, all foreign prices are below the highest Belgian reimbursement tariff and most even below the lowest Belgian reimbursement tariff.

5.8.2 The neck collars

5.8.2.1 Prefab stiff neck collar with support chin and/or back of the head adjustable in height (nomenclature code 645212)

Figure 33 : Price comparison neck nomenclature code 645212

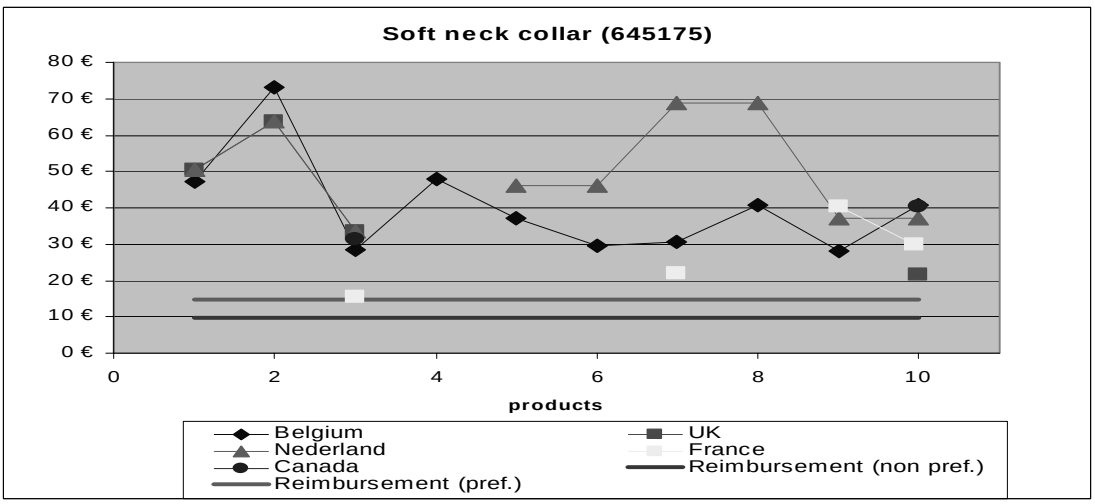


For the hard adjustable neck collars of the sample, one can conclude the Belgian prices are considerably higher than those in all other countries. As we could see in the price comparison per country, the Belgian price of the Jerome Miami J. collar, (first product on the graph with a market share of more than 75 % on the Belgian market) is considerably higher than the corresponding price in all other countries. In all other countries, the price of this collar is below than the lowest reimbursement tariff in Belgium.

5.8.2.2 Prefab soft collar (nomenclature code 645175)

The graph below gives an overview of all market prices collected in the different countries for the soft neck collar.

Figure 34 : Price comparison neck nomenclature code 645175

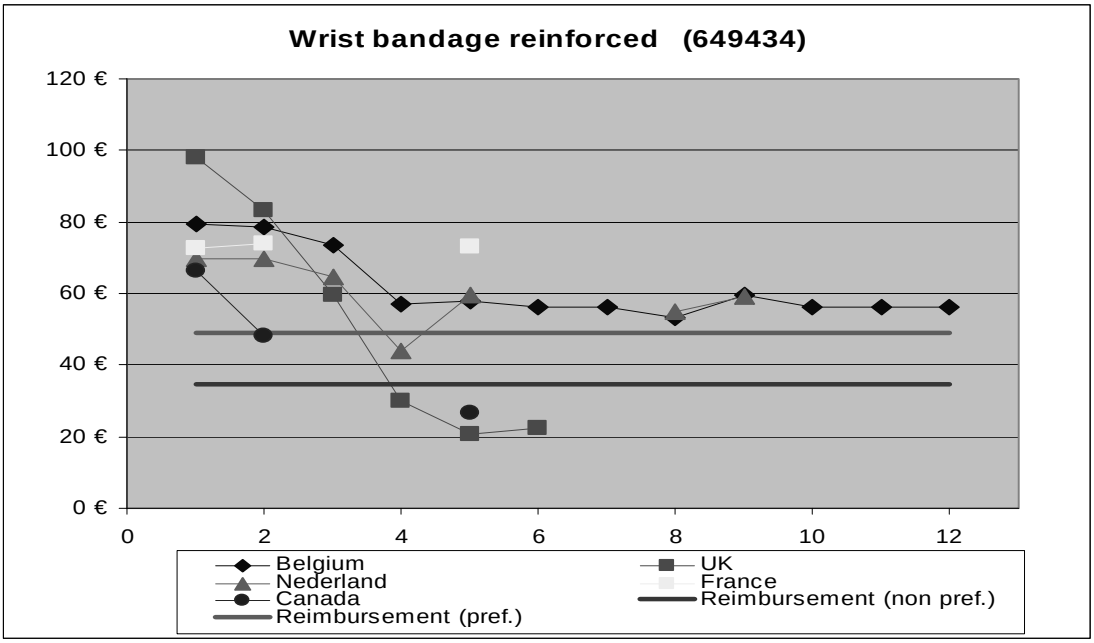


The graph shows very important difference in pricing for the soft neck collar. All prices are above the highest reimbursement tariff in Belgium (for preferential patients). Prices in the Netherlands mostly prove to be higher. This soft neck collar is not reimbursed in the Dutch and the Canadian health insurance system. For the other countries, prices are mostly lower than the Belgian prices.

5.8.3 The Wrist orthoses

5.8.3.1 Prefab wrist bandage, reinforced limiting movement (nomenclature code nr. 649434)

Figure 35 : Price comparison wrist nomenclature code 649434



Most of prices are in the same range. For the UK and for Canada most prices are lower than the ones in Belgium. For The Netherlands and for France prices are much the same as the ones in Belgium. Six products are sold at foreign prices below the highest Belgian reimbursement tariff.

Key points

- **Belgian market prices (at end – user level) for the hard knee braces, when compared with the corresponding prices in the other countries, are much higher. Different products in other countries are sold at a lower price than the amount reimbursed to the non-preferential patients in Belgium.**
- **For reinforced knee bandages, the Belgian market prices on the whole are higher than the prices in all other countries. In the other countries there are different products that are sold at a lower price than the amount reimbursed to the non preferential patients in Belgium**
- **For the elastic reinforced knee brace, the all Belgian market prices are much higher than those in the other countries. One finds different products that are sold at prices lower than the amount reimbursed to the Belgian non-preferential patients.**
- **For the hard adjustable neck collar the Belgian market prices are considerably higher than those in all other countries. The Belgian price of the Jerome Miami J. collar is much higher than the corresponding price in all other countries. In all other countries, the price of this collar is much lower than the amount reimbursed in Belgium**
- **For the soft neck collar, there are very important differences in market pricing. All prices are above the amount reimbursed in Belgium (for the non- preferential patients).**
- **For the reinforced wrist bandage, most of the market prices are in the same range. Nearly all prices exceed the amount that is reimbursed to the Belgian non – preferential patients Differences in prices are very substantial.**

5.9 SIMULATION OF TOTAL EXPENSES AND COMPARISON BETWEEN BELGIUM AND OTHER COUNTRIES

In the following paragraphs, we make a simulation of total expenses per product and per group of products (grouped according to the nomenclature codes). For each country, we calculate the total expenses for the different products for which the price comparison was made (at the prices found in the different countries). We compare these total expenses with the corresponding expenses for Belgium (at Belgian prices). This type of analysis enables us to make a cross-product assessment of cost differences for patients and third party payers between Belgium and the various countries in our panel of comparison.

To calculate the total expenses, we use the numbers of each product that have been sold in Belgium (sales 2006). These numbers are the numbers we collected through the survey to the distributors in Belgium[75]

Prices are the market prices (at end – user level) for all countries (at comparative price level - CPL).

By means of an overall comparative cost indication, simulation exercises were performed in order to estimate what the Belgian expenditures would be if foreign prices would have applied to similar products sold on the Belgian market. The tables below give the results of the comparison, per product, per nomenclature code and for the whole of the sample of products. For each country, we use the products for which a comparable price was found in Belgium and in the country under consideration.

75 See tables in paragraph 1.3 of this chapter

5.9.1 Comparison between Belgium and the Netherlands:

The table gives an overview of the expenses per product and per nomenclature code for Belgium and the Netherlands. The numbers of products used in the simulation are the numbers of the respective products sold on the Belgian market.

Table 54 : Comparison prices all nomenclature codes

RIZIV /INAMI Nomenclature code	Product	Number products sold/Year Belgium	Average market price BELGIUM (incl.VAT)	Average End-user Price NETHERLANDS (incl.VAT)	Prices Netherlands ADAPTED * 1,00	Total expenses Belgium	Total corresponding expenses NL	Difference total spending NL/B	Differ. in % NL/B
	Bledsoe Aligner ESE L/R	988	951 €	643 €	643 €	939.825	635.338	-304.487	-32%
	Bledsoe Axiom Sport	948	948 €	662 €	662 €	898.619	628.003	-270.616	-30%
	Bauerfeind SecuTec® Genu LR	319	948 €	558 €	558 €	302.383	177.934	-124.449	-41%
	Bauerfeind MOS Genu® Short	269	966 €	558 €	558 €	259.741	150.062	-109.679	-42%
	Donjoy Legend Funct. brace ACL	642	951 €	615 €	615 €	610.394	394.758	-215.637	-35%
	Thuasne Genu Pro Control C	259	948 €	652 €	652 €	245.509	168.989	-76.520	-31%
	C.Ti.2 (OSSUR)	350	1.030 €	1.117 €	1.117 €	360.581	390.860	30.279	8%
	Generation II unloader adj.	350	970 €	1.155 €	1.155 €	339.556	404.250	64.694	19%
Knee 647592	Medi M.4 ® OA	20	948 €	784 €	784 €	18.958	15.682	-3.277	-17%
SUBTOTALS						3.975.566	2.965.875	-1.009.691	-25%
	Bauerfeind Genutrain®	10.092	106 €	63 €	63 €	1.074.319	637.587	-436.731	-41%
	Bauerfeind Genutrain® P3	3.124	114 €	84 €	84 €	357.042	263.439	-93.603	-26%
	Bauerfeind Genutrain® A3	1.503	111 €	84 €	84 €	167.449	126.740	-40.709	-24%
	Push Care knee	328	103 €	105 €	105 €	33.722	34.488	767	2%
	Push Med knee	605	128 €	134 €	134 €	77.700	81.277	3.577	5%
Knee 647555	Thuasne Silistab Genu	261	106 €	92 €	92 €	27.786	23.924	-3.862	-14%
SUBTOTALS						1.738.018	1.167.456	-570.561	-33%
	Donjoy Drytec	342	223 €	154 €	154 €	76.283	52.689	-23.594	-31%
	Bauerfeind Genutrain® S	2.011	223 €	157 €	157 €	448.795	314.988	-133.807	-30%
	Thuasne Ligaflex Evolution	1.184	225 €	156 €	156 €	265.832	184.784	-81.048	-30%
	Thuasne Ligaflex 2370	1.036	216 €	100 €	100 €	223.714	104.035	-119.679	-53%
Knee 647533	Otto Bock Genu Track	60	237 €	217 €	217 €	14.228	13.017	-1.211	-9%
SUBTOTALS						1.028.851	669.514	-359.338	-35%
	Jerome Miami J.Collar	477	241 €	103 €	103 €	114.776	48.958	-65.818	-57%
Neck 645212	Malibu halskraag 06/3020	50	259 €	153 €	153 €	12.939	7.639	-5.300	-41%
SUBTOTALS						127.714	56.597	-71.117	-56%
	Push Care 8 cm en 10 cm	1.288	47 €	50 €	50 €	60.575	64.899	4.324	7%
	Push nek Med 8 cm en 10 cm	1.274	73 €	64 €	64 €	93.168	81.151	-12.017	-13%
	Thuasne Ortel C1	2.118	28 €	34 €	34 €	60.215	71.340	11.125	18%
	Basko Camp 5750	950	37 €	46 €	46 €	35.188	43.736	8.548	24%
	Thamert 49/190	1.691	30 €	69 €	69 €	51.525	116.218	64.693	126%
Neck 645175	DeRoyal Foam cervical collar	837	28 €	37 €	37 €	23.670	31.063	7.393	31%
SUBTOTALS						324.340	408.406	84.066	26%
Wrist 649434	Bauerfeind ManuLoc®	474	79 €	70 €	70 €	37.617	33.114	-4.503	-12%

RIZIV /INAMI Nomenclature code	Product	Number products sold/Year Belgium	Average market price BELGIUM (incl.VAT)	Average End-user Price NETHERLANDS (incl.VAT)	Prices Netherlands ADAPTED * 1,00	Total expenses Belgium	Total corresponding expenses NL	Difference total spending NL/B	Differ. in % NL/B
	Bauerfeind ManuTrain®	1.124	79 €	70 €	70 €	88.324	78.523	-9.801	-11%
	Push Med wrist	5.820	73 €	65 €	65 €	427.130	375.725	-51.405	-12%
	Push Care wrist	456	57 €	44 €	44 €	25.919	19.945	-5.974	-23%
	Donjoy Elastic wrist brace	1.690	58 €	59 €	59 €	97.598	100.449	2.852	3%
	DeRoyal - Manex Reuma Long	234	53 €	55 €	55 €	12.465	12.818	353	3%
	DeRoyal - Manex Reuma Pollus	536	60 €	59 €	59 €	31.956	31.655	-302	-1%
SUBTOTALS						721.008	652.229	-68.780	-10%
TOTALS						7.915.498	5.920.077	-1.995.421	-25%

For all products for which comparable prices were obtained in Belgium and in the Netherlands, the simulation results in a difference of total spending of 1.995.420,91 € or 25,21 % between Belgium and the Netherlands. This means the total cost for the Netherlands is 25,21 % lower than for Belgium.

The Dutch end – users would pay between 25,40 % to 34,93 % less for the different types of knee orthoses (within the scope of the study) than the coresponding sum paid for in Belgium (for the same products at the numbers of products sold in belgium over 2006).

For the hard neck collar the total expenses at market prices are 55,68 % lower for the Netherlands compared with Belgium. For the soft neck collar, the situation is reverse as the Netherlands pay 25,92 % more than Belgium. We draw attention to the fact that, contrary to the Belgian reimbursement system, the soft collar is not reimbursed in the Netherlands.

For the wrist bandage the results of the comparison demonstrate the calculated expenses for the Netherlands are 9,54 % lower than the respective expenses for Belgium.

5.9.2 Comparison between Belgium and France:

The table gives an overview of the expenses per product and per nomenclature code for Belgium versus the simulated expenses for France. The numbers of products used in the simulation are the numbers of the respective products sold on the Belgian market.

Table 55 : Comparison prices all nomenclature codes

RIZIV /INAMI Nomenclature code	Product	Number products sold/Year Belgium	Average market price BELGIUM (incl.VAT)	Average End-user Price FRANCE (incl.VAT)	Prices France ADAPTED * 1,02	Total expenses Belgium	Total corresponding expenses FRANCE	Difference total spending FR/B	Difference in % FR/B
Knee 647592	Bauerfeind SecuTec® Genu LR	319	948 €	425 €	434 €	302.383 €	138.287 €	-164.097 €	-54%
	Bauerfeind MOS Genu® Short	269	948 €	690 €	704 €	254.988 €	189.322 €	-65.666 €	-26%
	Donjoy Legend Funct. brace ACL	642	951 €	595 €	607 €	610.394 €	389.630 €	-220.765 €	-36%
	C.Ti.2 (OSSUR)	350	1.030 €	947 €	966 €	360.581 €	338.179 €	-22.402 €	-6%
	Generation II unloader adj.	350	970 €	947 €	966 €	339.556 €	338.079 €	-1.477 €	-0%
SUBTOTALS						1.867.902 €	1.393.496 €	-474.405 €	-25%
Knee 647555	Bauerfeind Genutrain®	10.092	106 €	66 €	67 €	1.074.394 €	679.393 €	-395.001 €	-37%
	Bauerfeind Genutrain® P3	3.124	114 €	118 €	120 €	357.042 €	374.411 €	17.369 €	5%
	Bauerfeind Genutrain® A3	1.503	111 €	86 €	88 €	167.449 €	131.843 €	-35.606 €	-21%
	Thuasne Silistab Genu	261	106 €	59 €	61 €	27.786 €	15.824 €	-11.962 €	-43%
	Medi.ortho Genumedi®	250	106 €	57 €	58 €	26.610 €	14.550 €	-12.060 €	-45%
	Medi.ortho elastic knee support	150	106 €	26 €	26 €	15.969 €	3.938 €	-12.031 €	-75%
SUBTOTALS						1.669.251 €	1.219.961 €	-449.290 €	-27%
Knee 647533	Donjoy Drytec 11-0555	342	223 €	102 €	104 €	76.283 €	35.683 €	-40.600 €	-53%
	Bauerfeind Genutrain® S	2.011	223 €	156 €	159 €	448.795 €	318.965 €	-129.830 €	-29%
	Thuasne Ligaflex Evolution	1.184	225 €	141 €	143 €	265.832 €	169.884 €	-95.947 €	-36%
	Thuasne Ligaflex 2370	1.036	216 €	44 €	45 €	223.714 €	46.760 €	-176.954 €	-79%
SUBTOTALS						1.014.623 €	571.292 €	-443.332 €	-44%
Neck 645175	Thuasne Ortel C1	2.118	28 €	16 €	16 €	60.215 €	33.680 €	-26.535 €	-44%
	Thamert	1.691	30 €	22 €	22 €	51.525 €	37.946 €	-13.579 €	-26%
	DeRoyal Foam cervical collar	837	28 €	41 €	41 €	23.670 €	34.576 €	10.906 €	46%
	Otto Bock Necky Color	685	41 €	30 €	31 €	27.955 €	20.961 €	--6.994 €	-25%
SUBTOTALS						163.365 €	127.164 €	-36.201 €	-22%
Wrist 649434	Bauerfeind ManuLoc®	474	79 €	73 €	74 €	37.617 €	35.091 €	-2.526 €	-7%
	Bauerfeind ManuTrain®	1.124	79 €	74 €	75 €	88.324 €	84.840 €	-3.484 €	-4%
	Donjoy Elastic wrist brace	1.690	58 €	73 €	75 €	97.598 €	126.268 €	28.671 €	29%
SUBTOTALS						223.538 €	246.199 €	22.661 €	10%
TOTALS						4.938.679 €	3.558.111 €	-1.380.568 €	-28%

For all products for which we obtained comparable French market prices, the simulation results in a difference of total spending of 1.380.567,53 € between Belgium and France. This means the total cost for the same orthoses, in France is 27,95 % lower than in Belgium.

For the knee orthoses, the differences in spending would vary between 25,40 % to 43,69 %.

For the hard neck collar, no simulation was possible since we do not have comparable prices for France.

The amounts spent on the soft neck collar for Belgium versus France differ less with a difference of 22,16 %. The total expenses (at market prices) for the wrist bandage are higher in France. The simulated expenses for France are 10,14 % higher than the expenses for Belgium.

5.9.3 Comparison between Belgium and the UK:

The table represents the expenses per product and per nomenclature code for Belgium compared with the UK. As mentioned in the paragraph on the UK prices, the prices for the UK are the contract prices paid for the orthoses by the NHS, which do not not include the salary costs of the orthotists.

Table 56 : Comparison prices all nomenclature codes

RIZIV /INAMI Nomenclature code	Product	Number products sold/Year Belgium	Average marketprice BELGIUM (incl.VAT)	Average End-user Price UK (incl.VAT)	Prices UK ADAPTED * 1,01	Total expenses Belgium	Total corresponding expenses UK	Difference total spending UK/B	Differ. in % UK/B
Knee 647592	Bauerfeind SecuTec® Genu LR	319	948 €	516 €	521 €	302.383 €	166.343 €	-136.040 €	-45%
	Bauerfeind MOS Genu® Short	269	948 €	641 €	647 €	254.988 €	174.161 €	-80.826 €	-32%
	Donjoy Legend Funct. brace ACL	642	951 €	511 €	516 €	610.394 €	331.407 €	-278.987 €	-46%
	Donjoy 4-titude	874	948 €	546 €	551 €	828.473 €	481.755 €	-346.718 €	-42%
	C.Ti.2 (OSSUR)	350	1.030 €	885 €	894 €	360.581 €	312.738 €	-47.843 €	-13%
	Medi M.4 ® ACL	134	948 €	511 €	516 €	127.020 €	69.172 €	-57.848 €	-46%
	Medi M.4 ® OA G045203	20	948 €	632 €	639 €	18.958 €	12.774 €	-6.184 €	-33%
	SUBTOTALS					2.502.797 €	1.548.352 €	-954.445 €	-38%
Knee 647555	Bauerfeind Genutrain®	10.092	106 €	83 €	84 €	1.074.394 €	847.643 €	-226.751 €	-21%
	Bauerfeind Genutrain® P3	3.124	114 €	132 €	133 €	357.042 €	415.450 €	58.408 €	16%
	Bauerfeind Genutrain® A3	1.503	111 €	132 €	133 €	167.449 €	199.879 €	32.430 €	19%
	Push Care knee	328	103 €	58 €	59 €	33.722 €	19.277 €	-14.444 €	-43%
	Push Med knee	605	128 €	104 €	105 €	77.700 €	63.415 €	-14.285 €	-18%
	Thuasne Silistab Genu	261	106 €	68 €	68 €	27.786 €	17.807 €	-9.979 €	-36%
	Otto Bock Genu Sensa	250	106 €	50 €	50 €	26.615 €	12.501 €	-14.114 €	-53%
	Medi.ortho Genumedi®	250	106 €	45 €	46 €	26.610 €	11.378 €	-15.232 €	-57%
	Medi ortho elastic knee support	150	106 €	24 €	25 €	15.969 €	3.675 €	-12.294 €	-77%
	SUBTOTALS					1.807.287 €	1.591.026 €	-216.262 €	-12%
Knee 647533	Bauerfeind Genutrain® S	2.011	223 €	118 €	119 €	448.795 €	239.285 €	-209.510 €	-47%
	Thuasne Ligaflex Evolution	1.184	225 €	135 €	137 €	265.832 €	162.024 €	-103.807 €	-39%
	Otto Bock Genu Track	60	237 €	178 €	180 €	14.228 €	10.798 €	-3.429 €	-24%
	Otto Bock Genu Direxa stable wrap	60	226 €	111 €	112 €	13.564 €	6.750 €	-6.815 €	-50%
	Donjoy Tru-Pull hinged	96	223 €	139 €	140 €	21.413 €	13.439 €	-7.974 €	-37%
	Medi hinged knee Proo	160	223 €	85 €	86 €	35.688 €	13.720 €	-21.968 €	-62%
						799.519 €	446.016 €	-353.503 €	-44%
Neck 645212	Jerome Miami J.Collar	477	241 €	130 €	131 €	114.776 €	62.601 €	-52.175 €	-45%
	SUBTOTALS					114.776 €	62.601 €	-52.175 €	-45%
Neck 645175	Push Care 8 cm en 10 cm	1.288	47 €	50 €	51 €	60.575 €	65.551 €	4.977 €	8%
	Push nek Med 8 cm en 10 cm	1.274	73 €	64 €	64 €	93.168 €	81.965 €	-11.202 €	-12%
	Thuasne Ortel C1	2.118	28 €	34 €	34 €	60.215 €	72.048 €	11.833 €	20%
	Otto Bock Necky	685	41 €	22 €	22 €	27.955 €	14.985 €	-12.969 €	-46%

RIZIV /INAMI Nomenclature code	Product	Number products sold/Year Belgium	Average marketprice BELGIUM (incl.VAT)	Average End-user Price UK (incl.VAT)	Prices UK ADAPTED * 1,01	Total expenses Belgium	Total corresponding expenses UK	Difference total spending UK/B	Differ. in % UK/B
	Color								
SUBTOTALS						241.912 €	234.550 €	-7.362 €	-3%
Wrist 649434	Bauerfeind ManuLoc®	474	79 €	98 €	99 €	37.617 €	46.945 €	9.329 €	25%
	Bauerfeind ManuTrain®	1.124	79 €	83 €	84 €	88.324 €	94.407 €	6.083 €	7%
	Push Med wrist	5.820	73 €	60 €	60 €	427.130 €	350.341 €	-76.789 €	-18%
	Push Care wrist	456	57 €	30 €	30 €	25.919 €	13.849 €	-12.070 €	-47%
	Donjoy Elastic wrist brace	1.690	58 €	21 €	21 €	97.598 €	35.486 €	-62.111 €	-64%
	Medi wrist support	1.866	56 €	23 €	23 €	105.093 €	42.461 €	-62.632 €	-60%
SUBTOTALS						781.680 €	583.489 €	-198.191 €	-25%
TOTALS						6.247.972 €	4.466.034 €	-1.781.938 €	-29%

As is clear from the numbers in the table above, the total costs for the corresponding orthoses for the UK is 1.781.937,75 € lower than for Belgium. The difference is of 28,52 %.

For the knee braces, the differences are between 11,97 % and 44,21 %.

Total expenses for the hard neck collar are (only for the Jerome Miami J. collar) 45,46 % lower in the UK.

The expenses for the soft neck collar for Belgium versus the UK are comparable. The total expenses (at market prices) for the wrist bandage are 25,35 % lower in the UK.

5.9.4 Comparison between Belgium and Ontario - Canada:

The table below gives an overview of the expenses per product and per nomenclature code for Belgium compared with Ontario. The numbers of products used in the simulation are the numbers of the respective products sold on the Belgian market.

Table 57 : Comparison prices all nomenclature codes

RIZIV /INAMI Nomenclature code	Product	Number products sold/Year Belgium	Average market price BELGIUM (incl.VAT)	Average End-user Price Ontario (incl.VAT)	Prices Netherlands ADAPTED * 0,92	Total expenses Belgium	Total corresponding expenses Ontario	Difference total spending CAN/B	Differ in % CAN/B
	Bauerfeind SecuTec® Genu LR	319	948 €	426 €	392 €	302.383 €	125.111 €	-177.273 €	-59%
	Bauerfeind MOS Genu® Short	269	948 €	566 €	521 €	254.988 €	140.118 €	-114.870 €	-45%
	Donjoy Legend Funct. brace ACL	642	951 €	708 €	651 €	610.394 €	418.220 €	-192.174 €	-31%
	Donjoy 4-titude	874	948 €	708 €	651 €	828.473 €	569.353 €	-259.120 €	-31%
	THUASNE GENU PRO Control CI	259	948 €	854 €	786 €	245.509 €	203.484 €	-42.025 €	-17%
Knee 647592	Generation II unloader adj.	350	970 €	477 €	439 €	339.556 €	153.555 €	-186.001 €	-55%
SUBTOTALS						2.581.303 €	1.609.841 €	-971.462 €	-38%
	Bauerfeind Genutrain®	10.092	106 €	49 €	45 €	1.074.394 €	453.462 €	--620.933 €	-58%
	Bauerfeind Genutrain® P3	3.124	114 €	82 €	76 €	357.042 €	235.991 €	-121.051 €	-34%
	Bauerfeind Genutrain® A3	1.503	111 €	82 €	76 €	167.449 €	113.538 €	-53.911 €	-32%
	Thuasne Silistab Genu	261	106 €	84 €	77 €	27.786 €	20.064 €	-7.722 €	-28%
Knee 647555	Otto Bock Genu Sensa	250	106 €	37 €	34 €	26.615 €	8.515 €	-18.100 €	-68%

RIZIV /INAMI Nomenclature code	Product	Number products sold/Year Belgium	Average market price BELGIUM (incl.VAT)	Average End-user Price Ontario (incl.VAT)	Prices Netherlands ADAPTED * 0,92	Total expenses Belgium	Total corresponding expenses Ontario	Difference total spending CAN/B	Differ in % CAN/B
SUBTOTALS						1.653.287 €	831.570 €	-821.717 €	-50%
	Bauerfeind Genutrain® S	2.011	223 €	115 €	106 €	449.036 €	212.227 €	-236.809 €	-53%
	Thuasne Ligaflex Evolution	1.184	227 €	160 €	147 €	268.330 €	174.448 €	-93.882 €	-35%
	Thuasne Ligaflex 2370	1.036	226 €	91 €	83 €	233.670 €	86.276 €	-147.393 €	-63%
Knee 647533	Donjoy Tru Pull hinged	96	223 €	175 €	161 €	21.413 €	15.492 €	-5.921 €	-28%
SUBTOTALS						972.449 €	488.444 €	-484.005 €	-50%
Neck 645212	Jerome Miami J.Collar	477	241 €	95 €	87 €	114.776 €	41.523 €	-73.253 €	-64%
	Thuasne Ortel C1	2.118	28 €	31 €	29 €	60.215 €	61.048 €	834 €	1%
Neck 645175	Otto Bock Necky Color	685	41 €	41 €	37 €	27.955 €	25.542 €	-2.413 €	-9%
SUBTOTALS						88.170 €	86.590 €	-1.579 €	-2%
	Bauerfeind ManuLoc®	474	79 €	66 €	61 €	37.617 €	28.890 €	-8.726 €	-23%
	Bauerfeind ManuTrain®	1.124	79 €	48 €	44 €	88.324 €	49.739 €	-38.585 €	-44%
Wrist 649434	Donjoy Elastic wrist brace	1.690	58 €	26 €	24 €	97.598 €	41.156 €	-56.442 €	-58%
SUBTOTALS						223.538 €	119.785 €	-103.753 €	-46%
TOTALS						5.633.522 €	3.177.754 €	-2.455.768 €	-44%

The table above shows the hypothetical total expenses for Ontario are 2.455.768,10 € lower than those for Belgium. This results in a difference of 43,59 %.

For the different types of knee braces, the differences in expenses vary from 37,63 % to 49, 77 %. (classified per nomenclature code).

Total expenses for the hard neck collar in Ontario are 63,82 % lower than expenses for Belgium. The total expenses on the soft neck collar for Belgium versus Ontario are nearly equal. They differ only 1,79 %. For the wrist bandage total expenses (at market prices) are also much lower in Ontario where one sees a difference of 46,41 %.

Key points

- **The simulation shows a much higher total spending for Belgium versus the Netherlands. For the compared product basket, the aggregate difference is 1.995.420,91 €. The total cost for the Netherlands would be 25,21 % lower than for Belgium.**
- **Comparing Belgium with France for all products for which we obtained comparable market prices, the simulation results in a higher total spending of 1.380.567,53 € for Belgium. The total cost for France would be 27,95 % lower than for Belgium.**
- **Comparison between Belgium and the UK is not completely possible. The NHS pays the wages of the orthotists in surplus to the prices of the orthoses. The results of the simulation are, the global spending at product level would be 1.781.937,75 € more in Belgium than in the UK. The difference is of 28,52 %.**
- **Compared with Canada, total expenses for Ontario are 2.455.768,10 € lower than those for Belgium. This results in a difference of 43,59 %**

6 COST ANALYSIS OF TWO ORTHOSES

6.1 INTRODUCTION

One objective of this study was to estimate the production costs for two selected prefab orthoses.

First, we will give an overview of the general methodology. We describe the criteria used to select two brands, the involvement by manufacturers and alternative sources used to build the cost model.

Second, we will describe the methodology underlying the cost model starting by the identification of the main cost drivers. Afterwards we mapped the relationships between - and the calculations behind the different elements (cost drivers) and quantified the cost elements using various hypotheses. In the last phase the model was reviewed by an external expert and adapted according to his remarks. The results of the aggregated model were disseminated towards the industry for feedback.

In the third part of this chapter we describe the data collection process and the data used

In the following part we elaborate the development of the calculation model which is based on the different production steps for a hard knee brace and a hard neck brace. We describe the general assumptions applicable to every production step, as well as the specific assumptions regarding machinery and specific production steps. Finally we present the results of the aggregated model for the hard knee brace and the hard neck brace in absolute figures and the relative importance of the different cost drivers in the total manufacturing cost and the total price FOB (free on board)

Finally, we will compare the results of the aggregated model with the price level in Belgium.

6.2 GENERAL METHODOLOGY

6.2.1 Selection of two products (brands)

The selection of 2 products was based on a combination of the following criteria

- Critical appraisal of scientific literature on (cost) effectiveness, as described in chapter II, resulting in the observation that medical indications were found for the nomenclature code for hard knee braces (647592) and the nomenclature code for hard neck braces (645212).
- The reimbursement expenses for RIZIV / INAMI in 2005, as described in chapter IV "market analysis on orthotic devices", indicating that the nomenclature code for hard knee braces (647592) represented 63,1 % of the all reimbursed expenses for prefabricated knee orthoses. From a budgetary viewpoint this nomenclature code was of utmost importance. Furthermore, the nomenclature code of hard neck braces (645212) represented with only 6,6 % of the reimbursed cases 19,3 % of the total reimbursed expenses for prefabricated neck orthoses.
- The market share of brands as described in chapter IV "market analysis" on orthotic devices, showing that the most important manufacturers for hard knee braces, active on the Belgian market are Bledsoe, Donjoy and Bauerfeind. The decision was taken to take the Donjoy 4 titude brace as a basis for the development of the cost model and the related cost price estimation. With respect to the most important product (brand) in the category of hard neck braces, the Jerome Miami collar is taken as a basis for the development of the cost model and related cost price estimation.

Key points

- **The selection of the two nomenclature codes (product categories) and the two specific brands for the cost price analyses was based on the following criteria:**
- **Medical indications (chapter II)**
- **The importance of RIZIV / INAMI reimbursement expenses**
- **The market share of specific brands within a nomenclature code.**
- **As a result the Donjoy 4 titude (hard knee brace) and the Jerome Miami collar (hard neck brace) were selected for further investigation.**

6.2.2 Involvement of manufacturers / local distributors

In order to give a correct view on the production cost of hard knee braces and hard neck braces, not only from the end user's or third part payer's view point (see also chapter V international price comparison for a selection of orthotic devices), the manufacturers were actively involved in an information round for this part of the study.

Questionnaire on production cost for hard knee braces and hard neck braces

A questionnaire was sent to representatives of various manufacturers. The questionnaire aimed at providing more information on:

- the importance of orthoses for the company;
- the production type of the company (custom made versus standard production);
- the market share in a selection of countries;
- the general cost structure – cost elements in the production cycle;
- research & development indicators (budget, number of people, patents, development time, success rate);
- raw materials used and their cost impact;
- the manufacturing process (production sites, products, personnel involved, capital versus labour intensive, production organisation, manufacturing equipment, production steps, mark-up for sustainable activity).

In this questionnaire the possibility was given to provide confidential information not to be part of the formal evaluation, but to inform internal opinion of the study experts.

As there are no Belgian manufacturers of hard knee braces or hard neck braces, we asked the cooperation of the Belgian distributors in order to reach their respective manufacturers.

8 manufacturers, all active on the Belgian market, received the questionnaire through their local distributors.

The complete questionnaire can be found in appendix VI.

6.2.3 Visit production site

The research team was given the opportunity to visit the Bauerfeind production site in Germany – Kempen where hard knee braces are manufactured. This visit was very instrumental in our search for accurate knowledge of the production of hard knee braces and the assembling process of semi finalised products.

6.2.4 Feedback on the cost model

The manufacturers and/or local distributors have the opportunity to transmit comments on the aggregated cost model

Key points

- **Manufacturers and/or local distributors were invited to participate in the information gathering process by means of a questionnaire and feed back on the aggregated results of the production cost exercise.**

6.2.5 Involvement of materials experts

In order to learn more about raw materials used to manufacture hard knee and hard neck braces, the research team visited three material experts from the following institutions:

- Centre for Materials Science and engineering (UGent)
- Leuven Materials Research Centre (MRC - KULeuven)
- Division of Biomechanics and engineering design (KULeuven)

6.2.6 Involvement of manufacturers of semi finished products

To learn more about the production process of hard knee braces the research team visited a sheet-metal stamping manufacturer. These products are used as semi manufactured articles in the production cycle.

To learn more about the production process of hard neck braces the research team visited a manufacturer, specialised in injection moulding processes.

Both visits gave the research team a good insight in the complexity of the production cycle.

6.2.7 Desk research

6.2.7.1 Public health obligations

Every manufacturer of medical devices that wants to sell these products on the European market should follow the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Medical devices are grouped into four product classes. Orthoses are, as all non-invasive devices, Class I products. The conformity assessment procedures for Class I devices can be carried out, as a general rule, under the sole responsibility of the manufacturers in view of the low level of vulnerability associated with these products.

The manufacturer must draw up a written declaration of conformity to the directive and the products themselves must bear the CE marking of conformity when they are placed on the market.

Key points

- **According to the Council directive 93/42/EEC of 14 June 1993 concerning medical devices, orthoses (hard knee braces and hard neck braces) are Class I products. Manufacturers must draw up a written declaration of conformity to the directive and the products must bear the CE marking of conformity.**

6.2.7.2 Economic and market information

Annual reports and other financial information for manufacturers have been studied to gain the necessary knowledge on the firm, its structure and key financial figures that could be useful.

For this study we also had access to Deloitte's Life Sciences Global Benchmark Study. This benchmark study provides information on business performance, customer service, inventory, sourcing, manufacturing, distribution and product innovation in the life sciences industry. Especially the information on the medical devices industry sub segment was of interest.

Key points

- **Desk research was performed in order to provide accurate information to build the cost model.**

6.3 DEVELOPMENT OF A COST MODEL

6.3.1 Introduction

The ambition of the production cost analysis is to present an accurate and reliable cost price for two specific products: a hard knee brace (Donjoy 4 titude) and a hard neck brace (Jerome Miami J. collar). To attain this result and execute the study in a transparent and open way Deloitte involved manufactures of this type of products via their local distributors. A questionnaire that contained elements for the development of the cost model was sent to all of them. As a result of the little information given by the industry, the resulting cost model can only approximate this initial ambition. The cost price presented here gives an idea on the order of the price without claiming to give the exact cost price of each item.

6.3.2 Methodology

The methodology followed for the development of a cost model consists of four different phases.

In a first phase the different cost drivers that have an impact on the cost of the product were determined. These include elements as raw materials, machinery, direct and indirect labour, manufacturing overhead, research and development, etc. To make sure that all cost drivers involved in the production were covered, the cost model was built according to a generic production process and contained the detailed cost drivers for all production steps.

In the second phase the relationships between and the calculations behind the different elements (cost drivers) were mapped. Here also the production process was used as guidance. As a result the actual cost model was developed using a spreadsheet application. The focus of the calculation is based on the costs incurred by the product as it leaves the factory of the producer, referred to as the price FOB (i.e. Free On Board).

In the third phase all cost elements involved were quantified using a number of hypotheses. Information for this analysis was obtained by contacts with the industry / local distributors, the visit of a production site, desk research, contacts with experts in the field, contacts with other companies (e.g. suppliers, similar products or production types) and industry knowledge. For every cost driver that had to be quantified we used present day market prices as given for the different cost items.

In the last phase, the draft of the model was reviewed by an external expert (08/05/2007). We adapted the model accordingly to the comments received before sending it to the manufacturers / local distributors.

Manufacturers / local distributors also had the possibility to share comments on the results of the aggregated cost model.

Key points

- **The development of the cost model consisted of four phases:**
- **Determining the cost drivers**
- **Mapping the relationships between and the calculations behind the cost drivers**
- **Quantification of the cost elements**
- **Review/ validation of the cost model at two levels: external expert (modeling and assumptions) – manufacturers/local distributors (aggregated results of the cost model)**

6.4 DATA COLLECTED AND USED

6.4.1 Scarce Information from the manufacturers/local distributors on the production process

To obtain industry information on the production of the specified product categories (hard knee brace and hard neck collar) a questionnaire was developed and sent to the manufacturers, as described in the previous paragraphs.

Two reactions on this questionnaire were received. A first firm indicated they were not willing to complete the questionnaire. A second firm did send the questionnaire back with limited information. According to this manufacturer the break up of production costs for hard knee braces is as follows:

- Research & development: 30 %
- Raw material: 10 %
- Manufacturing process: 20 %
- Warehousing: 5 %
- Distribution and transport: 5 %
- Marketing: 20 %
- Others: 10 %

It became clear that the response of the industry which could have created more transparency in the production cost make-up, was very low.

6.4.2 Diverse data sources

The research team gathered information from a wide range of sources including

- Disassembly, analysis and study of finished samples of finished products;
- Expert input on the technical details for raw materials (e.g. LDPE - low density poly ethylene)
- Information from catalogues, brochures and internet websites, describing the (main) product components, and the principal raw materials (ingredients) used for the manufacturing of each component;
- Information based on the patents of the brands
- Visit of a production site;
- General and specific information received on the product life cycle, the (global) amount of investments made, the quality control activities and organisation, … during the interviews with the manufacturer's local distributors (see chapter market analyses)

- Information received from machine constructors concerning the purchase, operational and maintenance costs for the typical machines used in these manufacturing processes (injection moulding, sheet-metal stamping,etc.)
- Information obtained for raw materials, in particular average market price levels;
- Information on the turnover and operational costs of the manufacturers, as published in annual reports (R&D costs, …)
- General industry, manufacturing and distribution knowledge: average labour personnel costs, warehousing, etc.

6.5 DESCRIPTION OF THE COST MODEL – THE HARD KNEE BRACE AND THE HARD NECK BRACE

6.5.1 Introduction – Product and production characteristics

The hard knee brace and the hard neck brace can be categorized as rather uncomplicated products.

The used materials are of high to very high quality, but relatively easy to find on the market. The production and the production process of the different pieces of the knee brace and hard neck brace are, although of high quality, relatively straightforward. Also the assembling process does not show a high level of complexity.

The dominant aspect in the cost factor is the fact that this relatively simple product can not be seen as a mass product. This fact has an important, negative impact on different aspects of the pricing. Due to the limited volumes the manufacturers are not in a comfortable position to negotiate and lower the prices for raw materials; the cost of investment in machinery has to be written off over a limited number of products (due to this phenomena these costs are by far the most important) and due to the limited volume the robotization of the assembly process is not yet reality.

6.5.2 Production steps

6.5.2.1 Hard knee brace

The production of the hard knee brace at the manufacturing site can typically be split into the following steps: production of different types of moulds – cutting, rolling, bending and injection moulds

Specifically for the production of the hard knee brace are

- Production of the two hardware parts of the knee brace (frame)
- Coating of the hardware parts (frame)
- Accessory pieces (fittings) to adjust the hard knee brace
- Production of protective materials
- Production of hinge pieces
- Production of attachment parts
- Assembly of semi finished products picking, packaging, shipping, warehousing.

In the detailed cost model the following cost items were taken into account to calculate the manufacturing costs:

Mould costs for:

- Production of moulds (upper and lower part) for cutting, rolling, cutting & cleaning, bending first move, bending second move

- Production of mould for the fittings
- Production of mould – protection pieces with as sub items front part, side part, knee joint
- Production of mould for hinge pieces and attachments parts

Start up and direct costs for:

- Cutting of pieces (lower and upper part)
- Rolling of pieces (lower and upper part)
- Cutting and cleaning (lower and upper part)
- Bending first move (lower and upper part)
- Bending second move (lower and upper part)
- Production of fittings
- Injection of hinge pieces
- Injection of attachments parts

Start up costs includes the stand still costs of the machinery, the labor cost of the operator for the preparation of the machinery

Direct costs for:

- Coating of metal pieces
- Production of attachment pieces (ribbons)
- Other materials
- Assembly and packaging

6.5.2.2 Hard neck brace

Specific factors for the production of the hard neck brace are:

- Production of the four frame pieces (front above / front below / back above / back below), which are the results on an injection moulding process.
- Production of protective materials
- Production of fastening materials
- Assembly of semi-finished products, packaging, shipping, warehousing, picking, distribution.

In the detailed cost model the following cost items were taken into account to calculate the manufacturing costs:

Mould costs for:

- The two front components
- The two back pieces components
- Angulation rivets
- Transparent rivets

Start up and direct costs for the injection process of the

- Two front components
- Two back components
- Angulation rivets
- Transparent rivets

Direct costs for:

- Protection pieces
- Attachment pieces
- Sternal pad
- Assembly and packaging

6.6 AGGREGATED RESULTS

The costs incurred in these production steps have been divided into the following components in our model:

- Raw materials used in the production step;
- Direct labour such as operating and packaging;
- Indirect labour such as engineering;
- Machine cost.

Research and development, warehousing, general overhead and profit were not split by the above components. It is assumed that warehousing, general overhead, Research & Development and profit can be calculated as a function (mark-up) of an intermediate cost calculation (incl. manufacturing costs). As the products are manufactured in small quantities, between fixed and variable costs were distinguished.

6.6.1 Assumptions used

Given the confidential information and insights received from several sources and used in this model, it is unfortunately not possible to disclose all estimates and hypotheses in this publication. Some of the information is related to a certain manufacturer and can therefore not be disclosed.

The assumptions used can be divided into two broad categories. General assumptions are presented here with figures. Some more detailed assumptions related to specific production steps and machines are only explained in brief in this report.

6.6.1.1 General assumptions

The mark-up added to manufacturing costs for **warehouse operations** is set at 2 % of manufacturing costs. This is based on the Deloitte Global Benchmark Study on Life Sciences (August 2004), indicating this figure holds for the sector of medical devices.

The mark-up for **general overhead** is set at 8 % added to the intermediate cost price (manufacturing costs + warehouse costs)

The mark-up for **research and development** is set at 10 % of manufacturing costs + warehouse costs + general overhead costs. In the Eucomed report, the percentage of research & development in terms sales is 12,9 % for the U.S and 6,35 % for Europe (15) This is based on the annual accounts of the manufacturers. For this purpose only producers whose core business is the production of braces were taken into account.

The mark-up for overall profit is set at 15 % on manufacturing costs + warehouse costs + general overhead + research & development,, based on the annual accounts of the manufacturers.

6.6.1.2 Assumptions for processes and machines

Estimated costs of raw materials are based on information from the metal industry, who are suppliers for the medical devices industry. The weight of raw materials was determined from actual product samples. Waste of raw materials during production was taken into account to determine the cost.

The cost of machinery has been determined in cost per hour (total investment cost for machinery / total hours of production capacity). The total hours of production

capacity are documented in the model. This capacity is related to the number of hours a machine is active over one year (one or two shifts) and machine lifetime.

To calculate the cost of machinery in the start up phase (stand still period), the same hourly rate for the machinery has been used

All machinery used in the production process is multi-purpose machinery. For that reason full utlisation rates were hypothesized for the machinery. An exception was made for specialized cutting and welding machinery used for the protection material applied in the knee brace. For this machinery the research team did use a 50 % utilisation rate (one full shift capacity).

As **energy costs** are immaterial we did not foresee a specific line item in de calculation model.

An estimated number of **pieces produced per time unit** make the attribution of these and other production costs to the individual product pieces possible.

Labour cost is very dependent on the wage level in the country of production. For this study European industry averages of €25 per hour for operators and maintenance technicians and €40 per hour for engineering and quality assurance were used.

Quality assurance is an integrated part of the production process. The time spent on quality assurance is by consequence integrated in the labour cost/time.

Key points

- **The production steps were described and used as guidance to determine the cost model and calculate the costs.**
- **Costs incurred in the production steps were divided into the following components: raw material, direct labour, indirect labour and machine cost**
- **R&D, warehousing, general overhead and profit were determined as a mark up of the previous result (total manufacturing cost)**
- **General assumptions were used when applicable on the cost model as a whole for all production steps**
- **Specific assumptions for processes and machines could vary for the different production steps.**

6.6.2 Aggregated model for hard knee brace

The aggregated model gives an overview (see Table 58) of the different cost types added up over the subsequent production steps. As one can notice in the table the total price FOB varies between 93,73 € and 148,04 € (excl. VAT) depending on the difference between scenario 1 and 2 (total life cycle production volume / volume production batch).

Table 58 : Results for hard knee brace cost model

Main Cost Components		Fixed Costs		Direct	Unit costs	
		Moulds / Tot Production	Machine start up / Batch prod. Vol	Costs / Unit	Scenario 1	Scenario 2
Total live cycle production volume					18.000	180.000
Volume production batch					300	3.000
Cost Moulds - total		342.523,35 €			19,03 €	1,90 €
Start up costs of machinery	machinery		4.216,51 €		14,06 €	1,41 €
	labour		1.400,00 €		4,67 €	0,47 €
Costs direct production and assembly	machinery			19,20 €	19,20 €	19,20 €
	labour			13,48 €	13,48 €	13,48 €
	material			25,25 €	25,25 €	25,25 €
Coating	service			5,00 €	5,00 €	5,00 €
TOTAL MANUFACTURING COSTS					100,68 €	66,70 €
+ File COSTS (patents + cerificates)		100.000,00 €			106,23 €	67,26 €
+ WAREHOUSING	2%				108,36 €	68,60 €
+ GENERAL OVERHEAD	8%				117,03 €	74,09 €
+ RESEARCH & DEVELOPMENT	10%				128,73 €	81,50 €
+ PROFIT	15%				148,04 €	93,73 €
TOTAL PRICE FOB					148,04 €	93,73 €

In Table 59 we have defined the different cost items as percentages of total manufacturing costs (indicated in yellow) and the percentual break-down of the total price FOB by various cost items.

Table 59 : Hard knee brace: break-down of production cost

		Breakdown (%) per produced unit					
Main Cost Components		**Scenario 1**	**Manuf. Cost**	**Total price FOB**	**Scenario 2**	**Manuf. Cost**	**Total price FOB**
Total life cycle production volume		18.000			180.000		
Volume production batch		300			3.000		
Cost moulds Total		19,03 €	18,9%	12,9%	1,90 €	2,8%	2,0%
Start up costs	Machine	14,06 €	18,6%	12,7%	1,41 €	2,8%	2,0%
	Labour	4,67 €			0,47 €		
Cost direct production and assembly	Machine	19,20 €	57,5%	39,1%	19,20 €	86,8%	61,8%
	Labour	13,48 €			13,48 €		
	Material	25,25 €			25,25 €		
Coating	Service	5,00 €	5,0%	3,4%	5,00 €	7,5%	5,3%
Total manufacturing cost		100,69 €	100,0%		66,71 €	100,0%	
File cost		5,56 €		3,8%	0,56 €		0,6%
Warehousing		2,12 €		1,4%	1,34 €		1,4%
General overhead		8,66 €		5,9%	5,48 €		5,8%
Research & development		11,70 €		7,9%	7,40 €		7,9%
Profit		19,30 €		13,0%	12,22 €		13,0%
Total price FOB		148,03 €		100,0%	93,71 €		100,0%

Key points

- **The total manufacturing cost for the hard knee brace varies between 66,7 € and 100,68 € depending on the total life cycle production volume and the volume of production per batch.**
- **The unit cost for moulds (indirect cost) drops significantly from 19,03 € to 1,9 € in the scenario with high volumes**
- **The unit cost for start up (indirect cost) drops significantly from 18,73 € to 1,88 € in the scenario with high volumes**
- **Indirect costs represent 37,5 % of the total manufacturing costs in the scenario with low volumes, 5,6 % in the scenario with high volumes.**
- **Direct costs for "production and assembly" and "coating" are identical in absolute figures in both scenario's**
- **Direct costs represent 94,3 % of the total manufacturing cost (= 66,71 €) in the scenario with high volumes and 62,5 % of total manufacturing cost (= 100,68 €) in the scenario with low volumes.**
- **The total manufacturing cost increases significantly in the scenario of low volumes as a result of high indirect cost**
- **The costs for warehousing, general overhead, research and development and profit were taken into account as a % mark up of the total manufacturing cost (cumulative approach)**
- **The total price FOB (Free on board) is the sum of the total manufacturing cost and the mark ups for warehousing, general overhead, research and development and profit. Based on the cost model, the total price FOB (free on board) varies between 93,73 € and 148,04 € (excl. VAT)**
- **In the scenario with low volumes indirect costs represent 29,4 % of the total price FOB, direct costs 42,5 % and the mark up for warehousing, general overhead, R&D and profit 28,2 %**
- **In the scenario with high volumes indirect costs represent 4,6 % of the total price FOB, direct costs 67,1 % and the mark up for warehousing, general overhead, R&D and profit 28,2 %**

6.6.3 Aggregated model for hard neck brace

The aggregated model gives an overview (see Table 60) of the different cost types added over the subsequent production steps. As one can notice in the table the total price FOB varies between 15,47 € and 32,02 € (excl. VAT) depending on the applied scenario (total life cycle production volume / volume production batch).

Table 60 : Results for hard neck brace cost model

Main Cost Components		Fixed Costs: Moulds / Tot Production	Fixed Costs: Machine start up / Batch prod. Vol	Direct Costs / Unit	Unit costs: Scenario 1	Unit costs: Scenario 2
Total life cycle production volume					18.000	180.000
Volume production batch					300	3.000
Cost Moulds - total		35.088,21 €			1,95 €	0,19 €
Start up costs of machinery	machinery		807,42 €		2,69 €	0,27 €
	labour		900,00 €		3,00 €	0,30 €
Costs direct production and assembly	machinery			1,42 €	1,42 €	1,42 €
	labour			3,55 €	3,55 €	3,55 €
	material			4,82 €	4,82 €	4,82 €
Coating (Service)				-	-	-
TOTAL MANUFACTURING COSTS					17,42 €	10,54 €
+ File COSTS (patents + ceritificates)		100.000,00 €			22,98 €	11,10 €
+ WAREHOUSING	2%				23,44 €	11,32 €
+ GENERAL OVERHEAD	8%				25,31 €	12,23 €
+ RESEARCH & DEVELOPMENT	10%				27,84 €	13,45 €
+ PROFIT	15%				32,02 €	15,47 €
TOTAL PRICE FOB					32,02 €	15,47 €

In Table 61 we have defined the different cost items as percentages of total manufacturing costs (indicated in yellow) and the percentual break-down of the total price FOB by various cost items.

Table 61 : Hard neck brace: break-down of production cost

Main Cost Components		Breakdown (%) per produced unit					
		Scenario 1	Manuf. Cost	Total price FOB	Scenario 2	Manuf. Cost	Total price FOB
Total life cycle production volume		18.000			180.000		
Volume production batch		300			3.000		
Cost moulds	Cost moulds total	1,95 €	11,2%	6,1%	0,19 €	1,8%	1,2%
Start up costs	Machine	2,69 €			0,27 €		
	Labour	3,00 €	32,6%	17,8%	0,30 €	5,4%	3,7%
Cost direct production and assembly	Machine	1,42 €			1,42 €		
	Labour	3,55 €			3,55 €		
	Material	4,82 €	56,2%	30,6%	4,82 €	92,8%	63,3%
Total manufacturing cost		17,43 €	100,0%		10,55 €	100,0%	
File cost		5,56 €		17,4%	0,56 €		3,6%
Warehousing		0,46 €		1,4%	0,22 €		1,4%
General overhead		1,88 €		5,9%	0,91 €		5,9%
Research & development		2,53 €		7,9%	1,22 €		7,9%
Profit		4,18 €		13,0%	2,02 €		13,0%
Total price FOB		32,03 €		100,0%	15,48 €		100,0%

Key points

- **The total manufacturing cost for hard neck brace varies between 10,54 € and 17,42 € depending on the total life cycle production volume and the volume of production per batch.**
- **The unit cost for moulds (indirect cost) drops significantly from 1,95 € to 0,19 € in the scenario with high volumes**
- **The unit cost for start up (indirect cost) drops significantly from 5,69 € to 0,57 € in the scenario with high volumes**
- **Indirect costs represent 43,8 % of the total manufacturing costs in the scenario with low volumes, 7,2 % in the scenario with high volumes.**
- **Direct costs for "production and assembly" are identical in absolute figures in both scenario's**
- **Direct costs represent 92,8 % of the total manufacturing cost (= 10,54 €) in the scenario with high volumes and 56,2 % of total manufacturing cost (= 17,42 €) in the scenario with low volumes.**
- **The total manufacturing cost increases significantly in the scenario of low volumes as a result of high indirect cost**
- **The costs for warehousing, general overhead, research and development and profit were taken into account as a % mark up of the total manufacturing cost (cumulative approach)**
- **The total price FOB (Free on board) is the sum of the total manufacturing cost and the mark ups for warehousing, general overhead, research and development and profit. Based on he cost model the price FOB (free on board) varies between 15,47 € and 32,02 € (excl. VAT)**
- **In the scenario with low volumes indirect costs represent 41,3 % of the total price FOB, direct costs 30,6 % and the mark up for warehousing, general overhead, R&D and profit 28,2 %**
- **In the scenario with high volumes indirect costs represent 8,5 % of the total price FOB, direct costs 63,3 % and the mark up for warehousing, general overhead, R&D and profit 28,2 %**

6.7 COMPARISON AGGREGATED MODEL AND PRICE LEVEL BELGIUM

To derive reasonable market prices from our cost estimates, set to include both reimbursement tariffs and an possible patient co-payments, the total price FOB was multiplied by a factor of 3,5.

The multiplication with factor 3,5 takes into account:

- The mark-up for the importer / distributor: FOB X 1, 66 = Whole Sale Price
- The mark-up for the orthopaedics / retailer: Whole Sale Price X 2,13 = Market Price

Mark-up for importer / distributors: X 1,66

Several distributors mentioned during the interviews that when the average purchasing price from the manufacturers was 60, their average sales prices to the retailers were approximately 100, meaning that we had to multiply the calculated FOB price with a 1,66 factor to estimate their selling price to retailers (orthotist).

This chapter was sent to the manufacturers via their local distributors. A group of distributors offered feedback to the research team on the size of this mark-up and provided us with spreadsheet calculations (included in appendix VI). Referring to these calculations, the involved parties stated their average mark-up, between purchase price and selling price, is 2,2. The reseach team did not investigate these data.

Mark up for orthotists / retailers: X 2,13

As described in chapter III, when the 'nomenclature' [xxx] of orthotic devices was developed in 1992, the mean price to dispensers across similar products was multiplied by the so-called 'Walkiers coefficient' to obtain the reimbursement tariff of each category of orthotic devices. The Walkiers coefficient covers a pay-off for general costs, wages, measurement and adaptation of orthotic devices, and costs of materials. In other words, the delivery margin is determined by the Walkiers coefficient, although strictly this is not legally mandatory.

The Walkiers coefficient that is used now b y the Commission of Orthotists and Health Insurance Funds to determine the reimbursement tariff of new nomenclature codes is currently set at 2.13 for prefabricated devices.

Taken into account both mark-up levels (local distributors and "retailers - orthotists"), we should expect that the products are available on the market for

Price FOB x 1,66 (margin importers / distributors) x 2,13 (Walkiers coefficient as margin retailers)

Based on the cost model for hard knee braces, a market price for hard knee braces should be expected to be between 331 € (scenario with the highest production volumes) and 523 € (scenario with the lowest production volumes). The lowest market price we found for this product was around 550€ in the UK (see Chapter V).

If we apply the 2,2 factor (cf. supra) as margin for importer/distributors on our cost model for the hard knee brace, a market price should be expected between 439 € (scenario with the highest production volumes) and 694 € (scenario with the lowest production volumes).

[xxx] Set of billing codes describing the public reimbursement applying to products and/or services in Belgian healthcare.

Based on the cost model for hard neck braces, a market price for the hard neck braces should be expected to be situated between 54,7 € (scenario with the highest production volumes) and 113 € (scenario with the lowest production volumes). The lowest market price we found for this product was around 100€ in The Netherlands as well as in Ontario, Canada (se Chapter V).

If we apply the 2,2 factor as margin for importer/distributors on our cost model for the hard neck brace, a market price should be expected to be between 72 € (scenario with the highest production volume) and 150 € (scenario with the lowest production volumes).

The research team stresses the fact that these end prices are based on the cost model for a traditional hard knee brace / hard neck brace. In the market we noticed that more comfortable / innovative knee braces do exist. These braces are – in the actual state – classified in the same category as the traditional once. A review of the nomenclature classifications should aim at a better match between the characteristics / costs of the products and reimbursement level.

As described and inventoried in chapter V (international price comparison for a selection of orthoses), we noticed that for the two nomenclature codes (647592 prefab hard knee brace hinged and 645212 prefab stiff neck collar) to which the products under investigation in this chapter belong, market prices are:

- Comparable between the different retailers, meaning standard deviation of market prices at product level is low
- Situated in most cases around the RIZIV price
- Strongly linked with the reimbursement level which is high in Belgium for those two nomenclature codes.

The relation between the market price and the production costs (manufacturing costs / cost free on Board) seems to be very weak in Belgium.

Key points

- **The estimated market prices for the two products defined in the project scope are based on the cost model, a mark up of 1,66 for distributors and a mark up for orthotist (Walkierscoefficient 2,13) expected to vary between:**

  331 € and 523 € for the hard knee brace

  54,7 € and 113 € for the hard neck brace

- **In reality we noticed for both nomenclature codes (hard knee brace and hard neck brace) that prices are comparable between retailers and mostly situated around the /INAMIRIZIV price. The INAMI/RIZIV advised selling price is 947,91 € for the hard knee brace and 258,77€ for the hard neck brace**
- **Market prices seem to be strongly linked with the reimbursement level which is high in Belgium for those two nomenclature codes.**
- **The reimbursement tariff for the hard knee brace is 816,56 € for preferential beneficiaries and 579,59€ for regular beneficiaries and the reimbursement tariff for the hard neck brace is 258,77€ for preferential beneficiaries and 194,08 € for regular beneficiaries.**
- **The relation between the market price and the production costs (manufacturing costs / cost free on Board) seems to be very weak for the products investigated.**

7 GENERAL SUMMARY AND DISCUSSION

7.1 INTRODUCTION

The aim of this chapter is in first instance to summarize and link the conclusions of the different sections (scientific literature on braces, international comparison of institutional aspects, economic aspects: market analysis and international comparison of prices, and development of a model for the productions costs) and to highlight the shortcomings of the current Belgian healthcare system with regard to the regulatory and economic aspects of the medical devices market, with an emphasis on prefab braces.

The primary scope of the study was set to prefabricated braces used in the ambulatory care for the neck, the wrist and the knee. The limitation to the prefabricated devices, i.e. homogenous products with standardized large scale production, allows straightforward comparisons across countries. Besides, within the three device categories in our scope, prefabricated products as compared to custom-made products, make up the vast majority of booked expenses.

The total reimbursed expenditures for outpatient orthopaedic care represented about 94,5 million euro in 2005 (or around 0,5% of the INAMI/RIZIV health care budget). The amount reimbursed for prefabricated orthopaedic devices in outpatient care was more than 24 million Euro in 2005 (i.e. 26% of booked public reimbursements of outpatient orthopaedic devices) dominated principally by the market of knee braces (around 10 million Euro). The expenditures for prefabricated neck orthoses and wrist orthoses represent respectively 0,8 million Euro and 0,6 million Euro.

7.2 GENERAL SUMMARY

7.2.1 Clinical evidence

The results of the scientific literature on effectiveness, cost and cost-effectiveness of wrist, neck and knee braces provide clinical evidence on proper indications for those braces.

7.2.1.1 Wrist braces

The medical indication for the use of wrist braces are related with the following pathologies: carpal tunnel syndrome, rheumatoid arthritis, first carpometacarpal osteoarthritis. For other pathologies, the use of a brace is not directly recommended as there is no medical indication or the clinical evidence is insufficient.

7.2.1.2 Neck and knee braces

There are two kinds of devices treating neck or knee pathologies: the soft and the rigid braces. Based on the clinical evidence coming from the literature analysis, only the use of the rigid brace is indicated in specific cases.

- A rigid cervical brace is indicated in the treatment of cervical fracture and spinal immobilization for trauma patients.
- Rigid knee braces are recommended for the treatment of medial compartment osteoarthritis of the knee and the medial collateral ligament injuries to the knee. A functional knee brace may be indicated for anterior cruciate ligament reconstruction.

Key points

- **There are only few clinical indications in the scientific literature justifying the use of braces.**
- **Specifically for neck and knee braces, only the use of rigid braces is indicated in certain cases.**

7.2.2 The Belgian regulatory system

The main characteristics of the system are pointed out here below.

7.2.2.1 No link between reimbursement tariffs and intrinsic market trends

The reimbursement of orthotic devices to the patients is legally determined by the nomenclature developed for the sector of braces in 1992 and the reimbursement of each category of devices is still based on prices fixed in 1992. The evolution of those reimbursement tariffs is in line with the Belgian consumer price index (the so-called "health index") and ceiled by a closed overall budget.

As the market for medical devices is characterised by a relatively fast evolution in tandem with the development of new technologies, the tariffs determined in 1992 are likely to no longer reflect the real value of the products sold today on the market.

7.2.2.2 No standardized procedure like a cost effectiveness analysis

There is no standardised procedure linked to the actual system of reimbursement and factors like the effectiveness or general product quality of the brace, the comparison with other similar products and the validation of the results by a cost effectiveness study are not taken into account.

7.2.2.3 No mention of clinical indication

The reimbursement of orthoses is subject to prescription by a specialist and the Belgian nomenclature covering the sector of braces is not based on clinical indications. As there is little regulation governing the prescribing of orthotic devices, no registration system exists on the different types of products admitted for reimbursement.

7.2.2.4 One global price

The nomenclature system reimburses the delivery of the product and the intellectual act performed by the officially recognised orthotist. The value of the nomenclature code make no distinction between the part allocated to the product itself and the part aimed to reattribute the orthotist for his work. The actual system is then characterised by a lack of transparency and the impact of any tariff variation can not be attributed to the product or to the orthotist.

7.2.2.5 Complexity of the nomenclature

The nomenclature used for the prefabricated orthoses is very complex. The current nomenclature is based on technical/typological descriptions which no longer fit the market reality. This is certainly the case for new innovative products. A further consequence may be that current purchasing prices for orthotists are out of tune with reimbursement fees, possibly installing incentives that are not consistent with optimal patient care. The nomenclature for the prefabricated orthoses is quite complicated as there are 69 different nomenclature codes (out of a total of 581 billing codes in use for outpatient orthopaedic devices[yyy]) used for the reimbursement of various devices.

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yyy Article 29 of nomenclature regulation.

Key points

- **The Belgian nomenclature system is rather complex, based on a technical/typological description.**
- **The nomenclature developed in 1992 no longer reflects the market reality and the price evolution of braces.**
- **The reimbursement is not conditional on the results of a cost effectiveness analysis.**
- **There is no link with medical or chronic indications and there is no registration system of the products sold on the market.**
- **One global lump sum reimbursement is set to cover both the product and the intellectual act performed by the officially recognized orthotist, leading to a lack of transparency.**

7.2.3 Institutional comparison with other countries

The comparison of institutional systems for a selected number of countries (Belgium, The Netherlands, France, United Kingdom, Sweden and Ontario Canada) demonstrates the particular position of Belgium in the market of orthoses.

7.2.3.1 Registration

In Belgium, the launch of a medical device on the market is conditional to the registration agreement delivered by the Public Health Authorities. As in other countries like France and England, registration will imply that the product can be entitled for reimbursement.

7.2.3.2 Belgian prices and market mechanisms

Belgian prices for braces are set freely like in France, England and the Netherlands. In Belgium, there are not market mechanisms based on public procurement or maximum prices regulating the fixation of prices. Market mechanisms are nevertheless playing a role in price competition between the manufacturers as reimbursement tariffs are often equal or lower than the market price.

7.2.3.3 Cost effectiveness analysis

Contrary to the procedure applied for drug reimbursement in Belgium, there is no requirement concerning the fulfilment of criteria like cost-effectiveness of a medical device introduced on the Belgian market. In England, France and the Netherlands, the reimbursement procedure is conditional to the results of a cost or a cost effectiveness analysis. Nevertheless, given the relative absence of cost-effectiveness analyses surfacing in our literature review on orthotic devices, one may argue that the latter condition is rather theoretical. This is also demonstrated in the case of England where the actual reimbursement is not linked to medical or chronic conditions of the patient, despite a prerequisite need to demonstrate the cost-effectiveness of reimbursed devices.

7.2.3.4 Clinical indication and chronic patients

In Belgium as in England, the reimbursement is not linked to a medical or a.chronic condition and the use of a limitative list of the classes of orthotic devices has not been considered until now. The French social insurance system fully reimburses orthotic devices if the patient is suffering from a chronic condition (more than 6 months) In Ontario, orthotic devices are reimbursed for patients with a physical disability requiring the use of a brace which improves the function of the patient in a variety of activities of daily living for at least 6 months. The Dutch insurance system restricts the reimbursement to rigid orthotic devices for long-term use. With regard to clinical indication, the new orthotic devices introduced on the Swedish market are free of charge if there is a medical/functional need for the device and in the Netherlands, there

is a clinical indication applied to the knee braces as they are reimbursed only for the two pathologies quoted in the literature search as being effective.

Key points

- **The comparison of Belgium with other countries (The Netherlands, France, England (United Kingdom), Sweden and Ontario (Canada) shows the particular position of Belgium on the international market.**
- **Contrary to other countries, a product is not submitted to different conditions in order be reimbursed, except its registration by the Public Health Authorities.**
- **Market mechanisms are not really playing a role except in price competition between manufacturers.**
- **Although some other countries are using a procedure based on cost effectiveness analyses or the fulfillment of medical conditions, Belgium does not apply a similar approach.**

7.2.4 Market analysis and price comparison

The market analysis and international price comparisons are based on a selection of 6 nomenclature codes summarized in Table 62.

Table 62 : Overview final selection nomenclature codes

Type of Brace	NMLL code	Nomenclature description	Reimbursement tariff 2007	
			Preferential	Non Preferential
Knee	647533	Elastic woven reinforced with metal knee brace	213 €	159 €
	647555	Soft elastic woven reinforced knee bandage	92 €	65 €
	647592	Hard knee brace	817 €	580 €
Neck	645175	Soft neck collar	15 €	10 €
	645212	Adjustable hard neck collar	259 €	194 €
Wrist	649434	Soft wrist bandage	49 €	35 €

Source: RIZIV / INAMI data

7.2.4.1 Results

Prefab hard knee brace (code 647592)

The market for hard knee braces is characterised by a high concentration: the three main manufacturers are Donjoy, Bledsoe and Bauerfeind and the most important distributors are Ortho-Medico, Sprofit, Dirame and Bauerfeind. These devices are mostly prescribed to a younger, male population in the northern part of Belgium. Belgian market prices for hard knee braces, when compared to corresponding prices abroad, are much higher.

Prefab knee bandage woven reinforced (code 647555)

The market is dominated by one manufacturer and distributor: Bauerfeind. The modal patient profile for these devices concerns women between the ages of 40 and 60 in the

South(west)ern part of Belgium. The Belgian market prices mostly are higher than the prices in all other countries.

Prefab knee brace elastic tissue or neoprene reinforced with metal (code 647533)

The Belgian market is dominated by two manufacturers (and distributors):Thuasne and Bauerfeind. The most representative patient profile is that of a person (no marked distinction according to sex) residing in the center of the country (area surrounding the capital) between the ages of 35 and 55. The Belgian market prices all are much higher than those in the other countries.

Prefab hard neck collar (code 645212)

The Belgian market for hard neck braces is characterized by a limited number of products and this market is dominated by one product, the Jerome Miami J. Collar distributed by Ortho-Medico and Distrac. These devices are mostly worn by people between the ages of 35 and 65 residing in the Southern part of Belgium. The Belgian market prices, and in particular the price of the Jerome Miami J. collar, are substantially higher than those in all other countries. For this type of hard cervical collar, we conclude the reimbursement level is high and clearly affects the average selling prices. In Belgium, the Jerome Miami J. collar is sold at more than three times the purchase price.

Prefab soft collar (code 645175)

The market for soft neck braces is an important market in Belgium in term of products sold although there is no clinical evidence for this product. Almost all manufacturers have products in this category and the products are distributed by almost all distributors active in the sector of prefabricated braces. As is the case for billing code 647555, the modal patient profile for these devices relates to women between the ages of 40 and 60 in the South(west)ern part of Belgium. The soft neck collar is also largely being sold outside the circuit of reimbursed products through alternative distribution channels (such as pharmacies and department stores).

There are very important differences between the different countries in prices at market level. The soft neck collar is not reimbursed in the Dutch and the Canadian health insurance system. For the other countries, prices are mostly lower than the Belgian prices.

Prefab wrist bandage (code 649434)

The market is quite important in terms of number of products sold which is higher than the number of reimbursed cases. The manufacturers Push and Bort represent 50% of the Belgian market and the other 50 % of the market is divided between a lot of different manufacturers and distributors. As is the case for billing code 647555 and 645175, the modal patient profile for these devices relates to women between the ages of 40 and 60 in the South(west)ern part of Belgium.

Most of the foreign market prices are in the same range. Nearly all prices exceed the amount that is reimbursed to the Belgian non – preferential patients. Differences in prices are very substantial.

Simulation exercise

By means of an overall comparative cost indication, simulation exercises were performed in order to estimate what the Belgian expenditures would be if foreign prices would have applied to similar products sold on the Belgian market. Not surprisingly given the observed tendency of higher Belgian prices at the product level, this comparison shows that total Belgian expenses when applying foreign prices to Belgian market volumes, would have been substantially lower.

Key points

- **The market of orthoses is very fragmented, both at retail level and at manufacturer level.**
- **The price comparison with other countries shows that Belgian prices are often higher than foreign prices for the products reimbursed by the nomenclature codes we examined.**

7.2.5 Production cost model

One objective of our study was to estimate the production costs for two selected prefabricated orthoses. In agreement with the conclusions from the scientific literature review, a production model for two products belonging to the categories of hard knee braces and hard neck braces has been developed for respectively the Donjoy 4 titude (hard knee brace) and the Jerome Miami collar (hard neck brace).

7.2.5.1 Results

The total price FOB (i.e. Free On Board: the price of the product as it leaves the factory of the producer) for the model for hard knee brace varies between 94 € and 148 € and the total price FOB for the hard neck brace varies between 15 € and 32 €. The variations of the estimated production cost correspond to model scenarios on feasible low and high production volumes.

The estimated market price for hard knee braces (based on the cost model – a mark up of 1,66 for distributors – mark up of 2,13 (Walkierscoëfficient) for orthotist) is between 331 € and 523 €; this market price is much lower than the market price (947,91€) and the reimbursement tariff (816,56 € for preferential beneficiaries and 579,59€ for regular beneficiaries).

The estimated market price for the hard neck braces (based on the cost model – a mark up of 1,66 for distributors – mark up of 2,13 (Walkierscoëfficient for orthotists) is between 55 € and 113 €; this market price is much lower than the market price (240,62€) and the reimbursement tariff (258,77€ for preferential beneficiaries and 194,08 € for regular beneficiaries).

The relation between the market price and the production costs seems to be very weak for the products investigated.

Key points

- **Two productions models have been developed: one for the hard knee brace and one for the hard neck brace as the use of those braces is sustained by clinical evidence.**
- **For this analysis, the Donjoy 4 titude (hard knee brace) and the Jerome Miami collar (hard neck brace) have been chosen.**
- **The total market price (based on the cost model / mark up of 1,66 for distributors / mark up of 2,13 (walkierscoëfficient for orthotists) is estimated between 331 € and 523 € for the hard knee brace and between 55 € and 113 € for the hard neck brace.**
- **The relation between actual market prices and estimated production costs seems to be very weak .**

7.3 GENERAL DISCUSSION

Following the preceding analyses, current Belgian policies can be shown to suffer from two important drawbacks that raise the overall public cost and do not bring any additional benefit to patients.

Size of reimbursement fees

The international price comparison for commonly sold prefab devices in Belgium reveals that Belgian market prices are considerably higher when set next to ruling prices in comparable countries. This observation is further corroborated by the report's production cost analyses, related to two selected hard bracing devices (knee and neck). Based on these production cost estimates market prices can be derived that are both lower than current Belgian prices and approximate current foreign prices.

Consequently, it can be argued that Belgium is a relatively expensive market for the products in our scope. Since the Belgian regulation is not designed to take intrinsic market trends (that can be observed internationally) into consideration, the relatively high Belgian reimbursement fees probably do not reflect the correct market value of the devices in our scope. In effect, they are likely to raise prices on the Belgian market. This will in turn lead to the comparatively high price levels described in our report.

This hypothesis is supported by the relative absence of market clearing mechanisms in Belgium in comparison to other countries. Belgium differs from the countries in the report's price comparison as it sets relatively high reimbursement fees (compared to France), which are not the (partial) outcome of negotiations between market actors (as in the Netherlands between insurers and suppliers), nor of a tendering procedure (as in England). Finally, on the other end of this spectrum we find Ontario, which foresees no public reimbursement at all for prefabricated orthotic devices and hence can be considered a "pure" example of free market clearing.

Patient (and product) eligibility for reimbursement

As public authorities in Belgium do not link product reimbursement to the fulfillment of prerequisite conditions in respect of (cost-)effectiveness, no formal restrictions are made on the type of indications that qualify patients for specific devices. It could be argued that this assessment should be left entirely to the prescribing physician. Nevertheless, in the majority of countries compared in our report, the reimbursement of orthotic devices is limited to specific medical conditions. Furthermore, the wide variations our report found in geographical utilization patterns would suggest there is ample room for more uniform prescribing practices.

A logical corollary of the above principle suggests that orthotic devices for which no clinical effectiveness can be demonstrated should not qualify for any form of reimbursement. The Netherlands, for instance, restrict the reimbursement of orthotic devices to rigid devices. This is in agreement with our literature review's conclusions on neck and knee braces.

However, a caveat should be regarded when it comes to imposing overly strict conditions on product reimbursement as testified by the case of England where the actual reimbursement is not linked to medical or chronic conditions of the patient, despite a prerequisite need to demonstrate the cost-effectiveness before public reimbursement is granted.

The next chapter will sketch the general form policy recommendations may take on in addressing the two main shortcomings we identified in our scientific analysis.

Key points

- **A first major shortcoming in Belgian policies is that the relatively high Belgian reimbursement fees probably do not reflect the correct market value of the devices in our scope and are likely to raise prices on the Belgian market.**
- **A second major shortcoming in Belgian policies is that no formal restrictions are made on the type of indications that qualify patients for specific devices.**

8 RECOMMENDATIONS

This project has illustrated that there is little scientific evidence supporting the (cost-) effectiveness of the majority of the products sold in Belgium and reimbursed by the public health insurance. Besides, market clearing mechanisms do not play an important role in the particular sector of braces in Belgium. This is clearly shown by current prices on the Belgian market which are much higher than foreign prices for the same products. In light of the preceding analyses, the Belgian Healthcare Knowledge Centre makes the following policy recommendations for the public reimbursement of prefabricated orthotic devices in outpatient care:

- In order to raise overall price transparency and to foster impartiality in choice of product by orthotists, current reimbursement tariffs should be split into two lump sums:
    - A lump sum reimbursement covering the intellectual act for judicious product choice, patient advice and follow-up by the orthotist. It can be envisaged that this reimbursement would be the same for all types of prefabricated devices.
    - A lump sum reimbursement covering the cost related to the delivered product. This type of reimbursement may be the same for a group of devices similar in terms of clinical indication, materials, etc. as is the case for the current nomenclature.

  This new procedure implies that the Walkiers coefficient, currently applied to determine the reimbursement tariff would not be used anymore

- To guarantee that lump sum product reimbursements do not substantially exceed or underrate price levels to be expected under competitive market conditions, we propose two realistic policy options to be directly implemented in the Belgian policy context : (1) an international price comparison analyses of the products which would be performed on a regular basis and (2) a public tendering organised by INAMI/RIZIV.
    - Proposal 1 : International price comparison

      An international price comparison of the various products belonging to the same brace category should be performed on a regular basis, much like the analysis presented in this report. The most commonly sold (and publicly reimbursed) prefabricated devices on the Belgian market, by category, should be identified to serve as a baseline product basket. The ruling reimbursement tariffs should be revised in light of this price comparison analysis. Reimbursement levels should be adapted for product groups displaying average prices in foreign countries that consistently deviate from related Belgian reimbursement tariffs. Further, if wide variations between prices consistently persist across foreign countries for products attracting the same reimbursement under Belgian regulations, this may indicate that more specific subgroup reimbursement levels are required. In line with the price comparison made in our report it should be considered to revise current reimbursement tariffs for related orthotic devices following the above procedure.
    - Proposal 2 : Public tendering

      A public tendering could be set up and organised by RIZIV-INAMI for all the products currently reimbursed under the nomenclature and for other products as well if certain criteria are met. The

RIZIV/INAMI would specify the technical and medical features for each distinct brace category. It is a prerequisite condition that these categories are made up of comparable products. For each brace category under consideration, the market price of the product which wins the public tender would determine the reimbursement tariff. All other products belonging to the same brace category would either no longer qualify for reimbursement or qualify for a lower reimbursement than the winning product would attract.

- No procedure is foreseen to assess clinical indications for orthotic, and in a more general sense, orthopaedic devices in outpatient care that qualify for public reimbursement. Our report indicates that the current regulation may be faulty on this aspect as the clinical review revealed certain indications and contra-indications prevail for wrist, neck and knee braces. Moreover, most foreign countries take medical effectiveness –and cost effectiveness- into consideration as a condition for public reimbursement.

  The nomenclature should be revised in order to integrate transparent objective criteria regarding aspects of effectiveness and cost effectiveness.

- Up to date, there are no legal guarantees for the products sold in Belgium. The only assurance the patient can have with regard to product safety is its registration as a medical device with the Federal Agency for Drugs and Health Products. The procedure to be developed following the recommendations should be accompanied by stricter measures in order to guarantee the quality of orthotic appliances as is the case for any other consumer product.

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Dépôt légal : D/2007/10.273/15

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16. Etude relative aux coûts potentiels liés à une éventuelle modification des règles du droit de la responsabilité médicale. Phase II : développement d'un modèle actuariel et premières estimations. D/2005/10.273/16.
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20. HTA Diagnostic Moléculaire en Belgique. D/2005/10.273/24, D/2005/10.273/26.
21. HTA Matériel de Stomie en Belgique. D/2005/10.273.28.
22. HTA Tomographie par Emission de Positrons en Belgique. D/2005/10.273/30.
23. HTA Le traitement électif endovasculaire de l'anévrysme de l'aorte abdominale (AAA). D/2005/10.273.33.
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28. Recommandations provisoires pour les évaluations pharmacoéconomiques en Belgique. D2006/10.273/11.
29. Recommandations nationales Collège d'oncologie : A. cadre général pour un manuel d'oncologie B. base scientifique pour itinéraires cliniques de diagnostic et traitement, cancer colorectal et cancer du testicule. D2006/10.273/13.
30. Inventaire des bases de données de soins de santé. D2006/10.273/15.
31. Health Technology Assessment : l'antigène prostatique spécifique (PSA) dans le dépistage du cancer de la prostate. D2006/10.273/18.
32. Feedback: évaluation de l'impact et des barrières à l'implémentation - Rapport de recherche: partie II. D2006/10.273/20.
33. Effets et coûts de la vaccination des enfants Belges au moyen du vaccin conjugué antipneumococcique. D2006/10.273/22.
34. Trastuzumab pour les stades précoces du cancer du sein. D2006/10.273/24.

35. Etude relative aux coûts potentiels liés à une éventuelle modification des règles du droit de la responsabilité médicale – Phase III : affinement des estimations. D2006/10.273/27.
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56. Matériel orthopédique en Belgique: Health Technology Assessment. D2007/10.273/15.