Future scenarios about drug development and drug pricing

Strategies to provide patients sustained access to the safe and effective drugs they need, with particular attention to **the role of pricing.**

Future scenarios about drug development and drug pricing

This report is the result of a consultative and deliberative process — initiated by the Belgian Healthcare Knowledge Centre (KCE) and Zorginstituut Nederland (Dutch Health Care Institute, ZIN) — to explore in an unfettered way potential solutions to the complex societal challenge of high drug prices. The aim of the project was to elaborate creative scenarios and to explore novel, more sustainable ways to ensure patient access to safe and effective drugs, while providing strong incentives for innovation and focussing on real health needs.

The scenario project benefited from the active contribution of a carefully selected group of experts and stakeholders from Europe and North America, including patient representatives, industry leaders, academics, not-for-profit research organizations, regulators, payers, and government representatives. This report presents four coherent scenarios, developed on the basis of in-depth interviews of the experts, followed by two 2-day deliberative workshops in Amsterdam, in March and April 2016.

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Foreword

Developments in the field of medicine are happening at a rapid pace. New technologies and important breakthroughs in research have resulted in new medicines now also being able to offer perspective to many people with serious conditions, which were previously difficult or impossible to treat, such as lung cancer, cystic fibrosis and hepatitis-C. In short, for many people these medicines can literally mean the difference between life and death, or significantly improve their quality of life.

Yet at the same time this presents us with some major dilemmas. The costs associated with these new medicines are high and will continue to rise over the forthcoming years. So far we have always been able to give patients access to new and promising medicines by managing the costs. But our current instruments are now proving increasingly insufficient for addressing this problem. It's becoming progressively harder to find suitable solutions at national level in a strongly globally operating market.

Countries have to dare to work together more if we want to be able to continue providing patients with truly innovative medicines in the changing conditions, whilst at the same time effectively managing the costs. We took the first steps towards realising this around a year and a half ago. We have since been exchanging information, sharing knowledge and expertise and are working together more in various fields. This includes our collaboration on pilot projects to jointly negotiate the cost of an expensive medicine.

But working together within the traditional medicine policy frameworks, paired with the pharmaceutical industry's current business model, won't lead to long-term solutions. This is where a social debate is required, where we also need to dare to think outside of the box regarding the contours of a sustainable development of our pharmaceutical care.

The Dutch Health Care Institute and the Belgian Healthcare Knowledge Centre took the initiative to have a shot at a more distant future and to look for possible scenarios to break through the spiral of ever increasing medicine prices.

They realised this problem clearly goes beyond our two countries and decided to compile a select panel of international experts, who met in Amsterdam for a couple of days in March and April.

They were asked to do exactly what was needed: to use their knowledge and experience to think about the desired future of pharmaceutical care, freely and radically.

We can now present you with the result: an interesting report which describes various different future scenarios. They are intended to stimulate you and encourage discussions. Not really classic policy advice, as we have grown accustomed to from ZIN and KCE. But to us therefore no less of a challenge to include this broader perspective in our dialogue regarding today's and tomorrow's policies.

Mrs Dr Edith I. Schippers
Dutch Minister of Public Health, Wellbeing and Sport

Mrs Dr Maggie De Block
Belgian Minister of Social Affairs and Public Health

The challenge

Over recent decades, the list prices of new medicines have increased significantly. Pharmaceutical companies do not set prices on the basis of the aggregated costs of drug discovery, development and production, but are increasingly seen to push prices towards the upper limit of or even beyond the 'willingness to pay' of governments or health insurers.

Some argue that the problem of high drug prices is limited to distinct therapeutic classes. Furthermore, they assert that the increasing effectiveness of new drugs means that the cost per health outcome is not necessarily going up. Finally, while list prices have gone up, it is unclear how the actual prices paid have evolved, because they are the subject of confidential agreements between drug development companies and individual countries/payers.

In any event, high drug prices are an increasingly topical and urgent issue on the agenda of political decision makers and the international health care community. A growing number of observers, politicians and even industry leaders admit that the current trend is not sustainable in the long run.

Most drug purchasers (governments, health insurers,hospitals, managed care organizations) obviously do not succeed in setting limits to drug prices, or setting reasonable boundaries to their own willingness to pay. They struggle to find the budgets needed to provide coverage for these expensive medicines. As a result, they are increasingly faced with difficult moral dilemmas: either deny patients the reimbursement of a potentially life-saving drug or be forced to pay prices that draw resources from other health and social needs and put the health system under threat. In either case, the patient and public health end up not being well served.

Towards a public health needs-driven drug development and pricing system

The guiding principle to this reflection is that effective healthcare should be available to all who need it. According to the Constitution of the World Health Organization (WHO), the 'enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being.' Since effective, safe and affordable medicines play a vital role in healthcare, they should be developed, tested, and assessed to address the priorities of patients as well as public health, and not in the first place for maximizing profit.

Four key features of the existing drug development and pricing system come under scrutiny:

The privatisation of public investment in R&D

Many, if not most, breakthroughs in biomedical science are based on research conducted at publicly funded research institutes, universities, and government laboratories. Taxpayers fund the vast majority of the basic research that ultimately leads to the discovery of new medicines. Yet, this public investment in high-risk research to produce a public good (new knowledge), becomes privatised during the drug development phase. Thus taxpayers risk paying twice, first by funding most of the research prior to development, and again by paying budget-threatening prices when the new drugs come onto the market.

Vulnerability to monopolistic practices

The current system of drug development and marketing depends heavily on patents, which makes it vulnerable to monopolistic practices, especially in the case of severe or life-threatening diseases. Furthermore, patents incentivise incremental research and late-stage treatment rather than breakthrough research, prevention and radical cures. There are several examples of replacements of effective, cheap medicines with expensive patented ones with limited clinical added value.

Lack of alignment with public health needs

Today, corporate innovation in drug development is driven by multiple motives, not all of which are aligned with real patient and public health needs.
Investment decisions are taken without the involvement of parties that represent these public interests. Authorities often do not have the processes in place to identify these needs.
The result is an innovation process that is, to an extent, wasteful and fails to address true public health priorities.

Efficacy rather than therapeutic added value as basis for approval

Regulatory authorities often approve medicines on the basis of their better efficacy as compared to placebo and not seldom looking only at surrogate outcome measures. This provides no guarantee of clinically added value and incentivizes incremental research instead of development of genuinely new, effective medicines. Ultimately, this hampers public payers and prescribers in making appropriate reimbursement and clinical decisions.

Why scenarios

Scenarios are stories in which complex and difficult to formalise factors are meshed into coherent and plausible narratives about the future. Scenarios are not a forecast of the future. Rather, they are believable and internally consistent descriptions of what might happen. The scenarios presented here do not aim to offer immediate, short-term and concrete solutions, but they have the intention to be inspirational and to widen the scope of the societal debate about how to deal with the challenge of high drug prices.

Scenario narratives

Scenario 1

Needs-oriented Public-Private Partnerships

Public actors and drug developers are tackling public health priorities in vigorous and pragmatic partnerships. The public actor identifies indications representing high public health needs; specifies criteria for the performance levels of drugs to be developed for those indications; and indicates his willingness to pay. Through procurements with enforceable contractual commitments, the public actor enters into a partnership with drug developers to find solutions for these needs. Developers are prepared to enter into the partnership and to give price concessions for a pre-negotiated fixed agreement on price and volume, which reduces their development risk.

Members of the partnership

The public actor can be the European Union, the government of one (large) country, or a group of countries, forming a coalition. The latter might be needed to achieve critical mass and a large enough market.

The developer or clinical research actor is typically a private enterprise, either a biotech or pharmaceutical company, but it can also be a public actor, an independent academic or governmental research institute with drug development capacities. In some cases, it may even be a combination of both that will develop the requested drug.

Strong public governance

The public actor is the one who is pulling the strings in terms of governance and responsibility. This avoids partnerships from being driven towards the priorities of the developers, rather than those of the public.

Enforceable contractual commitments with pre-specified performance requirements are key to these partnerships. The public actor specifies the performance criteria for the new drug — profile, safety, efficacy and clinical effectiveness — beforehand. Moreover, it is transparent about its willingness to pay for a drug that meets these pre-specified performance criteria.

The drug developer obtains access to the market and is reimbursed only if he successfully develops a drug that meets these criteria.

Several governance mechanisms are in place ensuring that independent researchers and expert-institutions validate the outcomes after each development phase; that there is transparency to the public; and that the partnership delivers on its promises, i.e. that the public only pays for what it asked for. Early-stage involvement of regulators and health technology assessment bodies bring added value to all parties.

Possible other parties involved in the partnership are public or private payers, patient representatives, and any other relevant stakeholder (a charity fund, an NGO,…), dependent on the specific indication, the needs, the required expertise and the opportunities.

Enforceable contractual commitments with pre-specified performance requirements are key to these public-private partnerships.

A close eye on development

Development is monitored by a clinical development platform with experts and representatives from both the developer and the public partner. Here, decisions are made on the design of clinical trials, the endpoints used, etc. Complete transparency and access to the data is guaranteed within the platform. Whoever is part of the collaborative framework has access to the data, and based on mutual agreement it is decided how these data will be managed. There are different options, from independent management to co-management. Also, independent academics and clinicians with expertise — with no links to the private partner — are present in this platform, as well as patient representatives. In addition, each milestone is validated by a review board completely independent from the private and public teams involved in the development. The partnership can also decide in favour of full transparency and to make all data publicly available.

Flexibility during the development process is crucial, especially on the scientific methodologies to generate evidence, but without compromising on the criteria for safety and efficacy. After all, science is

evolving, and this should be taken into account during the development process of the drug.

On the other hand, the demands of the public actor in terms of performance levels need to be consistent with the status of scientific knowledge at the start of the partnership.

Since this is a collaborative framework, the role of patents and data exclusivity is discussed and negotiated at the very start of the partnership. It can be agreed that no patents will be issued, or that there will be joint ownership, or that the ownership remains with the developer. This is part of the negotiated contract.

Incentives

Pharmaceutical companies are prepared to engage in such partnerships because there are clear and convincing incentives, even if they have to give in on pricing. Among those incentives are the opportunity of early negotiations and collaboration with regulatory and health technology assessment (HTA) bodies on the expected performance levels of the drug and the type of evidence needed to demonstrate this performance.

Also, the guarantee to market access and a commitment from the payer to a listed price and a pre-specified volume are convincing incentives: they take away the uncertainties around market approval and reimbursement present in the current system. As a result, the pharmaceutical company does not have to take undue risks when investing heavily with an unsure outcome. Furthermore, individual countries can give additional incentives, including tax benefits, innovation bonuses or research grants.

Public procurement-guided partnerships are geared towards developing affordable drugs for public health needs with high priority. The process of obtaining market access and

reimbursement is shorter for these drugs, since levels of performance, prices and volume were agreed on beforehand with the public partner.

An existing model in other industries

This drug development and pricing model is close to existing governmental procurement practices in research intensive areas such as public transport, defence and space exploration. Likewise, for big science projects, public actors usually specify a number of performance criteria and guarantee a purchase commitment for a certain price if a developer meets the criteria. Technology providers can decide whether they will invest in such projects based on known public commitments.

Also in the health care sector, there are examples of successful partnerships between public and private partners for developing highly needed medicines for neglected diseases, e.g. partnerships aiming at curbing malaria and other tropical diseases in Africa.

Successful pilot partnerships pave the way for a gradual conversion of the innovation system in healthcare.

Ground-breaking in the long run

As the public procurement-guided partnership model is likely to start with pilots in a few limited disease areas, it will not change the way drugs are being developed in the short term. Therefore, profit remains an important incentive for the drug development enterprise and pharmaceutical companies continue to play a major role in health care innovation.

However, successful pilot partnerships have the potential to pave the way for a gradual conversion of the innovation system in healthcare. Increasingly, diseases that represent a significant public health challenge will be tackled by such public-private partnerships. Drug development becomes better aligned with health priorities based on needs, and is decreasingly steered by offer.

Because of the increased transparency in the system, it also becomes clearer to citizens and patients what they can expect from their healthcare systems. Lessons coming out of the pilot partnerships are used to trigger changes in legislation on transparency, pricing mechanisms, market access, etc. Ultimately, payers and governments are better able to plan and properly allocate their expenditure for healthcare.

Scenario 2

Parallel Drug Development Track

EU member states have set up a parallel, not-for-profit drug development track that exists alongside, but independent of, the pharmaceutical and biotechnological industry. The aim of the parallel track is to develop cheaper drugs without compromising safety and effectiveness.

Public research coalitions

After having made up an inventory of the public health gaps and priorities in healthcare, EU member state authorities ask leading public research institutes which discoveries, assets, tools and capabilities they possess in order to develop solutions addressing (some of) the needs that were identified. Among those research centres are academic medical centres, governmental and independent research institutes, universities, etc.

Starting from the match between demand and available expertise, coalitions are built between these (not-for-profit) research institutes, payers, authorities and patient organisations. All these partners make the commitment to participate in an open and transparent way in clinical research projects.

In competition

On the one hand, this parallel track is filling in the gaps in which the industry is not prepared to invest (i.e. new antibiotics, neglected diseases, and certain rare conditions…).

On the other hand, the parallel track also develops drugs in competition with the 'for-profit' industry. Yet, in the parallel track these drugs are being developed without the side effect of high drug prices by avoiding huge profits and extra costs for sales forces, marketing expenses, high salaries and bonusses for company management.

Creative funding schemes compensate R&D efforts. They can consist of upfront or milestone payments for development instead of payment for drug use. But sources such as crowdfunding, social bonds, and other financing options can also be brought in.

'To IP' or 'not to IP'?

Intellectual property (IP) rights are acquired early on in the development process by the partners of the consortium, and ownership is shared. Alternatively, the parallel research infrastructure can completely de-prioritise ownership, i.e. inventions and developments in the parallel track are not protected and are in the public domain. This fosters open science, collaboration and innovation, as other players (even from industry) are welcome to pick up promising results at any stage and build further on these.

The main concern of the consortia is the outcome — the product or the solution for an affordable price — not the entity that develops it. From that perspective, ownership becomes irrelevant, as long as the goals are reached.

Because of this new opportunity in medical research and drug development, several public research centres enhance their medicinal chemistry capabilities in order to produce therapeutic grade molecules. Furthermore, some leading public centres in fundamental research, medicinal chemistry and clinical research align their research lines to optimise drug development. Also, more and more industrial partners are taking part in the system by providing technical and scientific expertise and production capabilities for drugs originally developed in the parallel track.

From here to there... alternative for monopolies

Many quantum leap discoveries in medical science have often come from publicly financed research at universities, research institutes and government laboratories. Usually these discoveries were further developed in private, profit-seeking spinoffs. Only after successful pre-clinical and early clinical research phases, larger biotech or pharmaceutical companies picked up the most promising drug candidates for late phase development, market authorisation, and marketing and sales.

In essence, the new parallel drug development track provides health authorities with a 'try out' option if they believe that there are opportunities for alternative development at lower prices for certain indications or unmet needs. Such a parallel track does not force the industry to change its modes of action or habits, but, if successful, it could significantly diversify the way new drugs are developed. However, one of the conditions to make the parallel track feasible was a redesign of the litigation system on intellectual property and licensing, that could all too easily block or delay competing, non-commercial drug development.

Such a parallel track could significantly diversify the way new drugs are developed.

The parallel track offers policy makers a gradual path towards a more cost effective drug development system. In the beginning it was not disruptive for the existing system. However, as it gains momentum and demonstrably leads to affordable innovation, the pharmaceutical industry is forced to 'jump on the bandwagon' of cost-effective drug development and marketing at affordable prices.

Scenario 3

Pay for Patents

A consortium of European countries has joined forces and has established a 'Public Fund for Affordable Drugs'. Each of the participating countries deposits a fixed annual percentage of what they currently spend on drugs into the Fund. Private payers (including insurance companies) can also join the Fund.

The Fund continuously screens the research market for 'interesting' drugs that are being developed in phase II or in phase III for indications with clear health priorities. The Fund buys off the patents from developers, conducts or commissions the last phases of research in public research institutes, or subcontracts to private partners (but then with strict public oversight), and guides the submission process for market authorisation. Because the drug is then put on the market at a relatively low price, this generates substantial savings for the public payer. Once the system is functioning 'at cruising speed', these savings can (partly) serve to replenish the Fund.

Decoupling

The 'Pay for Patents' model delinks research and development from manufacturing and sales. The prices decrease because the partners in the Fund consider medicines as public goods, which should not be financed through monopoly prices. Hence, once the patent is owned by the public sector, after a successful development and authorisation trajectory, the rights to produce, distribute and sell the drug can be licenced to manufacturers and distributors that provide the best deal in terms of quality, safety, and accessibility for the lowest cost. As a rule, various private partners compete with each other, with the result that 'new drugs enter the market at generic prices'.

Countervailing power

The Fund radically changes the market conditions for expensive new drugs in the countries that participate. Typically, it looks for candidate compounds in disease areas in which several competitors have nearly equally effective candidate drugs in development. Other good drug candidates for the Fund are slightly better alternatives to an expensive 'first on the market' product. Developers may prefer to transfer the rights to a potential new drug to the Fund, in return for a fair reward for already conducted research and development, rather than take all the risks associated with further in-house development of the drug and the prospect of fierce competition in an already crowded niche.

Although the competitors will still be able to develop their candidate molecules, the Public Fund-owned molecule can be mobilised as a price breaker, and force considerable price reductions for the initial product, or even dominate the market.

Because the Fund breaks the monopoly power of Big Pharma and induces at least some of them to contract with the Fund to guarantee returns on investment, gradually more countries or payers join the Fund. Since the Fund combines paying good money for innovation with competitive pricing, all parties involved can win. Patients obtain access to effective and needed medicines, investments and innovation incentives are still there and health budgets are under less pressure.

Scenario 4

Public Good from A to Z

Drug development is essentially a public enterprise, and has been radically reoriented from serving private profits towards serving the public interest and the needs of patients. In a drug development system that is essentially a public enterprise, private drug companies still have a role, albeit with a completely different business model. They mainly manufacture drugs and deliver services to the public provider on a competitive basis. With drugs and other health technologies being essentially public goods, there is no role for patents or monopolistic prices.

A public good developed by the public

Patients and public health providers, not corporations, choose which unmet needs research should address. Public authorities regularly publish lists of research priorities, based on objectively established and patient-informed unmet medical needs. Governments organise and fund that research through a variety of mechanisms, including requests for proposals based on well-defined targets that any research team, public or private, can compete for, or milestone compensation, and active management of the innovation process.

By paying directly for R&D and active management of the drug development pipeline, nations and healthcare systems pay much less than the patent-protected prices of the past. Ultimately, drug prices are set on the basis of the real costs of manufacturing, quality control and distribution, which are decoupled from R&D.

Key steps towards a transformed system

In order to bring this public health-driven drug development system into being, the strong protection by international trade agreements on restricted ownership, secrecy and commercial confidentiality had to be scrapped or renegotiated for the medicopharmaceutical sector. New treaties were negotiated and adopted to remove barriers to improvements in public health, equity and savings in healthcare budgets.

In a transition period, all regulations that impeded the introduction of generic medicines to the market when patents expire were removed, and minor changes to a molecule were no longer patentable. Also, instead of individual countries entering into price negotiations, the EU started to negotiate drug prices on behalf of the whole Union. This gave public authorities considerably more leverage over prices. For life-saving drugs and for drugs that had the potential to prevent serious disability, the EU also started to rely on compulsory licencing. In return for a limited fee to the drug company holding the patent, a third party manufacturer was allowed to produce a generic version of the drug. Eventually this EU-led negotiation platform evolved into a European Medicopharmacology Institute of Public Health responsible for developing drugs and bringing them to the market.

The new healthcare R&D system goes beyond developing affordable drugs. It also conducts research on non-drug interventions, both therapeutic and preventive. It is science and needs-driven, and there is no room for protection of data, intellectual property and monopolies. As the public pays for all research, the public also owns the results of that research.

Independent and open source, with public funding

All clinical trials of drugs or devices are performed by completely independent institutions and researchers with no financial, commercial or other interest in the outcome (positive or negative) of the trial. Trial protocols are registered and made publicly available, allowing patients and others to comment on them to ensure that they study patient-relevant outcomes and are as useful for public health as possible.

Ultimately, drug prices are set on the basis of the real costs of manufacturing, quality control and distribution, which are decoupled from R&D.

All information related to the trials, without exception, is publicly available; all pre-planned outcomes are published; and the raw (anonymous) patient data are made available on request, giving other researchers the opportunity to conduct their own analyses.

Publicly conducted drug trials also ensure that new drugs are being compared with existing alternatives in a fair manner, including with non-drug interventions when appropriate.

Public funding for independent trials does not require financial resources beyond what was routinely invested in healthcare. Because drugs have become much cheaper, part of the health budgets that had previously been spent on pharmaceuticals was re-routed to pay for research.

Drug regulation

The regulatory agencies have become fully publicly funded, and drugs are approved according to quality, efficacy, safety, and, importantly, therapeutic added value.

> **Drugs are only approved and reimbursed if they have shown clinical advantages in independently conducted trials in relevant patient populations.**

Furthermore, criteria for minimal clinically relevant effects are established in advance and lived up to. A general requirement for drug approval is also that the trials are large enough and run for sufficient lengths of time to capture long-term clinical benefits and harms.

Drugs are no longer approved based on surrogate outcomes. They are only approved and reimbursed if they have shown clinical advantages in independently conducted trials in relevant patient populations. The regulators also apply modern principles for evidence-based medicine by incorporating all relevant trials in meta-analyses.

Public education and participation

Energetic efforts educate patients and the general public on what the basis is for this innovative system and how research and development programs work. Although the risk of aborted projects cannot be avoided, these educational efforts prevent tax payers from feeling that costly drug development failures are a poor use of their money. Moreover, regular healthcare priority consultations are held, with public participation. The system is governed by a transparent structure that is accountable to patients and citizens.

Coda

The four scenarios offer possible evolutionary pathways of the current drug development and pricing system. They all rest on the principle that being entitled to medical care is a basic human right. Consequently, they project a range of futures in which the development of new medicines is emphatically guided by the public interest.

In recent years, many of the conceptual building blocks of these scenarios have been discussed in various fora. Here, they are brought together in a few shared frameworks. The scenarios should not be seen as mutually exclusive. It is not inconceivable that a future will emerge in which public procurement-guided partnerships, state-sponsored drug development efforts and decoupling mechanisms appear side by side. The 'Public Good from A to Z' future should arguably be seen as extending to their limit some of the principles at work in the other scenarios.

An inescapable conclusion of this work is that drug development and pricing will have to go through a significant transition to respond to 21st century public health challenges. Informed by new rationales to weigh the risks and benefits of investments in health improvements, the relationship between patients, payers, and drug developers will change. Conventional ways of dealing with intellectual property rights will have to be revised for medicines, which, after all, are not consumer goods but products with a public goods character. Appropriate incentives, skills and attitudes will render the drug development and pricing system more responsive, accountable… and responsible. Foresight and stewardship are poised to become key competencies for public authorities. Increased transparency and an unwavering commitment to good governance are essential ingredients of all futures imagined in this project.

These are important challenges that will demand political will, ingenuity, common sense, and a willingness to experiment.

Colophon

Title
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