FUTURE SCENARIOS ABOUT DRUG DEVELOPMENT AND DRUG PRICING

a project initiated by
Belgian Healthcare Knowledge Center (KCE)
National Health Care Institute of the Netherlands (ZIN)
designed and facilitated by
shiftN

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BACKGROUND
Observation

Govts’ willingness to pay

Drug prices
A complex phenomenon
What we see happening
Two competing narratives
Prices for new drugs have significantly increased and are putting an increasing burden on health care budgets in developed nations.

The pricing logic is wrong.

The drug development system is wrong.

The values and principles are wrong.

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This 'chicken game' is unsustainable

There is a concern that we are heading for a lose-lose-lose situation:

• value destruction on the side of industry;
• reduced opportunities for innovative therapies;
• drug shortages;
• loss of political capital;
• underserved patients.
THE SCENARIO PROJECT
The task

To develop future scenarios that describe ways to provide patients sustained access to the safe and effective drugs they need, with particular attention to the role of pricing.

The client

KCE (Belgium) and Zorginstituut Nederland, research institutes with an advisory role towards their Ministries of Public Health.

The ambition

To stimulate public debate through the articulation of medium- to long-term strategies to deal with the drug pricing challenge.
The participants

A group of 35 high-level and authoritative experts, with significant North American representation, reflecting the following stakeholder segments:

- Organizers (KCE/ZIN);
- Belgian and Dutch payers;
- Regulators, Public authorities;
- Experts in the area of Intellectual Property Rights;
- Experts in the area of Drug Development;
- Experts in the area of Corporate Innovation;
- Experts in the area of Health Economics;
- Experts in the area of Business Ethics;
- Pharmaceutical industry;
- Patient representatives;
- Health care insurers and investors.
APPROACH
Scenario types

The spectrum ‘exploratory’ vs ‘normative’ scenarios

- **WINDTUNNEL**: Developing and testing strategies against the background of different futures
- **ANTENNA**: Making sense of what is happening in the outside environment
- **ALIGNMENT**: Making sure that the organisation is aware of the strategic challenges ahead
- **DIALOGUE**: Providing a platform for building trust and engaging in constructive conversation
- **INFLUENCING**: Influencing the political agenda by exploring negative/unintended implications of policies

**Non-normative**

- DECISION SCENARIOS
  - few
  - #stakeholders

**Normative**

- ADVOCACY SCENARIOS
  - many
Scenario types

Typological scenarios

• **Exploratory scenarios**: focus on understanding the future context in which decisions today will play out. Also: Context scenarios, Decision making scenarios

• **Normative scenarios**: focus on making explicit the positive and negative implications of certain courses of action and/or certain worlds coming into being. Also: Advocacy scenarios

• **Typological scenarios**: focus on understanding the different future forms that a complex system or phenomenon might take. Also: Solution scenarios, Design scenarios
Every set of scenarios partakes of any of these orientations.

- How these layers mix is a matter of interpretation.
- It is important to think this through a priori.
- Mixing these orientations is an important design variable in shaping scenario processes in line with their intended outcome.
From building blocks to scenarios

Seed scenarios as functional clusters of building blocks

Narrative Scenarios
Building blocks rather than driving forces

1. Increase transparency in drug development cost, priority setting & pricing (+ B)
2. Introduce independent validation of clinical trials.
3. Increase payers’ purchasing power.
5. Abandon international reference pricing.
6. Adopt value-based pricing based on principled negotiation processes.
7. Fund comparative effectiveness research.
9. Rely on indication-specific pricing (different prices for different uses).
10. Subject new drugs to a requirement for therapeutic effectiveness (avoid surrogate endpoints).
11. Prioritise reimbursements within a fixed macro-budgetary envelope (portfolio management of health care ambitions, e.g. MOCA).
12. Engage in early dialogue (binding or not) to collaboratively assess effectiveness and pricing.
13. Engage in drug development PPPs.
14. Value the contribution of publically financed research in drug prices.
15. Find alternative ways to compensate R&D efforts that allow to modulate exclusivity rights at the market access stage (decoupling).
16. Support a competitive, transparent research infrastructure that de-prioritizes ownership.
17. Introduce compulsory licensing.
18. Reduce demand for drugs through prevention.
19. Refocus and revamp international treaties in favour of public health and equity.
20. Develop a tiered pricing logic on a pedestal of true development costs.
21. Develop foresight capacity.
22. Align drug development with clear health priorities.
23. Educate and empower patient/citizens and preserve their independence from commercial interests.
24. Create clarity on what our societies expect from our health systems.
A. Monitor real life use with focus on evidence and guidelines development.
B. Create transparency on payers’ priorities and willingness to pay.
C. Preserve independence from commercial interests of institutions, regulators, and health professionals dealing with drug development, pricing and purchases.
D. Ensure a fair competitive environment for generics (e.g. combat anti-competitive practices).
E. Back up post-authorization real-life use monitoring of accelerated market evaluation with un-biased evaluation of safety and efficacy trials.
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Building blocks

• Building blocks target a wide range leverage points. Political feasibility, needed time and resources have not been made explicit.

• Any one building blocks is unlikely to provide a way forward. Need to think in terms of functional clusters of elements.

• There is no consensus on the contribution of any of these building blocks.

• It is vital to attend to the specific ways in which the building blocks are operationalised.
MAKE EXPLICIT SOCIETAL EXPECTATIONS EARLY DIALOG/PPP ETHICALLY DEFENSIBLE REGULATION FOR PUBLIC GOODS DECOUPLING COMPETITIVE RESEARCH INFRASTRUCTURE TRANSPARENCY LINK TO DEVELOPMENT COST VALUE-BASED PRICING FLEXIBLE PRICING INCREASE BARGAINING POWER THINK ICEBERG ALIGN WITH CLEAR HEALTH PRIORITIES EMPOWER CITIZENS/PATIENTS MAKE EXPLICIT SOCIETAL EXPECTATIONS MAKE VALUE-BASED PRICING FLEXIBLE PRICING INCREASE BARGAINING POWER LINK TO DEVELOPMENT COST COMPETITIVE RESEARCH INFRASTRUCTURE TRANSPARENCY DECOUPLING VALUE-BASED PRICING FLEXIBLE PRICING INCREASE BARGAINING POWER LINK TO DEVELOPMENT COST COMPETITIVE RESEARCH INFRASTRUCTURE TRANSPARENCY DECOUPLING.
The scenario seeds

8 seeds

4 have been more extensively developed. They overlap considerably in the incorporated building blocks.

4 are really embryonic and pivot around one or two key ideas.
The scenarios

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.

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.
The scenarios

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.

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 essentially public goods, there is no role for patents or monopolistic prices.
The publication

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 in-depth way potential solutions to the complex national 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 focusing on real health needs.

The scenario project benefitted from the active contribution of a carefully selected group of experts and stakeholders from Europe and North America, including patient representatives, industry leaders, academics, legislators, 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 deliberation workshops in Amsterdam, in March and April 2018.

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
Thanks for your attention

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