

Transparency and affordability: a view from national authorities

Momir Radulović, 18. 1.2022



Situational analysis



1. Spiralling cost
 - ✓ Spending on pharmaceuticals is rapidly outpacing the overall health expenditures and economic growth
 - ✓ Spiralling costs of new cancer treatments
 - ✓ Usurious prices of gene therapy
2. Absence of a connection between the price of drug, sales volume, and clinical performance
3. In spite of billion investments in R&D, urgent public health priorities remain unmet

Situational analysis (2)



- ✓ Drug shortages
- ✓ Non-transparency of industrial data and unpublished data
- ✓ Methodological-scientific inefficiencies of pharmaceutical companies
- ✓ The industry's overall rate of innovation remains incommensurate with our vast drug spending; many drugs are marketed each year, but few represent substantial clinical improvement
- ✓ Commercial imperatives distort drug trials, research priorities and drug regulation
- ✓ **SHORTLY:** The current system is dysfunctional, new drugs are out of reach for many patients!

Pharmaceutical Strategy for Europe



- Adopted in November 2020
- Ambitious long-term agenda in the field of pharmaceutical policy
- Objective: **creating a future proof regulatory framework** and supporting industry in promoting research and technologies that actually reach patients in order to fulfil their therapeutic needs



Elements for access to affordable medicines



- Reward innovation for unmet medical needs
- Balanced system of regulatory incentives – link to access
- Enhance competition from off-patent medicines
- Promote the repurposing of medicines (SI Presidency focus)

Legislation change



- Review regulatory incentives where they may lead to unaffordability of products (e.g., orphan medicines) and ensure that awards for innovation do not lead to a lack of competition and monopolistic prices.
- Should we have more granularity in the data protection periods: some innovative MP 6+2, other 8+2 (e.g. based on predefined criteria, such as highest medical need, Sales/profit threshold, making rewards and incentives (for innovative MP) conditional on launch obligations
- Post-launch evidence generation (re-)confirming the authorisation requirements of quality, safety and efficacy

Legislation change (2)



- Attach conditionalities to both national and European public funding (e.g., Horizon Europe, Innovative Medicines Initiative - IMI) and ensure that public investment in R&D is accounted for and that medicines resulting from publicly funded research are available for a fair and affordable price.
- Ensure that criteria and processes for priority setting in health care are explicit, transparent and that there is a clear link between priorities, national pricing.

Legislation change - basic Pharma act, Orphan and Paediatric Regulations



- Unmet medical need vs therapeutic or societal needs

We would like to remark that the term “unmet medical need” might be misleading and restrictive. We prefer using the term “therapeutic need” instead of unmet medical need for two main reasons.(1) A need is only really “unmet” if there is no alternative at all for helping the patient. However, rarely patients are not helped at all, especially in the case of severe conditions (e.g. symptomatic treatment, supportive care). As soon as something is done for the patient, that activity should be considered as the alternative with which the new treatment or clinical management strategy should be compared.(2) Related to this, we would argue that need is not a categorical feature which is “present” or “absent”, but that there are gradations of the

- Unmet medical need vs therapeutic

The term “therapeutic need” refers to the need for a better treatment than the treatment currently reimbursed (or the best supportive care currently reimbursed). This concept allows to define gradations of need: the more effective the current treatment, the lower will be the therapeutic need, even if it concerns a very severe disease like diabetes. By defining need in this way, it will be possible to identify those diseases which should get priority in terms of investment decisions. Also conditions which are partially met can get into the list of needs, which seems more in line with the spirit of the law than including only conditions which are unmet. The objective of the legislator was presumably to target the high medical needs (i.e. severe diseases), for which no alternative treatment exists yet or for which the alternative treatment is insufficiently effective.

Transparency



Payers risk overpaying, the information asymmetry limits the negotiation power as they are not even level playing field with Pharma industry, which has the full picture in all countries where medicines is marketed

- Revision of Transparency directive (1989)
- Provide structures, control systems and incentives to either reward socially responsible and highly ethical industrial behaviour or penalize unethical behaviour

Transparency (2)



- Expand existing structures e.g., the EURIPID database, to share information on net prices of medicines and strive toward full implementation of the WHA Resolution on improving the transparency of markets for medicines, vaccines and other health products.
- Review regulatory incentives where they may lead to unaffordability of products (e.g., orphan medicines) and ensure that awards for innovation do not lead to a lack of competition and monopolistic prices.
- AIM Model on Fair Pricing¹

Past SI Presidency Focus



Policy brief

Improving access to essential antibiotics

Christine Årdal, Norwegian Institute of Public Health
Yohann Lacotte, University of Limoges, INSERM
Marie-Cécile Ploy, University of Limoges, INSERM

POLICY BRIEF

Repurposing of medicines in oncology – the underrated champion of sustainable innovation

Recommendations of the UN Panel



- The prevailing research and the development business model requires systemic changes in transparency of data and costs
- The Panel recommends public return on public investments for development of new drugs. Namely, basic research and early-stage discovery is largely provided by publically funded academic and public laboratories. The public share of development is even greater in areas of neglected diseases.
- To delink research funding from end-product pricing
- The commentaries of some panelists pointed to incoherencies in the human rights and trade frameworks as they relate to the current system of intellectual property.

Basic principles by BMJ 2018



- Medical needs, not financial means, should determine access to medications
- Drugs must be affordable to society
- Drug development should be geared toward real innovation that maximizes population health
- The human right to health must take precedence over intellectual property rights (patents)
- The safety and effectiveness of medications must be independently and rigorously evaluated
- Comprehensive and unbiased information on drugs should be available to prescribers and patients



Thank you for your attention!

© mongabay.com