



# Building Healthy Markets: Overcoming Information Asymmetries

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Second Fair Pricing Forum, 11-13 April, Johannesburg

# The Market for Medicines: Key Figures

- Global spending on medicines reached \$1.2 trillion in 2018 and is set to exceed \$1.5 trillion by 2023.
- The number of new products launched is expected to increase from an average of 46 in the past five years to 54 through 2023.
- Specialty medicines share (high-cost medicines used to treat complex chronic conditions) exceeded 42% of total medicines spending in 2018 and will approach 50% by 2023 in most developed markets.

Sources: 2018; IQVIA Institute for Human Data Science. The Global Use of Medicine in 2019 and Outlook to 2023. January 2019

## Current Scenario

- Information asymmetries between public and private actors
- Limited data from clinical trials
- Unclear investment flows for research and development
- Lack of information on availability and reimbursability of medicines
- Lack of easily accessible information on patent landscape
- High prices and unequal access
- Accountability of institutions on public spending

# Global efforts towards Transparency

- 1988. December 21. **EU Directive** on transparency on pricing of medicinal products.
- 2015. Resolution 2071 (2015) of the **Council of Europe**: Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?
- 2016. February 18. Joint NGO, member of EU parliament submission to **United Nations SG HLP** on A2M.
- 2018. January 17. **EU Report** on Innovative Payment Models for High-Cost Innovative Medicines.
- 2018. August 30. **WHO Bulletin article** on transparency.
- 2018. December. **WHO Draft Road Map** for access to medicines, vaccines and other health products, 2019-2023.
- 2018. December 18. **WHO Report**: Pricing of cancer medicines and its impacts.
- 2018. July. **EURIPID guidance document** on external reference pricing.
- 2018. The **OECD Report** on Drug Pricing.
- 2007. February 9. **U.S. General Accounting Office (GAO)** report on oversight of drug pricing in federal programs.

## ... On R&D Transparency

*"The Assembly calls on the Council of Europe member States [...] to oblige pharmaceutical companies to ensure absolute transparency regarding the real costs of research and development, particularly in relation to the public research portion".*

2015. Resolution 2071 of the Council of Europe: Public health and the interests of the pharmaceutical industry:  
how to guarantee the primacy of public health interests?

- Acts as an implicit deterrent to applying very high margins
- Allows the definition of appropriate policies regarding the financing and priority setting of R&D
- Results in targeted rewards for innovation in priority areas for public health
- Provides better grounds for assessing R&D incentives
- Facilitates development of new financing mechanisms (delinking R&D and pricing)
- Ensures fair return for public investment actors and public funders

## ... On Price Transparency

*"At a conceptual level, a lack of price transparency is not consistent with the notion of good governance and contravenes the principles of economic theory in enhancing market efficiency".*

2018. December 18. WHO Report: Pricing of cancer medicines and its impacts.

- Supports decision-making on Pricing & Reimbursement
- Improves capacity for negotiation avoiding excessive pricing
- Enhances market efficiency by promoting competition
- Allows more equitable access (right to highest attainable level of health) and fairness in pricing
- Improves performance of international benchmarking
- Enables better allocation of available health resources
- Provides clear lines of accountability and strengthens confidence in public institutions
- Facilitates dialogue between public payers, government decision-makers and industry

## ... On Clinical Trials Data

*"Governments should require that the unidentified data on all completed and discontinued clinical trials be made publicly available in an easily searchable public register established and operated by existing mechanisms [...] or in peer reviewed publications, regardless of whether their results are positive, negative, neutral or inconclusive".*

2018. March 19. Report by the WHO Director-General addressing the global shortage of, and access to, medicines and vaccines (A71/12)

- Supports ability of clinicians, researchers and patients in making informed decisions about which is the safest, best treatment
- Allows reconstruction and reinvestigation of failures
- Provides access to knowledge that is critical for competition and scientific progress
- Supports the elaboration of clinical guidelines
- Supports assessments of HTAs

## ... On Patent Information

*"Transparent patent information can be an important a determinant of health outcomes [...]. Currently, patent information is often confusing, incomplete and fragmented".*

2016. September 14. Report of UN Secretary General High Level Panel on Access to Medicines.

- Facilitates review and opposition to questionable patent applications and grants
- Allows monitoring of application by officials of patentability criteria in compliance with legislation
- Legitimizes competition by providing information on which patents holders plan to enforce and extend
- Encourages market access of generics



# A successful example: Price and Quality Reporting

- Publicly accessible online database that collects and displays data on procurement transactions made by Global Fund-supported programs
- Data in the database from purchases of ARVs, anti-malarial, anti-tuberculosis and anti-hepatitis pharmaceutical products
- Data is entered by Principal Recipients and verified by Local Fund Agents

# Italian submission of a DRAFT WHO Resolution

- The Italian Minister of Health, H.E. Giulia Grillo, wrote to the Director General of WHO, dr. Tedros Adhanom Ghebreyesus on 1/2/2019 during the last WHO EB in connection with the presentation of the WHO Roadmap on access to medicines and vaccines and the Cancer Report.
- Like-minded countries are encouraged to join for the next drafting of the text.

# International Attention

March 6, 2019

Open letter to WHO member states

On 1 February 2019, Italy submitted a draft resolution on transparency to the World Health Organization (WHO). This resolution is to be discussed in May 2019, at the 72nd session of the World Health Assembly (WHA).

The title of the proposed resolution is "Improving the transparency of markets for drugs, vaccines and other health-related technologies," and it sets out a number of measures designed to achieve this objective.

There are deplorable asymmetries of access to information about many aspects of the innovation and supply chain for medicines, vaccines and other health technologies. The lack of information creates confusion about basic facts related to prices, research and development costs and other aspects of the value chain for medicines, vaccines and health technologies.

The resolution would create a work program for the WHO and norms for governments to cooperate in improving the transparency of various aspects of these technologies.

This is a critical time for governments to consider reforms in pricing and incentives for innovation for health technologies. The transparency measures proposed in the resolution will ensure that consideration of such reforms will be based upon the best possible evidence.

We urge your government to support the resolution.



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