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Médecins Sans Frontières (MSF) briefing on provisional agenda item 11.7: Access to medicines and vaccines, Draft resolution on improving the transparency of markets for medicines, vaccines and other health-related technologies

Transparency on prices

As individual consumers, it is usually easy to compare the exact prices we will pay for things like cars, clothes and food in order to make informed purchasing decisions. But the same does not hold true for medicines. Prices charged by pharmaceutical corporations vary wildly for the same medicine depending on who's buying, and **the exact prices that are paid are typically shrouded in secrecy.**

There is no correlation between the prices pharmaceutical companies set and the economic situation in different countries. Pneumonia, for example, remains the world's leading cause of childhood mortality, killing over one million children each year despite the existence of an effective vaccine: the pneumococcal conjugate vaccine (PCV). In 2016, after a successful public campaign, the vaccine's two producers, Pfizer and GSK, committed to reduce PCV prices for MSF and other humanitarian organisations¹ vaccinating vulnerable children in emergency settings. However, in many countries, particularly middle-income countries ineligible for international donor support for vaccines, PCV remains priced out of reach. Although pharmaceutical companies claim to give poorer countries lower prices, Pfizer's PCV13 has been sold at higher prices in Tunisia and Morocco (both lower middle-income countries) than in France.²

There is no public health logic to the way pharmaceutical companies set prices. Pricing policies are not driven by an interest in ensuring access for all people in need of medicines; they are driven by an interest in maximising profit. In the absence of competition, companies often set high prices targeting a portion of the population that is willing and able to pay. This leads to rationing of medicines when patients and health systems cannot afford the prices companies charge. The prices that Gilead set for the hepatitis C medicine sofosbuvir illustrate this very clearly.³

There is no correlation between medicine prices and research and development (R&D) costs. In a recent observational study of 99 cancer drugs approved by the FDA from 1989 to 2017, "the median income return by the end of 2017 was found to be [US]\$14.50 (range, \$3.30-\$55.10) for every \$1 of research and development spending"⁴. Recently, Novartis has faced heavy criticism in the Netherlands over its pricing of the cancer drug lutetium octreotate. A significant part of this drug's development was paid for with public funding and conducted in a public hospital. For many years, hospital pharmacies have produced the medicine themselves – but in 2018, the rights to produce and sell the drug in Europe were acquired by Novartis, who subsequently increased its price by more than 500%.⁵ This illustrates the way in which public contributions to medical research are rendered invisible, and unaccounted for in medicine pricing.

Lack of transparency on medicine prices gives pharmaceutical corporations the upper hand in price negotiations, keeping prices as high as possible while overstretched health systems and people in need of lifesaving medicines lose out.

There can be no fair price without fair negotiations, and fair negotiations are impossible without transparency.

Price transparency is both possible and desirable. MSF began documenting and publishing the prices of HIV antiretroviral (ARV) drugs in 2001. The Global Fund to Fight AIDS, Tuberculosis and Malaria has also long required that prices paid for the medicines it finances be publicly reported through its Price and Quality Reporting System. Price transparency for ARVs has enabled competition and fair price negotiations, and the price of HIV treatment has dropped dramatically – from around US\$10,000 per person per year in 2001 to around \$100 today – enabling treatment scale-up to over 22 million people living with HIV/AIDS and saving millions of lives. One thing is very clear: when countries know what others are paying for medicines, they have more leverage to demand fairer deals and make the right decisions to allow access to treatment and avoid treatment rationing.

Countries do not have to consent to being blindfolded. There is no legal barrier that prevents transparency on prices. For decades now, Switzerland has been able to be transparent about the prices it pays for medicines. All countries can be if policy makers demonstrate the political will. **Governments must stop signing confidentiality agreements.**

Transparency on R&D costs

As policymakers in countries around the world consider how to remedy unaffordable medicine prices, a lack of transparency on R&D costs hinders informed public debate on how best to finance and conduct biomedical R&D. We need to understand who has paid for and assumed the risks of R&D, what those costs and risks are, and to what extent medicine pricing is reflective of this.

A lack of transparency on R&D and manufacturing costs is currently the norm:

- Companies submitting a product for marketing approval are neither incentivised **nor required to disclose the product's R&D or manufacturing costs**. In the report, "Lives on the Edge: Time to align medical research with people's health needs,"⁶ MSF identified cost estimates or reported figures for drug development for a single product. Of the 19 sources identified, the cost of R&D estimates ranged **from US\$30.3 million to \$2.6 billion**, in 2013 U.S. dollars. This is a huge variation and reflected a lack of standardisation of methods and assumptions underpinning calculations of costs and risks.
- **Actual costs (expenditures), not opportunity costs:** Companies often present 'fully loaded' costs, which factor in the so-called opportunity costs of developing a drug versus investing in the stock market. Such loaded costs often disguise actual expenditures. MSF is calling for full transparency on the actual costs of R&D, i.e. what has been spent on the medicine in question.
- **Manufacturing cost information is similarly scarce.** This information is rarely provided by the manufacturer, and while some estimates are available for specific products, these are only estimates provided by third parties.⁷ By contrast, manufacturers could provide information on their actual costs.

Having full visibility on the costs of R&D as well as manufacturing costs for a medicine is vital for negotiating lower prices:

- **Asymmetry of information** – where companies have full visibility of the costs of R&D, the cost of manufacturing, and the mark-up they are set to make, *as well as* the purchasing

country's health needs – leads to asymmetrical negotiations between the buyers and suppliers. When combined with the fact that suppliers often hold a monopoly on the supply of the medicine, **unacceptable power imbalances prevail** that disadvantage those needing to purchase medicines. Increasing transparency on these costs is thus foremost a tool for increasing the bargaining power of buyers, be they medical treatment providers, payers, health insurers, countries or private individuals.

- **Transparency on R&D costs is a tool to de-bunk pharmaceutical companies' baseless arguments** that high costs and high risks legitimise their practice of charging (often extremely) high prices for medicines. Examples of the \$2.6 billion-dollar myth or vague references to costs of 'billions of dollars' cited as fact continue to proliferate. Achieving transparency on R&D costs will help society to take back control over what it is willing and able to pay, based on an assessment of what has actually been spent on drug development and by whom.

Transparency on the costs of R&D is an enabling condition for R&D reform. Full transparency is needed to challenge the predominant, commercial model of biomedical R&D. The industry has responded to arguments for increased R&D cost transparency by arguing that it is not just the costs of R&D but the 'value' of the medicine that needs to be considered in pricing decisions. This is an indication that they are starting to feel uncomfortable. The inevitability of measures to increase transparency will force companies to reveal their real costs, undermining their justification for maintaining high medicine prices. In this context, companies are looking for a new narrative to justify sky-high prices, and to prop up a system that works very well for them but often works very badly for patients and healthcare providers.

MSF recommendations

Lack of transparency on medicine prices and R&D costs hinders access to lifesaving medicines around the world. Adopting transparency as the norm is an urgent necessity.

MSF calls upon WHO Members States to adopt the resolution on transparency during the 72nd World Health Assembly and set strong standards that mandate transparency on medicine prices and R&D costs.

References

¹ MSF. A Far Shot. [Online]. Available from: <https://www.afairshot.org/>

² MSF. The Right Shot: Bringing down barriers to affordable and adapted vaccines - 2nd Ed. [Online]. 2015. Available from: https://msfaccess.org/sites/default/files/VAX_The_Right_Shot_Report_2ndEd_2015.pdf

³ Wyden-Grassley Sovaldi investigation finds revenue-driven pricing strategy behind \$84,000 hepatitis drug. United States Senate Finance Committee. [Online]. 2015 Dec 1 [Cited 2018 Jul 10]. Available from: <https://www.finance.senate.gov/ranking-members-news/wyden-grassley-sovaldi-investigation-finds-revenue-driven-pricing-strategy-behind-84-000-hepatitis-drug>

⁴ Tay-Teo K, Ilbawi A, Hill SR. Comparison of Sales Income and Research and Development Costs for FDA-Approved Cancer Drugs Sold by Originator Drug Companies. *JAMA Netw Open*. 2019;2(1):e186875. doi:10.1001/jamanetworkopen.2018.6875

⁵ Dutch join backlash at expensive drugs by making their own, Reuters, March 7, 2019. <https://www.reuters.com/article/us-netherlands-pharmaceuticals-insight/dutch-join-backlash-at-expensive-drugs-by-making-their-own-idUSKCN1QP0M4>

⁶ MSF. Lives on the Edge: Time to align medical R&D with people's health needs. Doctors Without Borders [Online]. 2016 May [cited 2017 Dec 22]. Available from: https://www.msfaccess.org/sites/default/files/R&D_report_LivesOnTheEdge_Updated29Sept_ENG_2016.pdf

⁷ For example: Hill A, Gotham D, Fortunak J, Meldrum J, Erbacher I, Martin M, et al. Target prices for mass production of tyrosine kinase inhibitors for global cancer treatment. *BMJ Open* [Internet]. 2016 Jan 27 [cited 2017 Dec 22];6:e009586. Available from: <http://bmjopen.bmj.com/content/6/1/e009586>