

The Office of the United Nations High Commissioner for Human Rights (OHCHR)

Expert Workshop on Good Practices in Ensuring Access to Medicines, Vaccines and Other Health Products

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Dear delegates,

Access to medicines is an essential element of a functioning health system.¹ The Sustainable Development Goal (SDG) 3.8 is “Achieve universal health coverage, including [...] access to safe, effective, quality and affordable essential medicines and vaccines for all.”²

The common view that medicines including vaccines are mere commodities managed for technical aspects by the national regulatory authority has serious consequences as it leaves key functions of health systems vital for access to medicines underfunded and underrepresented. A system approach taking into consideration financing, service delivery, governance among others is needed to ensure access to essential medicines.³

The challenges of ensuring access to medicines, vaccines and other health products is not new. Indeed, The Lancet Commission Report “Essential Medicines for Universal Health Coverage” published six years ago lays the groundwork for working towards SDG 3.8⁴ emphasizing the multi-dimensional concept of access including (1) availability, (2) affordability, (3) acceptability, (4) product quality assurance and (5) quality of use.⁴

In the following I will highlight 5 areas of **good practices for member states as well as bilateral and multilateral organizations in ensuring access to medicines, vaccines and other health products touching on these five access dimensions.**

1. **Donation standards.** The World Health Organization (WHO) established guidelines on international medicine donations⁵ following four principles:

(1) donations should benefit the recipient to the maximum extent possible; (2) donations should be given with due respect, and be in conformity with, the policies of the recipient; (3) there should be effective coordination between donor and recipient; and (4) there should be no double standard in quality. Implementing these principles means member states have the obligation to waive duties, facilitate entry and ensure equitable distribution of medicines.

Guaranteeing access to medicines and vaccines as a human right can start with ensuring that member states adhere to the four core obligations mentioned above. The COVID-19 pandemic has made evident that there are still many challenges when it comes to the four core obligations including the equitable distribution where often urban elites have access and rural and poor populations are neglected or left behind. Measuring unmet need of access stratified by income, gender, religion, ethnicity, and other

¹ World Health Organization. *Everybody's business: strengthening health systems to improve health outcomes*. <https://apps.who.int/iris/handle/10665/43918>

² United Nations. *Indicators and a Monitoring Framework*. <https://indicators.report/targets/3-8/>

³ Wirtz VJ, Ravinetto R, Veronika J. Wirtz, Raffaella Ravinetto. Chapter 24. *Enhancing equitable access to medicines and health technologies*. In: Making health systems work in developing countries. Ed. Sameen Siddiqi and Awad MATARIA. Oxford University Press, 2022.

⁴ Wirtz VJ, Hogerzeil HV, Gray AL et al. Essential medicines for universal health coverage. *The Lancet* 2017; 389 (10067): 403–476.

⁵ World Health Organization. *Guidelines for medicine donations*, revised 2010. <https://www.who.int/publications/i/item/9789241501989>

relevant equity dimensions is a key first step for member states to demonstrate accountability towards human rights.⁴

2. Monitoring access to medicines. The WHO together with civil society has established core indicators to measure access to medicines as a human right and created tools and manuals to implement such measurements.⁶ These core indicators assess two core dimensions of access, namely availability and affordability of medicines at the point of care in the public and the private sector. Member states should carry out routine measurement that can be done at low cost given the new technologies⁷ that transmit data in real time. However, many member states have not implemented routine surveillance systems for medicines access with a few exceptions, often with strong support by civil society. But it cannot and should not be left to civil society to create such surveillance systems which are a public good.

3. Creating best medicines procurement practices. Even before the pandemic it has become very clear that the lack of medicines and vaccine price transparency is hindering member states in making prudent medicines procurement decisions for their population.⁸ Unfortunately, not adhering to good procurement practices comes at a huge cost for taxpayers as their money is wasted and in the worst case, untreated patients die because of the access gap.⁹

The Global Fund and the WHO among other have created tools to promote medicines price and quality transparency to ensure best procurement practices. Examples are the Market Information for Access to Vaccines (MI4A)¹⁰ and Global Fund Price Reporting¹¹ that are public reporting platforms where the recipients -in this case governments – report their purchase prices and the quality test certificates of analysis. The data are vital for governments in benchmarking their purchase prices and making good procurement decisions. Member states should report into such public repositories to inform the global community. Taxpayers and patients should demand that their governments publish the prices of vaccines and medicines procured with taxpayer money.

4. Diversifying production and promoting viable markets. The pandemic has shown that a highly concentrated market with only one or a few manufacturers can result in a deadly bottleneck to access, resulting in critical access gaps and the worst cases death. It has been estimated that due to gaps in vaccine access in 2021 about 600,000 lives have been lost.¹² Regional vaccine production needs to go hand-in-hand with advanced purchase agreements with *regional or national* manufacturers. Advanced purchase agreements are critical to ensure that the regional or national manufacturers will have a viable market that they service.¹³ Without such agreements, it will not be possible for local manufacturers to ramp up production (e.g. support for the South Africa vaccine facility). Regional vaccine production also needs to go hand in hand with mutual acceptance of WHO Pre-Qualification and United States Food and

⁶ World Health Organization. *SDG Indicator 3.b.3. Access to essential medicine. Tier re-classification request.*

<https://unstats.un.org/sdgs/files/meetings/iaeg-sdgs-meeting-08/4.4%20WHO%203.b.3%20Reclassification.pdf>

⁷ World Health Organization. *Med Mon – WHO Essential Medicines and Health products price and availability monitoring mobile application.* Geneva, WHO, 2023. Also new technologies that as [Maisha Meds](#), [mPharma](#), [PharmaRack](#) that measure real data at the point of sales and can be used to collect availability and affordability at low cost.

⁸ World Health Organization. WHO recommends highly successful COVID-19 therapy and calls for wide geographical distribution and transparency from originator. <https://www.who.int/news/item/22-04-2022-who-recommends-highly-successful-covid-19-therapy-and-calls-for-wide-geographical-distribution-and-transparency-from-originator>

⁹ Gomez Dantes O et al. Challenges of guaranteeing access to medicines in Mexico. *Health Systems & Reform* 2022, 8: e2084221 <https://www.tandfonline.com/doi/full/10.1080/23288604.2022.2084221>

¹⁰ World Health Organization. Immunization, Vaccines and Biologicals. <https://www.who.int/teams/immunization-vaccines-and-biologicals/vaccine-access/mi4a>

¹¹ Global Fund Price Reporting. <https://www.theglobalfund.org/en/sourcing-management/price-quality-reporting/>

¹² Watson et al. Global impact of the first year of COVID19 vaccination: a mathematical modelling study. *The Lancet Infectious Diseases* 2022, 9, 1293-1302. [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(22\)00320-6/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00320-6/fulltext)

¹³ Thornton I, Wilson P, Gandhi G. N. <https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-022-00851-3>

Drug Authority (FDA) preapproval. If some bilateral organizations, such as United States Agency for International Development (USAID), only except one or the other standard, local manufacturers must invest in the recognitions of both standards which puts an unfair high burden on them.

5. Governance of public and private financing for health. Current government policies fail to regulate biopharmaceutical companies profiting from R&D that is significantly funded via public investments.¹⁴ Taxpayers pay double: first for the research and later for the finished product. Member states need to introduce conditionalities for public investments to ensure that the resulting medical technologies that receive public subsidies in its development process will be available and accessible to those in need, domestically and globally.¹⁴

The WHO convention, agreement or other international instrument on pandemic prevention, preparedness¹⁵ and response, commonly known as the “Pandemic Treaty”, will address some of the catastrophic failures that have been made during the pandemic; however, member states should not wait for the agreement to be finalized before they act. As laid out here, there are already many opportunities for member states to promote policies that address the global inequities in access to vaccines and other health products. It is in the hands of member states to use the existing tools and best practices that I described above to make access to medicines, vaccines and other health technologies a reality now.

¹⁴ World Health Organization. Governing health innovation for the common good. Council Brief No.1. 2021
https://cdn.who.int/media/docs/default-source/council-on-the-economics-of-health-for-all/who_council4a_councilbrief-no1_re-edition_1.pdf?sfvrsn=72ff5801_5&download=true

¹⁵ World Health Organization. Zero draft of the WHO CA+ for the consideration of the intergovernmental negotiating body at its fourth meeting.
<https://www.keionline.org/wp-content/uploads/WHO-zero-draft-pandemic-treaty-1Feb2023.pdf>