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Shaping the future of global access to safe, effective, appropriate and quality health products

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INTRODUCTION

Treaties and covenants confirming the right to health would suggest that everybody is entitled to access essential diagnostic, preventive and therapeutic products.[1] However, before the COVID-19 pandemic, an estimated two billion people lacked access to essential medicines and vaccines, and most primary care facilities in low-income and middle-income countries (LMICs) lacked essential diagnostic services.[2] The pandemic has wide-deepened pre-existing gaps. The inequitable access to COVID-19 vaccines uncovered multiple structural problems in the organisation, financing and governance of the medical research and development (R&D) and supply ecosystem,[3] encompassing unclear demand, weak distribution systems, poor donation practices and corruption, historic inequalities in access to knowledge, training and technological capabilities, lack of technology sharing and transfer, limited local production, and the absence of public health perspective in intellectual property governance. Globally, the response to the pandemic tested our world's solidarity and brought to light continued (colonial) power dynamics that fuelled inequities, misinformation and mistrust. It also blatantly ignored lessons from the past, including the importance of gender equity.[4]

SUMMARY BOX

- ⇒ The response to the COVID-19 pandemic tested our world's solidarity and brought to light continued power dynamics that fuel inequities, misinformation and mistrust.
- ⇒ ·Global, sustained and equitable access to quality health products remains an unachieved goal.
- ⇒ Important lessons from the past about access to essential health products, either for infectious or noncommunicable diseases, have not adequately informed national and international policies yet.
- ⇒ Coordinated progress is urgently needed in four domains: redesigning the pharmaceutical innovation ecosystem and its policy environment to resolve the incoherence between market-driven approaches and public health needs; applying evidence-based and transparent prioritisation criteria in the national health systems; strengthening the regulatory and supply systems; and promoting financial health protection as part of universal health coverage.
- ⇒ Medical innovation and essential health products are critical public health tools and should be treated as common goods instead of private commercial assets.

LESSONS (NOT) LEARNT FROM THE PAST

Back in 2000, six million HIV patients in LMICs lacked access to life-saving antiretrovirals (ARVs), due to high prices linked to pharmaceutical monopolies.[5] Health and human rights advocates, such as the Treatment Action Campaign in South Africa, played a pivotal role in advocating for affordable and equitable access to ARVs, and ultimately contributed to important changes in policy and practice.[6] The World Trade Organization (WTO) adopted in 2002 the Doha Declaration on the Trade-Related Aspects of Intellectual Property Rights and Public Health (TRIPS) agreement,[7] clarifying that countries have the right under this international law to use so-called 'TRIPS-flexibilities' to overcome possible intellectual property barriers and facilitate and accelerate access to cheaper generic versions of essential medicines under patent. The coordinated efforts of civil society organisations, the generic industry, the WHO Pre-Qualification Programme[8] and donors such as the Global Fund for HIV/

AIDS, Tuberculosis and Malaria (The Global fund) and the United States President's Emergency Plan for AIDS Relief (Pepfar) allowed scaling-up ARV programmes in LMICs,[9] paving the way for having millions people with HIV being alive today thanks to ARVs. If this sounds like a success story, many more lives would have been saved if the affordable quality-assured generics had been introduced earlier.

Unfortunately, this experience was not used to improve policies for early, systematic access to essential medicines for other diseases. About 10 years later, when the breakthrough antiviral medicine sofosbuvir (a 3-month oral hepatitis C treatment, the early development of which relied extensively on public funding) was brought to market by Gilead, the initial price charged for this hepatitis C cure amounted to about US$84 000.[10] It took several years before much cheaper generics became available in the majority of LMICs, either through voluntary licensing by Gilead or via the Medicines Patent Pool (https://medicinespatentpool.org/). Yet the lack of adequate funding for procurement and systematic screening and treatment programmes still precludes broad uptake of hepatitis C treatment in many LMICs. Meanwhile, efforts by the United Nations to come to a binding Research and Development treaty or convention to support collective public-health focused R&D and hold governments accountable regarding public funding of health-related R&D and commitments for access have not succeeded.[11] In fact, equitable access to the latest generations of medicines is increasingly hampered by monopolies and high prices, even in wealthy countries (eg, cancer treatments and the newest gene-based and cell-based therapies), with governments unable (or unwilling) to leverage their power to negotiate or enforce fair pricing, alongside a lack of transparency on development and production costs.[12] For example, the lack of transparency about the pricing of COVID-19 vaccines, and the associated power imbalance between governments seeking to procure vaccines for their population and pharmaceutical companies, has caused some blatant inequities, such as the South Africa government being charged more than some high-income countries.[13] In the near future, this gap in access to essential medicines and vaccines could become even more pronounced, with the evolution to personalised medicine.

For some critical health needs related to neglected tropical diseases, there is a lack of new and improved treatments as people suffering from such diseases are not considered a lucrative enough market. For instance, melarsoprol, an extremely toxic arsenic derivative, used to be the only treatment available for advanced Human African trypanosomiasis. After decades of neglect, a not-for-profit public–private collaboration led by the Drugs for Neglected Diseases Initiative (DNDi) delivered the safer nifurtimox-eflornithine combination therapy and, more recently, oral fexinidazole.[14] Even though this is undoubtedly an important advance, such product-by-product initiatives remain insufficient to address all unmet needs in global health, and their long-term sustainability is uncertain. Moreover, access problems are not limited to new medicines. For instance, insulin, discovered in 1921, is still unaffordable to half of those who need it globally: the quasi-monopoly of three manufacturers hampers competition, price negotiations,[15] and inclusion in health insurance packages. Essential opioid analgesics are critical to control severe pain but are also prone to abuse, and subject to special control under international and national laws. The tension between control and access exacerbates the largely ignored North-South gap in access to adequate pain therapy for adults and children.[16] Rabies vaccination is life-saving, and pre-exposure prophylaxis (PrEP) increases the likelihood of survival in bitten persons. While PrEP is actively promoted in international travellers, it is rarely available or affordable for people at risk in endemic LMICs, even now that simplified schedules and a combined yellow fever/rabies vaccination is available, with lower programmatic costs and improved feasibility.[17] When it comes to essential antibiotics, even if access has greatly improved in many countries, their quality assurance remains problematic. Substandard and falsified (SF) formulations are common in countries with weak regulatory oversight, hampering the cure (or worsening the health) of individual patients and potentially contributing to antimicrobial resistance[18] (the same accounts for other therapeutic fields, eg, ARV drug resistance is triggered when substandard ARVs are unwantedly used).

A FOUR-LANE ROAD TO EQUITABLE ACCESS TO QUALITY HEALTH PRODUCTS

The task of tackling all existing challenges in access to essential medicines and vaccines, and of anticipating the future challenges, is complex. Achieving equitable access will require multilayered intervention at different levels, as well as a strong commitment from all concerned national and international stakeholders. Here, we propose that coordinated progress is urgently needed in four domains: the pharmaceutical innovation ecosystem; evidence-based and transparent prioritisation in the health sector; strengthening the regulatory and supply systems; and promoting financial health protection as part of universal health coverage (UHC).

The pharmaceutical innovation ecosystem

The practice of awarding pharmaceutical developers a commercial monopoly through patents allows them to unilaterally decide in which country to seek marketing authorisation, to whom to sell and at what price. This practice ignores that pharmaceutical R&D is increasingly the result of collective efforts, often supported by taxpayers,[19] rather than the enterprise of one individual company. The consequences of viewing health products as business opportunities are far-reaching: prices charged are often too high for most LMICs,[20] and increasingly for HICs,[21] while production and availability may not match

global needs.[22] Often referred to as 'market failures', these are in reality public policy failures resulting from an over-reliance on markets dynamics to solving public health problems. In addition, commercial developers are reluctant to invest in disease areas that do not provide attractive financial returns, leading to what has now been called neglected diseases.[23]

Various measures have been proposed for accelerating access to patented health products in LMICs, such as compulsory and voluntary licences.[24 25] However, in practice, these measures are applied on a product-by-product basis, in a post hoc approach at the end of the R&D cycle: access is not systematically obtained for all products (or countries), and even in the best experiences, it comes with important delays and unnecessarily lost lives. Measures to encourage R&D in neglected fields include a patchwork of public, private and philanthropic funding mechanisms and product development partnerships, rooted in equity considerations, but are insufficient to sustainably address all unmet global needs.

To resolve the incoherence between market-driven approaches and public health needs, transformative changes are needed in the R&D ecosystem to foster the developments of products that address prioritiy health needs and are designed ex ante for wide availability and affordability.[26] The new regional vaccine research and manufacturing hubs that are being created through knowledge and technology transfer,[27] including the WHO-led mRNA technology transfer programme, seem promising.[28] This expertise and technology sharing could achieve a continuum of local (regional) activities, from setting contextualised basic research, to product R&D including well-designed clinical trials, and to production and distribution. This approach has a great potential (a) to prioritise local disease burden and context-specific health needs, (b) to improve the self-sufficiency and resilience of LMICs[29] and (c) to focus on comprehensive 'health interventions' rather than individual products. Such an end-to-end approach should be accompanied by a strengthening of regulatory capacities, adequate financing and procurement policies, proactive technology transfer in line with the original intent of the TRIPS Agreement (as per articles 7 [The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.] and 66.2 [Developed country members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country members in order to enable them to create a sound and viable technological base.]),[30] and a flexible ecosystem for intellectual property management that prioritises health and promotes essential health technologies as global common goods, as recommended by the 2016 UN Secretary General's High Level Panel On Access to Medicines,[31] and in line with recommendations from the WHO Council on the Economics of Health for All.[32] Last but not least, R&D partnerships must be designed, governed and financed for the common good, with conditionalities that link funding to needs-driven R&D priorities and to equitable, affordable access to the resulting health technologies where needed.[33]

Evidence-based and transparent prioritisation in the health sector

National health systems need to maximise their ability to set evidence-based priorities in order to efficiently use limited resources to satisfy increasing and competing demands,[34] in parallel to efforts to increase financing for health and to pursue a whole-of-government approach that puts health for all at the centre of the (national) economy. This includes designing economic and industrial policies that pursue improving health outcomes for the population as their core objective, rather than just (or primarily) GDP growth. It also means ensuring that the R&D efforts respond to the critical questions for public health practice and adopt a gender lens throughout.[4]

Within the health sector, the explicit adoption of health technology assessment (HTA) may contribute to transparency and sustainability of the national health systems, by allowing informed decisions on which effective interventions (including medicines, vaccines and diagnostics) should be prioritised for public funding, procurement and subsidisation in a holistic public health approach.[35] In many LMICs, there is an urgent need to build HTA capacity, next to systems-wide models connecting health supply with health needs. Furthermore, HTA could inform fair price-setting, which implies a balance between fair reward for innovation and production, and timely and equitable access to essential products for all.[36] Effective price regulation also requires transparency on the costs of R&D, production and distribution,[37] and clear and transparent pricing and mark-up rules along the national supply chains.[38]

The pharmaceutical regulatory and supply systems

Whether single or multisource, imported or locally manufactured, all essential health products should be quality-assured and equitably available to all.[39] This can only be achieved in the presence of solid and well-integrated pharmaceutical and regulatory systems, able to foster the timely availability of essential health products while at the same time preventing and responding to SF medical products.[40] Despite valuable initiatives, such as the WHO Global Benchmarking Tool that supports the strengthening of the National Regulatory Authorities through a structured, transparent collaborative process,[41] various countries are still lagging behind in this respect. Between 2022 and 2023, the deaths of hundreds of children who had ingested cough syrups heavily contaminated with diethylene glycol and ethylene glycol, reminded the global health community that

there remains much to do for preventing, detecting and responding to SF medicines.[42] India, a major actor in the pharmaceutical sector and the supplier of many WHO prequalified essential medicines, is also at the centre of a controversy surrounding the weak regulatory system allowing for multiple instances of poor-quality generic medicines and the trade-offs therein.[43] While some may unfairly use these cases to erode trust in all generics, the issue at hand is serious and more efforts are needed to prevent systematic suboptimal quality which, like some diseases of poverty, systematically hit the most vulnerable communities.

Assuring quality is not the only challenge. The weakness of supply systems, due to a combination of chronic underfunding, poor needs quantification, lack of integration across public, private and not-for-profit sectors,[44] and poorly planned donor withdrawal,[45] often results in shortages and stock-outs—even more during outbreaks and emergencies.[46] Moreover, the inappropriate (irrational) use of medicines remains an important driver of therapeutic failure, toxicity, resistance and unnecessary health expenditures. Far from being the sole responsibility of prescribers and/or patients, the inappropriate use of medicines has multifactorial drivers including poor prescribing, poor adherence, self-prescription, illicit use, unethical marketing practices, lack of availability, lack of affordability, etc. As such, it can only be addressed through a multipronged approach involving educational, regulatory and management strategies involving all concerned stakeholders, including healthcare providers, educational establishments, professional bodies and communities,[47] as well as anticorruption strategies.

Overall, strengthening and capacitating national regulatory and supply systems, including establishing robust pharmacovigilance platforms, and supporting regulatory harmonisation initiatives, such as in the forthcoming African Medicine Agency and regional groups,[48 49] should be a priority for LMICs governments, policy-makers and donors.

Universal health coverage

The availability of quality-assured health products is not enough, if they remain unaffordable to a part or the totality of a community. In contrast to most high-income countries, where public and/or private health insurance systems are the primary payers for essential health products and healthcare services more broadly, in many LMICs, pharmaceutical expenditure is overwhelmingly financed through out-of-pocket payment.[50] As a result, poorer households spend proportionally more than others and are pushed into catastrophic expenditures, substandard healthcare or lack of healthcare. In line with WHO's long-standing policy priority for UHC, out-of-pocket financing should be replaced by pooled payment mechanisms, such as payments from public funds or through inclusive health insurance mechanisms, aiming at a comprehensive package of 'healthcare for all.[51] To do so, countries need to accurately track expenditures in pharmaceuticals and medical devices, make better use of existing budgets, fight corruption and increase the fiscal space for health, through public financial protection arrangements,[52] integrated with support from bilateral and multilateral cooperation as needed. National efforts should be supported by innovative reforms of the global financial architecture,[53] such as initiatives for debt relief, transnational taxation initiatives[32] or at least for ensuring access to affordable capital to invest in health.

CONCLUSION

Global, sustained and equitable access to quality health products, whether new or old, remains an unachieved goal. More than ever, the persisting inequalities in access, fuelled by asymmetric power dynamics globally and prominence of market-driven approaches to pharmaceuticals, indicate that we need a change in perspective towards treating essential health products as common goods. The international community needs to pursue a value proposition that prioritises public health goals, integrates equity from the research stage through to availability, quality, access and uptake, and strengthens the global capacity to develop and use health technologies to improve public health, including controlling epidemics. Governments (and, where applicable, donors) need to invest in a health-needs-driven innovation ecosystem in which researchers in LMICs are empowered to develop solutions for their communities' health needs, adequately financed, informed by evidence and transparency, grounded in solid pharmaceutical and regulatory systems, and unconditionally aiming at UHC, under an overarching public health-driven framework.

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