*Global Equitable Access to Quality Health Products*

*Raffaella Ravinetto and Rodrigo Henriquez, Institute of Tropical Medicine, Antwerp, Belgium; Els Torreele, Independent Researcher and Advisor, Geneva, Switzerland; Nico Vandaele, Access-To-Medicines Research Centre, KU Leuven, Leuven , Belgium*

Most countries have acceded to at least one global or regional covenant or treaty confirming the right to health. The right to health entitles everybody to access any needed diagnostic, preventive and therapeutic products. The Sustainable Development Goal target 3.8 aims to "*achieve universal health coverage (UHC), including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all*". Nonetheless, in 2017 an estimated two billion people did not have access to essential medicines and vaccines and a great proportion of them were in sub-Saharan Africa. Similar figures are applicable to other health products, such as diagnostic tests and personal protective equipment. Problems and gaps in equitable access to quality health products have been aggravated by the COVID19 pandemic. The Lancet Commission on Essential Medicines explored in 2016 the progress and challenges in access to medicines along their life cycle and formulated actionable recommendations, that also apply to other health products, in five key areas, i.e. paying for a basket of essential medicines; making essential medicines affordable; assuring the quality and safety of medicines; promoting quality use of essential medicines; and a global research and development (R&D) policy framework[[1]](#endnote-2). For reader-friendliness, our analysis of areas of intervention is categorised by key areas; however, these areas are interconnected, and that global, sustained and equitable access to quality health products can only be achieved by simultaneously acting at all these levels.

***1. Research and development (R&D) of (missing) essential health products***

The international ecosystem for pharmaceutical innovation is failing to address many unmet needs[[2]](#endnote-3). On the one hand, innovative health products are too expensive for most LMICs[[3]](#endnote-4), and increasingly also for HICs[[4]](#endnote-5) , or simply unavailable because global production does not match global needs. On the other hand, the development of some missing health products is not incentivised: R&D investments are compensated through a market monopoly, thus, pharmaceutical companies are reluctant to invest in fields that cannot deliver profitable market returns. These include rare diseases that affect small proportions of the population[[5]](#endnote-6) , and neglected tropical diseases (NTDs) that disproportionally hit communities in poor countries[[6]](#endnote-7). Furthermore, the current system does not consider that pharmaceutical R&D is becoming a collective effort, significantly supported by the taxpayers[[7]](#endnote-8), rather than the (research and financial) effort of one organisation or company alone.

So far, efforts to resolve the incoherence between market-driven approaches and public health needs, include the creation of new funding mechanisms, e.g. the European and Developing Countries Clinical Trials Partnership (EDCTP), and of Product Development Partnerships (PDP), such as the DNDi and the Medicines for Malaria Venture (MMV). However, the patchwork of public, private and philanthropic funding cannot comprehensively and sustainably address the lack of R&D for all rare diseases and NTDs (and probably also for new antibiotics that, once developed, should be kept as "rescue" therapy for patients with multiple resistance); nor timely address the global needs in case of outbreaks. This approach, while valuable and rooted in equity considerations, focuses on (case-by-case) individual product development, rather than at creating the structural capacity and conducive environment to expand the R&D and production capacity. To structurally address the problem, it has been proposed to explore solutions that would reshape the global R&D agenda and align it with global health needs, by adopting new incentives that delink the costs of R&D from the end prices of health products[[8]](#endnote-9). Innovative approaches, such as creating regional hubs for transferring vaccine technology[[9]](#endnote-10), seem more promising for building access into the R&D cycle instead of trying to achieve it post-hoc. Furthermore, there is a need to shift the focus from 'individual products' (case-by-case approach) to 'health interventions', i.e. to plan a collective R&D portfolio approach for public health.

Once new products are developed, local production could improve the self-sufficiency of LMICs[[10]](#endnote-11), particularly of Africa[[11]](#endnote-12) as supported by the WHO initiative ‘World Local Production Forum’ ([World Local Production Forum (WLPF) (who.int)](https://www.who.int/initiatives/world-local-production-forum)).. However, local production is not a magic bullet: it should be built with a public health approach (as in Thailand and Brazil, where local production allowed governments to scale up ARV treatment[[12]](#endnote-13)), and should be accompanied by the upgrade of regulatory capacities, transparency in price-settings, advanced market commitments from regional and global purchasers and – at international level- by a flexible ecosystem for IPRs. If these conditions materialise, local production could make a difference in regional and continental access to essential health products. Initiatives have been taken by the G20[[13]](#endnote-14) in terms of a Global Vaccine Research Collaborative, instructive to coordinate R&D activities with special attention towards the needs of LMICs and NTD’s. Also here, the need for a system wide approach to put R&D affirmatively in the regional eco-system settings of LMICs is part of the necessary conditions.

*Recommendations*: creating an innovation ecosystem based in the Global South and support investments in R&D that address local/regional health needs[[14]](#endnote-15), including technology transfer and know-how sharing; supporting financing approaches that delink -in case of monopolies- the investments in R&D from the end prices of health products; keeping on supporting the creation of regional R&D and manufacturing capacities (e.g. via hubs and eco-system modelling), embedded in a regional manufacturing ecosystem to ensure longer term manufacturing sustainability; and promoting technology transfer, open science and early sharing of patents and knowledge.

***2. Affordability of essential health products***

Pharmaceutical expenditures challenge the financial sustainability of many national health systems, particularly due to the high prices of products under patent, resulting from the current innovation ecosystem, as discussed in the previous chapter. As of today, making these products (available and) affordable requires a balanced interpretation of intellectual property rights[[15]](#endnote-16), for facilitating early generic manufacturing in contexts (e.g. sub-Saharan Africa) or situations (e.g. a pandemic) where essential medical products are unavailable or unaffordable. Various concrete measures have been proposed by different authors for facilitating early generic manufacturing (and if relevant, price competition) and/or striking fair deals for equitable access to medicines, including applying rigorous criteria for patentability[[16]](#endnote-17), facilitating compulsory licensing [[17]](#endnote-18), encouraging voluntary patent pooling and technology transfer[[18]](#endnote-19)promoting local production[[19]](#endnote-20), considering temporary but timely intellectual property waivers[[20]](#endnote-21)- and building such measures into the forthcoming Pandemic Treaty[[21]](#endnote-22). However, most of these measures are either not applied, or they are applied in a post-hoc approach, meaning that important aspects such as price decrease and technology transfer are negotiated on a product-by-product basis at the end of the R&D cycle. As discussed above, transformative change requires developing products that are designed to be affordable ex-ante. Furthermore, independently of who are the product's developers, prices should always be transparently informed, regulated and negotiated [[22]](#endnote-23) at least in line with 2019 resolution of the World Health Assembly[[23]](#endnote-24).

*Recommendations*: creating an innovation ecosystem that not only facilitates early access to innovative essential health products to all, but also support local innovation efforts to structurally respond to health needs when and where they occur. Specifically, it is important to promote the implementation of articles 66.2[[24]](#footnote-2) and 7 of the TRIPS Agreement[[25]](#footnote-3); the voluntary sharing of patents; and transparency policies at international level[[26]](#endnote-25), in line with 2019 resolution of the World Health Assembly[[27]](#endnote-26), the recommendations of the WHO council on the Economics of Health for All[[28]](#endnote-27) and with the ongoing revision of the EU's pharmaceutical legislation[[29]](#endnote-28).

***3. Availability of essential health products***

To make essential health products available to all, a national pharmaceutical system needs adequate procurement systems, informed by accurate quantification of needs, with adequate pre-qualification (and re-qualification) of products and suppliers, and adequate purchasing methods[[30]](#endnote-29). Furthermore, it needs distribution systems able to minimise stock-outs and overstocks, to assure adequate conditions and monitoring during storage and distribution, to harmonise the stock management tools, and to rationalise storage points. Unfortunately, under-resourced national pharmaceutical systems often lack some of these capacities, or an adequate coordination across them[[31]](#endnote-30). Poor procurement practices, weak information systems, and corruption may also play a role in distorting the adequate assessment of needs and the supply. This results in poor planning, procurement and distribution practices - in routine conditions and even more during public health emergencies[[32]](#endnote-31). Difficulties can be compounded by the poor integration of global health initiatives and international NGOs in local pharmaceutical systems[[33]](#endnote-32), and by poorly-planned donors' withdrawal[[34]](#endnote-33).

*Recommendations*: strengthening national and regional pharmaceutical systems in a coordinated and integrated way, which requires carefully balancing "the inherent tensions between the short-term focus on the efficiency of vertical programmes and broader, longer-term health and development objectives"[[35]](#endnote-34).

***4. Toward an essential and comprehensive package of "health care for all"***

Pharmaceuticals account for about 25% of global health expenditures - up to 70% in some LICs. In many LMICs, pharmaceutical expenditure is overwhelmingly financed by individuals and households, through out-of-pocket (OOP) financing. This is an inequitable mechanism: poorer households spend proportionally more than others, and are pushed either into "catastrophic expenditures", or toward the informal and unregulated market, or toward non-adherence, or they simply cannot get the diagnostic, preventive and treatment measures they need, which generates harm both at individual and at population level[[36]](#endnote-35). To address this situation and to move towards a comprehensive package of "health care for all" regardless of the ability to pay[[37]](#endnote-36), countries need both to make better use of (often, largely insufficient) budgets, and to increase the fiscal space for health. This require, at country level, adequate public financial protection arrangements[[38]](#endnote-37), integrated with support from bilateral and multilateral cooperation as needed; and at international level, innovative reforms of the global financial architecture[[39]](#endnote-38), such as initiatives for debt relief or at least for making sure that LMICs have access to affordable capital to invest in health.

*Recommendations*: supporting governments and national health systems to design policies and strategies that allows to finance the pharmaceutical expenditures in an equitable way; to develop efficient and comprehensive health insurance schemes; to reduce the amount of out-of-pocket spending; and to accurately track pharmaceutical expenditures at government and households level.

***5. Quality of essential health products***

Universal health coverage cannot be attained if the quality of health products is not fully assured everywhere[[40]](#endnote-39). Therefore, countries need effective regulatory systems, as an essential component of national health systems[[41]](#endnote-40). In countries with under-resourced national regulatory authorities (NRAs), both the formal and informal sector can be infiltrated by substandard and falsified (SF) products[[42]](#endnote-41), which to date have been detected in almost every therapeutic or preventive field[[43]](#endnote-42). Between 2022 and 2023, the death of some hundred children due to paediatric medicines contaminated with diethylene glycol was a dramatic reminder of the size of threats to health from SF medicines[[44]](#endnote-43). Falsified products always stem from illegal activities, while substandards have a regulatory approval but fail to meet adequate standards due to undetected poor practices[[45]](#endnote-44). Both can cause therapeutic failure and toxicity, resistance, wrong diagnosis, and spreading of infectious agents, in addition to harming confidence in health systems and inflating healthcare expenditures.

*Recommendations*: actively supporting the strengthening of local capacities, in line with the African Union public health agenda, e.g. by supporting the development of the African Medicine Agency[[46]](#endnote-45), and related regional harmonisation initiatives[[47]](#endnote-46); and by supporting the countries' efforts to strengthen their NRAs toward an adequate maturity level[[48]](#endnote-47) .

***6. Quality use of essential health products***

The inadequate use (partly overlapping with the concept of "irrational use") of health products, and of medicines in particular, remains an important driver of therapeutic failure, toxicity, resistance (e.g., suboptimal doses contributing to antimicrobial resistance) and unnecessary expenses at health system and household level. Inadequate practices may extend to 'after administration and/or end-of-shelf life', e.g. in case of unsafe disposal of expired products. Reasons are located at various level: poor prescribing practices, self-prescription, hesitancy, poor adherence, illicit use of some substances, unethical promotion and marketing practices (which foster inadequate prescribing and influence patient's expectations )[[49]](#endnote-48) , misleading information in mainstream and social media[[50]](#endnote-49), inadequate pharmaceutical formulations[[51]](#endnote-50), etc. Furthermore, the lack of availability and affordability at patient level is an important, under-looked determinant of inadequate use of health products. Addressing this problem requires complex interventions and strategies that enable collaboration among patients, health-care providers, insurers, supply chain managers, and other stakeholders[[52]](#endnote-51). Unfortunately, many NRAs lack an efficient, fully-resourced function that coordinates activities and strategies to comprehensively promote appropriate use of medicines.

*Recommendations*: strengthening NRAs, as described in the previous section, to empower them to develop and coordinate missing functions that impact on adequate use of medicines.

***7. Health technology assessment and priority setting for UHC***

Ensuring equitable access to high-quality, affordable health care for all is critical for Universal Health Coverage. Evidence-based priority-setting processes are necessary to maximise the health system's ability to use limited resources to efficiently satisfy increasing and competing demands. However, many effective interventions favouring low-income populations continue to be under-used while funding less cost-effective or wasteful interventions[[53]](#endnote-52). Health Technology Assessment (HTA) has a distinct role in determining the added value of a health technology over existing ones from clinical and economic perspectives. Assessing a technology facilitates decisions on effective health interventions for patients and contributes to the sustainability of national health systems. A wide variety of different organisations and structures are already in place in the EU Member States[[54]](#endnote-53). Complementary to HTA is the availability of systems wide models, connecting health supply with the health needs, which reveal levers for improvement to impact various health indicators.

*Recommendations*: supporting the adoption and strengthening of health technology assessment and system model building, to inform evidence-based decision-making in the selection of technologies to be funded by health systems in LMICs.

**8. Conclusion**

Hafner and colleagues wrote in 2020 that "global health programme design should shift away from a narrow view of medicines primarily as an input commodity to a more comprehensive view that recognises the various structures and processes and their interactions within the broader health system that help ensure access to and appropriate use of medicines and related services"[[55]](#endnote-54). Overall, this informal review indicates that approaches that unilaterally rely on fostering favourable market dynamics for driving research and development (R&D) of new health products, as well as the sustained production and availability of new and old health products, have proven to be insufficient to achieve global, sustained and equitable access to quality health products for public health purpose, i.e. adapted to needs and context, available, affordable, quality-assured, with adequate evidence-base to support use, and manufactured in quantities that match global needs[[56]](#endnote-55).

We need innovative and solid policies to promote equitable access to quality health products for all, and to pursue a value proposition that prioritises public health goals, integrates equity from the research stage through to availability, access and uptake, strengthens the global capacity to develop and use health technologies to improve public health, including controlling epidemics, and eventually reconciliates the interests of different stakeholders into an overarching public health-driven framework. Such policies would be built under the overarching assumptions that (a) areas of interventions are interconnected to each other[[57]](#endnote-56), (b) improvements must be framed under health system strengthening and include creating adequate fiscal space (c) and **essential health products are common goods**.

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