SDC Health Network

The Private Sector as a partner in Health

Engagement modalities, limits and perspectives

16 June 2021

The **fourth module** of the PSE in Health webinar series was the **second of two parts** that focused on private-public partnership modalities that enable the equitable **access** to innovative and affordable health technologies in low-income settings. Part II explored different public-private partnership models that **ensure quality of affordable medicines**.

Summary

Poor quality medicines can have **many adverse effects**, not just for the **patient's health**. Substandard medicines threaten **public health** with resurgent diseases or new resistances. They can also cause **economic loss**, and **breach public trust**. Counterfeit products are equally – if not more – problematic for both patients and the public, and are commonly found in low- and middle-income countries (LMICs).

Medicine quality can be compromised at various stages, from the production of active ingredients to patient uptake. Therefore, ensuring quality requires considering a multitude of aspects: formulation, effectiveness and stability of medical products, but also packing and labelling (is it understandable? Can the product be used correctly? Is it going to hold up under difficult environmental conditions?), shelf-life, or even appearance. Considering policy and financing is also critical, because new medicines and/or generic drugs are likely to cost more than existing or substandard ones on the market. Therefore, ensuring quality, as well as affordability and access, **requires *continuous* interventions throughout the entire journey of a product**, from laboratory to regulatory approvals and product readiness for the field.

Lower- and middle-income economies are particularly vulnerable to substandard and fake medical products. Specific instruments and programmes have been put in place to address their needs – WHO Prequalification of Medicines Programmes (PQP) of medical products, WHO Global Benchmarking Tool[1] (GBT), regulatory systems strengthening programmes, Good Manufacturing Practices (GMP), and the push for the production of generic medicines, to name a few.

To learn more about the specific challenges, opportunities, and possibilities for donor organisations to contribute to quality assurance in LMICs, the SDC Health Network invited **expert speakers**, active in different areas of **quality assurance** in lower- and middle- economies and whose organisation engages in different private-public partnership modalities: **Swiss TPH** is a long-standing SDC implementing partner in various health-related projects; **Medicine Patent Pool (MPP)** sub-licences patents to generic manufacturers to produce high quality, yet low-cost, drugs for LMICs; **QUAMED** seeks to increase the base of reliable suppliers with quality assurance audits of pharmaceutical vendors and a certification programme that reflects medicine suppliers' level of compliance to good storage and distribution practices; **Swissmedic** is the Swiss authority responsible for authorising therapeutic products, but also engages in strengthening regulatory systems in LMICs and building up capacity of national medicine authorisation agencies; and finally, **Medicines for Malaria Venture (MMV)**, a Product Development Partnership (PDP)[2] involved in the research, development and delivery of antimalarial drugs, is pushing towards bringing drug manufacturing closer to the patients.

In a round of brief presentations followed by a facilitated round table, guest speakers shared their experiences and views on how to balance access and affordability with quality of medical products.

[1] See also: https://gh.bmj.com/content/5/8/e003181

[2] The PSE in Health module 3 explored the PDP model more in depth. Summaries and additional material are available on the SDC Health Shareweb.

Bottlenecks

The private sector services 60 to 70% of patients in LMICs, engaging private actors is therefore necessary. Yet, quality assurance systems are often unsatisfactory or even non-existent for the private sector in LMICs. With **limited regulatory capacity** in terms of financial resources, enforcement and sanctions, developing countries are particularly vulnerable to medical products of poor quality: 10% of drugs in circulation are substandard or counterfeit, with and alarming rise in the latter since the onset of the COVID-19 pandemic. **Constrained purchasing power** for both public procurement and self-financed patients, as well as the **lack of knowledge and know-how** of public and private actors alike on the importance of quality and which quality assurance measures can be taken, further undermine access to good medicines.

While manufacturing of medicines is concentrated in Asia (active product ingredients are mainly produced in China and finished generic pharmaceutical products in India), the African continent imports 80 to 90% of the finished products it consumes. This **regional imbalance and the multiplicity of intermediary actors complicate regulatory control**, as **regulatory frameworks vary** from one country to the other, traceability cannot always be guaranteed, and longer supply chains increase the odds of quality deterioration.

Disruptions in supply chains and protectionism measures during the COVID-19 pandemic have further highlighted the extent to which the production-consumption geographical divide can affect patients in LMICs. Ensuring the security of supply chains, while guaranteeing quality, has been challenging. **Political accountability and visibility** have pressured political leaders to focus on availability of medicines with a lesser regard for quality, or favoured local suppliers, not all of which are up to standards. With the experiences from the pandemic, the industry has observed a growing interest in **diversifying the pharmaceutical production landscape and strengthening the global supply chain** to ensure that medicines are closer to where the patients need them. However, **building local manufacturing capacity can hardly happen from scratch**. Resources being a limiting factor, capacity building focuses on **actors with existing manufacturing capabilities, capacity and good market penetration prospects**, i.e. with an existing market outreach network.

Finally, as show-cased by guest speakers, many quality assurance strengthening activities rely on **voluntary-based** mechanisms. If regulatory, control, and monitoring processes require too much efforts, **private actors can simply decide not to opt in**. For example, MPP's model is based on sub-licencing to *several* generic manufacturers. The lack of exclusivity inevitably leads to price pressures. Yet, licencing agreements requires private manufacturers to take the necessary quality assurance measures to go through approval by a stringent regulatory authority, which discourages some actors**. Willingness of actors** is therefore key.

Opportunities

Guest speakers' experiences have shown that private actors willing to invest in quality assurance training and measures are out there. They just need the **right incentives**. Guaranteeing that **demand** not only exists, but that it is **also ready to purchase quality-assured products**, is crucial. This has for example been the case for malaria and HIV drugs, where procurement is backed by big players, such as the Global Fund and other financing mechanisms. WHO prequalification has gone a long way in **securing bulk purchasing**.

However, **new entrants** in the generic medicine market **face high costs** in dealing with WHO pre-qualification and CMP standards, with little insurance on demand volume. This has notably been the case for non-communicable diseases like diabetes, for which out-of-pocket remains the main source of financing. PDP-like partnership models are active in alleviating some of these costs and risks for pharmaceutical companies. Quality certification programmes, such that of QUAMED, also contribute to securing demand by **enlarging the pool of reliable and quality-assured pharmaceutical vendors and lowering transactional costs** for procurers (governments, donor agencies, NGOs, etc.). In any case, it is critical to develop partnerships with an **enabling environment for pharmaceutical actors to alert to problems** as they arise and to **co-develop solutions** that emphasise quality considerations, as MPP's experiences have shown.

Albeit, **government support** is essential to make demand forecasting easier and to foster good quality assurance practices through **conducive policies and strong regulatory systems** at country-level. Programmes like Swissmedic's Marketing Authorisation for Global Health Products (MAGHP)[3] seek **to build up capacity of regulatory authorities**. At the same time, they address the double standard in quality assurance between high- and lower-income countries by **harmonising regulation processes between jurisdictions**, since applicants to the programme must fulfil the same requirements as if they were to market a product in Switzerland.

Finally, bi-/multilateral **donors** and **development and cooperation organisations** can contribute to strengthening quality assurance by **raising awareness** amongst authorities and local stakeholders on the importance of quality to avoid the trade-off between availability and quality, especially in emergency situations. Collaboration with and capacity-building of all actors in the supply chain can help to effectively **detect, report and respond to quality problems**. Last but not least, **quality assurance should be clearly and explicitly stated** in all contracts and policies with partners in the field.

Take-home messages:

1. The **willingness of manufacturers and vendors** to engage in quality assurance is key.
2. This requires giving them **the right incentives**.
3. Fostering quality requires a **competitive space**: if there is competition, there is an incentive to work on product quality, while lowering the price.
4. In the case of **voluntary-mechanisms**, the price pressure from market competition can deter investments in quality assurance.
5. Ensuring **enough demand** and **responsiveness to quality-assured products** once they enter the market are important components of competition.
6. We cannot set aside the fact that the primary goal of pharmaceutical manufacturers and suppliers is to make profit. The goal is to make sure that **the need to sell does not trump the need for quality**.
7. This requires **strong regulatory systems**, including monitoring and enforcement mechanisms.
8. These require sufficient **resources** (financial, human), appropriate **regulations**, **knowledge and know-how**, but also the **political will** to put quality at the forefront.
9. Actors in development and cooperation (NGOs, donors) can contribute by making **pharmaceutical quality assurance explicit and clear in their policies** and to all the stakeholders with whom they engage.

[3] On 23 February 2021, Swissmedic and SDC co-organised a virtual event to present the first results of the MAGHP programme. More information on the SDC Health shareweb or the event recording.