Quality medicines in Africa: the importance of good knowledge of the supply chain and synergy between regulators and industry

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Pharmaceutical production grew globally over the last decades: active ingredients and finished products are manufactured across different regions, and circulate through multiple distribution channels. Sadly, globalisation of production was not accompanied by strengthening of the regulatory systems worldwide: many national medicines regulatory authorities (NMRAs), especially in sub-Saharan Africa, are under-resourced and struggle to control their markets.

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The responsibility of assuring the quality of medicines on the global market is spread among actors with unequal capacity and diverging interests, and the sub-Saharan African market is, in particular, characterised by multiple quality standards, so that a large majority of the population is at risk of receiving poor quality products (see diagram). Furthermore, poverty limits access to reliable vendors, and unhealthy price competition foster the trade of non-quality assured products. Substandard drugs in sub-Saharan Africa are estimated to range from 12% to 48%. But the problem is broader: according to the World Health Organization (WHO), the rate of poor-quality medicines is approximately 10.5% in low- and middle-income countries.1

Poor-quality medicines include falsifications, which are “deliberately or fraudulently misrepresented with regards to their identity, composition or source”, and substandards, which are “authorised by the NMRA but fail to meet national and/or international standards”, due to poor manufacturing and quality control practices that are not detected by regulators.2 Both falsifications and substandards cause therapeutic failure, toxicity and resistance, leading to human suffering, loss of faith in health systems and resources’ waste. But causes and corrective measures are different. Falsifications result from a deliberate willingness to fraud, and they must be fought by repressing illegal manufacturing and distribution. Conversely, substandards result from human error or negligence at manufacturing sites, or from degradation due to poor storage and transport conditions; thus, prevention and elimination require a complex set of measures, i.e. strengthening the capacity of NMRAs, of manufacturers and distributors, and promoting ethical behaviour of all stakeholders.

Some Positive Initiatives

The WHO launched in 2001 the Prequalification (PQ) Programme, which had a major impact for ensuring the quality of HIV, malaria and tuberculosis medicines worldwide. The WHO PQ recently designed a Collaborative Procedure with NMRAs for the assessment and accelerated national registration of WHO-prequalified products. This enables NMRAs to make use of work already carried out by the WHO and to strengthen their own regulatory oversight processes. Of greatest interest to manufacturers is that application of the procedure enables faster registration in the participating countries. Meanwhile, the WHO Expert Committee on Specifications for Pharmaceutical Preparations makes available technical guidelines to help market players improve their manufacturing, distribution and procurement practices.4
At African level, a Medicines Regulatory Harmonisation Initiative was started in 2009 under the New Partnership for Africa’s Development (NEPAD); and the launch of the African Medicines Agency (AMA) is expected in 2018, to ensure that all Africans have access to affordable medical products that meet adequate standards. It is hoped that AMA will establish an enabling environment for the development of the pharmaceutical industry, since upscaling access to quality-assured medicines requires both a functioning regulatory framework, and a local pharmaceutical sector able to work according to international standards.

During recent years QUAMED, a network of non-governmental organisations and local procurement centres, has developed an innovative approach to improve the quality of medicines in sub-Saharan Africa. QUAMED members pool resources for auditing distributors and manufacturers according to the WHO standards, in order to orient purchase practices toward quality-assured suppliers. QUAMED also increases the knowledge and quality assurance skills of partner organisations through specific training, sharing of information and support. In the future, it hopes to further develop its auditing capacity, in order to build a more direct interaction with manufacturers willing to invest on public health needs in Africa.

**Advocacy and Pedagogy**

Awareness of poor-quality medicines remains quite low among non-specialists, i.e. academics, policy makers and actors involved in the supply chain, at least partly because pharmaceutical issues are insufficiently addressed in the study curricula. Thus, more and better advocacy is needed for universal access to quality-assured medicines, targeting regulators, manufacturers and suppliers, international organisations, journalists, purchasers, prescribers, program managers, policy makers, public health actors and patients. Adequate communication tools, in lay language, are needed to address non-specialists that may play a role in defining policies and/or in advocating for universal access to quality-assured medicines. QUAMED, for instance, increasingly builds on collaboration with academic institutions, scientific and public health platforms and policy makers, to contribute to documenting the extent of the problem, and to feed advocacy for universal access to quality-assured medicines.

Upgrading and strengthening the regulatory and legislative pharmaceutical framework in sub-Saharan African is of outmost importance to make quality-assured products available to the most vulnerable populations and to increase health systems’ performance. Though, a virtuous integration between health policies and local pharmaceutical production is needed to synchronise commercial and health interests. Several existing models can inspire new initiatives or enlarge existing ones. As underlined in a recent UN/WHO joint publication: “(...) this endeavour [ensuring reliable and sustainable manufacturing of medicines] requires a far-sighted vision, the optimal combination of mutually supportive national policies, good governance and rule of law, the establishment of robust national regulatory authorities and other relevant institutions, the availability of diverse technical expertise and access to viable markets. Quality of medicines is non-negotiable and must be assured through the strict application of Good Manufacturing Practices and other quality assurance systems across the pharmaceutical value chain.”

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**The Role of the Private Sector: Food for Thought**

Many manufacturers in sub-Saharan Africa would benefit from technical assistance and technology transfer for upgrading to the WHO standards. It is important for the private sector to be able to engage in such collaborative partnerships, for example through public-private partnerships, and as part of corporate social responsibility policy.

Some essential medicines do not currently exist in WHO PQ formulations, e.g.: benzathine penicillin, for mother-to-child transmission prevention of syphilis. The European private sector
should be able to invest in these products, either directly or through a local company in sub-Saharan Africa, and through equitable pricing policies.

Specific initiatives may support countries and/or their regulatory authorities to set up sustainable programs in areas that are currently lagging behind, such as Merck for Mothers (for strengthening the supply chain) 8; and/or to carry out R&D programs for neglected tropical diseases 9.

The private sector plays a key role in setting the price of pharmaceuticals. High prices in poor countries often hampers affordability and push desperate patient toward non-secured supply chains. Ad hoc mechanisms could be envisaged to systematically improve the affordability of innovator essential medicines in such contexts, such as differential (equity) pricing, or the model of the Patent Pool 10.

Footnotes:

1  A study on the public health and socioeconomic impact of substandard and falsified medical products: executive summary. (« Etude sur les impacts sanitaires et socioéconomiques des produits médicaux non-conformes ou contrefaits : les points essentiels »), Genève, Organisation mondiale de la Santé, 2017
3  https://extranet.who.int/prequal/content/collaborative-registration-faster-registration
4  http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1003/en/
10 https://medicinespatentpool.org/