A quality assurance system for pharmaceutical manufacturers: unmet needs and opportunities. A policy-shaping workshop bringing together key-informants

Take-home messages

Background

The Sustainable Development Goal 3.8 aims at universal health coverage, including "quality and affordable essential medicines and vaccines for all". But the increasing globalization of pharmaceutical production makes it difficult to assess the quality of medicines, especially in low- and middle-income countries (LMICs), where under-resourced regulatory authorities cannot fully assure the quality of products manufactured, imported or distributed in their territory. Today, the global pharmaceutical supply chains are not (fully) secured. Many initiatives have been launched to strengthen the quality assurance (QA) systems, in first place the WHO Prequalification, and then the QA policies of some donors. Since 2011, 29 Non-Governmental Organizations and Procurement Agencies joined forces in QUAMED (http://www.quamed.org). They pool resources and share knowledge for auditing distributors/manufacturers according to the WHO standards, providing tailored trainings in pharmaceutical QA, and promoting research and advocacy for universal access to quality-assured medicines. Findings from inside and outside QUAMED suggests that important gaps remain, so that most stakeholders are unable to adequately master the selection of the sources (medicines and other medical products) they supply. It has been suggested that this problem should be addressed by harmonizing the assessment of quality assurance systems for manufacturers. Thus, QUAMED, the Belgian Development Cooperation (DGD) and the Be-cause Health platform jointly organized a workshop (Brussels, 23-24 November 2016) to bring together key-informants to discuss the current gaps to orient/guide further policy development. Extensive Proceedings of the workshop will be circulated and disseminated to a broader audience in the first quarter of 2017. The present document is meant to preliminarily share the main results of the Workshop among the organizers and participants, and it may trigger further comments and contributions.

Take-home messages

The funders and the purchasers of medicines in/for LMICs (NGOs, African Procurement Centers) needs concrete instruments to select quality suppliers, and they also need to develop a strong(er) negotiation capacity *vis-à-vis* these suppliers.

Overall, *we should move from the current "parallel paradigm, where each organization relies on its (often limited) resources and means, to a "collaborative paradigm", based on information-sharing and on a collaborative approach*. Concrete ways to build the new paradigm include:

- *(SHORT TERM) Create an easy-to-access platform that brings together the existing information on QA policies and standards, and on dossiers assessment outcomes.* Such information is often already publicly available, but scattered and difficult to retrieve. A user-friendly website where this information/links to concerned websites can be found, would be of great help. It was suggested that this could be achieved by developing the existing QUAMED website[1].

- *(MEDIUM TERM) Create the conditions to allow the different stakeholders to share validated information on the assessment of pharmaceutical manufacturers and distributors.* Information-sharing appears to be the greatest need, since all stakeholders have limited resources for GMP audits and their purchase policies would greatly benefit from it. However, information-sharing should be grounded in *harmonization of audits standards and procedures*, including an *harmonized matrix for the assessment of manufacturers* and *harmonized qualification of GMP experts*. Noteworthy, an harmonized matrix for the assessment of manufacturers has been

[1] Challenges : ensuring adequate human resources and long term sustainability

preliminary developed in collaboration with QUAMED and Mary Stopes. It could be adapted by current and future QUAMED partners, and it could be proposed in the long-term as an international tool.

- *(LONG TERM)* A *quality label* that allows a quick identification of reliable manufacturers would be greatly appreciated by actors/purchasers in the South, provided that it does not collide with regulatory systems. Such a "certification system", based on a clear set of requirements and on a clear standard for qualifying the GMP auditors, could come out as a long term outcome of the collaborative work across the different stakeholders including regulators.

- *(TRANSVERSAL WORK)* Advocacy should focus both at general and technical audiences. Advocacy toward the general (medical) community and policy makers should be sustained, because the threats to individual and public health caused by poor-quality medicines in LMICs are still too often ignored, neglected or misunderstood. It should make good use of medical journals and lay press. Advocacy toward technical audiences could aim at promoting our specific messages, such as the need of a "harmonized GMP matrix". It should make use of existing fora, such as the pre-ICDRA, the UNICEF-UNDP-WHO-Manufacturers stakeholders meeting[2], the World Health Assembly etc., and it should be based on ad hoc developed documents (e.g. a White Paper).

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[2] Next is in April 2017, not on invitation (interested organization can register on-line).