

Assuring Quality in Medicines Procurement



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Context

Significant global health gains have been made in the last few decades, in part thanks to increased access to prevention, therapeutics, and services provided by government donors and global financing bodies. Progress is also being made in strengthening regulatory medicines quality assurance systems in low-income regions. Dedicated programs, including the World Health Organization's (WHO) Prequalification (PQ) Program and its efforts to benchmark and strengthen national regulatory authorities (NRAs), focus on sustainable oversight of medical products so when they reach patients, they may deliver their intended effects

without causing avoidable harm. Nonetheless, the risk of poor-quality medicines remains a major threat to patients and economies, with an average of one in 10 medicines (more in areas with poor regulatory oversight) thought to be substandard and/or falsified in low- and middle-income countries (LMICs)¹ at an estimated cost of \$30 billion per year.²

While the pharmaceutical supply chain has become more globalized and has contributed to greater medicines access, effective regulatory oversight remains uneven. Prior to the 1990s, most active pharmaceutical ingredients (APIs) and finished products were produced in high-income countries under stringent regulatory oversight. Today, more than 80 percent of APIs are produced in Asia, while the majority of



Cohosts and speakers from "Assuring Quality in Medicines Procurement," a roundtable discussion on the margins of the 72nd World Health Assembly in Geneva, Switzerland.

finished products, particularly generics, are manufactured in India. Moreover, the supply chain from the manufacturing site(s) through wholesalers and warehouses is complex and fragmented. To date, many LMICs still have under-resourced regulatory authorities as they face increasingly complex supply chains and procurement channels. As a consequence, these regulators are challenged in fully assuring the quality of medicines circulating in their territories. Donor organizations, as well as humanitarian and development partners, play a key role in these procurement and supply chains and often determine de facto, through their purchasing decisions, the availability of “quality” medicines as they supply them through their programs. They have an ethical responsibility to make certain the medicines they fund are quality-assured.

In addition, countries transitioning from global medicines procurement programs to domestic procurement are faced with a unique set of challenges in securing quality medicines for the people they serve. Markets that contain a mix of quality-assured medicines, poor-quality medicines, and medicines of unknown quality, threaten the integrity of the overall supply chain, put the health and well-being of individuals and communities at risk, and undermine trust in medicines and health systems. These market dynamics are shaped by numerous other factors, including underfinanced health coverage, shortages of essential medicines, and very high prices for certain therapeutics.

On May 21, 2019, the Government of Belgium, the Bill & Melinda Gates Foundation, Sida (the Swedish International Development Cooperation Agency), the Republic of South Africa’s Department of Health, and USP cohosted “Assuring Quality in Medicines Procurement,” a roundtable discussion on the margins of the 72nd World Health Assembly in Geneva, Switzerland. The roundtable discussion was opened by Ambassador Geert Muylle, presently Permanent Representative of Belgium to the United Nations and international institutions in Geneva, to the Conference on Disarmament and the World Trade Organisation. It was moderated by Katherine Bond, Vice President, Global Public Policy Advocacy, USP. This discussion paper summarizes the proceedings of the meeting and calls for action toward the procurement of quality-assured medicines.

Medicines quality needs to be assured throughout the entire supply chain

To achieve universal health coverage, medical products must reach patients with their safety, identity, strength, quality, and purity intact. Standards for procurement of quality-assured medical products exist, but adherence to them has not been uniform due to contextual and environmental conditions.

As discussed by WHO’s Director of Regulation of Medicines and other Health Technologies, Emer Cooke, the WHO Essential Medicines Program provides an integrated approach to quality assurance through the development of norms and standards, national and regional regulatory systems strengthening efforts, the WHO PQ program for medicines and other medical products, and market safety surveillance and vigilance. The WHO PQ program³ plays a critical role in assessing and assuring the safety, quality, and efficacy of medical products in some therapeutic areas: medicines (both APIs and finished pharmaceutical products), and quality control laboratories, vaccines, vector control products, and in- vitro diagnostics. Prequalification fosters market entry of essential products, thereby increasing healthy competition, which expands access to quality medicines.

Jude Nwokike, Director of the Promoting the Quality of Medicines program, which is funded by the U.S. Agency for International Development (USAID) and implemented by USP, explained that only the consistent application of international standards and guidelines provides assurances that generic medicines are pharmaceutically-equivalent to their originators. Unfortunately, achieving and maintaining adequate quality specifications can be challenged by poor manufacturing, procurement, and storage and distribution practices, as well as poor traceability along distribution channels.

The WHO Model Quality Assurance System for Procurement Agencies (MQAS) provides guidance for the accreditation of suppliers and the purchasing, storage, distribution, and reassessment of pharmaceutical products.⁴ Raffaella Ravinetto, Senior Researcher, Institute of Tropical Medicine, discussed the complex global supply chain and implications downstream, referring to recent research that suggests critical MQAS components are not consistently applied, in

particular supplier accreditation and reassessment by major procurement agencies, and general quality requirements, distribution practices, and cold chain management by local distributors in LMICs. All of these create significant threats to quality⁵⁺⁶ because major risks in quality assurance emerge when a medical product has not been subject to stringent review criteria and when medicines degrade or are diverted through lax distribution chains.

WHO's Regulatory Systems Strengthening (RSS) program, mandated by WHA Resolution 67.20, is implementing the Global Benchmarking Tool (GBT) to inform NRA institutional development plans to address gaps. Of 194 WHO member states, only 50 have NRAs that have reached "maturity" levels 3 or 4 (as measured by the GBT), reflecting their abilities to undertake critical oversight functions. The RSS program supports member states to identify strategies for regulatory reliance, convergence, harmonization, and work-sharing. These efforts are critical for achieving long-term, sustainable oversight of medicines quality throughout the supply chain.

Impacted governments are rising to the challenge

Representatives from several countries and regions shared success elements for strengthening procurement systems, regulatory functions, and coordination among procurement, regulatory, and other stakeholders.

The representative from the West African Association of the Central African Medicines Stores, Mr Aser Minoungou, underlined the importance of working to harmonize standards for the accreditation/certification of suppliers and products. Harmonized criteria would allow mutual recognition of accreditation/certification, avert duplication of efforts by individual central medical stores, rationalize the use of limited resources, and protect public health.

Nigeria has faced considerable medicines quality challenges over the years but has made significant strides to improve



the situation. Professor Moji Adeyeye, Director General of Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC), considered the major challenges to include a weak regulatory framework, insecure supply chains, and knowledge gaps on good manufacturing practices and quality systems. In her tenure, she has focused improvements on workforce discipline, quality systems, and finance reform. NAFDAC is participating in the WHO global benchmarking process and investing to improve quality control laboratories. The Agency is also increasingly present at ports of entry, including with "track and trace" and substandard and falsified detection technologies, for which funding, partnerships, and technical assistance are particularly needed.

In South Africa, quality assurance is integrated into procurement policy by restricting national tenders to suppliers whose products are registered in the country. Anban Pillay, Deputy Director General for Health Regulation and Compliance, indicated that there must be full traceability of procured products, which are to be obtained from the manufacturers, not distributors or wholesalers. Also, post-marketing product quality surveillance is achieved through random quality control checks, and a barcodes system has been introduced to track products along the supply chain to clinics and hospitals. The risk of substandard and falsified products entering the market mainly originates from a general shortage of medicines, which restricts the ability to identify a reliable supplier in country or (even more challenging) in the international market. The problem of shortages clearly indicates that there is a great interdependency among supply chains, quality assurance, access, and affordability, and that all of these elements must be taken into account to achieve universal health coverage.

Tanzania's approach to quality assurance has focused both on improving quality through its procurement policy and strengthening its regulatory system. Daudi Msasi, Director of Pharmaceutical Services in the Ministry of Health, explained how Tanzania's Medical Stores Department (MSD) collaborates closely with the Tanzania Food and Drug Authority (TFDA). MSD requires TFDA approval for all products procured and buys directly from TFDA-approved manufacturers. The National Pharmaceutical Sector Action Plan formalized procurement priorities, which led to improved warehousing practices and optimized distribution routes. Tanzania also significantly invested in training in supply chain functions. Hiiti Sillo, Group Lead of the Country RSS Team at WHO, pointed out TFDA's consistent leadership

over a 15-year period. Along with political commitment, an enabling legal and regulatory framework, and a sustainable financing mechanism, the leadership continuity allowed for ongoing development of TFDA's regulatory system, functions, and workforce, resulting in TFDA being the first NRA in Africa to reach WHO GBT maturity level 3. The close alignment between procurement and regulatory authority also resulted in significant declines in stockout rates and improvements in pharmacovigilance.⁷

Donor governments and regulators support principles for quality assurance in procurement

Representatives from governments, development agencies, and regulators agree that there is an ethical, as well as a fiscal, accountability case for using taxpayer funds to procure only fully quality-assured medicines for programs in LMICs. It is unacceptable for these funds to support a double standard in medicines quality (i.e., one standard in the donor country and another in the recipient country). Even if donor governments and development agencies may have had different approaches to quality assurance in the past, all agree that there is a need to align approaches among donors, implementing partners, and recipient governments.

Responding to this need, the Directorate-General for European Civil Protection and Humanitarian Aid Operations (DG ECHO) of the European Commission funds the purchase of medical products by implementers, including nongovernmental organizations (NGOs). Speaking on behalf of the organization, Chiara Giusto, from DG ECHO elaborated that partners must sign a framework partnership agreement and are required to procure quality-assured medicines. Often working in fragile or conflict settings, humanitarian organizations can go through two channels: either through a "humanitarian procurement center"⁸ assessed by ECHO auditors or through precertification of suppliers. Many NGOs are challenged in their ability to assess good distribution (GDP) and commercial practices, since shortcomings in these aspects result in long delays in procurement.

In the same vein, the Government of Belgium demonstrates both political and technical commitment to refusing double standards in quality assurance of medicines through donor procurement channels. Catherine Dujardin, Pharmacist and

Global Health Officer, Directorate-General for Development Cooperation and Humanitarian Aid, Belgian Ministry of Foreign Affairs, Foreign Trade and Development Cooperation presented the “Commitment to Quality Assurance for Pharmaceutical Products.”⁹ The Commitment was signed in October 2017 by the Belgian Deputy Prime Minister and Minister for Development Cooperation, along with 19 Belgian non-governmental implementing partners. Under the Commitment, which is in the early phases of stepwise implementation, the implementers commit to fully verify the quality of medicines procured in development and humanitarian programs, as well as to provide capacity-building to local stakeholders, such as central medical stores and other procurement agencies. Also as part of the Commitment, the state approves that a justified “quality assurance” budget is used to fund such activities through appropriate programs.

Prompted by such leading actions for accountability taken by donors, the USAID, the Gates Foundation, WHO, and several UN agencies developed “Guiding Principles for Donors Regarding Quality Assurance of Essential Medicines and Other Health Care Commodities.”¹⁰ The document outlines principles that donors should require of countries, multilaterals, and third-party procurers when they use donor funds to purchase essential medicines. Introduced by Hitesh Hurkchand, the Guiding Principles document defines what is meant by “quality assurance” and puts forward an algorithm that addresses gaps described earlier in terms of products and channels not currently reached by existing approaches.



Guiding Principles for Donors Regarding Quality Assurance of Essential Medicines and Other Health Care Commodities

The Guiding Principles include, in order of preferred mechanism, that the products be:

- WHO prequalified (PQ)*
- OR, approved by an agency upon which WHO relies for its abridged prequalification assessment* procedure, along with documentation that the product is suitable from a quality and labeling perspective (e.g., stability, language) for use in the intended geography.
- In the absence of a quality-assured product being available for purchase (i.e., either WHO PQ or approval by an agency upon which WHO relies for its abridged prequalification assessment procedure), on a defined interim basis, under specific circumstances, *product advised for purchase by a qualified Expert Review Panel (ERP), convened by WHO†* may be purchased.
- As a last resort, in the absence of all the above, product may be procured from accredited sources such as internationally approved wholesalers.†

In Addition

- All products purchased using donor funds must also be approved for use by the national authority in recipient countries or allowed to be used in country under special provisions of the Ministry of Health (if applicable.)

* These two mechanisms meet the definition of “quality assured.”

† While these two routes do not assure the quality of the product, they do increase the probability that the product is not substandard or falsified.

Of course, in addition to the above, all products procured using donor funds must be approved for use by the national authority in recipient countries.

Over 20 bilateral donors have been engaged in this initiative,¹¹ with the goal of adoption by at least 24 donors. Donors believe that, while implementation of such Guiding Principles may not help alleviate current “double standards” when it comes to product quality, it will help shape the market such that more manufacturers of quality-assured products will enter the market and make these quality-assured products more affordable.

Sida, the Swedish International Development Cooperation Agency, supports UN agencies and large civil society organizations that have their own procurement channels. Lead Policy Specialist Pia Engstrand indicated that Sida is the

first agency working to incorporate the Guiding Principles on quality assurance into its contractual requirements (but recognizes this takes time) and requires that other bilateral and multilateral donors move in the same direction.

Finally, mature regulatory authorities (WHO GBT maturity level 4) increasingly support multilateral and regional efforts. For example, Swissmedic works with WHO to support regional endeavors on good reliance practices under the African Medicines Regulatory Harmonization initiative. Such collaboration helps to ensure efficiencies in regulatory resources as well as consistent outcomes.

All stakeholders have a role to play

Philanthropic organizations, NGOs, global financing and procurement mechanisms, and financial institutions—along with technical, scientific, and academic organizations—also play a role in supporting patient access to quality-assured medicines.

Murray Lumpkin, Deputy Director, Integrated Development, Regulatory Affairs of The Bill and Melinda Gates Foundation indicated that donors should be part of the solution—not part of the problem. The Gates Foundation supports WHO's PQ program and its national and regional regulatory systems strengthening efforts to ensure medicines quality.

The Global Fund to Fight AIDS, Tuberculosis and Malaria recognizes, utilizes, and implements quality standards, according to Alain Prat, Quality Assurance Team Lead. To improve strategies in countries, more data on performance are needed, particularly to assess the countries' readiness to transition from receiving Global Fund-procured medicines to procuring their own. Brenda Waning, Chief of the Global Drug Facility–Stop TB Partnership described its focus on policies at the global level and work with WHO's PQ program, and suggested a need for the program to remain in Geneva. Big-buyer countries and procurers must align on quality assurance standards, and development bank procurement is essential in this alignment. QUAMED's CEO, Olivier De Santi, underlined the importance of shaping the quality of medicines available in LMICs through market demand: if purchasers join forces to assess potential suppliers and require stringent quality specifications, the suppliers will have a market incentive to upgrade standards. Epidemiologist Elizabeth Pisani emphasized the important role of non-regulatory stakeholders in shaping the market. Médecins Sans Frontières pointed to the essential link

between access and quality: quality-assured medicines should be affordable and available to all, and we must be vigilant to ensure that Global Fund's new policies do not cause a decrease in quality assurance in countries with limited regulatory and procurement capacity. Lembit Rago, Secretary General of the Council for International Organizations of Medical Sciences, restated the importance of quality assurance as a risk management measure, aimed at preventing quality-related incidents rather than finding them after persons have been harmed. Improved risk-based post-market product quality surveillance is also a critical component of quality assurance, together with the assessment of manufacturing sites and product dossiers.

Call to Action:

- Call on WHO to continue to play a leading role in providing guidance on quality assurance policies and practices in medicines production and procurement, as well as in facilitating information-sharing and coordination among member states and relevant stakeholders.
- Call on WHO to expand the scope of products eligible for the prequalification program, and to further strengthen their programs to build regulatory capacity to oversee and assure product and supply chains quality by national and regional regulatory authorities. Call upon Member States and others to support adequately both the prequalification program and the national and regional regulatory systems strengthening program at WHO.
- Call on the governments in LMICs, the governments in exporting countries, and all donors and implementers to implement effective procurement policies and practices in all programs and contexts to help assure the right of everyone to receive quality-assured medicines and medical products.
- Call on all purchasers and their funders to prioritize effective quality assurance requirements in their procurement policy and, in particular, to purchase only from accredited suppliers whose products meet or exceed WHO standards of product quality. This would help positively shape the market, by creating solid market incentives for manufacturers and suppliers to invest in quality.
- Call for predictable, accountable, and transparent mechanisms in procurement practices and policies for the benefit of patients and communities in LMICs.

1. World Health Organization (2017a) WHO Global Surveillance and Monitoring System for substandard and falsified medical products. Geneva: World Health Organization; 2017. See: <http://apps.who.int/medicinedocs/en/m/abstract/Js23373en/>
2. World Health Organization (2017b) A study on the public health and socioeconomic impact of substandard and falsified medical products. Geneva: World Health Organization; 2017. See: <http://apps.who.int/medicinedocs/en/m/abstract/Js23372en/>
3. To prevent confusion, in this paper, the term “prequalification” is only used to refer to the prequalification of products through the WHO prequalification program. When referring the other components of the supply chain (suppliers, wholesalers), the term “accreditation” is used.
4. “A Model Quality Assurance System for Procurement Agencies.” *WHO Interagency Guidelines*, World Health Organization, www.who.int/medicines/publications/ModelQualityAssurance.pdf.
5. Nebot Giralt A, Schiavetti B, Meessen B, et al Quality assurance of medicines supplied to low-income and middle-income countries: poor products in shiny boxes? *BMJ Global Health* 2017;2:e000172
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7. “Tanzania Food and Drug Authority Becomes the First to Reach Level 3 of the WHO Benchmarking Programme.” World Health Organization, www.afro.who.int/news/tanzania-food-and-drug-authority-becomes-first-reach-level-3-who-benchmarking-programme.
8. http://dgecho-partners-helpdesk.eu/actions_implementation/procurement_in_humanitarian_aid/start
9. Commitment to quality assurance for pharmaceutical products, between the Belgian Development Cooperation and the actors involved in the implementation of programmes including the purchasing, storage, distribution and/or control of pharmaceutical products. Brussels, Belgium, 25 October 2017. Available at: https://diplomatie.belgium.be/sites/default/files/downloads/commitment_to_quality_assurance_for_pharmaceutical_products.pdf; Ravinetto R, et al. The Belgian commitment to pharmaceutical quality: a model policy to improve quality assurance of medicines available through humanitarian and development programs. *JPPP* 2018. Available at: <https://joppp.biomedcentral.com/track/pdf/10.1186/s40545-018-0136-z>
10. <https://isg-health.org/resources>
11. These include GAC, the Gates Foundation, USAID, Sida, NORAD, DFID, Netherlands, EU, KOICA, JICA, MFAT, DFAT, Irish AID, AECID, Luxemburg, Denmark, Finland, France, GIZ, KfW, Switzerland.