

Europe should lead in coordinated procurement of quality-assured medicines for programmes in low-income and middle-income countries

Christophe Perrin,¹ Sandrine Cloez,¹ Catherine Dujardin,² Raffaella Ravinetto ³

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¹Independent Expert, Paris, France

²Belgian Directorate-General for Development Cooperation & Humanitarian Aid (DGD), Brussels, Belgium

³Public Health Department, Institute of Tropical Medicine, Antwerp, Belgium

Correspondence to
Raffaella Ravinetto;
rravinetto@itg.be

A secured supply of quality-assured medicines and other medical products is an essential prerequisite for universal health coverage. Unfortunately, on average one in 10 medicines do not meet acceptable quality standards in low-income and middle-income countries (LMICs).^{1 2} The high prevalence of poor-quality medicines in LMICs greatly depends on the globalisation of pharmaceutical production and distribution, combined with the weakness of many national medicines regulatory authorities (NMRAs).^{3 4} The use of non-quality-assured medicines, often undetected, causes poor case management and unfavourable medical outcomes in individual patients, while at population level, it is translated in poor control of communicable diseases, emergence of resistance to medicines and loss of trust in health systems.^{2 4-6} Risks are magnified by the COVID-19 pandemic, which triggered disruption of supply chains, stockouts, substandard production, falsification of repurposed medicines and irrational use of medicines.^{7 8}

European taxpayers' money is used to fund medical programmes in LMICs in the context of humanitarian aid and development. Medicines for these programmes are purchased either at international suppliers specialised in the humanitarian sector, or locally in the countries or regions of intervention. These purchases are not exempted from the quality risks that exist in the local and international market. Hence, adequate pharmaceutical procurement and quality assurance (QA) policies are needed for three reasons. First, to mitigate the risk of purchasing products of poor quality. Second, to assure the same quality standards that would be required for medicines marketed in the donor country.⁹ Third, these policies are needed to address fundamental moral

Summary box

- ▶ Thoughtful procurement policies in humanitarian and development medical programmes can mitigate the risk of purchasing poor-quality medicines, allowing to address fundamental moral obligation to equity, transparency and accountability.
- ▶ European donors are aware of the quality problems in the global pharmaceutical market, and some are already translating awareness into explicit procurement and quality assurance policies. However, a joint position and coordinated action is lacking.
- ▶ European donors should share existing knowledge and tools, seek the input of recipient countries, and develop a joint position on how the donor community can help to ensure access to affordable and quality-assured health products—also during public health emergencies such as the COVID-19 pandemic.
- ▶ Applying stringent and harmonised quality assurance requirements, European donors and their implementing organisations can help shaping the global pharmaceutical market towards affordable, quality assured products.

obligations in terms of equity, transparency and accountability.¹⁰

Various European donors play distinct and complementary roles here: the European Commission (EC), the national Ministries of Foreign Affairs and the national development cooperation agencies with their aid implementers. The role of donor agencies is particularly crucial. If a donor does not prioritise QA requirements in pharmaceutical procurement policies, and does not foresee a dedicated budget line to secure quality, its aid implementers might choose supply channels that are not fully reliable, or they might purchase medicines that are not subject to stringent regulation even if they are authorised in the recipient country.^{9 11}

AWARENESS VERSUS POLICIES

A stakeholder survey carried out at the end of 2019 by the Institute of Tropical Medicine in Antwerp, Belgium, shed some preliminary light on the procurement policies adopted by a sample of 26 European donors and implementing actors of the national cooperation programmes.¹²

Most European donors in the sample directly or indirectly fund the purchase of medicines for development or humanitarian assistance programmes within their Official Development Assistance (ODA) (73%). They are aware of the high prevalence of poor-quality medicines in these contexts (67%) and they acknowledge the need for stringent QA requirements in procurement policies.¹² But awareness is not always translated into formal QA policies and guidelines. Only a minority (20%) have developed or implemented internal policy briefs, or procurement policies with clear specifications for pharmaceutical QA. There is a lack of structured mechanisms for the monitoring and evaluation (M&E) of pharmaceutical quality in procurement, and no respondents mentioned any provisions for risk management plans.

Nonetheless, there are also some positive examples of targeted QA policies. In particular, four European donors set the tone. The Directorate-General (DG) European Civil Protection and Humanitarian Aid Operations (ECHO) of the EC specifically requires that their aid implementers use positive lists of approved procurement entities. To this aim, DG ECHO has published since 2003 a list of Humanitarian Procurement centres, assessed according to their quality systems, indicating where to procure medical supplies in priority.¹³ Among EU member states, Belgium explicitly requires since 2017 that aid implementers ensure the quality of medicines procured for medical programmes in LMICs and avoid double-quality standards between the donor and the recipient country.⁹ Sweden publicly acknowledges its effort to incorporate guiding principles on QA into its contractual requirements with aid implementing partners¹⁴; and in June 2019, the UK implemented an internal QA guidance for procurement and supply of medicines inspiring broader guiding principles for donors.¹⁴

There are various reasons for the apparent delay of other European donors. First, securing safe supply chains meets a variety of hurdles, such as the need of complex contractual arrangements with suppliers, as well as the need of adequate tools for M&E, the institutional lack of specific QA expertise at donors and aid implementers' level and the fear that products that have been rigorously assessed for quality would be more expensive. Second, some donors may consider that assuring the quality of medicines remains the sole responsibility of aid implementers and/or recipient countries. Third, 20% of donors in our sample explicitly rely on the QA policies of the international actors they support, such as United Nations (UN) agencies, the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM) and the Gavi Alliance—even if they did not mention any specific policy

dialogue with these organisations on pharmaceutical quality in procurement.

It is also encouraging that in absence of explicit formal QA policies, awareness is translated into a variety of other initiatives that aim to support recipient countries in pharmaceutical QA, and to mitigate the risk of purchasing poor-quality medicines (table 1). These initiatives are either *direct*, for example, QA trainings for staff and implementers, and/or capacity building projects for national procurement units or NMRAs; or *indirect*, through the support to international mechanisms such as the WHO Prequalification Programme¹⁵ and the WHO Global Surveillance and Monitoring System for Substandard and Falsified products.¹ Many European donors also have internal mechanisms to report quality incidents occurring with medicines purchased with their funds; but it is not clear to what extent findings are shared with peers, and used to adapt and improve existing procurement policies or to orient the policy setting agenda.

POLICIES VERSUS ACCOUNTABILITY AND RISK MANAGEMENT

In an ideal world, each country would count on a stringent NMRA, able to ensure the quality of medicines manufactured, distributed or imported into their territory. Bilateral and multilateral donors can contribute to reinforcing under-resourced NMRAs, through targeted capacity building programmes, in the frame of health systems strengthening. However, as long as this long-term aim is not achieved¹⁶ and many recipient LMICs cannot secure QA in their own procurement, donors can support them by setting explicit and stringent QA policies for procurement of medicines in the programmes they fund. By doing so, they would be accountable about the optimal and ethical use of ODA resources, both to recipient countries, and to tax payers and parliaments in their own countries.

Pharmaceutical QA should become an integral part of donors' risk management plans and policies. Adequate QA policies can be *direct* or *indirect*. When funds are *directly* disbursed by a donor, the donor would require its implementers to purchase medicines according to its own QA policy. When funds are *indirectly* disbursed through channels such as multilateral or bilateral cooperation, humanitarian programmes, non-governmental organisations, investment funds or development banks, the donors would make use of policy dialogue (eg, via their official representation at Board meetings) to monitor whether adequate QA standards are applied and evaluated. Monitoring and evaluating a (direct or indirect) QA policy requires donors and aid implementers having easy, ongoing access to disaggregated financial data within ODA budgets. This allows them to trace funds spent on pharmaceutical purchases and/or QA capacity building and provides access to up-to-date indicators of availability and quality of essential medicines in medical programmes.

Table 1 Initiatives to mitigate the risk of purchasing poor-quality medicines

Risk mitigating strategies	% of respondents
Procurement policies in place	
Recognising the pharmaceutical regulatory standards set by the WHO and/or Stringent Regulatory Authorities	33
Using positive lists of procurement agencies which have been assessed for compliance to WHO quality standards	17
Implementing some level of checks on medicine purchases done by implementing partners	17
Providing QA training to staff at donor and/or implementing partners	Implemented 42 Planned 17
Monitoring use of donor funding channelled through UN agencies, GFATM	25
Direct support to recipient countries	
Funding capacity building for pharmaceutical procurement/supply	58
Providing technical support from NMRA in the donor country, to NMRAs in LMICs	42
Providing QA training to Procurement Units	17
Funding national QC laboratory	8
Indirect support to recipient countries	
Supporting the WHO Prequalification Programme	17
Supporting regional regulatory harmonisation initiative(s)	25
Supporting the WHO's Global Surveillance and Monitoring System for SF products	8
Funding research and/or platforms providing technical support for implementing partners	8

GFATM, Global Fund to fight AIDS, Tuberculosis and Malaria; LMICs, low-income and middle-income countries; NMRAs, national medicines regulatory authorities; QA, quality assurance; SF, substandard and falsified.

Presently, the QA policies and the mechanisms for accountability and risk management still vary across European development and humanitarian aid programmes, and only a minority of European donors have explicit QA policies in place. Harmonisation of such policies across donors would allow setting adequate standards across aid programmes, and to achieve a better protection of individual and public health in recipient countries.

TOWARD EUROPEAN HARMONISATION AND GUIDANCE?

Efforts to build a common approach across European donors should be encouraged, but are still in their infancy. The existing models^{9 13 14} and best practices could serve as a basis for other European donors to develop internal policies adapted to their own cooperation strategies, in the frame of a process of European harmonisation. Importantly, the input of aid recipient countries should be requested and taken into due account, so as to codesign policies and procedures which respond to existing needs.

But European donors could be more ambitious. In line with the resolution developed for the seventy-third World Health Assembly on the COVID-19 pandemic,¹⁷ they could develop a joint guiding position to affirm how the European donor community should and can collectively ensure equitable access to and availability of quality-assured health products, including medicines. Compared with other approaches that focus on developing market opportunities, or that fail to integrate concerns about

pharmaceutical quality, European donors can collectively take leadership in promoting the universal right to safe, quality-assured medicines internationally, in partnership with their counterparts from LMICs.

European donors could also consider proactively sharing the available information on quality of medicines among themselves, and with recipient countries. They could consider adopting mutual recognition of policies and tools that help securing pharmaceutical quality for all. For instance, European donors could agree on positive lists of procurement entities, at international level and in aid recipient countries;¹³ they could share reports on qualified manufacturers at international level and in aid recipient countries; and they could share price lists for priority essential medicines in contexts where several European donors intervene.

These measures would be particularly helpful for emergency preparedness. During disasters and outbreaks of infectious diseases there are increased, urgent pharmaceutical needs. In a crisis, purchases need to be done rapidly, with no time for in-depth prequalification of products and suppliers. The ongoing COVID-19 pandemics shows that not only LMICs, but also high-income countries are confronted with quality problems under such circumstances, for example, for personal protective equipment and diagnostic tests.^{18 19} Under these complex circumstances, the resources and know-how of European donors and their aid implementers could contribute to securing a supply of quality-assured health products, by

addressing the underlying vulnerabilities in regulations, markets and supply chains. A comprehensive assessment of European initiatives to support recipient countries could help designing and refining shared best practices. This could be the basis for a reliable procurement system for health products, in line with the joint programming scheme where various European donors and their implementing partners aim at maximal complementarity when addressing health needs in the same recipient countries.²⁰

There may be fears that quality-assured products are costly, and that additional costs would not be compatible with the attainment of universal health coverage. However, the prices of health products do not depend on manufacturing and QA costs only, but also on manufacturing volumes and market opportunities. If all European donors and their aid implementers would apply stringent and harmonised QA requirements in their procurement policies, they could contribute to shaping the market of LMICs towards affordable and quality assured products.²¹ This would require awareness and political will at (higher) institutional level, enhanced coordination across European donors, and consideration for the hidden—yet high—cost of inaction for individual and public health.

Twitter Raffaella Ravinetto @RRRavinetto

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ORCID iD

Raffaella Ravinetto <http://orcid.org/0000-0001-7765-2443>

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