

## **Analysis of the Quality Assurance and pharmaceutical procurement policies of a sample of European donors**

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**Date of the final version of the report:** 22 April 2020

## **1. Introduction**

A significant part of public funding used by the implementers of the programs of the European national cooperations, the Ministries of Foreign Affairs and the European Commission (EC) are allocated to the purchase of medicines for humanitarian and development medical programs in/for Low and Middle Income Countries (LMICs).

While the “availability of medicines” is considered key by most, if not all, actors, less attention has traditionally been paid to the “Quality Assurance (QA) of medicines”. However, according to the World Health Organisation (WHO, 2017), on average one in ten medicines does not meet acceptable quality standards in LMICs<sup>1</sup>. Furthermore, the scientific literature shows that the use of non-quality-assured medicines is often translated in poor case-management and unfavourable medical outcomes. It also has deleterious effects at population level, especially for the control of communicable diseases, emergence of resistance, as well as on pharmaceutical and health systems.

As announced at the end of 2017, Belgium has designed a pharmaceutical procurement policy and related tools (contracts, capacity building, technical assistance, etc.) incorporating stringent quality assurance requirements in contractual frameworks with the implementing partners who procure medicines with their funds. This policy is now in an early implementation phase<sup>2</sup>.

Based on exchanges across different European stakeholders<sup>3</sup>, the Belgian Directorate-General for Development Cooperation (DGD) reached out the Institute of Tropical Medicine (ITM) in Antwerp, Belgium, to preliminarily explore the procurement policies and practices of a sample of European donors, with particular focus on the procurement policies for pharmaceuticals and related tools relevant to their Official Development Assistance (ODA) health programs. It is hoped that the findings of this survey could highlight opportunities for further harmonisation, joint positioning and leadership in this field at European level.

## **2. Methods**

A standard questionnaire (Annex 1) was developed by the ITM, with inputs from the Belgian DGD, and distributed to a sample of European stakeholders, all with a potential role in funding the purchase of pharmaceuticals used for development or humanitarian assistance programmes in LMICs.

Key representatives at each of these entities were reached out by Catherine Dujardin (Belgian DGD) based on her regular interactions with them. Overall, 26 stakeholders were reached out between October 2019 and January 2020.

During the first round, in October 2019, the questionnaire was sent to the DG DEVCO and the DG ECHO at the EC as well as to the Ministry of Foreign Affairs in Belgium, Denmark, France, Germany, Italy, Ireland, Luxembourg, Netherlands, Spain, Sweden and Switzerland. A preliminary feed-back of the de-identified

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<sup>1</sup> <https://www.who.int/medicines/regulation/ssffc/publications/gsms-report-sf/en/>

<sup>2</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5907286/>

<sup>3</sup> Minutes of the Pre-Meeting on “Quality of Medicines: Exchanges and Possible Areas for Further Cooperation and Collaboration” - EU Member States Experts’ Meeting on Global Health, Population and Development - Brussels, 3 April 2019

answers provided by these actors was presented on November 7<sup>th</sup>, 2019 at the European Union (EU) Member States Experts' meeting on Global Health, Population and Development held in Brussels.

During the second round, in November 2019, the questionnaire was sent to implementing actors of the national cooperation programs in Belgium, France, Germany, Italy, Ireland, Netherlands, Norway, Spain, Sweden, Switzerland and the United Kingdom. The deadline for answers was set on January 16<sup>th</sup>, 2020.

Considering that the same questionnaire was used for all European actors irrespectively of their status (i.e., either EC entity, or Ministry of Foreign Affairs, or implementing actors of the national cooperation programs), the de-identified results of the survey were compiled per question in this report, regardless of the status of the stakeholders.

A complementary Internet search was made in October 2019, to find and download any documents published online by the 26 European regarding their procurement policies for pharmaceuticals and related tools.

### **3. Results**

15 European actors out of 26 (58%) contributed to the survey by providing answers. Out of them, 13 actors provided a completed questionnaire and 2 did not, but provided general answers through an e-mail. For the latter, their feed-back was integrated in the survey analysis as long as the information provided was related to the topics listed in the questionnaire.

In addition, two Ministries of Foreign Affairs informed by mail that there was no need to reach out to their colleagues working at the implementing entity of the national cooperation programmes, since no funding was made available for medicines' purchase in their bilateral work. A third Ministry of Foreign Affairs replied that they would not answer to the questionnaire and delegate the feed-back from their country to the implementing entity of the national cooperation programmes, in charge for the procurement of medicines for development or humanitarian assistance programmes.

For those who answered the survey, when no answer was provided to a specific item in the questionnaire, no interpretation was made of these blank items.

The Internet search allowed integrating the survey findings with detailed information, found on-line, for 2 actors out of 26. These were used as complementary background information to the answers provided by these actors.

The table 1 below summarises the survey results by item as in the questionnaire. Results are summarized as number and percentage of how many stakeholders replied to each item. Each of these items is discussed more in details in the next sub-headings.

Topics	Main results	
Answers provided to the questionnaire	58%	15/26
3.1 Availability of fund for medicine purchases	73%	11/15
- <i>Indirect medicine purchases through international actors (e.g. GFATM, Gavi, UN agencies)</i>	27%	3/11
No direct responsibility in medicine purchases	27%	4/15
3.2 No disaggregated figure for ODA budget allocated to medicine purchases	47%	7/15
3.3 Awareness of quality problems in the current global pharmaceutical market	67%	10/15
3.4 Availability of pharmaceutical procurement policies/rules for implementing partners	20%	3/15
3.7 Availability of mechanism(s) to report quality incident by implementing partners	73%	11/15
3.8 Participation to initiatives mitigating the risk of purchasing / procuring poor-quality medicines	80%	12/15

Table 1. Summary of main results from the survey

### ***3.1 Responsibility to procure pharmaceuticals for development or humanitarian assistance programmes***

11 out of the 15 stakeholders who participated in the survey (73%), European actors acknowledged the availability of funding for the purchase of medicines for development or humanitarian assistance programmes. Within this group, the Ministries of Foreign Affairs of 2 European countries mentioned a close collaboration with their colleagues at the implementing entity of the national cooperation programmes. In addition, 3 out of 11 mentioned that an assistance budget was earmarked to support international actors active in pharmaceutical procurement such as United Nations (UN) agencies, the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM), Gavi, and the World Health Organisation (WHO) procurement unit.

Also, 4 out of 15 actors (27%) considered that they do not have a direct responsibility in the procurement of pharmaceuticals for development or humanitarian assistance programmes: 2 out of these 4 entities, in particular, stated that their main focus is on financing instead the strengthening health system capacities, and that there is not a budget line dedicated by their headquarter to the purchase of medicines. In addition, out of the 4 actors declaring no direct responsibility in funding pharmaceutical purchases, 2 Ministries of Foreign Affairs specified that the same applies for their colleagues from the implementing entity of the national cooperation programmes.

Overall, it appears that at least 6 of 26 European actors targeted by the survey do not have or take responsibility for the procurement of pharmaceuticals within their ODA.

### ***3.2 Official Development Assistance (ODA) budget allocated to health & purchase of pharmaceuticals***

7 European actors out of 15 answerers (47%) had no disaggregated figures regarding the budget allocated to pharmaceutical purchases, compared to their global health budget. Only 2 entities shared precise figures of budgets allocated to health and purchase of pharmaceuticals. In both cases, the purchase of medicines was representing less than 25% of their overall ODA expenses for health.

### ***3.3 Awareness of quality problems in the global pharmaceutical market***

10 of the 15 answerers (67%) stated that they were aware of quality problems in the global pharmaceutical market.

### ***3.4 Pharmaceutical procurement policies/rules for implementing partners***

3 European actors out of 15 (20%) stated they have developed internal documents such as a policy brief, Quality Assurance (QA) and procurement policies; and that at the time of the survey, these policies were either already implemented by all partners receiving funds to purchase medicines, or they were in the process of being implemented by more and more of them, in a stepwise approach. At the time of the survey, these 3 actors were either updating their policy on a continuous basis, in compliance with procurement rules set out by their national authorities and the WHO, or doing an in-depth review of their policy, or planning to do so in 2020.

2 other actors recognised the need to strengthen quality commitment in the internal policies of their implementing partners, but did not make reference to policies they would need at their level.

3 other actors stated that they required their implementing partners to follow national procurement policies in their countries of intervention.

3 further ones stated that they had no direct responsibility in pharmaceutical purchases, therefore had no need to develop specific policies.

Noteworthy, 3 European actors (20%) declared that part of their ODA was devoted to support international actors such as UN agencies, the GFATM, Gavi, and the WHO procurement unit active in medicines purchase. 2 of them explained that they relied on these partner organisations' policies and quality systems, rather than having their own internal policies, while the third one had also set its own internal rules.

### ***3.5 Major challenges, if any, identified by implementing partners with the current pharmaceutical procurement policies***

15 different challenges were identified within current pharmaceutical procurement policies by 11 answerers to the survey. This heterogeneous list reflects the complexity of setting up development or humanitarian assistance programmes. On the one hand, there are international standards that can dictate common pharmaceutical QA and procurement policies across all actors but on the other hand, their application is complicated by the broad range of donors' strategies, by the implementing partners' capacities, as well as the state of the local pharmaceutical markets in recipient countries.

For instance, some European entities made reference to the hardly reliable local medicines purchases in LMICs due to unregulated supply systems and to the increasing restrictions to import pharmaceuticals in those settings. Others regretted the lack of support from some donors and international development agencies to national procurement systems, which prefer to set-up parallel importation/distribution channels for health products. Some actors stated that they face both types of challenges in the same countries.

Some also mentioned the difficulty to keep up and expand the capacities of technical assistance platforms, such as QUAMED<sup>4</sup>, while capacity building in pharmaceutical procurement at implementing partners is highly needed. Reference was also made to the insufficient institutionalisation of QA policies within bilateral and multinational donors, international Non-Governmental Organisations, local health care providers.

### **3.6 Major practical obstacles to include QA requirements in pharmaceutical procurement policies/contracts with implementing partners**

4 answerers to the survey listed the following major practical challenges to include QA requirements in the pharmaceutical purchases done by their implementing partners:

- complex contractual arrangements to be made upfront, at both institutional and implementation levels, with potential increased workload at both ends,
- resource constraints at donors' level to monitor the implementation / achievement of their guidance, and the effectiveness of the quality system set up by implementing partners,
- poor planning of pharmaceutical needs and lack of QA capacities at the level of implementing partners
- fears of costs' increase, if requesting purchasing medicines that are compliant with stringent QA criteria,
- possible diversion of purchases, when donor funding are used to import medicines rather than purchasing locally through pharmaceutical supply systems in recipient countries.

### **3.7 Mechanisms to report quality incidents by implementing partners**

In 11 out of the 15 set of answers received (73%), European actors stated that there are mechanisms in place for their implementing partners to report quality incidents occurring with medicines purchased with their funds. In particular, 5 of these actors rely on the internal policy of their implementing partners, 3 on internal audit reports, 1 on external evaluations and 2 on staff from their headquarter checking medicine purchases done by their partners. 1 of these 2 last actors specified that checks of medicine purchases by their partners were done in conjunction with the National Medicine Regulatory Authority (NMRA) of the donor country.

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<sup>4</sup> <https://www.quamed.org/>

### **3.8 Procedures or tools in place to mitigate the risk of purchasing/procuring poor-quality medicines**

12 European actors out of the 15 which answered to the survey (80%) illustrated their support to a variety of initiatives which are thought to mitigate the risk of purchasing/procuring poor-quality medicines. Some actors supported only one of them, others more than one.

The table 2 below provides an overview of these risk mitigating strategies.

<b>Risk mitigating strategies</b>	<b>Number of supporters</b>
<b>Internal procurement policies at European donors</b>	
Recognition of pharmaceutical regulatory standards set by WHO and/or Stringent Regulatory Authorities	4/12
Use of positive lists of approved procurement agencies and/or private wholesalers which have been assessed for compliance to WHO quality standards by relevant bodies	2/12
Donors' staff checking medicine purchases done by their implementing partners	2/12
Providing QA training for the purchase of medicines to staff at donor and/or implementing partners	. Implemented by 5/12 . Planned by 2/12
Funding channelled through UN agencies, GFATM, Gavi	3/12
<b>Direct support to recipient countries</b>	
Funding capacity building for pharmaceutical procurement/supply chain actors in recipient countries	7/12
Providing technical support from the NMRA in the donor country to NMRAs in LMICs	5/12
Providing QA training for medicine purchase to central medical stores through technical assistance entities (e.g., QUAMED, independent consultants)	2/12
Funding national QC laboratory in LMICs	1/12
<b>Indirect support to recipient countries</b>	
Supporting WHO Prequalification Programme	2/12
Supporting regional regulatory harmonization initiative(s)	3/12
Supporting WHO's Global Surveillance and Monitoring System for SF products	1/12
Funding research and/or platforms providing technical support for implementing partners	1/12

Several of these initiatives can assure more stringent internal rules at donor level, to guide their implementing partners in purchasing quality-assured pharmaceuticals. As such, 4 European actors out of 12 recognised pharmaceutical regulatory standards set by WHO and/or Stringent Regulatory Authorities for the purchase of medicines by their partners. Headquarter staff of 2 of these actors checked medicine purchases done by partners with their fund. 2 of these actors explicitly requested their implementing partners to use positive lists of approved procurement agencies and/or private wholesalers. 5 actors set up training on QA principles for the purchase of medicines to their own staff and/or implementing partners and 2 additional ones mentioned that they planned to do so.

3 out of these 12 European actors use an alternative strategy, by providing funding international actors such as UN agencies, GFATM and Gavi that are active in medicine purchases and which are thought to have (different) well-defined QA and pharmaceutical procurement policies.

Other answerers to the survey mentioned other types of initiatives, more targeted at supporting recipient countries, either by directly strengthening their pharmaceutical purchasing capacities, or through international mechanisms aimed at providing these countries with technical assistance. As such, 7 out of these 12 European actors had made funding available for capacity building for pharmaceutical procurement and/or supply chain actors in recipient countries. 2 were funding QA training for the purchase of medicines to national central medical stores through technical assistance entities (e.g., QUAMED, independent consultants). 5 promoted technical support between the NMRA from their country with the NMRAs in recipient countries where their implementing partners purchased medicines. 1 actor had initiated capacity building activities for national Quality Control laboratories in recipient countries.

In addition, 2 of these 12 European actors referred to their support to the WHO Prequalification Programme, 3 to regional regulatory harmonization initiative(s) and 1 to the WHO's Global Surveillance and Monitoring System for Sub-standard and Falsified products.

Finally, 1 actor mentioned that it allocated funding to research and/or technical assistance entities providing support to their implementing partners.

#### **4. Subjective assessments from the authors of the report**

The table 3 below provides an initial subjective assessment from the authors of the report, highlighting perceived strengths (“+”) and weaknesses (“-”) across the answers received from the panel of Europeans actors interviewed. Of course, this should be looked at critically, not only because of the subjectivity of the assessment, but also because the current study could not look into actual implementation of policies. For instance, it is laudable that there are reporting mechanisms for quality incidents, but we could not assess the effectiveness of such mechanisms in practice.



Topics	Main results	Assessments
Answers provided to the questionnaire	58%	-
3.1 Availability of fund for medicine purchases	73%	-
- <i>Indirect medicine purchases through international actors(e.g. GFATM, Gavi, UN agencies)</i>	27%	-
No direct responsibility in medicine purchases	27%	-
3.2 No disaggregated figure for ODA budget allocated to medicine purchases	47%	-
3.3 Awareness of quality problems in the current global pharmaceutical market	67%	+
3.4 Availability of pharmaceutical procurement policies/rules for implementing partners	20%	--
3.6 Availability of mechanism(s) to report quality incident by implementing partners	73%	++
3.7 Participation to initiatives mitigating the risk of purchasing / procuring poor-quality medicines	80%	+++

**Table 3. Subjective assessments by the authors of the report**

Overall, getting a feed-back from more than half of the European actors that were contacted looks in itself as a positive outcome, that shows a general interest and commitment. Nevertheless, the accuracy and clarity of the information provided with the questionnaire was not optimal for a significant proportion of those who answered.

Interestingly, the majority of the answers received to the questionnaire confirms the awareness of quality problems in the current global pharmaceutical market. Though, few Europeans donors have developed internal pharmaceutical procurement policies. This could appear contradictory when considering that setting up QA policies applying to implementing partners for pharmaceutical purchases is an important *risk management* tool. Together with the training of donors' staff and external partners as well as with the regular monitoring of their implementation, these policies could contribute to secure the purchase of quality-assured medicines, and in turn reassure national tax payers and parliaments about the optimal and ethical use of ODA.

It is laudable that a large majority of the European donors have developed mechanisms allowing quality incidents to be reported by their implementing partners, and that they participate in/support international bodies and initiatives that help mitigating risk when purchasing pharmaceuticals on the global market. However, it would be also important for these actors to actively monitor which corrective measures are put in place when they receive reports of quality incidents, and to document the concrete outcomes of the risk mitigating measures they plan or implement.

## 5. Discussion

### 5.1 Funding

When analysing the answers provided to the survey by 15 European actors, there was a significant heterogeneity across them in terms of how funds for medicine purchase were managed in the framework of their development or humanitarian assistance programmes.

73% of answerers managed directly these funds. Though, various strategies were found across European countries regarding which entities made funding available, either both Ministries of Foreign Affairs and implementing entities of the national cooperation programmes, or only the latter. Three European actors made also reference to the assistance budget that they channel through UN agencies, the GFATM, Gavi or the WHO Procurement unit which are active in pharmaceutical purchases.

Since 27% remaining actors declared no direct responsibility in funding pharmaceutical purchases in their health development or humanitarian assistance, it might be useful to perform a further assessment of funds that are *indirectly* spent for pharmaceutical purchases through the financial support of international entities, such as the World Bank. In case a majority of EU countries are supporting financially the World Bank and after analysing whether its pharmaceutical procurement rules are consistent with WHO QA recommendations, European donors should monitor whether these rules applying to countries benefitting from the World Bank's loans are regularly updated according to international quality standards.

Our findings also show that half of the answerers acknowledged the lack of disaggregated data within their health development assistance budgets. This situation is likely to prevent them from tracing which proportion of their funding is spent on pharmaceutical purchases and figuring out which level of risk they take by providing funds to their implementing partners for these activities. Within European cooperation strategies aiming at strengthening health care systems, it would be worth analysing whether specific budgets are systematically allocated to national pharmaceutical procurement mechanisms and related regulatory activities. In addition, it would be of major added value if donors and recipient countries could monitor and evaluate on an on-going basis the indicators of availability and quality assurance compliance for priority essential medicines<sup>5</sup>. There is indeed no access to adequate health care, even under the current Universal Health Coverage strategies, without rationale and secured supply to health care facilities of quality-assured medicines.

### 5.2 QA and pharmaceutical procurement policies

Not unexpectedly, those European actors that declared managing directly funds for pharmaceutical purchases also acknowledged their awareness of quality problems in the global pharmaceutical market. Despite the fact that around 70% of answerers were aware of the risks to purchase poor-quality medicines, only 20% of them have developed internal policies stating which standards have to be applied by their implementing partners to secure the purchase of quality-assured medicines.

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<sup>5</sup> [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)31599-9/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31599-9/fulltext)

It is encouraging that 73% of European actors which answered to the survey referred to internal mechanisms for their implementing partners to report quality incidents occurring with medicines purchased with their funds, even if we could not check how this was implemented in practice. This is linked to a general limitation of this survey, as answers could not be complemented by comparative desk reviews of donors' reports. To better understand these aspects, and how the "incident's reporting" can help to improve and refine procurement policies, it would be useful to plan an *ad hoc* assessment of the effectiveness of these reporting procedures, perhaps for a sub-sample of European actors. These mechanisms sound like an important vigilance mechanism to alert on possible double-standards between the quality of medicines available in the European market versus the quality of medicines purchased with European cooperation funds.

On a more general note, it seems that in the context of international development and humanitarian assistance, where most health care providers (e.g., local or international Non-Governmental Organisations/foundations) lack QA expertise and skills for pharmaceutical purchases, the European donors should reconsider how best guiding them in these risky activities. For instance, they could provide their partners with clearer guidance on medicine procurement, by developing policies making explicit reference to international quality standards, and to formal *risk management*, by providing QA training to implementing partners and by monitoring their pharmaceutical purchases in terms of compliance with quality requirements. These measures could also contribute to secure disbursement of assistance funds in the most adequate way in recipient countries. Some European donors have already internal policies related to QA and pharmaceutical procurement, and these examples could serve as a basis for other European donors to develop internal rules adapted to their own cooperation strategies.

Regarding European actors providing funds to UN agencies, the GFATM, Gavi or the WHO Procurement unit, it would be interesting to find out whether they closely monitor the QA and pharmaceutical procurement policies set by these international bodies/procurement mechanisms. For instance, do they check if these policies are consistent with international quality standards and regularly updated accordingly?

Among the answerers that had not developed QA and pharmaceutical procurement policies at the time of the survey, 3 actors required their implementing partners to follow national procurement policies in their countries of intervention. In many LMICs, however, national procurement policies may lead to risky pharmaceutical purchases, given that most NMRAs worldwide are unable to deliver the minimum regulatory package set by the WHO to secure availability of quality-assured medicines in their market<sup>6</sup>. Interestingly, these 3 actors also declared funding a variety of initiatives aiming at strengthening in country-capacities such as regional regulatory harmonisation initiative(s), technical support between the NMRA from their country and the NMRAs in the recipient countries, capacity building of national Quality Control laboratories in the recipient countries and QA training for the purchase of medicines to national

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<sup>6</sup> [https://www.who.int/medicines/news/2019/WHO\\_ActionPlanWeb.pdf?ua=1](https://www.who.int/medicines/news/2019/WHO_ActionPlanWeb.pdf?ua=1)

central medical stores. One also mentioned funding QA training for its own staff and/or implementing partners. It would be worth exploring which of these initiatives (single ones or in combination) have the best impact to secure safer purchases of medicines by implementing partners.

### *5.3 Pooling EU donors' assets and developing further leadership to secure pharmaceutical purchases in assistance programmes*

All the above-mentioned strategies illustrate a general conundrum faced by European (and other) donors, when investing in development or humanitarian assistance programmes: what are the most efficient approaches to support resource limited settings in building WHO-compliant pharmaceutical procurement systems in the long term, while in the short term ensuring that development assistance funds are used to purchase only quality-assured medicines?

It seems that European donors have an opportunity to make the most and the best, altogether, out of the variety of their development assistance objectives. The answers to the survey provide a comprehensive description of the whole spectrum of possible health strategies, and related procurement strategies, adopted by European actors: from exclusive focus on humanitarian aid operations to a focus on health system strengthening, with a variety of mixed development assistance approaches. *Important lessons could be drawn from the experiences already gathered by all these European actors.* They could pool best practices in procuring quality-assured pharmaceuticals in the short term (as it is particularly required in humanitarian crises) and in providing capacity strengthening to local supply chain entities as well as regulatory bodies (particularly when investing in development strategies).

Our survey confirmed that most European share key-values and technical knowledge, such as the recognition of the risks incurred in the global pharmaceutical market. Given the comprehensive experience gathered across European donors in terms of purchase of pharmaceuticals, the EU could develop a concise position paper stating core principles in this field. In line with the draft resolution developed for the seventy-third World Health Assembly<sup>7</sup> on the Covid-19 pandemic, such position could reaffirm the *EU leadership on how collectively the international community should ensure equitable access and availability of appropriate quality health products, including medicines.* Compared to some non-European international actors which may be mainly or exclusively focused on developing market opportunities, or fully focused on other pre-requisites of Universal Health Coverage without concerns about the quality of related health standards, *European donors may bring a valuable voice by promoting internationally the universal right to safe, quality-assured medicines.* The DG DEVCO with its strategic focus on health system strengthening could take the leadership to consult other European donors and design a balanced position paper. This work could be done with the support of the DG ECHO which has developed a pragmatic policy in terms of pharmaceutical purchases in humanitarian contexts by their implementing partners.

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<sup>7</sup> <https://www.keionline.org/32775>

Another joint approach across European donors could consist in developing *information sharing and mutual recognition* on key topics such as:

- positive lists of approved procurement agencies and/or private wholesalers at international level and in aid recipient countries,
- reports on qualified manufacturers at international level and in aid recipient countries,
- prices for a priority list of medicines in specific contexts where several European donors are intervening.

It seems positive that one of the surveyed European donors recommends its implementing partners to make use of the DG ECHO list of Humanitarian Procurement Centres (HPC). It could be explored how to further expand this list of HPC and decline it further in LMICs by pooling financial capacities and available technical expertise across EU donors.

Finally, when considering the broad range of targets chosen by the surveyed European actors to mitigate risks of purchasing/procuring poor-quality medicines, it would be worthwhile to *launch a comprehensive assessment of these initiatives* to find out whether further coordination across the EU could lead to enhanced outcomes. Indeed, current strategies appear all necessary. They can be categorized in two groups: those supporting recipient countries by directly strengthening their pharmaceutical purchasing capacities; and those supporting recipient countries through international mechanisms that provide technical assistance (e.g., WHO Prequalification Programme, regulatory harmonization initiative(s), WHO's Global Surveillance and Monitoring System for Sub-standard and Falsified products etc.).

To timely secure reliable procurement systems for health products in resource-limited setting, further synergetic approaches across European donors could be considered, also in what concerns capacity building for recipient countries. A more coordinated approach could work in line with the joint programming scheme<sup>8</sup> where various European donors and their implementing partners aim at being as complementary as possible when addressing health needs in the same recipient countries.

## 6. Limitations

This survey was based on data collected through a survey filled in by European actors, while it was not possible to assess concrete outcomes of how their current QA and pharmaceutical procurement strategies are implemented in recipient countries. Furthermore, the findings may be biased due to the fact that several European donors providing funding and technical assistance in the field of pharmaceutical procurement could not provide their answers in the timelines set for this report.

A next step, inspired by the findings of this survey, could consist in a formal assessment of these aspects, perhaps through a desk review of reports available at donors and field level for a sub-set of donors and/or of recipient countries. In the same spirit, desk reviews could be implemented by individual European donors to assess the effectiveness of reporting procedures from their implementing partners of medicines' quality incidents.

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<sup>8</sup> [https://ec.europa.eu/info/aid-development-cooperation-fundamental-rights/ensuring-aid-effectiveness/joint-programming-development-cooperation\\_fr](https://ec.europa.eu/info/aid-development-cooperation-fundamental-rights/ensuring-aid-effectiveness/joint-programming-development-cooperation_fr)

## 7. Conclusion & recommendations

The analyses of the answers received from a significant sample of European donors can lead to recommendations applicable throughout EU actors, bearing in mind the necessary flexibility for each European donor when defining its strategy for development or humanitarian assistance programmes.

These recommendations can be applicable to all European donors, regardless of their status (e.g., either EC entity, or Ministry of Foreign Affairs, or implementing actors of the national cooperation programmes). In addition, even if this survey focused on medicines, the recommendations listed below could be expanded to medical devices, bearing in mind that according to the WHO the regulatory oversight is generally weaker and quality risks probably higher for medical devices and in-vitro diagnostics on the global market.

A first set of recommendations could be achievable in the short term and a second one in the longer term.

**Short term recommendations** concern the development of:

- a *common position paper at EU level*, possibly under the coordination of the DG DEVCO and in collaboration with the DG ECHO, to state shared principles in securing purchases of quality-assured medicines with donor funds, whether in humanitarian programmes or health system strengthening strategies,
- *information sharing and mutual recognition* across European actors, for instance concerning positive lists of approved suppliers (e.g. procurement agencies, manufacturers, etc) and prices for a priority list of medicines in specific contexts where several European donors are intervening,
- *coordination within the EU of initiatives mitigating risks of purchasing/procuring poor-quality medicines* (listed in Table 2) to bring enhanced outcomes in aid recipient countries, in line with the EU joint programming scheme in the same recipient countries.

**Long term recommendations** concern the development of:

- a joint work across European donors *to document the existing evidence-based guidelines on QA and pharmaceutical procurement policies in development / humanitarian assistance*,
- in a customised manner based on their funding strategies (e.g., direct funding of pharmaceutical procurement by implementing partners, funding of health system capacity strengthening, funding of partners such as UN agencies, GFATM, Gavi, etc), all European donors that have not done so yet, could develop *adequate internal QA and procurement policies* (as some actors already did). These policies would re-inforce donors in reaffirming how they take a pro-active approach in managing risks linked to the purchase of pharmaceuticals with their funds.

Other recommendations could be more targeted at sub-sets of European actors. As such, donors relying on partner organisations' policies and quality systems (e.g., UN agencies, GFATM, GAVI, WHO procurement unit) should consider regularly verifying their QA and procurement policies, for instance by requesting independent analysis of these policies to be presented at board meetings in presence of funding partners. This scrutiny should be expanded to entities funded by EU countries such as the World Bank in case a

majority of EU countries are supporting it financially. After analysing whether its pharmaceutical procurement rules are consistent with WHO QA recommendations, European donors should monitor whether these rules applying to countries benefitting from the World Bank's loans are regularly updated according to international quality standards.

Relatedly, attempts should be made by all European donors to disaggregate the budget allocated to the purchase of pharmaceuticals out of their health budget for ODA, also in order to better understand their level of vulnerability to the unwanted purchase of poor-quality medicines (either directly, or indirectly such as via funds allocated to the World Bank and other entities).

Lastly, it is recommended that when funding the strengthening of health care systems, EU actors should systematically allocate specific budgets to national pharmaceutical procurement mechanisms and medicines' regulatory activities, with budget lines earmarked to capacity building of central medical stores and National Medicines Regulatory Authorities. They should also define upfront clear monitoring and evaluation criteria related to the availability and quality assurance compliance of priority essential medicines at donor and recipient country levels.

## **8. Acknowledgements**

The authors of this report are grateful to all European actors that accepted to answer to the survey despite the short timelines set. The design of this survey, as well as data collection, analysis and reporting, were funded by the Belgian DGD, through the DGD Framework Agreement 4, 2017–2021 with the Institute of Tropical Medicines, Antwerp.

## Annex 1



### Pharmaceutical procurement policies and related tools of a sample of European Donors

#### Standard questionnaire

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Please send your answers by ... to:

Catherine Dujardin at [catherine.dujardin@diplobel.fed.be](mailto:catherine.dujardin@diplobel.fed.be)

Raffaella Ravinetto at [rravinetto@itg.be](mailto:rravinetto@itg.be)

Christophe Perrin at [kristofperrin@yahoo.fr](mailto:kristofperrin@yahoo.fr)

When answering to each question, please add as many lines as necessary for your answers.

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#### Rationale

A significant part of public funding used by European national Cooperations' and the European Commission are allocated to the purchase by implementing partners of medicines for humanitarian and development medical programs in/for Low and Middle Income Countries (LMICs). While the "availability of medicines" is considered key by most, if not all, actors, less attention has traditionally been paid to the "quality assurance of medicines". However, according to recent data from the World Health Organisation (WHO), on average one in ten medicines does not meet acceptable quality standards in LMICs<sup>9</sup>. Furthermore, the scientific literature shows that the use of non-quality-assured medicines is often translated in poor case-management and unfavorable medical outcomes. It also has deleterious effects at population level, especially for the control of communicable diseases as well as on pharmaceutical and health systems.

As announced at the end of 2017, Belgium has designed a pharmaceutical procurement policy and related tools (contracts, capacity building, technical assistance, etc.) incorporating stringent quality assurance requirements in contractual frameworks with the implementing partners who procure medicines with their funds. It is now in an early implementation phase (*ref. Ravinetto R, Roosen T, Dujardin C. The Belgian commitment to pharmaceutical quality: a model policy to improve quality assurance of medicines available*

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<sup>9</sup> <https://www.who.int/medicines/regulation/ssffc/publications/gsms-report-sf/en/>



*through humanitarian and development programs. Journal of Pharmaceutical Policy and Practice 2018; 11:12: 1-5).*

This questionnaire has been designed with the Institute of Tropical Medicine in Antwerp, Belgium, on behalf of the Belgian Directorate-General for Development Cooperation based on exchanges across different European stakeholders, for describing the current policies and practices of a sample of European donors in terms of procurement policies for pharmaceuticals and related tools.

This “state of the art” of who does what and how for pharmaceutical procurement and capacity building among European national Cooperations could feed further possible joint positions and actions at European level.

If you agree to fill in this questionnaire, it will take from 30 minutes to 2 hours.

You are completely free to decline participation.

To mitigate potential risks related to your organization’s privacy and confidentiality rules, we will treat confidentially all data that will be collected. In particular, collected data will only be accessible to the Institute of Tropical Medicines and the Belgian Directorate-General for Development Cooperation, for the purpose of analyzing them.

These data will be analysed in an aggregated way, without referring any findings to a specific organisation. You will receive a copy of the final report and of any related publication.

We will be grateful that you may provide the following elements:

**C.1 General information regarding funding, such as:**

- the annual Official Development Assistance (ODA) budget allocated to the health sector in 2018 and 2019
- the annual Official Development Assistance (ODA) budget allocated to purchase medicines in 2018 and 2019

**Your response:** Click or tap here to enter text.

**C.2 Awareness of the quality problems in the global pharmaceutical market at the national Cooperation:**

**Your response:** Click or tap here to enter text.

**C.3 Tools/documents defining pharmaceutical procurement policy/rules for implementing partners?**

**Your response:** Click or tap here to enter text.

**C.4 Status of implementation of the current (pharmaceutical) procurement policy (i.e., already applied to all implementing partners, Monitoring & Evaluation planned with a specific set of indicators etc.):**

**Your response:** Click or tap here to enter text.

**C.5 Major challenges, if any, identified by implementing partners with the current pharmaceutical procurement policies/contractual agreements:**

**Your response:** Click or tap here to enter text.

**C.6 Mechanisms, if any, to report quality incidents experienced by implementing partners in their programs funded from the national Cooperation**

**Your response:** Click or tap here to enter text.

**C.7 Plans to update the current -pharmaceutical procurement policy, and, if applicable, relevant details (e.g., timing and contents of the revision)**

**Your response:** Click or tap here to enter text.

**C.8 Major practical obstacles, if any, to include Quality Assurance requirements in pharmaceutical procurement policies/contracts with implementing partners**

**Your response:** Click or tap here to enter text.

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**C.9 Any procedure or tool in place to mitigate the risk of purchasing/procuring poor-quality medicines with funds from the national Cooperation, such as:**

- a. Recognition of pharmaceutical regulatory authorities of the recipient countries (i.e., local registration of medicines when the national regulatory authority is granted WHO Maturity Level 3)

**Your response:** Click or tap here to enter text.

- b. Capacity building for pharmaceutical procurement or supply chain stakeholders in the recipient countries, *e.g.* by means of:
- directly, technical assistance from expert(s),
  - directly, technical assistance from your National Medicine Regulatory Agency,
  - indirectly, support to the WHO Prequalification Programme<sup>10</sup>,
  - indirectly, support to the WHO Regulatory System Strengthening unit<sup>11</sup> or Member State Mechanism on substandard and falsified medical products<sup>12</sup>,
  - other types of support

**Your response:** Click or tap here to enter text.

- c. Use of existing positive lists of procurement agencies and private wholesalers (*e.g.*, DG ECHO Humanitarian Procurement Centres<sup>13</sup>)

**Your response:** Click or tap here to enter text.

- d. Trainings of staff at donor and/or implementing partners (HQ + field) regarding Quality Assurance for the purchase of medicines

**Your response:** Click or tap here to enter text.

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<sup>10</sup> <https://extranet.who.int/prequal/>

<sup>11</sup> <https://www.who.int/medicines/regulation/rss/en/>

<sup>12</sup> <https://www.who.int/medicines/regulation/ssffc/mechanism/en/>

<sup>13</sup> [http://dgecho-partners-helpdesk.eu/actions\\_implementation/procurement\\_in\\_humanitarian\\_aid/hpc](http://dgecho-partners-helpdesk.eu/actions_implementation/procurement_in_humanitarian_aid/hpc)

e. Other practices and tools

**Your response:** Click or tap here to enter text.

**C.10 To the best of your knowledge, is there any specific legislation in place at your National Medicine Regulatory Agency concerning the requirements of medicines manufactured “for export only”? If so, does it affect the pharmaceutical procurement policy for your national Cooperation?**

**Your response:** Click or tap here to enter text.

Many thanks for your support!

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