

To: Dr. Suzanne Hill, Director
Dr. Emer Cooke, Head of Regulation of Medicines and Other Health Technologies
Essential Medicines and Health Products
World Health Organization
20 Avenue Appia
1211 Geneva 27, Switzerland

18 December 2017

Open letter: ensuring the sustainability and robustness of the quality-assured products market through reconsideration of the prequalification fee structure

Dear Dr. Hill and colleagues,

We write to congratulate and thank you for your responsiveness to concerns raised by suppliers, civil society, and other stakeholders about the need for a waiver process for the new World Health Organization (WHO) prequalification programme (PQP) annual maintenance fee. We would also like to suggest a path forward for addressing remaining concerns.

We were very encouraged to see PQP under your leadership create and publicly post a waiver process for the annual maintenance fee, and to see WHO's commitment to consulting immediately with manufacturers and partners on the publication of details about waivers granted.¹ We were heartened in particular to see so many products for the fragile markets in tuberculosis (TB), influenza, pandemics, and paediatrics on the list of specific products that are potentially at risk with the new fee structure.² This is laudable progress and very timely in having come out before payment of invoices according to the new structure is due.

To resolve remaining concerns, and prevent similar concerns from arising on the diagnostics side, we propose a meeting to bring together procurers, suppliers, civil society, and other key stakeholders, with robust representation from all the disease areas that WHO PQP serves, before the next WHO Executive Board meeting. We append to this letter a list of topics and requests that we hope can be addressed at the meeting.

The global community is poised and ready to support WHO PQP and its donors in ensuring an efficient, transparent, sustainable and equitable PQ process and system for financing it. The global health community needs PQ services. The WHO estimates that 1 in 10 medical products circulating in low- and middle-income countries is substandard or falsified, pointing to the great need for widely available, affordable, high quality

¹ WHO. Guidance Document: Prequalification Fees. 13 September 2017.
http://who.int/medicines/news/PQ_Fees_2017.pdf?ua=1

² WHO. Guidance Document: Prequalification Fees Annex. 13 September 2017.
http://who.int/medicines/news/PQ_Fees_Annex_092017.pdf?ua=1

medicines.³ WHO PQP and its donors have invested tremendous resources, time, and effort into the laudable and critically important goal of ensuring the development and availability of more affordable, quality-assured global health products and markets that support their entry and continued use. These investments in PQ have provided a remarkable return: every dollar invested in the prequalification programme saved \$200 in public medicine procurement.⁴ We want to make sure the important functions of WHO PQP can continue to succeed.

We again express our appreciation for your commitment to working with stakeholders to make the transition to the new fee structure as smooth as possible. We also acknowledge that much of the groundwork for the new fee structure was laid years ago under different leadership. We ask you to revisit current plans to ensure a consistent approach across all disease categories, an equitable approach that ensures access and protects markets for most at-risk products, engagement of partners in decision-making, and transparent systems, to avoid repeating what led to the implementation of these fees.

We look forward to your response, which we request by December 27, 2017, and can be directed towards Erica Lessem (erica.lessem@treatmentactiongroup.org).

Sincerely,

Global Alliance for TB Drug Development
Global Health Technologies Coalition
MSF Access Campaign
PATH
Treatment Action Group

³ WHO. WHO Global Surveillance and Monitoring System for substandard and falsified medical products. Geneva: 2017. http://who.int/medicines/regulation/ssffc/publications/GSMS_Report.pdf

⁴ 't Hoen EF, Hogerzeil HV, Quick JD, Sillo HB. A quiet revolution in global public health: The World Health Organization's Prequalification of Medicines Programme. J Public Health Policy. 2014 May;35(2):137-61. doi: 10.1057/jphp.2013.53.

Appendix: Discussion Items and Requests

- 1) *Articulates objectives of the PQP, their true costs, and if the new fee structure supports them*—first and foremost, we request the WHO and its donors to articulate objectives of the PQP in general, detail what associated costs are, and then analyse if the new application and annual fee structure is poised to support such objectives.
 - For example, if the PQP is intended to facilitate the availability of affordable, quality-assured medicines, is the current fee structure likely to lead to higher prices or fewer quality-assured products?
 - If the fee structure is intended to generate enough revenue to keep PQP going, is it likely to do so if many suppliers will opt to de-list products rather than pay fees?
 - If an objective is to create quality-assured markets, would an exemption for first-time application fees be worthwhile?
 - What are the details of the PQP's budget?
 - How will fees generated by the PQP be spent?
 - What evidence is there to reassure manufacturers and other stakeholders that core activities are not already covered by existing donor lines, and that fees collected for essential products with vulnerable markets are not being used to subsidize other activities—such as expansion into new disease areas or technical assistance to other regulators or suppliers? (For example, there is concern that technical assistance being provided by PQP to large developers of biopharmaceuticals including major multinational corporations is being financed by small manufacturers of products for fragile markets.)
- 2) *Risk assessment and monitoring and evaluation plan*—to ensure that the new fee structure does not lead to any adverse impacts on the objectives of the PQP (such as de-listing essential prequalified products on the market, or increased prices), and results in the desired outcome (e.g. sustainable financing for the PQP), we believe WHO has a responsibility to do a risk assessment and share it publicly before moving further with the PQ fees, and to develop and seek input on a monitoring and evaluation plan for the fee structure.
- 3) *Sharing of previous consultant reports*—we understand that prior to implementing the current fee structure, some consultations were held and a consultant report was generated. However, the consultant report has not been made available publicly. This report should be made available publicly so that the assumptions and analyses informing the new fee structure can be understood and, if necessary, debated.
- 4) *Consideration of alternate fee structures*—we request the WHO and its donors to consider a different approach to medicines fees for products not eligible for a fee waiver altogether, given the wide range in sales volumes for listed products. As is the case for vaccines, a tiered fee structure for medicines is warranted.
 - A fixed annual fee as currently is the case would have a very different impact on a supplier of a product with \$3.5 million in annual sales, for example, as it would on a product with \$50 million in annual sales.
- 5) *Analysis for products in other health areas such as HIV and malaria*— An analysis of vulnerable products for HIV and malaria, similar to what was done for TB, is urgently needed to determine which products should be eligible for waivers.

- The vast majority of products in the WHO annex were for TB, which is reflective of the market challenges in the TB space as well as the TB field's having a mechanism for centralized procurement through the Global Drug Facility, facilitating an understanding of vulnerable products.
 - However, other conditions such as HIV and malaria most certainly have vulnerable products (in addition to the blanket inclusion of products especially formulated for paediatric markets), such as third-line antiretroviral therapy, and we are concerned that these are not receiving sufficient attention.
- 6) *Firm, expedient review timelines*—to reassure manufacturers about what they can expect in return for fees, having firm commitments to efficient review timelines is necessary.
- We appreciated the WHO's posting of draft key performance indicators (KPI) for comment, but were concerned that these were not expedient enough, particularly compared to stringent regulatory authorities such as the U.S. Food and Drug Administration, and that the targets for meeting those timelines were unacceptably low, when they should be met 100% of the time.⁵
 - At least one signatory to this letter, Treatment Action Group, has submitted feedback on the KPIs and has not heard back, so we remain unclear what the plan is for finalizing the KPIs and what the prospects are for including more ambitious KPIs, and would appreciate clarification.
- 7) *Assurance regarding potential future fee increases*—currently, it is unclear how or when the WHO PQP may again implement a new fee structure or raise fees, and whether or by whom this would need to be approved. This lack of predictability is concerning to suppliers and other stakeholders. Clarification and reassurance from WHO about if and how future fee changes would be implemented would be helpful.
- 8) *Automatic exemption for products on the waiver list*—currently, suppliers of products listed as eligible for waivers must still apply for a waiver for the annual maintenance fee. We recommend that products listed as eligible for waivers be automatically granted them without having to go through an application process.
- 9) *Removing requirement for manufacturers applying for an annual maintenance fee waiver to include in their justifications the sales and net profit from the past year*—this presents a potential conflict of interest, as it is out of scope for regulatory bodies to request this proprietary information from companies, and WHO is involved in many activities beyond the regulatory functions of PQP that could use these data for unintended purposes.
- Additionally, we anticipate that requesting such self-reported sales data would be an exercise in futility, as product sales fluctuate greatly year to year and across suppliers, in part due to tendering processes.
 - Moreover, there would be no independent corroboration, and manufacturers would be incentivized to underreport sales to meet criteria for a waiver.
 - Instead, we suggest using independently collected data about market dynamics for products from other sources, such as from the Global Drug Facility, United

⁵ World Health Organization. Draft Guidance Document: Key Performance Indicators (KPIs). 24 July 2017 <https://extranet.who.int/prequal/content/key-performance-indicators-who-prequalification>

Nations Development Programme for HIV and TB, GAVI for vaccines, PEPFAR for malaria products, and the Global Fund's marketplace for HIV and malaria, and pharmaceutical sales data available for purchase to capture non-pooled purchases.

10) *Rationale for lack of waiver for additional fees*—The current waiver is only for the annual maintenance fee, but other fees such as the application fee for finished products, and the application and maintenance fees for active pharmaceutical ingredients, may also be prohibitive and require waivers or reconsideration of fees.

11) *Transparency on determination of criteria for fee waivers, and of waivers granted*—while a publicly posted list of products eligible for waivers is very helpful, there is no information on how eligibility was determined. It would be helpful and fair of the PQP to publish criteria on how eligibility for waivers is determined, as well as post a list of all products that have been granted waivers (not just ones eligible for it) so as to avoid giving an advantage to one supplier over another.

12) *Policies for de-listing products*—according to our understanding, there is currently no process to de-list products. Articulating a process for de-listing products and proactively informing the global community about de-listed products publicly would be useful.

- For example, several stavudine products are still listed.
- It is not known at this time what will happen if a supplier declines to pay all or part of an invoice for annual maintenance fees, which we understand has already been the case for several HIV products.
- Will WHO PQP de-list or suspend products, and if so, how will WHO PQP determine which products to de-list if an invoice is paid partially?
- How will PQP inform the global community that a product is no longer listed?