Interim Guidance

Interim Quality Assurance Requirements for the Procurement of COVID-19 Pharmaceutical Products

25 June 2021

Objective

1. This document provides operational guidance following Board Decisions on Additional Support for Country Responses to COVID-19 and the Global Fund COVID-19 Response Mechanism (C19RM)[1] related to the Quality Assurance (QA) Requirements to be applied for procuring COVID-19 Pharmaceuticals Products with Global Fund resources.
2. For the purpose of this Interim Guidance, "COVID-19 Pharmaceutical Products" are products used for the curative treatment and prevention of Coronavirus disease (COVID-19). The above definition of COVID-19 Pharmaceutical Products is exclusive of essential medicines used for the management of patients with suspected or confirmed COVID-19. For such medicines, quality assurance requirements are specified in Global Fund's Quality Assurance Policy for Pharmaceutical Products (the "QA Policy")[2].

Clinical Standards

3. All pharmaceutical products procured with Global Fund resources are to be compliant with:
   - current national or institutional standard treatment guidelines or essential medicines list ("National or Institutional STGs or EML"); or with
   - the World Health Organization (WHO) treatment guidelines or essential medicines list ("WHO STG or EML"); or
   - any technical guidance, as stated in Section 3 of the QA Policy.

[1] Decision GF/B42/EDP11 as extended by GF/B43/EDP12 and Decision GF/B44/EDP18
[2] The Global Fund Quality Assurance Policy for Pharmaceutical Products, as amended and restated on 14 December 2010 by Board Decision GF/B22/DP09: https://www.theglobalfund.org/media/5894/psm_qapharm_policy_en.pdf

4. In light of new, emerging evidence and rapidly evolving recommendations, it is imperative that Recipients[3] regularly refer to the latest WHO guidance documents.[4]

Quality Assurance Requirements

5. All pharmaceutical products procured with Global Fund resources, including those procured for treatment of COVID-19, may only be procured in accordance with the QA Policy.
6. As per the QA Policy, all pharmaceutical products need to comply with the relevant quality standards that are established by the National Drug Regulatory Authority (NDRA) in the country of use and need to have been authorized for use by the same NDRA in accordance with its standard practices for drug registration or other forms of authorization.

Specific Requirements for COVID-19 Pharmaceutical Products

7. Global Fund resources may only be used to procure COVID-19 Pharmaceutical Products that meet one of the following standards:
   - Prequalified by the WHO Prequalification Programme;
   - Authorized for use by a Stringent Regulatory Authority[5]; or
   - Recommended for use by the Expert Review Panel.

Recognition of the Emergency Situation and Related Emergency Procedures

8. The Global Fund retains the WHO definition of Public Health Emergency of International Concern (PHEIC), as defined in the International Health regulation (IHR). It relies on WHO's emergency processes and those of Stringent Regulatory Authorities (as defined in the QA Policy) during a PHEIC. This ensures efficient support to country efforts in facing serious public health emergencies while maintaining an adequate level of assurance on the quality, safety and efficacy of the pharmaceutical products procured with Global Fund resources.
9. The Global Fund Board decided[6] that Global Fund resources may be used to procure COVID-19 Pharmaceutical Products that are:
   - Approved pursuant to the WHO Emergency Use Listing (EUL) procedures; or
   - Approved pursuant to any other emergency procedure set up by one of the Stringent Regulatory Authority, as defined under the QA Policy.

Conditions Applied to the Duration of the Decision

10. This approach is applicable until 31 December 2023, unless otherwise decided or extended by the Global Fund Board[7].

[3] The term "Recipient" used in this Interim Guidance includes in particular Principal Recipients, grantees, sub-recipients, sub-sub-recipients and procurement service agents.
[4] Available at https://www.who.int/news-room/feature-stories/detail/a-guide-to-who-s-guidance
[5] As defined per the Quality Assurance Policy for Pharmaceutical Products
[6] Decision GF/B42/EDP11 as extended by GF/B43/EDP12 and Decision GF/B44/EDP18
[7] Board Decision GF/B44/EDP18

Operationalization of the Board Decision

Listing of Eligible COVID-19 Pharmaceutical Products

11. The Global Fund Secretariat's Quality Assurance (QA) Team will examine the decisions of the various Stringent Regulatory Authorities in accordance with the recent Board decisions and will identify the COVID-19 Pharmaceutical Products which satisfy the above-mentioned requirements.
12. At the time of the publication of this Interim Guidance, the following emergency procedures established by WHO and the Stringent Regulatory Authorities have been identified by the QA Team:
    - **WHO Prequalification** decisions made as per the Emergency Use Listing (EUL) procedure opened to candidate pharmaceutical products;
    - The **United States Food and Drug Administration**'s (USFDA) general recommendations and procedures applicable to the authorization of the emergency use of certain medical products under sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act;
    - The decisions taken based on the **Canada's Minister of Health interim order** (IO) Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19;
    - The COVID-19 Pharmaceuticals Products approved by the **Therapeutic Goods Administration** (TGA) for inclusion on the Australian Register of Therapeutic Goods (ARTG) on the basis of the Expedited TGA assessment; and
    - The **European Medicine Agency** (EMA) Conditional Marketing Authorization as the provisions of Article 14(7) of Regulation (EC) No 726/2004.
13. Based on these decisions, a list of eligible COVID Pharmaceutical Products which can be procured with Global Fund resources will be published and regularly updated on the Global Fund website:
    - COVID-19 page
    - Quality Assurance page .
14. The Global Fund maintains on its website non-exhaustive lists for orientation purposes indicating finished pharmaceutical products known to the Global Fund to be compliant with the above requirements, as per the approved indications[8].

National Registration

15. To facilitate implementation of Section 19 of the QA Policy, reiterated above in paragraph 6 of this Interim Guidance, National regulators are encouraged to take

[8] Such lists are updated monthly and are available at: https://www.theglobalfund.org/en/sourcing-management/quality-assurance/medicines/

benefit of the WHO Collaborative Procedure between the WHO Prequalification of Medicines Programme and National Medicines Regulatory Authorities in the Assessment and Accelerated National Registration of WHO-prequalified Pharmaceutical Products.[9]

Safety and Vigilance for Emergency Use Products

16. The Global Fund would like to emphasize the critical need for timely collection of safety information on pharmaceutical products used under emergency access situations, despite the difficulties that the emergency situation might present, in order to inform public health decisions and ensure patients' safety.
17. In this respect, Recipients' obligations to report any safety information as per Section 4 (in particular, paragraphs 4.19 and 4.20) of the Guide to Global Fund Policies on Procurement and Supply Management of Health Products is reiterated.

Transitional Arrangements

18. Emergency procedures put in place by the various regulators will likely become obsolete as the registration process returns to their current "non-emergency" mode. The implementation of the above quality assurance requirements related to the emergency procedures will cease when pharmaceutical products become eligible for procurement following the standard Global Fund QA requirements stated above in order to satisfy country needs.

Global Fund Quality Assurance Team Support

19. The Global Fund Secretariat's QA Team remains available to provide support to facilitate interpretation of such policy decisions and provide advice on QA-related matters. Recipients should send queries to the QA Team through their Global Fund Country Team.

Derogations Implied within Emergency Procedures

20. It is acknowledged that decisions taken within the framework of the various emergency procedures are not based on harmonized requirements for quality and performance at the international level. This may lead to differences in the level of assurance provided by different Stringent Regulatory Authorities. However, this risk is inherent to the current global regulatory arrangements.

Registration within the Price and Quality Reporting (PQR) Tool

21. Recipients will be required to report procurement transactions of COVID-19 Pharmaceutical Products in the PQR system as a new category of pharmaceutical products.

[9] More information available at *https://extranet.who.int/pqweb/medicines/collaborative-registration-faster-registration*