The Global Fund

Quality Assurance (QA) for Health Products

QA Information Notice

IN Nº 2021-02	Suspension of procurement of Personal Protective Equipment supplied by Protectcare,
Version: 27/07/2021	Bangalore (India) found defective after testing

Addressees

- Any person having products in stock,

- Any procurers, buyers

Purpose

The GF Quality Assurance Team is issuing this information notice to provide advice and support regarding the suspension of a UNICEF approved product - personal protective equipment (PPE).

Identification of the product(s) and manufacturer

Name of Manufacturer	**Protectcare, Maragondanahalli Main Road, Karnataka, Bangalore (India)**
Commercial Name(s)	**Medical Masks (with ear loops)**
Packaging & Pack size & Type	**All packaging**
Batch(es)	**All**
Manufacturing Date	**All**

Background

In the framework of its market surveillance program performed on PPE supplied by UNICEF Supply Division to ensure that QA requirements specified in the agreement between the two institutions are implemented, the Quality Assurance (QA) Team has identified potential non-compliance products (Type IIR surgical masks) supplied in Costa-Rica on the basis of initial visual inspection based on wrong year of the EN 14683 standard affixed as well as the absence of the name of European Representative.

Primary verification handled by distance with the support of the recipients of Global Fund grants did not increase the assurance of quality which led to the sampling and testing of the products as per the EN 14683 standard. The results received from the independent testing laboratory show non-compliance of the batch tested with requirements of the standard EN 14683:2019, in cleanliness microbial, determination of bacterial filtration efficiency (BFE) and resistance against penetration by synthetic blood.

Consequently, and in the interest of public health, TGF QA advises to temporarily suspend the manufacturer from supplying PPE until further notice.

Nature of defect(s)

Details of defect or problem.	**Failure to comply with Determination of bacterial filtration efficiency (BFE) and resistance against penetration by synthetic blood.**
Is there any evidence or suspicion of a risk to public health?	**The failure may increase the probability of transmission of airborn pathogen including COVID-19.**
Extent of the problem (e.g. No. of batches, date manufactured).	**All batches of PPE manufactured.**
Extent of distribution of the product / batch (es).	**List of the countries impacted :** **Costa Rica, Namibia, Angola** **But wider distribution cannot be excluded.**
Number of patients potentially impacted	**No impacted patients known/reported**

Action/Investigations taken

UNICEF has identified the affected countries where the masks from Protectcare have been delivered. UNICEF is applying internal procedures and will communicate accordingly. The remaining stock from Protectcare has been quarantined in the UNICEF warehouse.

Next Steps

Based on the information available to date from the supplier, the following actions are recommended by GF QA

- Stop to use the current PPE in stock

- Remaining stock of PPE within the supply chain should be put in quarantine for further destruction and replacement.

- New procurement of PPE from Protectcare should be halted until further notice.

- In agreement with GF QA, UNICEF will engage with Principal Recipients (PRs) of impacted Countries to facilitate the process of quarantine, destruction and replacement of the concerned batches. However, impacted countries are requested **not to destroy the products until UNICEF's engagement on the steps to take and to ensure that all costs induced by this notice are supported by adequate evidence.**

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Contacts

PRs should copy GF QA Team of any correspondence regarding the matter for follow-up.

Please direct the respective answers and any questions about this matter to the technical contact listed below

Organisation	Name / Function	E-mail address
Global Fund	Alain Prat, QA Specialist	Alain.Prat@theglobalfund.org
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