Quality Assurance (QA) for Health Products

QA Notice

IN Nº 2023-01 Version 2 - 04/10/2023	**Reinstatement** in the TGF QA eligibility list of **TLD 300/300/50mg from Strides and manufactured by Universal Kenya and 3TC/ZDV 150/300 mg from Universal and manufactured by Universal Kenya.**

Addressees

- All Principal Recipients (PRs) through Health Product Management (HPM) specialist.
- Any procurer, buyer.

Purpose

The GF QA is issuing this updated QA notice to inform of the reinstatement in the TGF QA eligibility list of the following Pharmaceutical Products:

- Dolutegravir/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg (Strides Pharma Science Limited, manufacturing site Universal Corporation Ltd)
- Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg (Universal Corporation Ltd, manufacturing site Universal Corporation Ltd)

This notice is for internal and external dissemination and country teams are expected to communicate this information to their relevant stakeholders.

Identification of the product(s) and manufacturer

Names of Manufacturer	• Strides Pharma Science Limited Manufacturing site: Universal Corporation Ltd, PO Box 1748, Club Road, Plot No 13777, Kikuyu, 902, Kenya • Universal Corporation Ltd Manufacturing site: Universal Corporation Ltd, PO Box 1748, Club Road, Plot No 13777, Kikuyu, 902, Kenya
Commercial / Brand Name(s)	NA
Formulation	- Dolutegravir/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg - Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg

Packaging & Pack size & Type	HDPE Bottle
Batch(es)	NA
Manufacturing / Release Date	NA

Background

Global Fund Quality Assurance Team received the information of several complaints concerning Dolutegravir/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg from Strides and manufactured at Universal Corporation Ltd Kenya.

The complaints were notified by the Pharmacy and Poison Board (PPB) – Kenya and reported discoloured induction seal observed for TLD (300/300/50) mg Tablets, Film-coated.

Kenyan Regulatory authority (PPB) has been closely following the case and has proceed with the voluntary recall of the TLD.

The ongoing quarantine/recall did NOT involve Global-Fund funded TLD but the identified defect was considered as a concern in terms of quality management at UCL manufacturing site.

The root cause for the product defects related to “Burnt Induction Seal” was due to inadequate control parameters in batch record for induction sealing machine of the bottle packing line.

The root cause is also affecting Efavirenz tablets 600mg and Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg. However, these products are not commercialized from Universal Corporation yet.

The Global Fund published a QA notice (ref. IN N^{o} 2023-01) on the 30th of January 2023 to inform about temporary suspension of procurement and delisting of TLD 300/300/50mg and EFV 600mg from Strides and manufactured by Universal Kenya and 3TC/ZDV 150/300 mg from Universal and manufactured by Universal Kenya.

WHO Prequalification unit was informed, performed a **for-cause inspection** at Universal manufacturing site in Kenya. Based on the outcome of the inspection together with the CAPA provided, WHO Prequalification unit **considered the investigation as closed on 25 July 2023**. As per WHO PQ feedback, the company requalified both the equipment and the process for sealing the bottle which was the main issue of the complaint received by TGF QA. No sealing defects have been reported after the investigation and implementation of remedial actions.

Nature of defect(s)

Details of defect or problem.	N/A
Is there any evidence or suspicion of a risk to public health?	N/A
Extent of the problem (eg. nb batches).	N/A
Extent of distribution of the product / batch (es).	N/A
Number of patients potentially impacted	N/A

Action/Investigations taken

Next Steps

Based on the information available to date and until further notice, the following actions are recommended by The Global Fund QA :

Dolutegravir/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg and Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg **will be reinstated in The Global Fund QA eligibility list.**

In the meantime, Strides has requested the withdrawal of Efavirenz 600mg (HA390) from the WHO prequalification database as there was no demand since the last two years. Therefore, this medicine will not be reinstated in the QA eligibility list.

The next TGF QA eligibility list update is planned at the end of Q3 2023 and will consider the decision described in this QA notice.

National Regulatory Authority

National authorities should consider the content of the updated QA notice.

Procurement Agent

- To consider the TLD 300/300/50mg and 3TC/ZDV 150/300mg manufactured at UCL site as eligible for procurement with The Global Fund Grant.
- To progressively scale-up the procurement volumes allocated from Universal.
- To closely monitor quality performance of UCL Kenya.

In Central & Regional warehouse and at health facility level

- No action required.

Users and/or Patients

- No action required.

Contacts

This QA notice does require specific written response from PR. 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**
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