

Quality Assurance (QA) for Health Products

QA Information Notice

IN N° 2020-03	Temporary suspension of procurement of Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride) dispersible tablets, manufactured by SKANT LTD, INDIA
Version: 05/02/2020	

Addressees

- Procurement Agents
- All PRs

Purpose

The GF QA is issuing this information notice to provide information regarding the temporary suspension of the procurement of Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride) Tablet, multiple strengths, manufactured by SKant Limited PLOT NO. 1802-1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT, INDIA.

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

Name of Manufacturer	S KANT HEALTHCARE LIMITED
INN Name	Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride)
Commercial Name(s)	Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride) Tablet, Dispersible 25mg/500mg + 150mg Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride) Tablet, Dispersible 12.5mg/250mg + 75mg
Pharmaceutical form	Dispersible Tablet
Strength	25mg/500mg + 150mg; 12.5mg/250mg + 75mg
Packaging & Pack size	Alu-PVC/PVdC co-blister of 25 and 50
Batch(es)	Several - See annex 1
Expiry Date	04/2021
GF QA Standards	ERP authorized

Background

Early January 2020, GF QA has been alerted that following an inspection conducted in March 2019, WHO Prequalification team (PQ) concluded that below mentioned Finish pharmaceutical product (FPP) manufacturing site was not compliant with Good Manufacturing Practices (GMP): SKant Limited PLOT NO. 1802-1805, G.I.D.C. PHASE III, VAPI 396 195. GUJARAT, INDIA,

This site is manufacturing the ERP authorized formulations of Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride) dispersible tablets (see table above).

Nature of Defect(s)

Details of defect or problem.	GMP Non compliance of FPP manufacturing site
Is there any evidence or suspicion of a risk to public health?	No concrete evidence of risk for patient.
Extent of the problem (eg. how many batches).	See annex 1 – listing is limited to products manufactured and exported from 4th March 2019 until today
Extent of distribution of the product / batch (es).	Mali. No procurement with Global Fund grants, but procurement with national funds.
Number of patients potentially impacted	No impacted patients known

Action/Investigations taken

- WHO PQ is currently investigating the issue and following up on the CAPAs.
- GF investigated and could confirm that no procurement using GF Grants occurred for this product within the ERP validity period.

Based on the information available to date and until further notice, the following actions are recommended by GF QA.

Next Steps:

- No recall requested at user level
- Pyrimethamine/Sulfadoxine + Amodiaquine (hydrochloride) Tablet, multiple strengths, manufactured by SKant Limited will be, until further notice delisted from GF list of eligible antimalarials.
- To suspend, until further notice, procurement using GF funds of the above listed products.
- GF QA recommend procurement agent to consider this notice for procurement of all other products manufactured at this site.

Contacts:

This IN does not require specific written response from PR.

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

Organisation	Name / Function	E-mail address
Global Fund	Amelie Darmon, Associate QA Specialist	Amelie.Darmon@theglobalfund.org

Annex 1: List of batches exported during ERP validity Period.

S Kant has supplied the following batches post March 2019 of Sulfadoxine Pyrimethamine Dispersible tablets co-blistered with Amodiaquine dispersible tablets to MEDICAL EXPORTS GROUP – Netherland. Country: MALI

1. Listed below are Product Details and strength wise- Batch Number, Mfg & Expiry Date

S No	PRODUCT NAME	PACK SIZE	BATCH NO	MFG DATE	EXP DATE
1	AMODIAQUINE (AS HYDROCHLORIDE) 75 MG + SULFADOXINE/PYRIMETHAMINE 250/12.5MG DISPERSIBLE TABLETS (Co-Blister) - SUPYRA DISPERSIBLE JUNIOR	50X(3+1)	WSB 9001	05/2019	04/2021
		50X(3+1)	WBS 9002	05/2019	04/2021
		50X(3+1)	WBS 9003	05/2019	04/2021
2	AMODIAQUINE (AS HYDROCHLORIDE) 150 MG + SULFADOXINE/PYRIMETHAMINE 500/25MG DISPERSIBLE TABLETS (Co-Blister) - SUPYRA DISPERSIBLE	50X(3+1)	WSA 9001	05/2019	04/2021
		50X(3+1)	WSA 9002	05/2019	04/2021
		50X(3+1)	WSA 9003	05/2019	04/2021
		50X(3+1)	WSA 9004	05/2019	04/2021
		50X(3+1)	WSA 9005	05/2019	04/2021
		50X(3+1)	WSA 9006	05/2019	04/2021
		50X(3+1)	WSA 9007	05/2019	04/2021
		50X(3+1)	WSA 9008	05/2019	04/2021