Quality Assurance Team

QA INFORMATION NOTICE (IN)

IN Nº 2016-01
Version 06/02/2018

All products manufactured by Svizera Labs Private Limited, Turbhe, Navi, Mumbai, India

Eligibility reinstated for procurement with Global Fund (GF) funds

Addressees

- All PRs through HPM specialist
- GF Sourcing

Purpose

The Global Fund QA Team is issuing this IN to advice on the reinstatement in the Global Fund List of eligible Products of the below listed formulation manufactured by Svizera Labs Private Limited, Plot D 16/6, TTC Industrial Area, MIDC, Turbhe, Navi, Mumbai – 400703, India.

Identification of the product(s) and manufacturer

<table>
<thead>
<tr>
<th>Name of Manufacturer involved and location</th>
<th>Svizera Labs Private Limited, Plot D 16/6, TTC Industrial Area, MIDC, Turbhe, Navi, Mumbai, India</th>
</tr>
</thead>
<tbody>
<tr>
<td>INN Name</td>
<td>Isoniazid/Rifampicin Tablets 75mg / 150mg (TB189)</td>
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<tr>
<td></td>
<td>Ethambutol/Isoniazid/Rifampicin Tablets 275mg/75mg/150mg (TB192)</td>
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<tr>
<td></td>
<td>Ethambutol/Isoniazid/Pyrazinamide/Rifampicin Tablets 275mg/75mg/400mg/150mg (TB193)</td>
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<tr>
<td></td>
<td>Ethambutol Tablets 400mg (SRA approved)</td>
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Background

Following an inspection conducted in June 2015, the Prequalification Team of WHO published on 2nd of September 2015 a Notice of Concern (NOC) on the manufacture of pharmaceutical products at the abovementioned Svizera site. The NOC includes several critical observations, including (among many other issues) cleanliness/contamination risk and potential falsifications of quality assurance data.

On the basis of the review of the plan of corrective actions provided by Svizera following the NOC and taking into consideration three recent complaints received on the products manufactured by the same manufacturer, GF QA decided to delist the above mentioned products.
Update
A follow-up inspection was performed between the 23-29 June 2017, by the inspectors of the WHO PQT, with the primary objective of further review of the implemented CAPAs and the assessment of the level of compliance with WHO GMP. The inspections findings and the responses to the CAPAs enabled the WHO PQT Services Group to recommend to the Prequalification Assessment Group that the site inspected may be named/continue to be named as FPP manufacturing site in the dossiers.

**The Notice of Concern (NOC) is hence lifted.**

**Nature of defect(s)**
N/A

**Action/Investigations taken**
N/A

**Next Steps**
Based on the Notice of Lifting of the Notice of Concern (NOC) issued by the WHO PQT on the 29th of January 2018, the above identified products will be listed in the next revision of the Global Fund List of eligible Pharmaceutical Product.

Procurement of the above mentioned products using GF funds can be envisaged without any further notice.

**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:

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Name / Function</th>
<th>E-mail address</th>
</tr>
</thead>
<tbody>
<tr>
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