I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2014 an application for Isoniazid/Pyridoxine hydrochloride/ Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets [1] (HA639) to be assessed with the aim of including Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets in the list of prequalified medicinal products for the treatment of tuberculosis.

Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets was assessed according to the 'Procedure for Assessing the Acceptability, in Principle, of Pharmaceutical Products for Purchase by United Nations Agencies' by the team of WHO assessors. The assessors are senior experts, mainly from national authorities, invited by WHO to participate in the prequalification assessment process. The countries of origin of the assessors involved with Isoniazid/Pyridoxine hydrochloride/ Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets were Botswana, Canada, the Democratic Republic of Congo, Germany, Ghana, the Netherlands, Nigeria, South Africa, Switzerland and the United Kingdom.

Licensing status:
Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets has been submitted for licence/registration in the following countries:

Malawi
Uganda
Zambia
Zimbabwe

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

2. Steps taken in the evaluation of the product

Nov 2014	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Jan 2015	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Jan 2015	The company's response letter was received.
Feb 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Mar 2015	The company's response letter was received.
Mar 2015	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Mar 2015	The company's response letter was received.
Nov 2015	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
Mar 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jul 2016	The company's response letter was received.
Jul 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jul 2016	The company's response letter was received.
Sep 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2016	The company's response letter was received.
Nov 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
Nov 2016	Product dossier accepted (quality assurance)
21 Dec 2016	Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim 300 mg/25 mg/800 mg/160 mg Tablets was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

3. Manufacturer, Commitments and Inspection status

Cipla Limited
Unit I, Plot No. A-2, A-33, MIDC, Patalganga
District - Raigad, Maharashtra
Pin code: 410 220, India

Commitments for Prequalification

None which have an impact on the benefit-risk profile of the medicinal product.

Inspection status

The sites inspected were found to be compliant with WHO requirements for GMP.
Not inspected for GLP /GCP. Previous site inspections by WHO showed acceptable outcome.

4. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:

https://extranet.who.int/prequal