# I BACKGROUND INFORMATION ON THE PROCEDURE

## 1. Submission of the dossier

The company NCPC International Corp. submitted in 2014 an application for Streptomycin (as sulfate) 1g powder for injection[1] (TB296) to be assessed with the aim of including Streptomycin (as sulfate) 1g powder for injection in the list of prequalified medicinal products for the treatment of tuberculosis.

Streptomycin (as sulfate) 1g powder for injection 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 Streptomycin (as sulfate) 1g powder for injection were Canada, Germany, Ghana, Italy, the Netherlands, South Africa, Switzerland and Zimbabwe.

**Licensing status:**
Streptomycin (as sulfate) 1g powder for injection has been licensed / registered in the following countries: China H13020650; Myanmar R2103AA3001; Zambia 033/015

## 2. Steps taken in the evaluation of the product

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| Sept 2014 | The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements. |
| Nov 2014 | During the meeting of the assessment team the quality data were reviewed and further information was requested. |
| Oct 2015 | The company's response letter was received. |
| Nov 2015 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| Feb 2016 | The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. |
| May 2016 | The company's response letter was received. |
| July 2016 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| Sept 2016 | The company's response letter was received. |
| Sept 2016 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| Oct 2016 | The manufacturer of the API was inspected for compliance with WHO requirements for GMP. |
| Nov 2016 | The company's response letter was received. |
| Nov 2016 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| Feb 2017 | The company's response letter was received. |
| March 2017 | The quality data were reviewed and found to comply with the relevant WHO requirements. |
| June 2017 | Product dossier accepted (quality assurance) |
| 30 June 2017 | Streptomycin (as sulfate) 1g powder for injection was included in the list of prequalified medicinal products. |

[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

## II GENERAL CONDITIONS FOR THE PREQUALIFICATION

### 1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

NCPC New Preparation Branch Factory
No.115 Hainan Road
Shijiazhuang Economic & Technological Development Zone
Hebei
China.

Commitments for Prequalification

None which has 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 GCP/GLP. No bioequivalence study was required due to the pharmaceutical formulation

### 2. (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