I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2016 an application for Praziquantel Tablets 600 mg[1] (NT004) to be assessed with the aim of including Praziquantel Tablets 600 mg in the list of prequalified medicinal products for the treatment of for the treatment of schistosoma infections.

Praziquantel Tablets 600 mg 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 Praziquantel Tablets 600 mg were Botswana, Ethiopia, Germany, Korea, the Netherlands, Nigeria, South Africa, Spain, Switzerland, Uganda and Zimbabwe.

Licensing status:
Praziquantel Tablets 600 mg has been licensed / registered in India the country of origin.

2. Steps taken in the evaluation of the product

July 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2016	During the meeting of the assessment team the safety and efficacy data and the quality da were reviewed and further information was requested.
July 2016	The company's response letter was received.
July 2016	During the meeting of the assessment team the additional efficacy data were reviewed an further information was requested.
Aug 2016	The company's response letter was received.
Sept 2016	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
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.
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.
Dec 2016	The company's response letter was received.
Jan 2017	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	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2017	The company's response letter was received.
May 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
July 2017	The company's response letter was received.
Aug 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
Aug 2017	Product dossier accepted (quality assurance)
05 Sept 2017	Praziquantel Tablets 600 mg 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:

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church road
Andheri (East)
Mumbai – 400 059
India

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 in compliance with WHO requirements for GCP, GLP and GMP.

API manufacturer not inspected for GMP. Previous inspections by a stringent regulatory authority showed acceptable outcome.

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/