I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd. submitted in 2012 an application for Zinc (as sulfate) Dispersible Tablets 20 mg * (DI005) to be assessed with the aim including Zinc (as sulfate) Dispersible Tablets 20 mg in the list of prequalified medicinal products for the treatment of diarrhoea.

Zinc (as sulfate) Dispersible Tablets 20 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 Zinc (as sulfate) Dispersible Tablets 20 mg were Canada, Germany, Ghana, Kenya, South Africa, Switzerland and Zambia.

Licensing status:
Zinc (as sulfate) Dispersible Tablets 20 mg has been licensed / registered in the following countries:

Kenya H2010/22097/822
Madagascar 29.1.1.045

2. Steps taken for the assessment of the product

Sept 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Jan 2013	The company's response letter was received.
Jan 2013	During the meeting of the assessment team the additional quality data and the safety and efficacy were reviewed and further information was requested.
April 2013	The company's response letter was received.
May and July 2013	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2013	The company's response letter was received.
Nov 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2013	The company's response letter was received.
Jan 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2014	The company's response letter was received.
March 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2014	The company's response letter was received.
July 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2015	The company's response letter was received.

* 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.

March 2015	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
April 2015	The company's response letter was received.
May 2015	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
June 2015	In between the meetings of the assessment team the company's response letter was received. The additional quality data were reviewed and further information was requested..
July 2015	The company's response letter was received.
July 2015	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2016	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Dec 2016	Product dossier accepted (quality assurance)
07 Dec 2016	Zinc (as sulfate) Dispersible Tablets 20 mg was included in the list of prequalified medicinal products.

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
Block N2 (Unit No.VI), Village Theda
P. O. Lodhi Majra, Baddi
Tehsil Baddi, Dist. Solan
Himachal Pradesh, 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 GMP and GCP. API manufacturer not inspected for GMP. Previous inspections by a stringent regulatory authority showed acceptable outcome.
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