Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2012 an application for [DI005 trade name] * (DI005) to be assessed with the aim including [DI005 trade name] in the list of prequalified medicinal products for the treatment of diarrhoea.

[DI005 trade name] 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.

2. Steps taken for the assessment of the product

September 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
January 2013	The company's response letter was received.
January 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.
November 2013	The company's response letter was received.
November 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2013	The company's response letter was received.
January 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 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.
February 2015	The company's response letter was received.
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.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

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.
December 2016	Product dossier accepted (quality assurance)
07 December 2016	[DI005 trade name] 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

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/medicines/prequalified/finished-pharmaceutical-products