Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd submitted in 2018 an application for [TB168 trade name]* (TB168) to be assessed with the aim of including [TB168 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[RH089 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 in the evaluation of the product

November 2005	One manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
December 2005	One manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
January 2006	During the meeting of the assessment team, safety and efficacy data of the dossier were reviewed and further information was requested.
March 2006	The company's response letter was received.
March 2006	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and found to be in compliance with the relevant WHO requirements.
May 2006	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
May/July 2006	During the meeting of the assessment team, the quality data were reviewed and further information was requested.
October 2006	One manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
January 2007	The company's response letter was received.
January 2007	During the meeting of the assessment team, the additional quality data of the dossi were reviewed and further information was requested.
March 2007	One manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
March 2007	The company's response letter was received.
March 2007	During the meeting of the assessment team, the additional quality data of the dossi were reviewed and further information was requested.
May 2007	The company's response letter was received.
June 2007	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July/September 2007	During the meeting of the assessment team, the additional quality data of the dossier were reviewed and further information was requested.

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

November 2007	The company's response letter was received.
November 2007	During the meeting of the assessment team, the additional quality data of the dossier were reviewed and further information was requested.
December 2007	The company's response letter was received.
January 2008	The additional quality data were reviewed and found to be in compliance with the relevant WHO requirements.
7 March 2008	[TB168 trade name] was accepted for the list of prequalified medicines.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Macleods Pharmaceutical Limited
Plot No. 25-27, Survey No. 366
Premier Industrial Estate
Kachigam, Daman – 396 210 (UT)
India
TEL: + 91 0260 2244337
Fax: + 91 0260 2241565

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP and GCP.

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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products