Steps taken for prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2018 an application for [HA714 trade name][1] (HA714) to be assessed with the aim of including [HA714 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA714 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

Aug 2016	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
July 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
Sept 2017	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
July 2018	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May (and Aug) 2018	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Aug 2018	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
Aug 2018	The applicant's response letter was received.
Sept 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Nov 2018	The applicant's response letter was received.
Nov (and Dec) 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2019	The applicant's response letter was received.
Jan 2019	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
April 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2019	The applicant's response letter was received.
June 2019	The additional quality data were reviewed and further information was requested.
July 2019	The applicant's response letter was received.
July 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2019	Product dossier accepted (quality assurance)
30 Aug 2019	[HA714 trade name] 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 responsibility.

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
Village Theda
P.O. Lodhi Majra
Tehsil Baddi, Dist. Solan
Himachal Pradesh, 174101, 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 GLP/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/prequal/