Steps taken for prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2018 an application for [HA635 trade name][1] (HA635) to be assessed with the aim of including [HA635 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA635 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

Jan 2013	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
April 2014	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
Sept 2014	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
Nov 2014	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
Dec 2014	The company's response letter was received.
Jan 2015	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Jan 2015	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Feb 2015	The company's response letter was received.
Feb 2015	The additional quality data were reviewed and further information was requested.
June 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2015	The company's response letter was received.
Sept 2015	During the meeting of the assessment team the additional quality data were reviewed and furth information was requested.
Oct 2015	The company's response letter was received.
Nov 2015	The quality data were reviewed and found to comply with the relevant WHO requirements.
Dec 2015	Product dossier accepted (quality assurance)
16 Dec 2015	[HA635 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

Mylan Laboratories Limited
F-4 & F-12, Malegaon M.I.D.C.
Sinnar, Nashik Dist. – 422 113
Maharashtra State, 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.

Not inspected for GLP/GCP. Previous site inspections by WHO 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/