Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cadila Pharmaceuticals Limited submitted in 2013 an application for [HA595 trade name][*] (HA595) to be assessed with the aim of including [HA595 trade name] in the list of prequalified medicinal products for managing nausea and vomiting induced by cytotoxic chemotherapy, radiotherapy and preventing postoperative nausea and vomiting in HIV patients.

[HA595 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

July 2013	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
August and November 2013	During the meetings of the assessment team the quality data were reviewed and further information was requested.
December 2013	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
March 2014	The applicant's response letter was received.
April 2014	The additional quality data were reviewed and further information was requested.
May 2014	The applicant's response letter was received.
May 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2014	The applicant's response letter was received.
July and November 2014	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
January 2015	The applicant's response letter was received.
January 2015	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2015	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
February 2015	Product dossier accepted (quality assurance)
27 August 2015	[HA595 trade name] was included in the list of prequalified medicinal products.

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

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Cadila Pharmaceuticals Limited

1389, Trasad Road

Dholka Ahmedabad

Gujarat 382 225

India

Inspection status

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

A joint inspection was conducted with EDQM.

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