Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ranbaxy Laboratories Limited submitted in 2012 an application for [HA551 trade name][*] (HA551) to be assessed with the aim of including [HA551 trade name] in the list of prequalified medicinal products for prophylaxis/treatment of HIV/AIDS.

[HA551 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

March 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2012	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Sept 2012	The applicant's response letters were received.
Sept 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March 2013	The applicant's response letters were received.
March 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sept 2014	The manufacturers of two of the APIs were inspected for compliance with WHO requirements for GMP.
Sept 2014	The applicant's response letters were received.
Nov 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2015	In between the meetings of the assessment team the company's response letter was received. The quality data were reviewed and found to comply with the relevant WHO requirements.
Feb 2015	Product dossier accepted (quality assurance)
12 Feb 2015	[HA551 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.

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II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Shasun Pharmaceuticals Limited
Unit – II, R.S No. 32-34, PIMS Road
Periyakalapet, Puducherry
India - 605014

Inspection status

The sites inspected were found to be compliant with WHO requirements for GMP.
Not inspected for GCP /GLP. 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/medicines/prequalified/finished-pharmaceutical-products

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