Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ranbaxy Laboratories Limited submitted in 2011 an application for [HA525 trade name]* (HA525) to be assessed with the aim of including [HA525 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA525 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 for the assessment of the product

January 2011	The manufacturer of the API 1 was inspected for compliance with WHO requirements for GMP.
March 2011	The manufacturer of API 2 was inspected for compliance with WHO requirements for GMP.
November 2011	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
January 2012	The company's response letter was received.
January 2012	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
April 2012	The company's response letter was received.
May 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested
May 2012	The company's response letter was received.
July 2012	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2012	Product dossier accepted (quality assurance)
11 September 2012	[HA525 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.

[1] Formerly Ranbaxy Labs Limited

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Shasun Pharmaceutical Limited
Unit-II, R.S. No. 32–34
Shasun Road, Periyakalapet
Puducherry 605 014
India
Tel. No.: (+91 1704) 227700, (+91 1704) 227779
Fax. No.: (+91-1704) 223492
Email:Paonta.Complaints@sunpharmasys.com

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 GCP and 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:

http://www.who.int/prequal/