Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company PT Sanbe Farma submitted in 2014 an application for [RH050 trade name]* (RH050) to be assessed with the aim of including [RH050 trade name] in the list of prequalified medicinal products for the management of labour, prevention and treatment of postpartum haemorrhage and for the management of complications of pregnancy.

[RH050 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

January 2014	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March 2014	During the meeting of the assessment team the quality data were reviewed and further information was requested.
July 2014	The company's response letter was received.
September 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2014	The company's response letter was received.
January 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2015	The company's response letter was received.
September 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2015	The company's response letter was received.
November 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2015	The company's response letter was received.
January 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2016	The company's response letter was received.
March 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2016	The company's response letter was received.
May 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2016	The company's response letter was received.

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

July 2016	The additional quality data were reviewed and further information was requested.
October 2016	In between the meetings of the assessment team the company's response letters were received. The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2016	Product dossier accepted (quality assurance)
February 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
30 June 2017	[RH050 trade name] was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

PT Sanbe Farma Unit 3

Sterile Preparation Plant

Jl. Industri Cimareme No. 8

Padalarang, Bandung, Indonesia

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.

API supported by a CEP. Inspection of the manufacturing site waived based on previous satisfactory inspection by a stringent regulatory authority.

Not inspected for GCP/GLP. No bioequivalence study was required due to the nature of the pharmaceutical formulation.

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