Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Shanghai Dahua Pharmaceutical Co. Ltd., Shanghai, China submitted in 2010 an application for [RH028 trade name][1] (RH028) to be assessed with the aim of including [RH028 trade name] in the list of prequalified medicinal products for contraception for women.

[RH028 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

Nov 2010	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Jan 2011	During the meeting of the assessment team the quality data were reviewed and further information was requested.
March and April 2011	The company's response letters were received.
May 2011	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
July 2011	The company's response letter was received.
July 2011	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
Dec 2012	The company's response letter was received.
Jan 2013	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
May 2015	The company's response letter was received.
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.
July 2015	During the meeting of the assessment team the additional quality data and safety and efficacy data were reviewed and further information was requested.
Oct 2015	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
March 2016	The company's response letter was received.
May 2016	During the meeting of the assessment team the additional quality data and safety and efficacy data were reviewed and further information was requested.
Aug 2016	The company's response letter was received.
Sept 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2016	The company's response letter was received.

[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's (NMRA) responsibility

Oct 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
Nov 2016	The company's response letter was received.
Dec 2016	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
April 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
April 2017	Product dossier accepted (quality assurance)
30 June 2017	[RH028 trade name] was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Shanghai Dahua Pharmaceutical Co. Ltd.
3503 Changzheng Road
Chongming County
Shanghai
China

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, GLP and GCP.

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/