I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company PT Sanbe Farma submitted in 2014 an application for Santocyn[1] (RH050) to be assessed with the aim of including Santocyn in the list of prequalified medicinal products for the treatment of reproductive health conditions in women on 30 June 2017.

Santocyn 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. The countries of origin of the assessors involved with Santocyn were Canada, Germany, Ghana, the Netherlands, South Africa, Spain, Switzerland, Uganda and Zimbabwe.

Licensing status:
Santocyn has been licensed / registered in the following countries:

None

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

2. Steps taken in the evaluation of the product

Jan 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.
Sept 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2014	The company's response letter was received.
Jan 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2015	The company's response letter was received.
Sept 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2015	The company's response letter was received.
Nov 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2015	The company's response letter was received.
Jan 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 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.
July 2016	The additional quality data were reviewed and further information was requested.
Oct 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.
Oct 2016	Product dossier accepted (quality assurance)
Feb 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
30 June 2017	Santocyn 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:

PT Sanbe Farma Unit 3
Sterile Preparation Plant
Jl. Industri Cimareme No. 8
Padalarang, Bandung, Indonesia

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.

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