Part 7: Steps taken for prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Steril-Gene Life Sciences (P) Ltd submitted in 2017 an application for [RH083 trade name][1] to be assessed with the aim of including [RH083 trade name] in the list of prequalified medicinal products for reproductive health conditions in women.

[RH083 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 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Feb 2018	The quality data were reviewed and further information was requested.
June 2019	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
July 2018	The applicant's response letter was received.
July + Aug 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2018	The applicant's response letter was received.
Nov 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2019	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
Feb 2019	The applicant's response letter was received.
Aug 2019	The additional quality data were reviewed and further information was requested.
Aug 2019	The applicant's response letter was received.
Sept 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sept 2019	The applicant's response letter was received.
Sept 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
Oct 2019	Product dossier accepted (quality assurance)
14 Oct 2019	[RH083 trade name] was included in the list of prequalified medicinal products.

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

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release:

Steril-Gene Life Sciences (P) Ltd
45, Mangalam Main Road
Mangalam Village
Villianur Commune
Puducherry- 605110
India

Inspection status

A desk review for evaluation of compliance of the manufacturer of the API and of the FPP for GMP was conducted and it met WHO requirements.

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

2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.