Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ferring International Center SA submitted in 2020 an application for [RH095 trade name]* (RH095) to be assessed with the aim of including [RH095 trade name] in the list of prequalified medicinal products for prevention of postpartum haemorrhage.

[RH095 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 and March 2021	During the meetings of the assessment team the quality data were reviewed and further information was requested.
March 2021	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
June 2021	The applicant's response letter was received.
July 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2021	The applicant's response letter was received.
September 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2021	The applicant's response letter was received.
November 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2022	The applicant's response letter was received.
January and April 2022	The additional quality data were reviewed and further information was requested.
June 2022	The applicant's response letter was received.
June 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2022	Product dossier accepted (quality assurance).
4 July 2022	[RH095 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.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Ferring Pharmaceuticals (China) Co., Ltd.
No. 6 HuiLing Lu (Ferring Road),
National Health Technology Park, Zhongshan City,
Guangdong Province,
People's Republic of China

Steril-Gene Life Sciences Private Ltd.
45, Main Road, Mangalam Village,
Villianur, Puducherry
605110, India

Inspection status

Not inspected for GMP/GLP/GCP. Previous inspections by a stringent regulatory authority were acceptable.

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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products