Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited, Hyderabad, Telangana, India submitted in 2021 an application for [RH094 trade name][*] (RH094) to be assessed with the aim of including [RH094 trade name] in the list of prequalified medicinal products for indicated for induction of labour, prevention of postpartum haemorrhage, induction of abortion (alone in combination with mifepristone or letrozole) and management of incomplete abortion or missed abortion & intrauterine fetal death (alone or in combination with mifepristone).

[RH094 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 2021	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
March 2021	The applicant's response letter was received.
March 2021	During the meeting of the assessment team the quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
April 2021	The applicant's response letter was received.
May 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 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.
August 2021	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
August 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.
January 2022	The applicant's response letter was received.
January 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2022	The applicant's response letter was received.
May and July 2022	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
August 2022	The applicant's response letter was received.

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

August 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2022	The analytical facilities, relevant for the acceptability of the biowaiver were inspected for compliance with WHO requirements for GMP (desk review)
August 2022	Product dossier accepted (quality assurance)
02 September 2022	[RH094 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

Mylan Laboratories Limited
Plot No: 20 & 21, Pharmez, Sarkhej-Bavla,
National Highway No. 8A, Near Village Matoda,
Tal.-Sanand, Dist.-Ahmedabad - 382 213.
Gujarat, India.

Inspection status

The FPP manufacturing site and biowaiver testing site were reviewed through desk assessment and found to be in compliance with WHO requirements for GMP and GLP/GCP respectively.

Inspection of API manufacturer waived based on risk assessment.

Not inspected for GCP/GLP since a biowaiver applies.

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