Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Joint Stock Company "Halychpharm" submitted in 2018 an application for [RH086 trade name][1] to be assessed with the aim of including [RH086 trade name] in the list of prequalified medicinal products for the treatment of reproductive health indications in women.

[RH086 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

Sept 2018	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Sept 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Dec 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Dec 2018	The applicant's response letter was received.
March 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2019	The applicant's response letter was received.
May 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July and Aug 2019	The applicant's response letters were received.
Sept 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2019	The applicant's response letter was received.
Feb 2020	The additional quality data were reviewed and further information was requested.
Feb 2020	The applicant's response letter was received.
Feb 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
March 2020	Product dossier accepted (quality assurance).
16 March 2020	[RH086 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

Joint Stock Company "Halychpharm"
6/8, Opryshkivska Str, Lviv, 79024, Ukraine

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

Commitments for Prequalification

None which has an impact on the benefit-risk profile of the medicinal product.

Inspection status

API manufacturer not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.
The FPP manufacturing site was inspected and found to be in compliance with WHO requirements for GMP.

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/prequal/