Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Farmak JSC submitted in 2019 an application for [HA734 trade name]* (HA734) to be assessed with the aim of including [HA734 trade name] in the list of prequalified medicinal products for the management of conditions responsive to parenteral treatment with a potent glucocorticoid.

[HA734 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

May 2019	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 2019	During the meeting of the assessment team the quality data were reviewed and further information was requested.
September 2019	The applicant's response letter was received.
September 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2029	The applicant's response letter was received.
November 2019 + January 2020	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
January 2020	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
February 2020	The applicant's response letter was received
March 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested
May 2020	The applicant's response letter was received
May 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested
June 2020	The applicant's response letter was received
July 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested
July 2020	The applicant's response letters were received.
July 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested
August 2020	The applicant's response letter was received
September 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested

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

October 2020	The applicant's response letters were received.
October 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2020	Product dossier accepted (quality assurance)
5 November 2020	[HA734 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

Farmak JSC

74 Kyrylivska St.

Kyiv

Ukraine

Inspection status

The sites inspected were 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/pqweb/