Part 7: Steps taken for prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company JSC Grindeks submitted in 2017 an application for [RH079 trade name][1] to be assessed with the aim of including [RH079 trade name] in the list of prequalified medicinal products for reproductive health conditions in women.

[RH079 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

July 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Sept 2017	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Dec 2017	The applicant's response letter was received.
Jan 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2018	In between the meetings of the assessment team the applicant's response letter was received. The additional quality data were reviewed and further information was requested.
June 2018	Two manufacturers of the FPP were inspected for compliance with WHO requirements for GMP.
June 2018	The applicant's response letter was received.
July 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2018	The applicant's response letter was received.
Sept 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 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.
Dec 2018	One manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Dec 2018	The applicant's response letter was received.
Jan and May 2019	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
June and July 2019	The applicant's response letters were received.
July 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	[RH079 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

Manufacturers of the finished product and responsible for batch release:

HBM Pharma s.r.o.,
Sklabinska 30, Martin, 036 80,
Slovakia

UAB Santonika,
Veiveriu str 134B,
Kaunas, LT-46353,
Lithuania

Inspection status

API manufacturer not inspected for GMP. Previous inspections by a stringent regulatory authority showed acceptable outcome.

The FPP manufacturers were found to be in compliance with WHO requirements for GMP.

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.