I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company AS Kalceks submitted in 2016 an application for Magnesium sulfate-Kalceks 500 mg/ml solution for injection, BP* (RH063) to be assessed with the aim of including Magnesium sulfate-Kalceks in the list of prequalified medicinal products for the treatment of reproductive health indications in women.

Magnesium sulfate-Kalceks 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. The countries of origin for the assessors involved with Magnesium sulfate-Kalceks were Botswana, Canada, Germany, Ghana, Netherlands, South Africa, Switzerland and Uganda.

Licensing status:
NA

2. Steps taken for the assessment of the product

May 2016	During the meeting of the assessment team the quality data were reviewed and further information was requested.
May 2016	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Aug 2016	The company's response letter was received.
Sept and Oct 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2016	The company's response letter was received.
Jan 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2017	The company's response letter was received.
March 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2017	The company's response letter was received.
April 2017	The additional quality data were reviewed and further information was requested.
June 2017	The company's response letter was received.
June 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2017	Product dossier accepted (quality assurance)
04 July 2017	Magnesium sulfate-Kalceks was included in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

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

Commitments for Prequalification

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

Inspection status

Not inspected for GMP. Previous site inspections by stringent regulatory authority showed acceptable outcome.

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.

Further information is available at:
https://extranet.who.int/prequal/