I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd submitted in 2014 an application for Oseltamivir (as phosphate) 75 mg Capsules* (IN016) to be assessed with the aim of including Oseltamivir (as phosphate) 75 mg Capsules in the list of prequalified medicinal products for the treatment and prevention of influenza.

Oseltamivir (as phosphate) 75 mg Capsules 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 of the assessors involved with Oseltamivir (as phosphate) 75 mg Capsules were Democratic Republic of the Congo, Ethiopia, Germany, South Africa, Spain, Switzerland, Tanzania, Uganda and Zimbabwe.

Licensing status:
Oseltamivir (as phosphate) 75 mg Capsules has been licensed / registered in the following countries:
None

2. Steps taken in the evaluation of the product

July 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Sept 2014	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Oct 2014	The company's response letter was received.
Nov 2014	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Sept 2014 Jan 2015	During the meetings of the assessment team the quality data were reviewed and further information was requested.
July 2015	The company's response letter was received.
Aug 2015	In between the meetings of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2015	The company's response letter was received.
Sept 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2016	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP/GLP.
Aug 2016	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Oct 2016	The company's response letter was received.
Nov 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
Dec 2016	Product dossier accepted (quality assurance)
21 Dec 2016	Oseltamivir (as phosphate) 75 mg Capsules was included in the list of prequalified medicinal products.

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

Macleods Pharmaceuticals Limited
Block No. 2
Village Theda
P.O. Lodhi Majra
Tehsil Baddi, Dist.: Solan
Himachal Pradesh, 174101
India
Tel: +91-1795 661400
Fax: +91-1795 661452

Commitments for Prequalification

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

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP and GLP. Not inspected for GCP.

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