I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Ltd. submitted in 2012 an application for Oseltamivir (as phosphate) Capsules 75 mg* (IN011) to be assessed with the aim including Oseltamivir (as phosphate) Capsules 75 mg in the list of prequalified medicinal products for the treatment and prevention of influenza.

Oseltamivir (as phosphate) Capsules 75 mg 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) Capsules 75 mg were Canada, Germany, Ghana, the Netherlands, South Africa, Spain, Switzerland, Uganda, and United Kingdom.

Licensing status:
Oseltamivir (as phosphate) Capsules 75 mg has been licensed/registered in the following countries:

Country	Registration number
Botswana	HDPE Bottle: BOT1402601A Blister: BOT1402601B
Kenya	H2014/CTD1757/528
Mozambique	3748
Namibia	14/20.2.8/0675
Uganda	8407/06/13
Zimbabwe	2014/7.13/4952

* 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.

2. Steps taken for the assessment of the product

Jan 2013	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
March 2013	During the meeting of the assessment team the quality data were reviewed and further information was requested.
April 2013	The company's response letter was received.
May 2013	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 2013	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
June 2013	The company's response letter was received.
Aug 2013	The additional quality data were reviewed and further information was requested.
Oct 2013	The company's response letter was received.
Nov 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2014	The company's response letter was received.
March 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2014	The company's response letter was received.
April 2014	The additional quality data were reviewed and further information was requested.
May 2014	The company's response letter was received.
May 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2014	Product dossier accepted (quality assurance)
13 June 2014	Oseltamivir (as phosphate) Capsules 75 mg 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:

Mylan Laboratories Limited
Plot No. H-12 & H-13
MIDC, Waluj Industrial Area
Aurangabad 431 136
Maharashtra State
INDIA

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 GCP.

2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:
http://www.who.int/prequal