I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Ltd. submitted in 2008 an application for Oseltamivir Capsules 75 mg* (IN001) to be assessed with the aim for acceptance, of Oseltamivir Capsules 75 mg for the list of prequalified pharmaceutical products for the treatment and prophylaxis of influenza.

Oseltamivir 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 Capsules 75 mg were Canada, Germany, Hungary, Netherlands and Spain.

Licensing status:
Oseltamivir 75 mg Capsules has been licensed / registered in Uruguay:

2. Steps taken for the assessment of the product

October 2006	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
March 2008	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2008	During the meeting of the assessment team, safety and efficacy data were reviewed and further information was requested.
May/July 2008	During the meeting of the assessment team, the quality data were reviewed and further information was requested.
June 2008	The company's response letter was received.
July 2008	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and found to be in compliance with the relevant WHO requirements.
February 2009	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
March 2009	The company's response letter was received.
May 2009	The additional quality data were reviewed and found to be in compliance with the relevant WHO requirements.
13 May 2009	Oseltamivir Capsules 75 mg was accepted for the list for prequalified medicines.

* Trade names are not prequalified by WHO. This is under local DRA 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:

Cipla Ltd.
Plot No.S-103−S-105,S-107−S-112,L-147, L-147-1
Verna Industrial Estate,
Verna,
Salcette - Goa.Pin-403 722
India

Commitments for Prequalification

The company committed to validate not less than the first three commercial batches prior to the marketing of the FPP to assure that production processes are well controlled.

Inspection status

The applicant was inspected and 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