I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Strides Arcolab Ltd. submitted in 2009 an application for Oseltamivir (as phosphate) 75mg Capsules* (IN002) to be assessed with the aim of including Oseltamivir (as phosphate) 75mg Capsules in the list of prequalified medicinal products for the treatment and prophylaxis of Influenza virus A and Influenza virus B infection.

Oseltamivir (as phosphate) 75mg 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) 75mg Capsules were Canada, China, Germany, Kenja, Netherlands, Spain, South Africa.

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

Sl no	Country	Registration number
1.	Malaysia	MAL09111816A
2.	Myanmar	1501 AA 2368

2. Steps taken for the assessment of the product

July 2009	During the meetings of the assessment team, the quality data and the safety and efficacy data were reviewed and further information was requested.
Sept 2009	The company's response letters were received.
Sept 2009	During the meeting of the assessment team, the quality data and safety and efficacy data were reviewed and further information was requested.
23 Oct 2009	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
21 Nov 2009	The manufacture of the FPP was inspected for compliance with WHO requirements for GMP.
Nov 2009	The company's response letters were received.
Nov 2009	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested. The additional safety and efficacy data were reviewed and found to be in compliance with the relevant WHO requirements.
Dec 2009	The company's response letter was received.
Dec 2009	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
Dec 2009	The company's response letter was received.
Jan 2010	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
Feb 2010	The company's response letter was received.
March 2010	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
Sept 2010	The additional quality data were reviewed and found to be in compliance with the relevant WHO requirements.
10 Oct 2010	The site relevant for the bioequivalence study was inspected for compliance with WHO

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

	requirements for GCP
25 Oct 2010	Oseltamivir (as phosphate) 75mg Capsules 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:

Strides Arcolab Limited
36/7, Suragajakkanahalli,
Indlavadi Cross, Anekal Taluk,
Bangalore-562 106, INDIA.

Commitments

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

Inspection status

The sites inspected were found to be compliant with WHO requirements for GMP. Previous site inspections by WHO showed acceptable outcomes regarding GCP.

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

Medicinal product subject to medical prescription.

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