I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Ltd submitted in 2010 an application for Oflox 400 Tablets* (TB225) to be assessed with the aim of including Oflox 400 Tablets in the list of prequalified medicinal products for the treatment of tuberculosis.

Oflox 400 mg Tablets 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 Oflox 400 Tablets are Canada, China, Germany, Kenya, Netherland, Singapore, Spain, South Africa and Switzerland.

Licensing status:
Oflox 400 Tablets has been licensed / registered in the following countries: Republic De Guinea, Benin, Uganda

2. Steps taken for the assessment of the product

July 2010	During the meeting of the assessment team the safety and efficacy data of the dossier were reviewed and further information was requested.
September 2010	During the meeting of the assessment team the quality data of the dossier were reviewed and further information was requested.
January 2011	The company's response letter was received.
January 2011	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and further information was requested.
February 2011	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2011	The company's response letter was received
March 2011	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 2011	The company's response letter was received.
July 2011	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
September 2011	The company's response letter was received.
November 2011	During the meeting of the assessment team, the additional quality data were reviewed and found to comply with the relevant WHO requirements.
November 2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP. The proximity of a cephalosporin manufacturing unit to the API manufacturing units was noted. Based on risk assessment the situation was deemed acceptable for the purpose of prequalification of this product, however containment measures are required (to be verified in a follow up inspection).
December 2011	Product dossier accepted (quality assurance)
22 December 2011	Oflox 400 Tablets was included in the list of prequalified medicinal products

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

Cipla Ltd, Patalganga Unit II
Manufacturing division Plot no. A - 42
Patalganga Industrial Area,
District - Raigad
410220 Patalganga
Maharashtra
India
Phone: + 91 2192 50811

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 compliant with WHO requirements for GMP.
Not inspected for GLP /GCP. Previous site inspections by WHO showed acceptable outcome.

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/