I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hainan Poly Pharm Co Ltd submitted in 2011 an application for Ganciclovir 500 mg Powder for Infusion* (HA515) to be assessed with the aim for acceptance of Ganciclovir 500 mg Powder for Infusion, on the list of prequalified pharmaceutical products for the treatment of tuberculosis.

Ganciclovir 500 mg Powder for Infusion 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 Ganciclovir 500 mg Powder for Infusion were Canada, Ethiopia, Germany, South Africa, Spain, Sweden, Switzerland, Uganda, and United Kingdom.

Licensing status:
No information available

2. Steps taken for the assessment of the product

May 2011	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2011	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Sept 2011	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Nov 2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Dec 2011	The company's response letter was received.
March 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2012	The company's response letter was received.
May 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2012	The company's response letter was received.
July 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2012	The company's response letter was received.
Oct 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2012	The company's response letter was received.
Nov 2012	The quality data were reviewed and found to comply with the relevant WHO requirements.
19 Dec 2012	Product dossier accepted (quality assurance)
20 Dec 2012	Ganciclovir 500 mg Powder for Infusion 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:

Hainan Poly Pharm Co Ltd
No.1 Simalu
Guilinyang Economic Development Area
Lingshan, Haikou City
Hainan Province, China

Commitments for Prequalification

None

Inspection status

The sites inspected were found to be compliant with WHO requirements for GMP and GLP. Not inspected for GCP. No bioequivalence study was required due to the pharmaceutical formulation.

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/