I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Ltd submitted in 2006 an application for Duovir N* (HA365) to be assessed with the aim of acceptance of Duovir N for the list of prequalified pharmaceutical products for the treatment of HIV/AIDS.

Duovir N 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 for the assessor involved with Duovir N were Canada, China, Germany, Hungary, Netherlands, Spain, South Africa, Tanzania, Uganda and United Kingdom.

Licensing status:
Duovir N has been licensed / registered in the following countries:

Name of country	Registration number
Zambia	099/019
Tanzania	TAN 05 627 J05A CIP
Nigeria	04-6918
Sierra Leone	07-055
Mozambique	439
Uganda	4463/06/04

2. Steps taken for the assessment of the product

June 2005	One API manufacturer was inspected for compliance with WHO requirements for GMP.
March 2006	During the meeting of the assessment team, safety and efficacy aspects of the dossier were reviewed and further information was requested.
April 2006	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
April 2006	The company's response letter was received.
May 2006	During the meeting of the assessment team, safety and efficacy aspects of the dossier were reviewed and further information was requested.
August 2006	The company's response letter was received.
September 2006	During the meeting of the assessment team the additional data concerning safety and efficacy aspects was reviewed found to be in compliance with the relevant WHO requirements.
October 2006	One API manufacturer was inspected for compliance with WHO requirements for GMP.
November 2006/ January 2007	During the meeting of the assessment team, quality aspects of the dossier were reviewed and further information was requested.
March 2007	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.

* 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.

August 2007	The company's response letter was received.
October 2007	One API manufacturer was inspected for compliance with WHO requirements for GMP.
January 2008	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
July 2008	The company's response letter was received.
July/September 2008	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
October 2008	The company's response letter was received.
November 2008	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
December 2008	The company's response letter was received.
January 2009	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
March 2009	During the meeting of the assessment team the additional data concerning quality aspects was reviewed found to be in compliance with the relevant WHO requirements.
10 March 2009	Duovir N was accepted for the list of prequalified medicines.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Cipla Ltd. Goa
Unit III
Verna Industrial Estate,
Verna, Salcete – Goa
403 722 Goa
India

Commitments for Prequalification

None.

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:

www.who.int/prequal/