I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2016 an application for Lamivudine/Tenofovir Disoproxil Fumarate 300 mg/300 mg Tablets * (HA666) to be assessed with the aim of including Lamivudine/Tenofovir Disoproxil Fumarate 300 mg/300 mg Tablets in the list of prequalified medicinal products for the treatment of HIV/AIDS.
Lamivudine/Tenofovir Disoproxil Fumarate 300 mg/300 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 Lamivudine/Tenofovir Disoproxil Fumarate 300 mg/300 mg Tablets } were Canada, Germany, Kenya, Korea, Philippines, South Africa, Spain, Switzerland and Uganda.

Licensing status:

Lamivudine/Tenofovir Disoproxil Fumarate 300 mg/300 mg Tablets has been licensed/registered in the following countries:

Countries	Registration Number
Cote d'Ivoire	E1-2015-148
Ghana	FDB/SD.163-11084
Kenya	H2016/CTD2716/636
Malawi	PMPB/PL167/127
Myanmar	2106AA9605
Tanzania	TZ12H142
Uganda	7193/30/10
Zimbabwe	2012/7.13/4728

2. Steps taken in the evaluation of the product

Feb 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2014	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Sept 2014	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
May 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May 2016 July 2016	During the meetings of the assessment team the quality data were reviewed and further information was requested.
June 2016	The company's response letter was received.
July 2016	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Aug 2016	The manufacturer of the API was inspected for compliance with WHO requirements for

* Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

	GMP.
Aug 2016	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Sept 2016	The company's response letter was received.
Sept 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2016	The company's response letter was received.
Nov 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
Dec 2016	Product dossier accepted (quality assurance)
21 Dec 2016	Lamivudine/Tenofovir Disoproxil Fumarate 300 mg/300 mg Tablets 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:

Cipla Limited
Plot No A – 42 (Unit – II)
MIDC Patalganga
District Raigad, 410 220
Maharashtra
India

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 in compliance with WHO requirements for GMP.
Not inspected for GCP/GLP. 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:
https://extranet.who.int/prequal/