I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd submitted in 2013 an application for Efavirenz/Lamivudine/Tenofovir disoproxil fumarate 600 mg / 300 mg/300mg Tablets* (HA611) to be assessed with the aim of including Efavirenz/Lamivudine/Tenofovir disoproxil fumarate 600 mg / 300 mg/300mg Tablets in the list of prequalified medicinal products for the treatment of HIV/AIDS.

Efavirenz/Lamivudine/Tenofovir disoproxil fumarate 600 mg / 300 mg/300mg 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 Efavirenz/Lamivudine/Tenofovir disoproxil fumarate 600 mg / 300 mg/300mg Tablets were Canada, Germany, Ghana, Kenya, Netherlands, Nigeria, South Africa, Spain, Switzerland and Uganda.

Licensing status:
Efavirenz/Lamivudine/Tenofovir disoproxil fumarate 600 mg / 300 mg/300mg Tablets has been licensed / registered in the following countries:

Botswana - BOT1502855
Kenya - H2015/CTD3617/376
Tanzania - TZ15H0428
Zimbabwe - 2016/7.13/5162
Ethiopia - MAC/IND/073
Uganda - 9195/30/15
Malawi - PMPB/PL280/20
Zambia - 10030/15
Nigeria - B4-5682
Ivory Coast - E-2015-624

* 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.

2. Steps taken for the assessment of the product

Jan 2014	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Feb 2014	The company's response letter was received
March 2014	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Feb 2014 April 2014	The quality data were reviewed and further information was requested.
April 2014	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
May 2014	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
June 2014	The company's response letter was received.
July 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Aug 2014	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
Oct 2014	The company's response letter was received.
Nov 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2015	The company's response letter was received.
Jan 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2015	The company's response letter was received.
March 2015	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2015	Product dossier accepted (quality assurance)
04 June 2015	Efavirenz/Lamivudine/Tenofovir disoproxil fumarate 600 mg / 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:

Macleods Pharmaceuticals Limited
Block No. 2
Village Theda
P.O. Lodhi Majra
Tehsil Baddi, Dist. Solan
Himachal Pradesh, 174101, INDIA

Commitments

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 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:
www.who.int/prequal/