I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2016 an application for Dolutegravir 50mg Tablets [1] (HA680) to be assessed with the aim of including Dolutegravir 50mg Tablets in the list of prequalified medicinal products for the treatment of HIV/AIDS.

Dolutegravir 50mg 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 Dolutegravir 50mg Tablets were Botswana, Brazil, Ethiopia, Germany, Ghana, Nigeria, South Africa, Spain, Switzerland and Zimbabwe.

Licensing status:
Dolutegravir 50mg Tablets has been licensed / registered in the following countries:

None

2. Steps taken in the evaluation of the product

June 2008	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
March 2016	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Sept 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Nov 2016	In between the meetings of the assessment team the company's response letter was received. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Nov 2016	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Jan 2017	The company's response letter was received.
Jan 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2017	The company's response letter was received.
March 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2017	The company's response letter was received.
May 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2017	The company's response letter was received.
July 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sept 2017	The company's response letter was received.

[1] 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.

Oct 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
Oct 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Oct 2017	Product dossier accepted (quality assurance)
24 Oct 2017	Dolutegravir 50mg 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 Indore (Unit –IV)
Plot No 9, 10 & 15
Indore Special Economic Zone, Phase II
Pithampur, District: Dhar
Madhya Pradesh – 454 775
India.

Commitments for Prequalification

None which has an impact on the benefit-risk profile of the product.

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP and GCP/GLP.

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/