STEPS TAKEN FOR PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Shanghai Desano Bio-pharmaceutical Co. Ltd. submitted in 2017 an application for Lamivudine/Nevirapine/Zidovudine 150mg/200mg/300mg Tablets* (HA684) to be assessed with the aim of including Lamivudine/Nevirapine/Zidovudine 150mg/200mg/300mg Tablets in the list of prequalified medicinal products for the treatment of HIV/AIDS.

Lamivudine/Nevirapine/Zidovudine 150mg/200mg/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.

Licensing status:
Lamivudine/Nevirapine/Zidovudine 150mg/200mg/300mg Tablets has not yet been licensed/registered in any country.

2. Steps taken in the evaluation of the product

January 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
January 2017	During the meeting of the assessment team the safety and efficacy 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 quality data and the additional efficacy data were reviewed and further information was requested.
April 2017	The company's response letters were received.
May 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
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.
July 2017	The company's response letter was received.
November 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
February 2018	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
July 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2018	The company's response letters were received.
August 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
September 2018	Product dossier accepted (quality assurance).
20 September 2018	Lamivudine/Nevirapine/Zidovudine 150mg/200mg/300mg Tablets was included in the list of prequalified medicinal products.

* 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.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection Status

Manufacturer of the finished product and responsible for batch release:

Shanghai Desano Bio-Pharmaceutical Co., Ltd.
1479 Zhangheng Road
China (Shanghai) Pilot Free Trade Zone
Shanghai 201203
China

Commitments for Prequalification
None which has an impact on the benefit-risk profile of the medicinal product.

Inspection status
The finished product manufacturing site and the bioequivalence study site were found to be in compliance with WHO requirements for GMP, GLP and GCP.

Inspection of the API manufacturers waived based on risk assessment.

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/