I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Shanghai Desano Bio-pharmaceutical Co., Ltd. submitted in 2015 an application for Lamivudine and Zidovudine Tablets 150 mg/300 mg [*] (HA655) to be assessed with the aim of including Lamivudine and Zidovudine Tablets 150 mg/300 mg in the list of prequalified medicinal products for the treatment of HIV/AIDS.

Lamivudine and Zidovudine Tablets 150 mg/300 mg 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 and Zidovudine Tablets 150 mg/300 mg were Botswana, Germany, Ghana, South Africa, Spain, Switzerland, Tanzania and Zimbabwe.

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

2. Steps taken in the evaluation of the product

July 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
July 2015 and Sept 2015	During the meetings of the assessment team the quality data were reviewed and further information was requested.
Aug 2015	The company's response letter was received.
Sept 2015	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
Oct 2015	The company's response letter was received.
Nov 2015	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Jan 2016	The company's response letter was received.
Jan 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2016	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2016	The company's response letter was received.
March 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
March 2016	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
July 2017	Product dossier accepted (quality assurance)
21 July 2017	Lamivudine and Zidovudine Tablets 150 mg/300 mg 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
Zhangjiang High-Tech Park
Shanghai 201203
China

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 GLP and GCP.
Not inspected for GMP. Previous inspections by a stringent regulatory authority 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