# Steps before prequalification

## I. BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2016 an application for [HA678 trade name]* (HA678) to be assessed with the aim of including [HA678 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA678 trade name] 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.

### 2. Steps taken in the evaluation of the product

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| April 2016 | The manufacturer of the API was inspected for compliance with WHO requirements for GMP. |
| July 2016 | The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP. |
| September 2016 | During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested. |
| September and November 2016 | During the meetings of the assessment team the quality data were reviewed and further information was requested. |
| November 2016 | In between the meetings of the assessment team the company's response letter was received. The additional safety and efficacy data were reviewed and further information was requested. |
| January 2017 | The company's response letter was received. |
| January 2017 | The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements. |
| July 2017 | The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP. |
| August 2017 | The company's response letter was received. |
| September 2017 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| February 2018 | The company's response letter was received. |
| March 2018 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| March 2018 | The company's response letter was received. |
| May 2018 | The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. |
| August 2018 | The additional quality data were reviewed and further information was requested. |
| September 2018 | During the meeting of the assessment team the quality data were reviewed and further information was requested. |
| September 2018 | The company's response letter was received. |
| September 2018 | The quality data were reviewed and found to comply with the relevant WHO requirements. |
| October 2018 | Product dossier accepted (quality assurance). |
| 31 October 2018 | [HA678 trade name] was included in the list of prequalified medicinal products. |

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

## II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

### 1. Manufacture, Commitments and Inspection status

**Manufacture of the finished product and responsible for batch release:**

Mylan Laboratories Limited,
Plot no: 11-12 & 13, Indore SEZ, Pharma Zone, Phase-II, Sector-III
Pithampur –454775
Dist. Dhar, Madhya Pradesh
India

**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/