## Steps before prequalification

# I. BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The company Sun Pharmaceutical Industries Limited submitted in 2019 an application for [HA742 trade name][*] (HA742) to be assessed with the aim of including [HA742 trade name] in the list of prequalified medicinal products for HIV/AIDS.

[HA742 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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| September 2019 | During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested |
| October 2019 | The applicant's response letter was received. |
| November 2019 | During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested. |
| October and November 2019 | The quality data were reviewed by the assessment team and further information was requested. |
| December 2019 | The applicant's response letter was received. |
| January 2020 | The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements. |
| May 2020 | A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements. |
| May 2020 | The applicant's response letter was received. |
| May 2020 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| July 2020 | The applicant's response letter was received. |
| July and August 2020 | The additional quality data were reviewed and further information was requested. |
| November 2020 | The applicant's response letter was received. |
| November 2020 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| January 2021 | The applicant's response letter was received. |
| January 2021 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| March 2021 | The applicant's response letter was received. |
| March 2021 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |

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

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| May 2021 | The applicant's response letter was received. |
| May 2021 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| August 2021 | The applicant's response letter was received. |
| September 2021 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| November 2021 | The applicant's response letter was received. |
| November 2021 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| January 2022 | The applicant's response letter was received. |
| January 2022 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| March 2022 | The applicant's response letter was received. |
| March 2022 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| June 2022 | The applicant's response letter was received. |
| July 2022 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| September 2022 | The applicant's response letter was received. |
| September 2022 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| September 2023 | The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP. |
| November 2022 | The applicant's response letter was received. |
| November 2022 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| December 2023 | The applicant's response letter was received. |
| April 2023 | The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. |
| January 2024 | One manufacturer of one API was inspected for compliance with WHO requirements for GMP. |
| January and February 2024 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| March 2024 | A desk review for evaluation of compliance of one manufacturer of one API for GMP was conducted and it met WHO requirements. |
| August 2024 | The applicant's response letter was received. |
| September 2024 | The quality data were reviewed and found to comply with the relevant WHO requirements. |
| September 2024 | Product dossier accepted (quality assurance) |
| 23 September 2024 | [HA742 trade name] was included in the list of prequalified medicinal products. |

# II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

## 1. Manufacturer and Inspection status

**Manufacturer of the finished product and responsible for batch release**

Sun Pharmaceutical Industries Limited

Village Ganguwala, Paonta Sahib

District Sirmour – 173025

Himachal Pradesh

India

**Inspection status**

A desk review for evaluation of compliance of one of the manufacturers of the APIs for GMP was conducted and it met WHO requirements

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

## 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/medicines/prequalified/finished-pharmaceutical-products