# I BACKGROUND INFORMATION ON THE PROCEDURE

## 1. Submission of the dossier

The company Janssen-Cilag International NV submitted in 2023 an application for PREZISTA 600 mg film-coated tablets [1] (HA780) to be assessed with the aim of including PREZISTA 600 mg in the list of prequalified medicinal products for the treatment of HIV/AIDS.

PREZISTA 600 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.

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

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| January 2023 | During the meeting of the assessment team the quality data were reviewed and further information was requested. |
| January 2023 | The company's response letter was received. |
| January 2023 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| January 2023 | The company's response letter was received. |
| January 2023 | The quality data were reviewed and found to comply with the relevant WHO requirements. |
| 03 February 2023 | PREZISTA 600 mg film-coated tablets was included in the list of prequalified medicinal products. |

# II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:

https://extranet.who.int/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products

https://www.ema.europa.eu/en/medicines/human/EPAR/prezista

[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's responsibility Throughout this WHOPAR the proprietary name is given as an example only