STEPS FOR PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Janssen Cilag International N.V. submitted in 2012 an application for PREZISTA 75 mg film-coated tablets[1] (HA529) to be assessed with the aim of including PREZISTA 75 mg film-coated tablets in the list of prequalified medicinal products for the treatment of HIV/AIDS.

PREZISTA 75 mg film-coated 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.

PREZISTA 75 mg film-coated tablets 's conformance to the requirements of the current SRA guideline was re-evaluated by the team of WHO assessors.

2. Steps taken in the evaluation of the product

February 2022	WHO letter of request for requalification was sent to the applicant.
April 2022	The application letter was received.
September 2022	The assessment team reviewed the submitted data and further information was requested
October 2022	The applicant's response letter was received.
November 2022	The submitted data were reviewed and found to comply with the relevant WHO requirements.
24 November 2022	Requirements of requalification were met. PREZISTA 75 mg film-coated tablets remained on the list of prequalified medicinal products.

Further information is available at:
https://extranet.who.int/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products

[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.