I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Unique Pharmaceutical Laboratories submitted in 2018 an application for Ciprofloxacin Tablets USP 250 mg[1] (HA716) to be assessed with the aim of including Ciprofloxacin in the list of prequalified medicinal products for the treatment of HIV/AIDS related conditions.

Ciprofloxacin 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.
Based on the data submitted the team of assessors advised that Ciprofloxacin is included in the list of prequalified medicinal products. Ciprofloxacin Tablets USP 250 mg was listed on 18 December 2018.

Ciprofloxacin's conformance to the requirements of the current SRA guideline was re-evaluated by the team of WHO assessors.

2. Steps taken in the re-evaluation of the product

August 2024	WHO letter of request for requalification was sent to the applicant.
February 2025	The application letter was received.
March 2025	The assessment team reviewed the submitted data and further information was requested.
April 2025	The applicant's response letter was received.
April 2025	The assessment team reviewed the submitted data and further information was requested.
May 2025	The applicant's response letter was received.
May 2025	The submitted data were reviewed and found to comply with the relevant WHO requirements.
17 May 2025	Requirements of requalification were met. Ciprofloxacin Tablets USP 250 mg remained on the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:

https://extranet.who.int/prequal/medicines/prequalified/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.