I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Unique Pharmaceutical Laboratories (A Division of J. B. Chemicals & Pharmaceuticals Ltd) Mumbai 400 030, India, submitted in 2018 an application for Ciprofloxacin Tablets USP 250 mg[1] (HA716) to be assessed with the aim of including Ciprofloxacin Tablets USP 250 mg in the list of prequalified medicinal products for the treatment of HIV/AIDS related conditions.

Ciprofloxacin Tablets USP 250 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.

Licensing status:
Ciprofloxacin Tablets USP 250 mg has been licensed / registered in the USA.

2. Steps taken in the evaluation of the product

June 2018	The quality data were reviewed and further information was requested.
July 2018	The company's response letter was received.
Sept 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2018	The company's response letter was received.
Nov 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
18 Dec 2018	Ciprofloxacin Tablets USP 250 mg was included in the list of prequalified medicinal products.

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