STEPS FOR PREQUALIFICATION

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 2019 an application for Ciprofloxacin Tablets USP 500 mg[1] (HA738) to be assessed with the aim of including Ciprofloxacin Tablets USP 500 mg in the list of prequalified medicinal products for the treatment of HIV/AIDS related conditions.

Ciprofloxacin Tablets USP 500 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 500 mg has been licensed / registered in the USA.

2. Steps taken in the evaluation of the product

April 2019	The quality data were reviewed and further information was requested.
April 2019	The company's response letter was received.
May 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
11June 2019	Ciprofloxacin Tablets USP 500 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.