I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Ltd. submitted in 2014 an application for Rifabutin Capsules, USP 150mg [1] (HA640) to be assessed with the aim of including Rifabutin Capsules in the list of prequalified medicinal products the treatment of HIV/AIDS related conditions.

Rifabutin Capsules 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 Rifabutin Capsules is included in the list of prequalified medicinal products. Rifabutin Capsules USP 150mg was listed on 17 November 2014.

Rifabutin Capsules '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

January 2024	WHO letter of request for requalification was sent to the applicant.
March 2024	The application letter was received.
July 2024	The assessment team reviewed the submitted data and further information was requested
September 2024	The applicant's response letter was received.
October 2024	The submitted data were reviewed and found to comply with the relevant WHO requirements.
02 October 2024	Requirements of requalification were met. Rifabutin Capsules USP 150mg remained on the list of prequalified medicinal 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.