I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Sanofi-Aventis U.S. LLC submitted in 2017 an application for Priftin[1] (TB336) to be assessed with the aim of including Priftin in the list of prequalified medicinal products for the treatment of tuberculosis.

Priftin 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 Priftin is included in the list of prequalified medicinal products. Priftin was listed on 14 February 2017.

Priftin '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.
April 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.
29 October 2024	Requirements of requalification were met. Priftin 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.