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. The countries of origin of the assessors involved with Priftin were Germany and South Africa.

Licensing status:

Priftin has been licensed / registered in the USA.

2. Steps taken in the evaluation of the product

Jan 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
14 Feb 2017	Priftin 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