I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Limited submitted in 2014 an application for Rifabutin Capsules USP 150mg[1] (HA640) to be assessed with the aim of including Rifabutin Capsules USP 150mg in the list of prequalified medicinal products for the treatment of HIV/AIDS related conditions (specifically for tuberculosis treatment in HIV/AIDS infected patients who require an antiretroviral therapy containing a boosted protease inhibitor).

Rifabutin Capsules USP 150mg 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 Rifabutin Capsules USP 150mg were Germany and South Africa.

Licensing status:

Rifabutin Capsules USP 150mg has been licensed / registered in at least one of the ICH regions.

2. Steps taken in the evaluation of the product

Sept 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
17 Nov 2014	Rifabutin Capsules USP 150mg 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.