I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Sandoz submitted in 2002 an application for Rimstar[1] (TB090). Assessment was ongoing when the Swedish Medical Agency approved the product. The application changed to SRA-route in 2004 to be assessed with the aim of including Rimstar in the list of prequalified medicinal products for the treatment of tuberculosis.
Rimstar 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:
Rimstar has been licensed / registered in Sweden.

2. Steps taken in the evaluation of the product

2002 -2004	During the meetings of the assessment teams the initially submitted and additionally requested quality as well as safety and efficacy data were reviewed. After approval by the Medical Products Agency of Sweden the application changed to SRA route according to "Procedure for prequalification of pharmaceutical products[2]"
14 Sept 2004	Rimstar 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

[2] http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS961_Annex10.pdf