I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Bristol-Myers Squibb submitted in 2007 an application for Reyataz[1] (HA 421) to be assessed with the aim of acceptance of Reyataz for the list of prequalified medicinal products for the treatment of HIV/AIDS.

Atazanavir 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 country of origin for the assessor involved with Reyataz was Hungary.

Licensing status:
Reyataz has been licensed / registered in at least one of the ICH regions.

2. Steps taken for the assessment of the product

January 2008	During the meeting of the assessment team, the quality data were reviewed and found to be in compliance with the relevant WHO requirements.
7 March 2008	Reyataz was included in the list for prequalified medicines.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:
http://www.ema.europa.eu/humandocs/PDFs/EPAR/reyataz/586503en7.pdf

[1] Trade names are not prequalified by WHO. This is under local DRA responsibility. Throughout this WHOPAR the proprietary name is given as an example only.