WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Reyataz[1]

International Nonproprietary Name (INN): Atazanavir

Abstract

The "Procedure for Assessing the Acceptability, in principle, of Pharmaceutical Products for purchase by United Nations Agencies"[2] defines different evaluation mechanisms for innovator products and multisource (generic) products. In relation to this the "Guidance note to Applicants (Manufacturers) on the compilation of the WHO Public Assessment Report"[3] defines that for an innovator product that was approved by a drug regulatory authority in one of the ICH regions and for which a public assessment report was published by the approving authority, the WHOPAR will for parts 1, 3, 4, 5, 6 and 8 refer to this public assessment report.

Reyataz, manufactured at Bristol Myers Squibb, Evansville, Indiana, USA, was submitted to be considered for prequalification in 2008 when the product was licensed / registered in at least one of the ICH regions and subsequently accepted for the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 7 March 2008.

Based on the above, the Reyataz WHOPAR refers for parts 1, 3, 4, 5, 6 and 8 to the previously issued public assessment report as follows:

WHOPAR part		**Reference[4, 5]**
Part 1	Summary for the Public	http://www.ema.europa.eu/humandocs/Humans/EPAR/reyataz/reyataz.htm
Part 3	Package Leaflets	http://www.ema.europa.eu/humandocs/PDFs/EPAR/reyataz/emea-combined-h494en.pdf
Part 4	Summaries of Product Characteristics	http://www.ema.europa.eu/humandocs/PDFs/EPAR/reyataz/emea-combined-h494en.pdf
Part 5	Labelling	http://www.ema.europa.eu/humandocs/PDFs/EPAR/reyataz/emea-combined-h494en.pdf
Part 6	Discussion	http://www.ema.europa.eu/humandocs/PDFs/EPAR/reyataz/586503en6.pdf
Part 8	Steps taken following Authorization	http://www.ema.europa.eu/humandocs/PDFs/EPAR/reyataz/586503en8a.pdf http://www.ema.europa.eu/humandocs/Humans/EPAR/reyataz/reyatazM2.htm

Parts 2 and 7 of the Reyataz WHOPAR are included here.

[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.

[2] http://who.int/prequal/info_general/documents/TRS943/TRS943.pdf#page=97

[3] http://www.who.int/prequal

[4] http://www.ema.europa.eu/htms/human/epar/eparintro.htm

[5] http://www.ema.europa.eu/humandocs/Humans/EPAR/reyataz/reyataz.htm

Summary of the Prequalification Status for Reyataz:

	Initial Acceptance	
	Date	**Outcome**
Status on PQ list	7 Mar 08	listed
Dossier Evaluation	Feb 08	mr
Quality	NA	NA
Bioequivalence	NA	NA
Safety, Efficacy	NA	NA
GMP (re-)inspection	NA	NA
API	NA	NA
FPP	NA	NA
GCP (re-)inspection	NA	NA
Batch Analysis	NA	NA

mr: meets requirements
NA: not applicable
The table represents the status of relevant completed activities only.