WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Relenza 5mg/dose, inhalation powder, pre-dispensed[1]

Zanamivir Powder for Inhalation 5mg/dose

Relenza 5mg/dose, inhalation powder, pre-dispensed was submitted in 2009 by GlaxoSmithKline AB, to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment and prevention of influenza on 22 September 2009.
Information on the site(s) involved in the manufacture of the product and the API is available at the products listing information https://extranet.who.int/pqweb/medicine/3643 .

The "Procedure for prequalification of pharmaceutical products[2]"defines specific evaluation mechanisms for products approved by regulatory authorities, which apply similar stringent standards for quality, safety and efficacy as those required by WHO.

The prequalification of this product by the WHO Prequalification Team: Medicines (PQTm) is based on the approval by the Swedish Medical Products Agency "lakemedelsverket" (https://www.lakemedelsverket.se/en), in line with the "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities" [3].

Hence, no assessment of the data underlying this approval has been undertaken within the WHO Prequalification Programme.

However, according to the SRA guideline WHO may request additional data when considered necessary for the safe use of the product in regions relevant for prequalified products and such information may be included in the WHOPAR as a separate piece of information. In order to safeguard product quality throughout its entire intended shelf-life in hot and very humid areas, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant[4].

Based on the submitted stability data WHO PQTm considers the following storage condition appropriate for the product when distributed in regions with zone III, IVa and IVb climatic conditions, based on available stability information:

Do not store above 30°C.
The shelf-life at this storage condition is 10 years.

This WHOPAR refers to the information available at the approving stringent regulatory authority in terms of the Patient Information Leaflet, the Summary of Product Characteristics, and the assessment of the quality, efficacy and safety as well as steps taken after the prequalification.
(https://www.lakemedelsverket.se/sv/sok-lakemedelsfakta/lakemedel?id=19990209000018).
(Nationellt Produktregister för Läkemedel: 19990209000018)

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's 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
[3] http://apps.who.int/prequal/info_general/documents/TRS986/TRS986_ANNEX-5_SRA-Guide.pdf
[4] https://extranet.who.int/pqweb/sites/default/files/documents/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

This WHOPAR for Relenza 5mg/dose, inhalation powder, pre-dispensed is comprised of parts 2, 5 and 7.

Relenza 5mg/dose, inhalation powder, pre-dispensed contains zanamivir.
Its WHO recommended use is for the treatment and prevention of influenza.

The efficacy and safety profile of zanamivir is well established based on the extensive clinical experience in the treatment and prevention of influenza.

Summary of Prequalification Status for Relenza 5mg/dose, inhalation powder, pre-dispensed

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	22 Sept 2009	listed	11 Jan 2018	listed
Dossier Evaluation	07 Aug 2009	MR	18 Dec 2017	requalified

MR: meets requirements

The table represents the status of relevant completed activities only.