I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company GlaxoSmithKline AB, Sweden, submitted in 2009 an application for Relenza 5mg/dose, inhalation powder, pre-dispensed[1]) (IN007) to be assessed with the aim of including Relenza in the list of prequalified medicinal products for or the treatment and prevention of influenza.

Relenza 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.
Based on the data submitted the team of assessors advised that Relenza is included in the list of prequalified medicinal products. Relenza was listed on 22 September 2009.
Relenza's conformance to the requirements of the current SRA guideline was re-evaluated by the team of WHO assessors.

2. Steps taken in the re-evaluation of the product

August 2024	WHO letter of request for requalification was sent to the applicant.
November 2024	The application letter was received.
December 2024	The assessment team reviewed the submitted data and further information was requested
February 2025	The applicant's response letter was received.
February 2025	The submitted data were reviewed and found to comply with the relevant WHO requirements.
25 February 2025	Requirements of requalification were met. Relenza 5mg/dose, inhalation powder, pre-dispensed remained on the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:

https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products

[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.