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 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.

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

March 2016	WHO letter of request for requalification was sent to the applicant.
July 2016	The application letter was received.
April 2017	The assessment team reviewed the submitted data and further information was requested
July 2017	The applicant's response letter was received.
Nov 2017	The assessment team reviewed the submitted data and further information was requested
Dec 2017	The applicant's response letter was received.
Dec 2017	The submitted data were reviewed and found to comply with the relevant WHO requirements.
11 Jan 2018	Requirements of requalification were met. Relenza 5mg/dose, inhalation powder, pre-dispensed remained on the list of prequalified medicinal 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.