I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company F. Hoffmann-La Roche Ltd submitted in 2009 an application for Tamiflu® 30 mg hard capsules [1] (IN004) to be assessed with the aim of including Tamiflu® 30 mg hard capsules in the list of prequalified medicinal products for the treatment and prophylaxis of influenza.

Tamiflu® 30 mg hard capsules 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 Tamiflu® 30 mg hard capsules is included in the list of prequalified medicinal products. Tamiflu® 30 mg hard capsules was listed on 21Sept 2009.

Tamiflu® 30 mg hard capsules's conformance to the requirements of the current SRA guideline[2] was re-evaluated by the team of WHO assessors.

The marketing authorization holder changed from Roche Registration Limited to Roche Registration GmbH on 06 April 2018.

Licensing status:
Tamiflu® 30 mg hard capsules has been licensed / registered in the European Union.

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

Dec 2015	WHO letter of request for requalification was sent to the applicant.
May 2016	The application letter was received.
Jan 2017	The assessment team reviewed the submitted data and further information was requested.
Dec 2017	The applicant's response letter was received.
Feb 2018	The submitted data were reviewed and found to comply with the relevant WHO requirements.
05 Feb 2018	Requirements of requalification were met. Tamiflu® 30 mg hard capsules remained on the list of prequalified medicinal products.

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

[2] "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities"