# 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 in the list of prequalified medicinal products for the treatment and prophylaxis of influenza.

Tamiflu 30 mg 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 is included in the list of prequalified medicinal products. Tamiflu 30 mg was listed on 21 September 2009.

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

Tamiflu 30 mg '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

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| October 2024 | WHO letter of request for requalification was sent to the applicant. |
| November 2024 | The application letter was received. |
| December 2024 | The submitted data were reviewed and found to comply with the relevant WHO requirements. |
| 16 December 2024 | Requirements of requalification were met.<br>Tamiflu® 30 mg hard capsules 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

https://www.ema.europa.eu/en/medicines/human/EPAR/tamiflu
EMEA/H/C/000402