

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® 45 mg hard capsules ¹ (IN005) to be assessed with the aim of including Tamiflu 45 mg in the list of prequalified medicinal products for the treatment and prophylaxis of influenza

Tamiflu 45 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 45 mg is included in the list of prequalified medicinal products. Tamiflu 45 mg was listed on 21 September 2021.

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

Tamiflu 45 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

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. Tamiflu 45 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>
EMA/H/C/000402