I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company McNeil Sweden AB submitted in 2024 an application for Nicorette Novum 10 mg/16 hours [1] (TD003) to be assessed with the aim of including Nicorette Novum 10 mg/16 hours in the list of prequalified medicinal products for treatment of disorders caused by use of tobacco.

Nicorette Novum 10 mg/16 hours 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.

2. Steps taken in the evaluation of the product

February 2024	The quality data were reviewed by the assessment team and further information was requested.
March 2024	The company's response letter was received.
March 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
04 April 2024	Nicorette Novum 10 mg/16 hours was included in 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