Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company NAARI BV, submitted in 2020 an application for Tomonil 1.5 mg tablet* (RH098) to be assessed with the aim of including Tomonil 1.5 mg tablet in the list of prequalified medicinal products for reproductive health conditions in women

Tomonil 1.5 mg tablet 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 and May 2021	The quality data were reviewed and further information was requested.
June 2021	The applicant's response letter was received.
June 2021	The quality data were reviewed and found to comply with the relevant WHO requirements
01 July 2021	Tomonil 1.5 mg tablet was included in the list of prequalified medicinal products.

Further information is available at:

https://extranet.who.int/prequal/medicines/prequalified-lists

* 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.