I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Janssen-Cilag submitted in 2018 an application for VERMOX CHEWABLE[1] (NT006) to be assessed with the aim of including Vermox Chewable (mebendazole) in the list of prequalified medicinal products for the for large scale preventive chemotherapy interventions for the control of soil-transmitted helminth infections.

Vermox Chewable 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.

Licensing status:
VERMOX CHEWABLE has been licensed / registered in the United States of America.

2. Steps taken in the evaluation of the product

May and July 2018	During the meetings of the assessment team the quality data were reviewed and further information was requested.
July 2018	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Oct 2018	The company's response letter was received.
Nov 2018	During the meeting of the assessment team the additional quality and efficacy data were reviewed and further information was requested.
Jan 2019	The company's response letter was received.
Feb 2019	The additional quality data were reviewed and further information was requested.
Feb 2019	The company's response letter was received.
March 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2019	The company's response letter was received.
March 2019	The quality data and the safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March 2019	Product dossier accepted (quality assurance).
05 April 2019	Vermox Chewable was included in 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.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Lusomedicamenta Sociedade Técnica Farmacêutica S.A.
Estrada Consiglieri Pedroso, 69 – B Queluz de Baixo
2730-055 Barcarena
Portugal

Inspection status

Not inspected for GMP/GLP/GCP.
Previous inspections by a stringent regulatory authority showed acceptable outcome

2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription

Further information is available at:
https://extranet.who.int/prequal/