I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company GlaxoSmithKline Australia Pty Ltd. submitted in 2024 an application for KOZENIS Tablet[1] (MA203) to be assessed with the aim of including KOZENIS in the list of prequalified medicinal products for the treatment of malaria.

KOZENIS 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

September 2024	During the meeting of the assessment team the quality data were reviewed and further information was requested.
October 2024	The company's response letter was received.
October 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
28 October 2024	KOZENIS Tablet 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