Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Novartis Pharma AG submitted in 2026an application for Riamet Baby [1] (MA217) to be assessed with the aim of including Riamet Baby in the list of prequalified medicinal products for the treatment of malaria.

Riamet Baby 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

March 2026	During the meeting of the assessment team the quality data were reviewed and further information was requested.
March 2026	The company's response letter was received.
April 2026	The quality data were reviewed and found to comply with the relevant WHO requirements.
23 April 2026	Riamet Baby 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