I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Novartis Pharma AG submitted in 2008 an application for RIAMET® Dispersible [1] (MA069) to be assessed with the aim of including RIAMET® Dispersible in the list of prequalified medicinal products for the treatment of malaria.

RIAMET® Dispersible 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. Based on the data submitted the team of assessors advised that RIAMET® Dispersible is included in the list of prequalified medicinal products. RIAMET® Dispersible was listed on 27 February 2009.

RIAMET® Dispersible's conformance to the requirements of the current SRA guideline[2] was re-evaluated by the team of WHO assessors.

2. Steps taken in the re-evaluation of the product

December 2015	WHO letter of request for requalification was sent to the applicant.
February 2016	The applicant's application letter was received.
September 2019	The submitted data were reviewed and found to comply with the relevant WHO requirements.
17 September 2019	Requirements of requalification were met. RIAMET® Dispersible remained on the list of prequalified medicinal 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.

[2] "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities"