I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Sigma-Tau Industrie Farmaceutiche Riunite SpA submitted in 2012 an application for Eurartesim 320 mg/40 mg film-coated tablets[1] (MA094) to be assessed with the aim of including Eurartesim in the list of prequalified medicinal products for the treatment of malaria.

The marketing authorisation was transferred to Alfasigma S.p.A. in 2017.

Eurartesim 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 Eurartesim is included in the list of prequalified medicinal products. Eurartesim was listed on 09 October 2015.

Eurartesim's conformance to the requirements of the current SRA guideline was re-evaluated by the team of WHO assessors.

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

January 2024	WHO letter of request for requalification was sent to the applicant.
October 2024	The application letter was received.
November 2024	The assessment team reviewed the submitted data and further information was requested
December 2024	The applicant's response letter was received.
January 2025	The submitted data were reviewed and found to comply with the relevant WHO requirements.
08 January 2025	Requirements of requalification were met. Eurartesim 320 mg/40 mg film-coated tablets remained on 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

https://www.ema.europa.eu/en/medicines/human/EPAR/eurartesim
EMEA/H/C/001199

[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

*Formerly
Sigma-Tau Industrie
Farmaceutiche Riunite SpA