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 film-coated tablets1 (MA093) to be assessed with the aim of including Eurartesim film-coated tablets in the list of prequalified medicinal products for the treatment of malaria.

Eurartesim film-coated tablets 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. The countries of origin of the assessors involved with Eurartesim film-coated tablets were Germany, South Africa and Switzerland.

Licensing status:
Eurartesim film-coated tablets has been licensed / registered in at least one of the ICH regions.

2. Steps taken in the evaluation of the product

June 2012	The quality data were reviewed and further information was requested.
Dec 2014	The company's response letter was received.
Jan 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2015	The company's response letter was received.
March 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2015	The company's response letter was received.
May 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2015	The company's response letter was received.
June 2015	The additional quality data were reviewed and further information was requested
Oct 2015	A company's response letter was received and the quality data were reviewed and found to comply with the relevant WHO requirements.
09 Oct 2015	Eurartesim film-coated tablets 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