I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company DEMO SA submitted in 2013 an application for ZOPHRALEN [1] (HA597) to be assessed with the aim of including ZOPHRALEN in the list of prequalified medicinal products for the treatment of HIV/AIDS related conditions.

ZOPHRALEN 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 ZOPHRALEN were Germany and South Africa.

Licensing status:

ZOPHRALEN has been licensed / registered in at least one of the ICH regions.

2. Steps taken in the evaluation of the product

July 2013	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Sept 2013	The company's response letter was received.
Sept 2013	The quality data were reviewed and found to comply with the relevant WHO requirements.
21 Oct 2013	ZOPHRALEN 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