I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company (DEMO S.A.) submitted in 2013 an application for Zophralen solution for injection 8 mg/4 mL[1] (HA607) to be assessed with the aim of including Zophralen in the list of prequalified medicinal products for the management of HIV/AIDS.

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.
Based on the data submitted the team of assessors advised that Zophralen is included in the list of prequalified medicinal products. Zophralen was listed on 21 October 2013.

Zophralen '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

February 2022	WHO letter of request for requalification was sent to the applicant.
December 2022	The application letter was received.
May 2023	The assessment team reviewed the submitted data and further information was requested
March 2024	The applicant's response letter was received.
April 2024	The assessment team reviewed the submitted data and further information was requested.
June 2024	The applicant's response letter was received.
August 2024	The submitted data were reviewed and found to comply with the relevant WHO requirements.
21 August 2024	Requirements of requalification were met. Zophralen solution for injection 8 mg/4 mL 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.