I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Gilead Sciences Ireland UC submitted in 2018 an application for AmBisome Liposomal Amphotericin B 50 mg Powder for Concentrate for Dispersion for Infusion[1] (HA705) to be assessed with the aim of including AmBisome in the list of prequalified medicinal products of HIV/AIDS related conditions.
AmBisome 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 AmBisome is included in the list of prequalified medicinal products. AmBisome was listed on 19 June 2018.

AmBisome '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

August 2024	WHO letter of request for requalification was sent to the applicant.
September 2024	The application letter was received.
November 2024	The submitted data were reviewed and found to comply with the relevant WHO requirements.
18 November 2024	Requirements of requalification were met. AmBisome Liposomal Amphotericin B 50 mg Powder for Concentrate for Dispersion for Infusion 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.