I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Gilead Sciences International Ltd., submitted in 2018 an application for AmBisome Liposomal Amphotericin B 50mg Powder for Concentrate for Dispersion for Infusion[1] (HA705) to be assessed with the aim of including AmBisome Liposomal Amphotericin B in the list of prequalified medicinal products for the treatment of HIV/AIDS related conditions.

AmBisome Liposomal Amphotericin B 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.

2. Steps taken in the evaluation of the product

March 2018	During the meeting of the assessment team the quality data were reviewed and further information was requested.
April 2018	The company's response letter was received.
May 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
19 June 2018	AmBisome Liposomal Amphotericin B 50mg Powder for Concentrate for Dispersion for Infusion 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 responsibility. Throughout this WHOPAR the proprietary name is given as an example only.