I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company G.L. Pharma GmbH submitted in 2014 an application for Vendal retard 30 mg Filmtabletten[1] (HA637) to be assessed with the aim of including Vendal retard 30 mg in the list of prequalified medicinal products for the treatment and management of HIV/AIDS related conditions.

Vendal retard 30 mg 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 Vendal retard 30 mg is included in the list of prequalified medicinal products. Vendal retard 30 mg was listed on 12 December 2014.

Vendal retard 30 mg '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

January 2024	WHO letter of request for requalification was sent to the applicant.
March 2024	The application letter was received.
May 2024	The assessment team reviewed the submitted data and further information was requested
June 2024	The applicant's response letter was received.
June 2024	The submitted data were reviewed and found to comply with the relevant WHO requirements.
16 July 2024	Requirements of requalification were met. Vendal retard 30 mg Filmtabletten 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.