I BACKGROUND ON THE PROCEDURE INFORMATION

1. Submission of the dossier

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

Vendal retard 30 mg film-coated tablets 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 Vendal retard 30 mg film-coated tablets were Germany and South Africa.

Licensing status:
Vendal retard 30 mg film-coated tablets has been licensed / registered in Austria.

2. Steps taken in the evaluation of the product

Nov 2014	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Dec 2014	The company's response letter was received.
Dec 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
12 Dec 2014	Vendal retard 30 mg film-coated tablets 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.