Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company AS GRINDEKS, Lativa submitted in 2025 an application for Ofost 10 IU/ml concentrate for solution for infusion or solution for intramuscular injection [1] (RH110) to be assessed with the aim of including Ofost 10 IU/ml in the list of prequalified medicinal products for facilitating reproductive health.

Ofost 10 IU/ml 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

July 2025	During the meeting of the assessment team the quality data were reviewed and further information was requested.
September 2025	The company's response letter was received.
September 2025	The quality data were reviewed and found to comply with the relevant WHO requirements.
27 September 2025	Ofost 10 IU/ml concentrate for solution for infusion or solution for intramuscular injection was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:

https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-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