Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Demo S.A. Pharmaceutical Industry submitted in 2021 an application for Dexamethasone Phosphate/DEMO, 4 mg/mL, Solution for injection (2 mL) [*] (CV006) to be assessed with the aim of including Dexamethasone Phosphate/DEMO, 4 mg/mL, Solution for injection (2 mL) in the list of prequalified medicinal products for the management of conditions responsive to parenteral treatment with a potent glucocorticoid.

Dexamethasone Phosphate/DEMO, 4 mg/mL, Solution for injection (2 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

June 2021	The quality data were reviewed and further information was requested.
July 2021	The applicant's response letter was received.
July 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2021	The applicant's response letter was received.
September 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.
29 September 2021	Dexamethasone Phosphate/DEMO, 4 mg/mL, Solution for injection (2 mL) was included in the list of prequalified medicinal products.

Further information is available at:

https://extranet.who.int/prequal/

[*] 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