I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Noridem Enterprises Ltd. submitted in 2021 an application for Dexamethasone 3.3 mg/mL solution for injection[1] (CV005) to be assessed with the aim of including Dexamethasone 3.3 mg/mL solution for injection in the list of prequalified medicinal products for the management of conditions responsive to parenteral treatment with a potent glucocorticoid.
Dexamethasone 3.3 mg/mL solution for injection 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 company'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.
October 2021	The company's response letter was received.
October 2021	The additional quality data were reviewed and further information was requested.
November 2021	The company's response letter was received.
November 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2021	The company's response letter was received.
December 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.
17 December 2021	Dexamethasone 3.3 mg/mL solution for injection 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