I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Kern Pharma, S.L. submitted in 2014 an application for Dexametasona Kern Pharma 4 mg/ml solución inyectable[1] (HA618) to be assessed with the aim of including Dexametasona Kern Pharma 4 mg/ml solución inyectable in the list of prequalified medicinal products for the treatment of HIV/AIDS related conditions.

Dexametasona Kern Pharma 4 mg/ml solución inyectable 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 Dexametasona Kern Pharma 4 mg/ml solución inyectable were Germany and South Africa.

Licensing status:
Dexametasona Kern Pharma 4 mg/ml solución inyectable has been licensed / registered in at least one of the ICH regions.

2. Steps taken in the evaluation of the product

March 2014	During the meeting of the assessment team the quality data were reviewed and further information was requested.
June 2014	The company's response letter was received.
July 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
13 Aug 2014	Dexametasona Kern Pharma 4 mg/ml solución inyectable 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