I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ethypharm UK Ltd. submitted in 2025 an application for Caffeine Citrate 10mg/ml Solution for Injection[1] (1 mL ampoule, AP002) to be assessed with the aim of including Caffeine Citrate in the list of prequalified medicinal products for prevention and treatment of apnoea in preterm infants.

Caffeine Citrate 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

November 2025	During the meeting of the assessment team the quality data were reviewed and further information was requested.
November 2025	The company's response letter was received.
November 2025	The quality data were reviewed and found to comply with the relevant WHO requirements.
05 December 2025	Caffeine Citrate 10mg/ml Solution for 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