Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Chiesi Farmaceutici S.p.A. submitted in 2026 an application for Peyona[1] (AP003) to be assessed with the aim of including Peyona in the list of prequalified medicinal products for prevention and treatment of apnoea in preterm infants.

Peyona 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

March and May 2026	During the meetings of the assessment team the quality data were reviewed and further information was requested.
June 2026	The company's response letter was received.
June 2026	The quality data were reviewed and found to comply with the relevant WHO requirements.
10 July 2026	Peyona 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

https://www.ema.europa.eu/en/medicines/human/EPAR/peyona

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[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