I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company DEMO S.A. submitted in 2013 an application for Erpizon 250 mg, powder for solution for infusion[1] (HA602) to be assessed with the aim of including Erpizon in the list of prequalified medicinal products for the treatment of HIV/AIDS related conditions.

Erpizon 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.
Based on the data submitted the team of assessors advised that Erpizon is included in the list of prequalified medicinal products. Erpizon was listed on 08 January 2014.

Erpizon's conformance to the requirements of the current SRA guideline was re-evaluated by the team of WHO assessors.

2. Steps taken in the re-evaluation of the product

February 2022	WHO letter of request for requalification was sent to the applicant.
December 2022	The application letter was received.
May 2023	The assessment team reviewed the submitted data and further information was requested.
March 2024	The applicant's response letter was received.
April 2024	The assessment team reviewed the submitted data and further information was requested.
July 2024	The applicant's response letter was received.
August 2024	The assessment team reviewed the submitted data and further information was requested.
October 2024	The applicant's response letter was received.
December 2024	The submitted data were reviewed and found to comply with the relevant WHO requirements.
07 December 2024	Requirements of requalification were met. Erpizon 250 mg, powder for solution for infusion remained on 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.