# I BACKGROUND INFORMATION ON THE PROCEDURE

## 1. Submission of the dossier

The company DEMO SA submitted in 2013 an application for ERPIZON [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. The countries of origin of the assessors involved with ERPIZON were Germany, South Africa and Switzerland.

**Licensing status:**
ERPIZON has been licensed / registered in at least one of the ICH regions.

## 2. Steps taken in the evaluation of the product

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| Sept 2013 | During the meeting of the assessment team the quality data were reviewed and further information was requested. |
| Oct 2013 | The company's response letter was received. |
| Nov 2013 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| Dec 2013 | The company's response letter was received. |
| Dec 2013 | The quality data were reviewed and found to comply with the relevant WHO requirements. |
| 08 Jan 2014 | ERPIZON 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.