# I BACKGROUND INFORMATION ON THE PROCEDURE

## 1. Submission of the dossier

The company Jacobus Pharmaceutical Company, Inc. submitted in 2014 an application for Dapsone Tablets, USP 100 mg 1 (HA645) to be assessed with the aim of including Dapsone Tablets, USP 100 mg in the list of prequalified medicinal products for the treatment of HIV/AIDS related conditions.

Dapsone Tablets, USP 100 mg 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 Dapsone Tablets, USP 100 mg were Germany and South Africa.

**Licensing status:**
Dapsone Tablets, USP 100 mg has been licensed / registered the USA.

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

| | |
|---|---|
| Dec 2014 | The quality data were reviewed and further information was requested. |
| Dec 2014 | The company's response letter was received. |
| Dec 2014 | The quality data were reviewed and found to comply with the relevant WHO requirements. |
| 13 Jan 2015 | Dapsone Tablets, USP 100 mg 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