I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Sanofi-Aventis France submitted in 2011 an application for Notezine [1] (NT001) to be assessed with the aim of including Notezine in the list of prequalified medicinal products for the large scale preventative chemotherapy interventions for the control of lymphatic filariasis.
Notezine 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 Notezine were Germany and South Africa.

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

2. Steps taken in the evaluation of the product

Sept 2011	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Oct 2011	The company's response letter was received.
Nov 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2015	The company's response letter was received.
Sept 2015	During the meeting of the assessment team the quality data were reviewed and further information was requested.
July 2016	The company's response letter was received.
Aug 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
06 Sept 2016	Notzine 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