I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Eisai Co., Ltd. submitted in 2012 an application for Diethylcarbamazine Citrate Tablets 100 mg USP* (NT002) to be assessed with the aim of including Diethylcarbamazine Citrate Tablets 100 mg USP in the list of prequalified medicinal products for large scale preventative chemotherapy interventions for the control of lymphatic filariasis.

Diethylcarbamazine Citrate Tablets 100 mg USP were 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 Diethylcarbamazine Citrate Tablets 100 mg USP were Canada, China, Germany, South Africa and Switzerland.

Licensing status:
At the time of prequalification the product was not licensed in any country.

2. Steps taken for the assessment of the product

Nov 2012	During the meeting of the assessment team the quality, safety and efficacy data were reviewed and further information was requested.
Dec 2012	The company's response letter on the outstanding efficacy issues was received.
Jan 2013	During the meeting of the assessment team the additional efficacy data were reviewed and found to comply with the relevant WHO requirements.
Jan 2013	The company's response letter on the outstanding quality issues was received
Jan 2013	The additional quality data were reviewed and further information was requested.
Jan 2013	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Feb 2013	The company's response letter on the outstanding quality issues was received
Mar 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Apr 2013	The company's response letter on the outstanding quality issues was received
May 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2013	The company's response letter was received.
June 2013	The additional quality data were reviewed and further information was requested.
July 2013	The company's response letter was received.
Aug 2013	The quality data were reviewed and found to comply with the relevant WHO requirements.
Aug 2013	Product dossier accepted (quality assurance).
20 Aug 2013	Diethylcarbamazine Citrate Tablets 100 mg USP was included in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is the local Drug Regulatory Authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:
Eisai Pharmatechnology & Manufacturing Pvt. Limited
Plot Nos. 96, 97, 98, 124 & 126
Ramky Pharma City (SEZ)
Parawada-531019,
Visakhapatnam District
Andhra Pradesh
India
Phone: +91 8924 660777, +91 891 3047100
Fax: +91 8924 660759

Commitments for Prequalification

None.

Inspection status

API manufacturer not inspected for GMP. Previous inspections by a stringent regulatory authority showed acceptable outcome.

The FPP site inspected was found to be compliant with WHO requirements for GMP.

Not inspected for GCP (bioequivalence study conducted in an ICH country).

2. (Advice on) conditions or restrictions regarding supply and use

Further information is available at:
http://www.who.int/prequal/