I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Nutriset SAS, France submitted in 2010 an application for ZinCfant® 20mg* (DI002) to be assessed with the aim of including ZinCfant® 20mg in the list of prequalified medicinal products for the treatment of Diarrhoea.

ZinCfant® 20mg tablets 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 ZinCfant® 20mg were Canada, Germany, Ghana, South Africa, Switzerland and Uganda.

Licensing status:
ZinCfant® 20mg has been licensed / registered in the following countries:

	Date of registration	Date of expiry	Product's status
Benin	08/01/2008	No date of expiry	Food supplement
Bolivia	07/05/2010	07/05/2015	Medicine
Cambodia	16/09/2010	16/09/2015	Medicine
DR Congo	22/06/2007	No date of expiry	Medicine
Guatemala	18/11/2009	18/11/2014	Food supplement
Madagascar	14/02/2006	14/02/2016	Food supplement
Myanmar	01/03/2011	01/03/2016	Medicine
Uganda*	21/04/2008	N.A	Medicine
Zimbabwe	On process	-	Medicine

* Dispersible zinc tablets are registered under the name Zinkid

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

Steps taken for the assessment of the product

Jan 2010	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
March/May 2010	During the meetings of the assessment team the quality and the safety and efficacy data were reviewed and further information was requested.
Aug 2010	The company's response letters were received.
Oct 2010	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Jan/March/May 2011	During the meetings of the assessment team the additional quality and efficacy data were reviewed and further information was requested.
June 2011	The company's response letters were received.
July 2011	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2011	The company's response letters were received.
Nov 2011	During the meeting of the assessment team the additional quality and efficacy data were reviewed and further information was requested.
March 2012	The company's response letters were received.
March/May 2012	During the meeting of the assessment team the additional quality and efficacy data were reviewed and further information was requested.
July 2012	In between the meetings of the assessment team a company response letter was received. The additional efficacy data were reviewed and further information was requested.
Sept 2012	The safety and efficacy data as well as the quality data were reviewed and found to comply with the relevant WHO requirements.
Nov 2012	Product dossier accepted (quality assurance).
04 Dec 2012	ZinCfant® 20mg was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturers of the finished product and responsible for batch release:

Laboratoires Pharmaceutiques Rodael
l, route de SOCX
59380 Bierne
France
Tel. +33(0)328658889
Fax +33 (0)328658890
e-mail: rodael@wanadoo.fr

Commitments for Prequalification

None.

Inspection status

API manufacturer not inspected for GMP.

Previous inspections by a stringent regulatory authority showed acceptable outcome.

The sites inspected were found to be compliant with WHO requirements for GMP and GLP.

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

Medicinal product not subject to medical prescription.

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