I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Egyptian International Pharmaceutical Industries Company submitted in 2009 an application for Ceftriaxone (as sodium) 500mg Powder for Injection [*] (HA480) to be assessed with the aim of including Ceftriaxone (as sodium) 500mg Powder for Injection in the list of prequalified medicinal products for the treatment of bacterial infections in Human Immunodeficiency Virus (HIV)/AIDS patients.

Ceftriaxone (as sodium) 500mg Powder for Injection 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 Ceftriaxone (as sodium) 500mg Powder for Injection were Canada, Ethiopia, Germany, Ghana, South Africa and Switzerland.

Licensing status:
Ceftriaxone (as sodium) 500mg Powder for Injection has been licensed / registered in the following countries:

Country	Registration Number
Armenia	1677/7623
Bahrain	DRN-7898/11
Belarus	7344/05
Georgia	000081
Kuwait	6359/Jun12
Moldova	13299

2. Steps taken in the evaluation of the product

Nov 2009	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March 2010	During the meeting of the assessment team the quality data were reviewed and further information was requested.
July 2010	The company's response letter was received.
Oct 2010	The additional quality data were reviewed and further information was requested.
July 2011 Sept 2011	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2011	The company's response letter was received.
March 2012 May 2012	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2012	The company's response letter was received.

[*] 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.

Sept 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2012	The company's response letter was received.
Jan 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2013	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
April 2013	The company's response letter 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.
July 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2013	The company's response letter was received.
Oct 2013	The additional quality data were reviewed and further information was requested.
Nov 2013	In-between the meetings of the assessment team the company's response letter was received. The additional quality data were reviewed and further information was requested.
Dec 2013	The company's response letter was received.
Jan 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2014	The company's response letter was received.
Feb 2014	The additional quality data were reviewed and further information was requested.
March 2014	The company's response letter was received.
April 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
April 2014	Product dossier accepted (quality assurance)
16 May 2014	Ceftriaxone (as sodium) 500mg Powder for Injection was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Egyptian International Pharmaceutical Industries Co. (EIPICO)
Tenth of Ramadan City
Industrial Area B1
Egypt

Commitments for Prequalification

None which has an impact on the benefit-risk profile of the medicinal product.

Inspection status

The site inspected was found to be in compliance with WHO requirements for GMP.

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

Not inspected for GCP/GLP. No bioequivalence study was required due to the pharmaceutical formulation.

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

Medicinal product subject to medical prescription.

Further information is available at:

http://www.who.int/prequal