I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Sinopharm Zhijun (Shenzhen) Pharmaceutical Co., Ltd., China, submitted in 2014 an application for 达力嗪 R (DALIQIN)* (HA622) to be assessed with the aim of including 达力嗪 R (DALIQIN) in the list of prequalified medicinal products for the treatment of bacterial infections in Human Immunodeficiency Virus (HIV)/AIDS patients.

达力嗪 R (DALIQIN) 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 达力嗪 R (DALIQIN) were Canada, Germany, Ghana, South Africa, Spain, Switzerland and Uganda.

Licensing status:
达力嗪 R (DALIQIN) has been licensed / registered in the following countries:

Country	Registration Number
China	国药准字 H44022819
Philippines	DR-XY33222
Hongkong	HK-61060
Sri Lanka	FR-037442
Burma	1308 AA 478
Malaysia	MAL12035007A
Nigeria	A4-1459
Thailand	1C 175/55

2. Steps taken in the evaluation of the product

July 2014	During the meeting of the assessment team the quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Dec 2014	The company's response letter was received.
July 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2015	The company's response letter was received.
Sept 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Dec 2015	The company's response letter was received.
Jan 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2016	The company's response letter was received.
March 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2016	The company's response letter was received.
May 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

July 2016	Product dossier accepted (quality assurance)
15 Aug 2016	达力嗪 R (DALIQIN) was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Sinopharm Zhijun (Shenzhen) Pharmaceutical Co., Ltd.
No. 16, Lanqing Yilu, Hi-Tech Zone
Guanlan, Longhua New District
Shenzhen
China

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.

Inspection of API manufacturer waived based on risk assessment.

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