Part 7: Steps taken for prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Celltrion Inc submitted in 2018 an application for [HA712 trade name][1] to be assessed with the aim of including [HA712 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA712 trade name] 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.

2. Steps taken in the evaluation of the product

May 2017	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
Sept 2017	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
Feb 2018	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
June and July 2018	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
Sept 2018	The applicant's response letters were received.
Sept 2018	During the meeting of the assessment team the additional efficacy and additional quality data were reviewed and further information was requested.
Nov 2018	The applicant's response letter was received.
Nov 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Nov 2018	In between the meetings of the assessment team the applicant's response letter was received. The additional quality data were reviewed and further information was requested.
Jan 2019	The applicant's response letter was received.
May 2019	A desk review for evaluation of compliance of the sites for the bioequivalence study for GCP/GLP was conducted and it met WHO requirements.
Aug 2019	The additional quality data were reviewed and further information was requested.
Aug 2019	The applicant's response letter was received.
Oct 2019	The additional quality data were reviewed and further information was requested.
Nov 2019	The applicant's response letter was received.
Dec 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
Dec 2019	Product dossier accepted (quality assurance)
17 Dec 2019	[HA712 trade name] 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 responsibility.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:
Celltrion Pharm Inc
82, 2 Sandan-ro
Ochang-eup
Cheongwon-gu
Cheongju-si
Chungcheongbuk-do 28117
Republic of Korea

Commitments for Prequalification
None which have an impact on the benefit-risk profile of the medicinal product.

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

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

Medicinal product subject to medical prescription.

Further information is available at:
https://extranet.who.int/prequal/