Steps before Prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Strides Pharma Global PTE Limited submitted in 2017 an application for [MA138 trade name]* (MA138) to be assessed with the aim of including [MA138 trade name] in the list of prequalified medicinal products for the treatment of malaria.

[MA138 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

June 2016	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2017	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
August 2017	The applicant's response letter was received.
September 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July & September 2017	During the meeting of the assessment team the quality data were reviewed and further information was requested.
October 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
December 2017	The applicant's response letter was received.
January 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2018	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
February 2018	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
March 2018	The applicant's response letter was received.
March 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2018	The applicant's response letter was received.
July & December 2018	The additional quality data were reviewed and further information was requested.
January 2019	The applicant's response letter was received.
January 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
January 2019	Product dossier accepted (quality assurance)
06 February2019	[MA138 trade name] was included in the list of prequalified medicinal products.

* 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:

Strides Pharma Science Limited
KRS Gardens
Tablet Block
36/7, Suragajakkanahalli
Indlavadi Cross
Anekal Taluk
Bangalore 562106
India

Commitments for Prequalification

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

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP and GLP/GCP. A desk review for evaluation of compliance with GMP was conducted for the API manufacturer (lumefantrine) and it met WHO requirements.

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/