I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Strides Pharma Science Limited submitted in 2016 an application for ARTECAP[1] (MA123) to be assessed with the aim of including ARTECAP in the list of prequalified medicinal products for the treatment of malaria.

ARTECAP 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.

Licensing status:
ARTECAP has been licensed / registered in the following countries:

S.NO.	COUNTRY	REGISTRATION NUMBER
1.	Burkina Faso	2018-214/MS/CAB
2.	Cameroon	4941801
3.	Congo-Brazzaville	7172/6/MSP/DGMPL/DPM-16 7166/6/MSP/DGMPL/DPM-16
4.	DR Congo	MS.1253/10/05/DEM/0465/2017
5.	Ethiopia	3617/3950/NMR/2017
6.	Gabon	6027/15, 5957/15
7.	Guinea	2155/2018/MS/DNPM, 2156/2018/MS/DNPM
8.	Tchad	910 113, 910 117
9.	Uganda	NDA/MAL/HDP/7210
10.	Zimbabwe	2018/7.5/5631

2. Steps taken in the evaluation of the product

Feb 2013	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
Jan 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Jan and March 2016	During the meetings of the assessment team the 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 efficacy data were reviewed and further information was requested.
July 2016	The company's response letter was received.
July 2016	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
March 2017	The company's response letters were received.
May 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for

[1]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.

	GMP.
June 2017	The company's response letter was received.
May and Aug 2017	The additional efficacy data were reviewed and further information was requested.
Oct 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Oct 2017	The company's response letter was received.
Nov 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2018	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.
Feb 2018	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Feb 2018	The company's response letter was received.
March and May 2018	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
May 2018	The company's response letter was received.
May 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2018	Product dossier accepted (quality assurance).
19 June 2018	ARTECAP 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:

Strides Pharma Science Limited
KRS Gardens
Soft Gel Capsules Block
36/7, Suragajakkanahalli
Indlavadi cross
Anekal Taluk
Bangalore – 562 106
India

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 in compliance with WHO requirements for GMP, GLP and GCP.

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

Medicinal product not subject to medical prescription.

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