



European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Escalquens, 08.12.2022

Subject: Withdrawal of Artesunate, 60 mg powder and solvent for solution for injection (EMA/H/C/005718)



For the withdrawal of initial marketing authorisation application I would like to inform you that, at this point of time, B and O Pharm (France) has taken the decision to withdraw the application for Marketing Authorisation of Artesunate, 60 mg powder and solvent for solution for injection, which was intended to be used for initial treatment of severe malaria caused by *Plasmodium falciparum* in adults and children.

This withdrawal is based on the applicants decision not to pursue the marketing of this product within the EU following revision of the business strategy.

There are currently no ongoing clinical trials with this product performed by the applicant.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

We would like to take this opportunity to thank the Rapporteurs and their assessment team as well as the whole CHMP and EMA members for their time and efforts in reviewing this application.

I agree for this letter to be published on the EMA website.

Yours sincerely

