SHERNACRE
ENTERPRISE Limited

[redacted]

Veterinary Medicines and Inspections Unit
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

14th September 2016

Subject: Withdrawal of the Marketing Authorisation Application for Somnena 3mg/ml Solution for Injection for Cats, EMEA/V/C/004293/0000

To Whom it may Concern,

For the withdrawal of an initial marketing authorisation application

I would like to inform you that, at this point in time, Shernacre Enterprise Ltd. has taken the decision to withdraw the application for Marketing Authorisation of Somnena, 3mg/ml buprenorphine extended release solution for injection for cats, which was intended to be used for analgesia for post-surgical pain.

This withdrawal is based on the following reasons:
• A key clinical study in the Somnena dossier, evaluating the control of post-surgical pain, did not reach a satisfactory end point in the view of the rapporteurs;
• The CVMP considers that the data provided do not allow the committee to conclude on a positive benefit risk balance;
[redacted]

The Applicant plans to carry out a further clinical study that will be able to address the concerns of the Rapporteurs, CVMP and EMA. It is clear at this time, however, that it will not be achievable within the timetable of the current Centralised Procedure.

We reserve the right to make further submissions at a future date in this or other therapeutic indications.

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

Yours faithfully,

[redacted]
Shernacre Enterprise Ltd.