



**New A Innovation**  
Netherlands

NO CD/DVD



036348

1 December 2014

██████████  
European Medicines Agency  
30 Churchill Place  
Canary Wharf  
London E14 5EU  
United Kingdom

Date : 11 - Dec - 14

B: \_\_\_\_\_

L: \_\_\_\_\_

**Subject: Withdrawal of Oxapex, 65 mg/ml solution for infusion for dogs**  
**(Procedure number: EMA/V/C/002794)**

Dear ██████████

***For the withdrawal of an initial marketing authorisation application.***

We would like to inform you that, at this point of time, New A Innovation (NL) Limited B.V. has taken the decision to withdraw the application from the Centralised Procedure for Marketing Authorisation of Oxapex 65 mg/ml solution for infusion for dogs, which was intended to be used as an oxygen carrying solution (oxygen therapeutic) to be administered in conjunction with standard resuscitative therapy in order to increase oxygen delivery and tissue oxygenation in dogs suffering from clinical signs of anaemia as a result of haemorrhagic shock. The withdrawal request is immediately effective as of the date of this letter.

This withdrawal is based on the strategic decision to supply data from an additional efficacy study that cannot be introduced at a re-examination. On-going research & development by the applicant as well as guidance with the EMA's Scientific Advice Working Party should provide the required efficacy evidence for a MUMS application, and confirm the therapeutic benefits of the product that the CVMP currently considers unsubstantiated with the current dossier. The applicant believes these new data will adequately address the confirmatory evidence requested by the CVMP.

The applicant thanks the Project Manager, ██████████ Rapporteur, Dr. Rory Breathnach and Co-Rapporteur, Dr. Frida Hasslung Wikstrom and members of the CVMP for their guidance during the course of the current Centralised Procedure.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s)/target species, if applicable.

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

**New A Innovation (NL) Limited B.V.**

Registered at the Commercial Register of the Chamber of Commerce in Amsterdam with number 34347876



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Netherlands

Yours sincerely,  
For and on behalf of New A Innovation (NL) Limited B.V.,



Assistant General Manager, Regulatory Affairs  
New A Innovation (NL) Limited B.V.

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