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## Pfizer Animal Health

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Veterinary Medicines and Inspections Unit European Medicines Agency 7 Westferry Circus Canary Wharf London E14 4BH

Dear Sirs.

## Withdrawal of Naxcel 200 mg/ml suspension for injection for horses (EMEA/V/C/079/X/008)

For the withdrawal of a Type II variation/Annex II application linked to an extension of the authorisation of a medicinal product already authorised

I would like to inform you that at this point in time Pfizer Ltd. has taken the decision to withdraw the application to add horses for the treatment of respiratory disease.

This withdrawal is based on the following reasons:

The CVMP considers that the data provided do not allow the committee to conclude on a positive benefit risk balance without further data.

Given the nature of the studies required, Pfizer Ltd. does not currently consider that the costs of this work against the potential for a positive outcome are economically justifiable.

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

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

Yours faithfully,

Dr. Matthew J. Marsden

Associate Director