



## ANIMAL HEALTH

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

**Subject:** Withdrawal of Aivlosin 42.5 mg/g Chicken Premix: New Indication- EMEA/V/C/083/X/055

Dear Sir/Madam,

*For the withdrawal of an 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 ECO Animal Health has taken the decision to withdraw the application for a new indication for Aivlosin 42.5 mg/g Premix for chickens in the treatment of respiratory disease associated with *Mycoplasma gallisepticum*.

This withdrawal is based on the following reason(s):

The CVMP considers that the data provided do not allow the committee to conclude on a positive benefit risk balance.

Other:

Please provide any further detailed comment as appropriate- no further comment at this stage.  
Provide additional information on any future plan for development of the product- to be advised.

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 sincerely,

*Dr Elizabeth Abbott*

*Global Director of Product Development and Regulatory Affairs*