11 July 2014
EMA/CVMP/345403/2014
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Nobilis IB Primo QX

Common name: avian infectious bronchitis virus strain D388

On 10 July 2014, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Nobilis IB Primo QX, lyophilisate and solvent for suspension for nasal administration, intended for the active immunisation of chickens from one day-old onwards in order to reduce respiratory signs of Infectious Bronchitis caused by QX-like variants of Infectious Bronchitis Virus.

The applicant for this veterinary medicinal product is Intervet International B.V.

The active substance of Nobilis IB Primo QX is live avian infectious bronchitis virus strain D388, an immunological veterinary medicinal product QI01AD07 that stimulates active immunity against the D388/QX type of avian infectious bronchitis.

The benefits of Nobilis IB Primo QX are the active immunisation of chickens in order to reduce respiratory signs of infectious bronchitis caused by QX-like variants of infectious bronchitis virus. The most common side effects are a mild transient respiratory reaction (including nasal exudates) which may occur for at least 10 days, however these reactions are very rare.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Nobilis IB Primo QX and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu