8 April 2011
EMA/CVMP/232001/2011
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

MS-H vaccine

Mycoplasma synoviae strain MS-H

On 7 April 2011, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion recommending the granting of a marketing authorisation for the veterinary medicinal product MS-H vaccine. MS-H vaccine, an eyedrops suspension for chickens, is intended for the active immunisation of future broiler breeder chickens, future layer breeder chickens and future layer chickens to reduce air sac lesions and reduce the number of eggs with abnormal shell formation caused by *Mycoplasma synoviae*.

The applicant for this veterinary medicinal product is Pharmsure Ltd.

The active substance of MS-H vaccine is a live attenuated thermosensitive *Mycoplasma synoviae* MS-H strain with a strength of at least $10^{5.7}$ Colour Changing Units.

The benefits of MS-H vaccine are that it induces active immunisation of chickens from 5 weeks of age (layer replacement chickens, future broiler breeder chickens, layer chickens) and has been shown to reduce air sac lesions caused by a combined IBV-*Mycoplasma synoviae* infection. Onset and duration of immunity of respectively 4 and 40 weeks after vaccination have been demonstrated. The relevance of the vaccine strain has been shown for EU.

No adverse reactions have been observed after the administration of an 8-fold overdose.

The approved indication is:

For active immunisation of future broiler breeder chickens, future layer breeder chickens and future layer chickens to reduce air sac lesions and reduce the number of eggs with abnormal shell formation caused by *Mycoplasma synoviae*.

Onset of immunity: 4 weeks after vaccination.

The duration of immunity to reduce air sac lesions has been demonstrated to be 40 weeks post vaccination.

[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.

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

The duration of immunity to reduce the number of eggs with abnormal shell formation has not yet been demonstrated.

No effect on respiratory clinical signs, systemic colonisation and vertical transmission has been demonstrated.

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 MS-H vaccine and therefore recommends the granting of the marketing authorisation.