Divergent position on a CVMP opinion on an Article 33(4) referral of Directive 2001/82/EC for

Coglapix suspension for injection for pigs (EMEA/V/A/109)

We, the undersigned, have a divergent opinion on the marketing authorisation for Coglapix suspension for injection for pigs. From the indications retained in the current Summary of Product Characteristics (SPC), the reduction of clinical signs is not supported by the available data, as the results between vaccinates and controls were statistically not significant in 4 out of 6 studies for serotype 1, and in 1 out of 6 studies for serotype 2.

Reduction of lung lesions is the only remaining indication for which the statistical analyses showed globally a significant difference between vaccinates and controls against a challenge by *Actinobacillus pleuropneumoniae*. However, the clinical significance (if any) of the level of reduction of lung lesions obtained with Coglapix is not known.

The fact that the efficacy of this vaccine is not sufficient enough is further supported by the following:

- the re-isolation rate of the challenge bacteria in lungs between vaccinates and controls was statistically not significant in 5 out of 6 studies for serotype 1, and in 6 out of 6 studies for serotype 2;
- the mortality rate between vaccinates and controls was statistically not significant in all 12 studies;
- the average daily weight gain between vaccinates and controls was statistically not significant in 3 out of 5 studies for serotype 1, and in 2 out of 5 studies for serotype 2.

Moreover, the field trials are not able either to substantiate the efficacy of the vaccine.

It is acknowledged that the re-isolation rate, the mortality rate and the average daily weight gain are no longer retained as indications, but the absence of statistical significance for these parameters shows that the reduction of lung lesions appears to be of no clinical benefit for farmers' focusing on animal health.

The fact that the new SPC proposal is now "…as an aid to control pleuropneumonia…" does not really improve the situation, as this terminology further depreciates the understanding of using the vaccine.

Moreover, the vaccine was not shown to be in compliance with Ph. Eur. requirements (monograph 1360) as all the criteria of the monograph are not met (e.g. no reduction on the incidence of mortality, no reduction of lung infections).

Finally, the fact that the qualitative and quantitative composition cannot be guaranteed, that the consistency of production is not proven, and that the potency test is not able to detect sub-potent batches either, casts further serious doubts about the efficacy of forthcoming vaccine batches.

Given the above mentioned points, the benefit-risk balance is therefore considered as not being in favour of granting a marketing authorisation to this vaccine.

London, 3 June 2015

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