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Veterinary Medicines Division

Questions and answers on Coglapix suspension for injection for pigs (inactivated porcine actinobacillosis vaccine)

Outcome of a procedure under Article 33(4) of Directive 2001/82/EC, as amended

On 3 June 2015, the European Medicines Agency (the Agency) completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicine Coglapix suspension for injection for pigs. The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Coglapix outweigh its risks, and the marketing authorisation granted in Hungary can be recognised in other Member States of the EU (see below). The product information for Coglapix in Hungary should also be amended.

What is Coglapix suspension for injection for pigs?

Coglapix is an inactivated bacterial vaccine against porcine actinobacillosis. The vaccine contains five formaldehyde-inactivated strains of *Actinobacillus pleuropneumoniae*. The vaccine is intended for active immunisation of pigs against pleuropneumonia caused by *A. pleuropneumoniae* serotypes 1 and 2, in order to reduce the clinical signs and lung lesions associated with the disease.

Why was Coglapix suspension for injection for pigs reviewed?

Ceva-Phylaxia Veterinary Biologicals Co. Ltd. submitted an application for Coglapix for mutual recognition on the basis of the initial authorisation granted by Hungary. The company wanted the authorisation to be recognised in other EU Member States (the 'concerned Member States', in this instance Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, Germany, Greece, Iceland, Ireland, Italy, Latvia, Lithuania, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Sweden and the United Kingdom).

However, the Member States were not able to reach an agreement and the National Food Chain Safety Office of Hungary referred the matter to the CVMP for arbitration on 24 October 2014.

The grounds for the referral were concerns raised by Italy that the efficacy of Coglapix has not been adequately demonstrated, that the benefit of the vaccine under practical conditions of use has not been demonstrated and that the results obtained from duration of immunity studies were inconsistent.

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What are the conclusions of the CVMP?

Based on the data presented it was concluded that following vaccination of pigs with Coglapix reduction of clinical signs and lung lesions associated with the disease has been demonstrated in laboratory efficacy studies, although some concerns on the statistical significance of the results still remain. Hence, the relevant sections of the Summary of Product Characteristics and package leaflet should be amended in order to reflect this. Duration of immunity was established for both serotypes (1 and 2) up to 16 weeks after vaccination according to the results of relevant challenge studies.

Therefore, based on evaluation of the currently available data and the scientific discussion within the Committee, the CVMP concluded that the benefits of Coglapix outweigh its risks, and recommended that the marketing authorisation be granted in all concerned Member States. The CVMP also recommended that the product information for the medicine in Hungary be amended.

The European Commission issued a decision on 28 August 2015.