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Veterinary Medicines Division

Questions and answers on CattleMarker IBR Inactivated emulsion for injection for cattle (inactivated gE Bovine Herpes Virus type 1 (BoHv-1), strain Difivac)

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

On 17 March 2016, 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 CattleMarker IBR Inactivated emulsion for injection for cattle (thereafter called CattleMarker IBR Inactivated). The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that, subject to conditions relating to risk mitigation and surveillance measures, the marketing authorisation granted in Belgium for CattleMarker IBR Inactivated can be recognised in other Member States of the EU.

What is CattleMarker IBR Inactivated?

CattleMarker IBR Inactivated is an inactivated infectious bovine rhinotracheitis (IBR) vaccine which contains inactivated glycoprotein E (gE) negative bovine herpes virus 1 (BoHV-1), strain Difivac. The product is indicated for active immunisation of seronegative cattle from 2 weeks of age to reduce the clinical signs (pyrexia and depression) of IBR and the duration of virus shedding caused by BoHV-1 infection. Active immunisation of female cattle from 6 months of age is also indicated to reduce the clinical signs (pyrexia and duration of dyspnoea) of IBR and virus shedding caused by BoHV-1 infection and to reduce the incidence of abortions associated with BoHV-1 infections as demonstrated during the second trimester of gestation following challenge.

Why was CattleMarker IBR Inactivated reviewed?

Zoetis Belgium SA submitted an application for CattleMarker IBR Inactivated for mutual recognition on the basis of the initial authorisation granted by Belgium. The company requested the authorisation to be recognised in Bulgaria, Croatia, France, Germany, Ireland, Italy, the Netherlands, Poland, Portugal, Romania, Slovenia, Spain and the United Kingdom (the 'concerned Member States').

However, the Member States could not reach an agreement and the Belgian Federal Agency for Medicines and Health Products referred the matter to the CVMP for arbitration on 29 September 2015.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

The grounds for the referral were concerns raised by Germany regarding the immunological safety of CattleMarker IBR Inactivated, as the composition and manufacture of this product are similar to PregSure BVD, a vaccine from Zoetis which has been shown to induce a long-lasting allogeneic antibody response that has been associated with Bovine Neonatal Pancytopenia, a neonatal alloimmune disease, in the progeny of vaccinated dams. CattleMarker IBR Inactivated is produced on the same bovine cell line and is adjuvanted with the same highly potent adjuvant as PregSure BVD.

The potential risk of recurrence of Bovine Neonatal Pancytopenia linked to the use of this vaccine in pregnant cows had been addressed by Zoetis; however Germany considered that the proposed handling of the risks was inadequate and that a large scale post authorisation study should be initiated by Zoetis.

What are the conclusions of the CVMP?

Based on evaluation of the currently available data and the scientific discussion within the Committee, the CVMP concluded that subject to the conduct of additional studies and the implementation of further measures specified in a Risk Management Plan the marketing authorisation for CattleMarker IBR Inactivated should be granted in all concerned Member States.

The European Commission issued a decision on 10 June 2016.