# I. BACKGROUND INFORMATION ON THE PROCEDURE

## 1. Submission of the dossier

Further to the submission of a letter of intent by Fort Dodge Animal Health on 13 December 2008, the CVMP accepted on 17 January 2008 that ZULVAC 8 Bovis was eligible for the submission of an application for the granting of a Community marketing authorisation under exceptional circumstances.

The Committee for Medicinal Products for Veterinary Use appointed Dr Maria Tollis from Italy as Rapporteur and Dr Ioannis Malemis from Greece as Co-Rapporteur for the assessment of the application for ZULVAC 8 Bovis during its meeting of January 2008. In accordance with Article 39 (8) of Regulation (EC) No 726/2004, the CVMP also accepted the request of the company for an accelerated assessment procedure on the grounds that ZULVAC 8 Bovis is a veterinary medicinal product of major interest, in view of the epidemiological situation in Europe regarding Bluetongue.

The company Fort Dodge Animal Health submitted an application to the EMEA on 13 March 2008 for the granting of a Community marketing authorisation in accordance with Article 31 of Regulation (EC) No 726/2004 of 31 March 2004. Furthermore the Company requested the application be considered under Article 39(7) of Regulation (EC) 726/2004 regarding exceptional circumstances.

The application was validated on 25 March 2008.

The Assessment team consisted of the following experts: Dr. Orestis Papadopoulos.

## 2. Steps taken for the assessment of the product

- The Rapporteur and Co-Rapporteur's assessment reports were circulated to all CVMP Members on respectively 12 May 2008 and 23 May 2008.
- A list of questions was adopted by the CVMP on 18 June 2008.
- The company submitted written responses on 17 October 2008.
- An Oral Hearing took place on 14 October 2009
- The CVMP on 11 November 2009 adopted a positive opinion recommending the granting of a Marketing Authorisation under exceptional circumstances for ZULVAC 8 Bovis. The CVMP considered that due to the current epidemiological situation of Bluetongue and the consequent threat to animal health there were objective and verifiable reasons for recommending the granting of a Marketing Authorisation under exceptional circumstances for this product, namely that
- the remaining epidemiological risk for European cattle populations constitutes an objective need to have authorised products available for use in the coming months.
- the application has met the requirements of the CVMP Reflection Paper on Minimum Data Requirements for an Authorisation Under Exceptional Circumstances for Vaccines for Emergency Use Against Bluetongue (EMEA/CVMP/ IWP/105008/2007).
- the Applicant has agreed to the necessary post-authorisation commitments and specific obligations, to assure the safe use of the product in the field.
- the Applicant cannot reasonably be expected to provide the results from certain trials on the target species for duly substantiated reasons.

The European Commission granted a marketing authorisation valid throughout the European Union for ZULVAC 8 Bovis on 15 January 2010.

Medicinal product no longer authorised


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## A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance(s)

Fort Dodge Veterinaria S.A. (Spain)
Ctra. Camprodón s/n "la Riba"
17813 Vall de Bianya
Girona
Spain

Fort Dodge Animal Health Holland
C J van Houtenlaan, 36
1381 CP Weesp
The Netherlands

Name and address of the manufacturer responsible for batch release

Fort Dodge Veterinaria S.A. (Spain)
Ctra. Camprodón s/n "la Riba"
17813 Vall de Bianya
Girona
Spain

## B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, Member States prohibit or may prohibit the import, sale, supply and/or use of the veterinary medicinal product on the whole or part of their territory if it is established that:

a) the administration of the veterinary medicinal product to animals will interfere with the implementation of national programmes for the diagnosis, control and eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which the veterinary medicinal product is intended to confer immunity is largely absent from the territory.

The use of this veterinary medicinal product is only allowed under the particular conditions established by European Community legislation on the control of Bluetongue.

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

Medicinal product no longer authorised

## C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

Not applicable

## D. STATEMENT OF THE MRLs

The following substances are included in Annex II of Council Regulation (EEC) No 2377/90 in accordance with the following table:

| Pharmacologically active substance(s) | Animal species | Other provisions |
|---|---|---|
| Aluminium hydroxide gel | All food producing species | |
| (Quillaia) Saponin | All food producing species | |
| Thiomersal | All food producing species | For use only as preservatives in multidose vaccines at a concentration not exceeding 0.02 % |
| Potassium chloride | All food producing species | |
| Potassium dihydrogen phosphate | All food producing species | |
| Disodium hydrogen phosphate dodecahydrate | All food producing species | |
| Sodium chloride | All food producing species | |

Water for injections is considered as not falling within the scope of Council Regulation (EC) 470/09

## E. SPECIFIC OBLIGATIONS TO BE FULFILLED BY THE MARKETING AUTHORISATION HOLDER

1. The Applicant is required to submit in 6 months following the authorisation of the product, an action plan together with timelines for all points that require resolution in order for the authorisation to revert to normal status. The above information will be evaluated and approved by the CVMP and will form part of the subsequent annual reassessment.

2. For the first and subsequent annual reassessments the Marketing Authorisation Holder should provide annually an updated risk assessment on the continuous use of the vaccine taking into account the continued need for the vaccine, its history of use over the previous twelve months and progress made in addressing the items that require resolution in order for the authorisation to revert to normal status.

3. The Applicant is required to submit 6-monthly Periodic Update Safety reports starting once the MA has been approved and, in addition to the legal requirements applicable to reporting of suspected adverse reactions, the Applicant is required to specifically monitor and evaluate the following suspected adverse reactions in the PSURs: abortions, spontaneous death, effects on milk production, local reactions, pyrexia, lethargy and hypersensitivity reactions, including severe allergic reactions. The frequency of submissions of PSUR reports will be assessed at the annual reassessment of the product.

Medicinal product no longer authorised