6 September 2010
EMA/CVMP/234339/2009
Veterinary Medicines and Product Data Management

1. Background information on the procedure

1.1. Submission of the dossier

Further to the submission of a letter of intent by Intervet International BV on 28 September 2007, the CVMP accepted on 10 October 2007 that Bovilis BTV8 was eligible for the submission of a dossier for granting of a Community marketing authorisation under exceptional circumstances via the centralised procedure.

The Rapporteur and Co-Rapporteur appointed by the CVMP were:

Rapporteur: Dr Maria Tollis from Italy, Co-Rapporteur: Dr Anna-Maria Brady from United Kingdom

The company Intervet International BV submitted an application to the EMEA on 15 April 2008 for the granting of a Community marketing authorisation in accordance with Article 31 of Regulation (EC) No 726/2004 of 31 March 2004. Further the Company requested for the application to be considered under Article 26(3) of Directive 2001/82/EC and Article 39(7) of Regulation (EC) 726/2004 regarding exceptional circumstances and Article 39 (8) of Regulation (EC) 726/2004 for an accelerated assessment.

The application was validated on 22 April 2008.

1.2. Steps taken for the assessment of the product

- The Rapporteur and Co-Rapporteur's assessment reports were circulated to all CVMP Members on respectively 9 June 2008 and 19 June 2008.
- A list of questions was adopted by the CVMP on 17 July 2008.
- The company submitted written responses on 17 January 2009.
- An Oral Hearing took place on 10 February 2010.
- The CVMP on 16 June 2010 adopted a positive opinion recommending the granting of a Marketing Authorisation under exceptional circumstances for Bovilis BTV 8. 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:
    - Bluetongue disease is spread by insect vectors and therefore presents particular challenges in terms of control due to an inability to prevent transmission from infected animals other than

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through insect control combined with reducing or preventing viraemia (virus in the blood) in susceptible animals by means of vaccination.

- Bluetongue disease is epizootic in nature and has the potential to result in high morbidity and mortality in susceptible populations, particularly of sheep.
- There is a remaining epidemiological risk from Bluetongue serotype 8 for European sheep and cattle populations, that constitutes an objective need to have authorised products available for use in the coming months.
- Consequently any delay should be avoided where possible in making available safe and effective vaccines that have been demonstrated to be in compliance with the CVMP guideline on Minimum Data Requirements for an Authorisation under Exceptional Circumstances for Vaccines for Emergency Use against Bluetongue (EMEA/CVMP/IWP/220193/2008).
- The application has met the requirements of the CVMP guideline on Minimum Data Requirements for an Authorisation under Exceptional Circumstances for Vaccines for Emergency Use against Bluetongue (EMEA/CVMP/IWP/220193/2008).
- 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 due to the difficulties in conducting large scale trials for a disease that is under community control and the need for any experimental studies to be conducted within high containment facilities.

The European Commission granted a marketing authorisation valid throughout the European Union for Bovilis BTV8 on 6 September 2010.

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

Name and address of the manufacturer of the biological active substance

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Intervet International GmbH
Osterather Strasse 1a
DE-50739 Köln
Germany

Name and address of the manufacturer responsible for batch release

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

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.

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

Not applicable

D. STATEMENT OF THE MRLs

The following constituents of the intended product Bovilis BTV8 are included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010:

Pharmacologically active substance	Marker residue	Animal Species	MRL	Target Tissues	Other Provisions	Therapeutic Classification
Aluminium hydroxide	Not applicable	All food producing species	No MRL required	Not applicable	No entry	No entry
Quillaia saponins	Not applicable	All food producing species	No MRL required	Not applicable	No entry	No entry
Sodium Chloride	Not applicable	All food producing species	No MRL required	Not applicable	No entry	No entry
Simeticone emulsion	Not applicable	All food producing species	No MRL required	Not applicable	No entry	No entry

In addition to the above constituents the product contains the following excipients: trometamol, maleic acid and water for injection. At the doses at which they will be administered, these excipients are considered as not falling within the scope of Regulation (EC) No 470/2009.

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

1. The applicant is required to submit data as requested in post-authorisation commitments and 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 Marketing Authorisation 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.