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Veterinary Medicines Division

Committee for Veterinary Medicinal Products (CVMP)

CVMP assessment report for a variation requiring assessment for Bluevac BTV (EMEA/V/C/000156, EMA/VRA/0000255727)

Vaccine common name: Bluetongue virus vaccine (inactivated)

Assessment report as adopted by the CVMP with all information of a commercially confidential nature deleted.

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1. Introduction

1.1. Submission of the variation application

In accordance with Article 62 of Regulation (EU) 2019/6, the marketing authorisation holder, CZ Vaccines S.A.U. (the applicant), submitted to the European Medicines Agency (the Agency) on 25 February 2025 an application for a variation requiring assessment for Bluevac BTV.

1.2. Scope of the variation

Variation requested	
G.I.4	Change in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data

This variation is to change the posology for sheep, to vaccinate with one single dose of the bivalent vaccine BTV1+4.

1.3. Changes to the dossier held by the European Medicines Agency

This application relates to the following sections of the current dossier held by the Agency:

Part 1

1.4. Scientific advice

Not applicable.

1.5. Limited market status

Not applicable.

2. Scientific Overview

Bluevac BTV is a multi-strain bluetongue vaccine containing a maximum of two out of three inactivated bluetongue virus serotypes: the BTV-8 virus strain BTV8/BEL/2006/01, BTV-1 virus strain BTV-1/ALG/2006/01 or BTV-4 virus strain BTV-4/SPA-1/2004.

The current vaccination scheme for sheep, as described in the product information, is as follows:

Primary vaccination

Sheep:

Sheep from 2.5 months of age:

Administer two doses of 2 ml subcutaneously 3 weeks apart.

For monovalent vaccine containing bluetongue virus serotype 1 or serotype 4 administer one dose of 2 ml subcutaneously.

Based on the above, for the target species sheep, the current authorisation allows the administration of one dose of 2 ml only for monovalent vaccines containing BTV-1 or BTV-4.

With this variation, the applicant intends to change the above posology for sheep as below, in order to vaccinate with one single dose of the bivalent vaccine BTV1+4 of Bluevac BTV.

Primary vaccination

Sheep:

Sheep from 2.5 months of age:

Administer two doses of 2 ml subcutaneously 3 weeks apart.

For **bivalent or** monovalent vaccine containing bluetongue virus serotype 1 **and/**or serotype 4 administer one dose of 2 ml subcutaneously.

The applicant's arguments are based on the fact that the efficacy of a vaccine based on a multi-strain dossier may be demonstrated by performing efficacy studies employing the respective monovalent vaccines. In fact, it is assumed that a combination of serotypes will be at least as efficacious as the monovalent vaccine. Therefore, the claim for efficacy for a multi-strain vaccine adds up for the respective serotypes contained in the product. This is in line with the Guideline on data requirements for multi-strain dossiers for inactivated veterinary vaccines (EMA/CVMP/IWP/105506/2007 Rev. 2) and therefore considered acceptable.

During the variation for the conversion of Bluevac BTV into a multi-strain dossier (EMEA/V/C/000156/II/0010/G), four satisfactory and well executed pre-clinical studies of the monovalent vaccines Bluevac-1 and Bluevac-4 were provided, demonstrating the efficacy (both onset and duration of immunity) of one single dose in sheep.

Therefore, based on the documentation provided, it can be concluded, that after administration of a single dose the efficacy of a bivalent multi-strain vaccine containing a combination of BTV-1 and BTV-4 antigens will be at least as efficacious as shown for each of the monovalent vaccines.

The applicant has modified the suggested wording in the product information which is now:

'For monovalent vaccines containing bluetongue virus serotype 1 or serotype 4 administer one dose of 2 ml subcutaneously. For bivalent vaccines containing bluetongue virus serotype 1 and serotype 4 administer one dose of 2 ml subcutaneously.'

3. Benefit-risk assessment of the proposed change

Bluevac BTV is a suspension for injection for cattle and sheep.

It can contain a maximum of two of the following inactivated bluetongue virus serotypes:

Inactivated bluetongue virus, serotype 1 (BTV-1), strain BTV-1/ALG/2006/01

Inactivated bluetongue virus, serotype 4 (BTV-4), strain BTV-4/SPA-1/2004

Inactivated bluetongue virus, serotype 8 (BTV-8), strain BTV8/BEL/2006/01

It is intended for the active immunisation of sheep to prevent the viraemia caused by bluetongue virus serotype 1 and/or 4 and/or 8 and to reduce clinical signs caused by bluetongue virus serotype 8 (combination of maximum 2 serotypes). It is also intended for the active immunisation of cattle to prevent viraemia caused by bluetongue virus serotype 1 and/or 4 and/or 8 (combination of maximum 2 serotypes).

The proposed variation is to change the posology for sheep, i.e. to vaccinate with one single dose of the bivalent vaccine BTV1+4 of Bluevac BTV.

3.1. Benefit assessment

Direct therapeutic benefit

The benefits of the product remain unaffected by this variation.

3.2. Risk assessment

Quality:

Quality remains unaffected by this variation.

Safety:

Safety (user, consumer, environmental, target animal) remains unaffected by this variation.

3.3. Risk management or mitigation measures

Risk management or mitigation measures remain unaffected by this variation.

3.4. Evaluation of the benefit-risk balance

No change to the impact of the product is envisaged on the following aspects: quality, safety, user safety, environmental safety, consumer safety and target animal safety.

The benefit-risk balance remains unchanged.

4. Conclusion

Based on the original data presented on efficacy the Committee for Veterinary Medicinal Products (CVMP) concluded that the application for variation to the terms of the marketing authorisation for Bluevac BTV can be approved, since the data satisfies the requirements as set out in the legislation (Regulation (EU) 2019/6).

The CVMP considers that the benefit-risk balance remains positive and, therefore, recommends the approval of the variation to the terms of the marketing authorisation for the above mentioned medicinal product.

Changes are required in the following Annexes to the union marketing authorisation:

I and IIIB

As a consequence of this variation, section 4.9 of the SPC is updated. The corresponding section of the Package Leaflet is updated accordingly.