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(Reference Member State)

MUTUAL RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR AN IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCT

BioBos BTV 3 suspension for injection for sheep and cattle

PRODUCT SUMMARY

EU procedure number	CZ/V/0212/001/MR
Name and pharmaceutical form	BioBos BTV 3 suspension for injection for sheep and cattle
Applicant	Bioveta, a.s. Komenského 212/12 683 23 Ivanovice na Hané The Czech Republic
Active substance(s)	Bluetongue virus, serotype 3, strain Bio-93:BTV3, inactivated 10 - 320 ELISA units* * The amount of antigen was determined using a quantitative ELISA method.
ATC vetcode	QI04AA02
Target species	Sheep and cattle
Indication for use	Sheep: Active immunisation to reduce viraemia and to prevent clinical signs caused by bluetongue virus (BTV) serotype 3. Cattle: Active immunisation to prevent viraemia and to prevent clinical signs caused by bluetongue virus (BTV) serotype 3.

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this immunological veterinary medicinal product (IVMP) are available in the Union Product Database (UPD).

As a marketing authorisation for this veterinary medicinal product is going to be granted in accordance with Article 25 of Regulation (EU) 2019/6, the SPC clearly state that:

“Only a limited assessment of quality, safety or efficacy has been conducted due to the lack of comprehensive quality, safety or efficacy data.”

SUMMARY OF ASSESSMENT

Legal basis of original application	Article 25 of Regulation (EU) 2019/6 - application in exceptional circumstances.
Date of completion of the original mutual recognition procedure	07/07/2025
Date immunological veterinary medicinal product first authorised in the Reference Member State (MRP only)	16/10/2024
Concerned Member States (CMS) for original procedure	BG, EE, HU, LT, LV, PL, SI, SK

The applicant applied for a marketing authorisation for BioBos BTV 3, through the mutual recognition procedure. The product was previously nationally authorized in the Czech Republic under Article 25 of Regulation (EU) 2019/6 (Application in exceptional circumstances).

BioBos BTV 3 is the same vaccine as Bultavo 3 (authorized through the decentralized procedure), both dossiers are the same in fact. Then, both names of the vaccine can appear in the dossier and in this assessment report. The vaccines have different marketing authorisation holders (based on duplicate application).

1. SCIENTIFIC OVERVIEW

The dossier has been submitted in line with the requirements for submissions under Article 25 of Regulation (EU) 2019/6 – application in exceptional circumstances. This legal basis was agreed due to the current epidemiological situation of Bluetongue virus serotype 3 in Europe.

The assessment of BioBos BTV 3 has been carried out according to Commission Delegated Regulation (EU) 2021/805 of 8 March 2021 amending Annex II to Regulation (EU) 2019/6 of the European Parliament and of the Council, and applicable guidelines, mainly Guideline on data requirements for authorisation of immunological veterinary medicinal products in exceptional circumstances (EMA/CVMP/IWP/251947/2021).

The IVMP is manufactured and controlled using validated methods and tests that ensure the consistency of the IVMP released on the market.

The IVMP can be safely used in the target species; the slight reactions observed are indicated in the SPC.

The IVMP is also safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the IVMP was demonstrated according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation in exceptional circumstances for this IVMP.

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

2.A. Product description

Each dose of 1 ml contains:

Active substances:
Bluetongue virus, serotype 3, strain Bio-93: BTV3, inactivated 10 - 320 ELISA units*

*The amount of antigen was determined using a quantitative ELISA method.

Adjuvants:
Aluminium hydroxide 2.25 – 2.75 mg
Quillaja saponin (Quil A) 0.2 mg

Excipients:
Thiomersal 0.085 – 0.115 mg
Formaldehyde
Sodium chloride
Potassium chloride
Disodium hydrogen phosphate dodecahydrate
Potassium dihydrogen phosphate
Water for injections

The IVMP is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

The choice of the vaccine strain, adjuvant, inactivating agent, presence of preservative and the formulation is justified.

The selection of the manufacturing process of the active substance and the finished product is explained.

The container/closure system:

The medicine vials are of hydrolytic class I containing 10 doses of 1 ml or hydrolytic class II containing 50 doses or 100 doses of 1 ml or HDPE vials containing 10 doses, 50 doses or 100 doses of 1 ml, closed with chlorobutyl elastomer closure.

Pack sizes:
10 vials of 10 doses (10 x 10 ml)

1 vial of 10 doses (1 x 10 ml)
1 vial of 50 doses (1 x 50 ml)
1 vial of 100 doses (1 x 100 ml)

The vials with the vaccine are placed in cardboard cartons. In bulk packaging the vials are placed in a plastic package.

2.B. Description of the manufacturing method

The IVMP is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

Process validation data on the IVMP are provided in accordance with the relevant European guidelines.

2.C. Production and control of starting materials

The active substance (Bluetongue virus, serotype 3) specifications are considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with these specifications are provided.

The master and working seeds were produced according to the seed lot system as described in the relevant guideline.

Biological starting materials used follow the relevant Ph. Eur. monographs and guidelines and are appropriately screened for the absence of extraneous agents according to the Ph. Eur.

Compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products was satisfactorily demonstrated.

Starting materials of non-biological origin used in production comply with indicate pharmacopoeia monographs or in-house specifications.

2.D. Control tests during the manufacturing process

The tests performed during production are described and the results of two consecutive runs (acceptable in exceptional circumstances), conforming to the specifications, are provided.

2.E. Control tests on the finished product

For all tests, a short description of the techniques for analysing the finished product is provided. The tests and their specifications and limits are justified and are considered appropriate to adequately control the quality of the IVMP.

Satisfactory validation data for each analytical method are provided, if appropriate.

The tests performed on the final product conform to the relevant requirements and monographs, if applicable; any deviation from these requirements is justified. The tests include in particular:

Appearance

Extractable package volume

Sterility

Potency and identity[1]

Inactivation[2]

pH

Aluminium oxide content

Thiomersal content

Formaldehyde content

Air-tightness

Quil A content

[1] Performed on bulk of vaccine

[2] Performed as in-process control during production

The demonstration of the batch-to-batch consistency is based on the results of 2 batches (acceptable in exceptional circumstances), produced according to the method described in the dossier. Other supportive data provided confirm the consistency of the production process.

2.F. Batch-to-batch consistency

Full protocols of two consecutive batches of the product, representative of the routine production and giving the results for tests performed during production and on the finished product, are provided in order to ensure that quality is consistent from batch to batch and to demonstrate conformity with the predefined specifications. These results of the test support consistency of vaccine production and its efficacy.

2.G. Stability tests

Stability data on the active substance are provided in accordance with applicable European guidelines, demonstrating the stability of the inactivated active substance when stored under the approved conditions. The proposed shelf life for inactivated BTV 3 virus is 3 months at a temperature 2 – 8 °C.

The proposed storage for up to 1 month at 2 - 8 °C for vaccine bulk was confirmed at stability study.

The full stability results for finished product are not available yet, however due to the application for registration under Article 25, the stability of the finished product can be accepted according to the stability of similar vaccine in composition (BioBos BTV 4). The proposed shelf life of the finished product is 24 months at 2-8°C.

The in-use shelf life of 10 hours after the first opening of the vaccine is supported by the data of similar vaccine in composition (BioBos BTV 4).

The efficacy of the antimicrobial preservation was demonstrated.

2.H. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

3.A. General requirements

The vaccine is administered subcutaneously in sheep and intramuscularly in cattle at dose of 1 ml:

Primary vaccination

In sheep: one injection from 1 month of age in naive animals.

In cattle:

- 1st injection: from 1 month of age in naive animals.
- 2nd injection: 3 weeks after the first injection.

Revaccination

Not established.

The laboratory studies were carried out according to the OECD's regulations for Good Laboratory Practice. The statement by the Director of the Study and the person responsible for Quality Assurance are included in each report.

The safety and efficacy studies were combined in the same pre-clinical (laboratory) study, using the same batch(es) of the immunology veterinary medicinal product in accordance with Guideline on data requirements for authorisation of immunological veterinary medicinal products in exceptional circumstances (EMA/CVMP/IWP/251947/2021). All results showed that the vaccine is safe for use in target animals under laboratory conditions according to the proposed vaccination schedule.

Due to the application for registration according to the Article 25, the field studies have not been performed. However, the vaccine BioBos BTV 3 (under the name BULTAVO 3) was used in Western Europe according to the Article 110 of the Regulation 2019/6 and all the adverse events were monitored.

3.B. Pre-clinical studies

The safety tests were designed in accordance with the recommended vaccination schedule, i.e. an initial vaccination with revaccination 3 weeks later in cattle and only one vaccination in sheep.

Safety of the administration of one dose in lambs (Testing of efficacy, onset of immunity against BTV3 in lambs by challenge)

Study aim	The evaluation of safety of BioBos BTV 3 after the administration of one dose to lambs
Animals and application scheme (study groups)	Twenty-four lambs at the age of 26–31 days and seronegative for BTV 3 were utilized in the study for evaluation of efficacy (onset of immunity). Animals were divided into three vaccinated groups (T01, T02 and T03) and one control group (C). Animals in group T01 received one dose of

	the vaccine containing very low content of BTV 3 antigen (1.53 EU/ml) at SD 0, one dose of the vaccine containing medium/standard content of BTV 3 antigen (10.39 EU/ml) was administered to animals of the vaccinated group T02 at SD 0 and finally, animals of the vaccinated group T03 received one dose of the vaccine containing high content of antigen (51.82 EU/ml) at SD 0.
Follow-up	The animals were observed for possible local and systemic reactions and rectal temperature were measured.
Results	No local reactions were reported after vaccination of animals in vaccinated groups T01, T02 and T03 during the observation period. No vaccinated animal displayed any systemic reactions after the vaccination in any vaccinated group (T01, T02 and T03). A low rectal temperature was observed in three lambs, but the animals were fine with no other symptoms. The temperature was back to normal rapidly without treatment. Considering the health status of these animals and the fact that it was only 1 or 2 abnormal points, it can be considered insignificant in connection with vaccination.
Conclusion	The safety of vaccine was demonstrated after administration of vaccine batches with the low/ medium/ high declared antigen content in target species – sheep.

Safety of the administration of one dose (2 doses within a 21 days) in calves (Testing of efficacy, onset of immunity against BTV3 in calves by challenge)

Study aim	The evaluation of safety of BioBos BTV 3 after the administration of the recommended vaccination schedule (2 doses administered within 21 days) to calves.
Animals and application scheme (study groups)	Eighteen calves at the age of 21 – 33 days and seronegative for BTV 3 were utilized in the study. The range of the calf age had to be extended from 21 days to cover the number of eighteen animals, but the vaccinated animals were at the age of 23 – 32 days on the day of the first dose. Animals were distributed in three groups: vaccinated groups T01 and T02 and the control group C, with six animals in each group. Vaccinated animals of group T01 received two doses of the vaccine BULTAVO 3 with medium/standard potency (10.39 EU/ml an interval of 21-day. Animals of the vaccinated group T02 were vaccinated with two doses of the vaccine BULTAVO 3 with the medium/standard potency (12.6 EU/ml) at 21-day interval.
Follow-up	The animals were observed for possible local and systemic reactions and rectal temperature were measured.
Results	Animals of both vaccinated groups did not exhibit any systemic or local reactions after the first and the second dose administration. No abnormal points of rectal temperature were measured in any vaccinated animal (groups T01 and T02) after the first and second dose administration.
Conclusion	The safety of vaccine was demonstrated after administration of vaccine batches with the medium/ standard declared antigen content in target species - calves.

Safety of reproductive performance

As Biobos BTV3 is intended for the application according to the Article 25 of the Regulation 2019/6 and due to the epidemic situation in EU, the studies to examine reproductive performances were not performed for vaccine BioBos BTV 3.

However, according to the EMA guideline (EMA/CVMP/IWP/251947/2021), there is a possibility to use the studies from similar vaccine in composition. The special studies were conducted for with vaccine BioBos BTV4 and the studies were provided.

According to the SPC, the vaccine can be used during pregnancy but the safety has not been established during lactation.

3.C. Clinical trials

Due to the application for registration according to the Article 25 of the Regulation 2019/6, the field studies have not been performed.
The pharmacovigilance surveillance of BioBos BTV 3 (BULTAVO 3) for the period 1. October 2024 - 31. May 2024 (resp. 01 May 2024 – 31 January 2025 - Bultavo 3) demonstrates that there is no indication of safety or efficacy concern. Incidences calculated support the conclusion that this vaccine does not show any disconcerting trend. The safety information remains in line with the cumulative experience to date and SPC.

3.D. Environmental Risk Assessment

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline, which showed that no further assessment is required. The assessment concluded that there is a negligible risk to the environment associated with the use of the vaccine.

Warnings and precautions as listed in the product literature are adequate to ensure safety to the environment when the product is used as directed.

3.E. Assessment required for veterinary medicinal products containing or consisting of genetically modified organisms

Not applicable.

3.F. Residue tests to be included in the pre-clinical studies

The adjuvant and excipients used are aluminium hydroxide, Quil A, thiomersal and formaldehyde. The final concentration is 2.25 – 2.75 mg of aluminium hydroxide and 0.2 mg/ml of Quil A. An usual concentration of Quil A in one parenteral dose of the vaccine is 0.35 mg (EMEA/MRL/055/95- FINAL). Formaldehyde as well as other adjuvants contained in the final product are listed in Annex II to Council Regulation (EEC) No. 2377/90 as substances for which MRL is not required. Based on this information, no withdrawal period is proposed.

4. EFFICACY DOCUMENTATION

4.A. General requirements

BioBos BTV 3 suspension for injection for sheep and cattle, is a veterinary medicinal product intended for active immunization:

In sheep - to reduce viraemia and to prevent clinical signs caused by bluetongue virus (BTV) serotype 3.

In cattle - to prevent viraemia and to prevent clinical signs caused by bluetongue virus (BTV) serotype 3.

The safety and efficacy studies were combined in the same pre-clinical (laboratory) study, using the same batches of the immunology veterinary medicinal product in accordance with Guideline on data requirements for authorisation of immunological veterinary medicinal products in exceptional circumstances (EMA/CVMP/IWP/251947/2021). The results showed that the vaccine is efficient for use in target animals under laboratory conditions according to the proposed vaccination schedule.

Due to the application for registration according to the Article 25, the field studies have not been performed. However, the vaccine BioBos BTV 3 (under the name BULTAVO 3) was used in Western Europe according to the Article 110 of the Regulation 2019/6 and all the adverse events were monitored.

4.B. Pre-Clinical Studies

Laboratory studies included monitoring of the onset of immunity of vaccinated animals.

The efficacy tests were designed in accordance with the recommended vaccination schedule, i.e. an initial vaccination with revaccination 3 weeks later in cattle and only one vaccination in sheep. The minimum age of sheep and cattle for vaccination is 4 weeks.

Challenge model – verification of the infectious dose of challenge strain of BTV3 for efficacy study in sheep

Study aim	The evaluation of the challenge dose of virulent strain BTV 3 in sheep. The obtained data were used to assess efficacy of an inactivated BTV 3 vaccine.
Animals and application scheme (study groups)	Six sheep at the age of 3 – 5 years, and seronegative for BTV 3 were utilized in this study. Animals were split into three groups according to dilution of the challenge strain and the route of application. The first group T01, containing two animals, received concentrated BTV 3 challenge strain by subcutaneous route, furthermore 10x diluted BTV 3 challenge virus was applied to the two animals of the second group T02 by subcutaneous route and, finally the third group T03 containing two animals received concentrated BTV 3 challenge strain by intradermal route.
Follow-up	Clinical signs, general and body condition were observed and anticoagulated blood samples were collected for BTV 3 pathogen detection.
Results	All challenged animals developed clinical signs of disease after challenge (anorexia, locomotion troubles, nasal discharge, conjunctivitis, cough and dyspnoea). Clinical signs persisted until the end of observation period (SD 16). The animals of the treatment group T02 started to display clinical signs later than groups T01 and T03 on SD 7 and they did not show dyspnoea.

	Viremia was detected in all animals; the first positive samples were determined on 3rd day of challenge and viremia persisted in all animals until SD 16 (termination day). The increase of the rectal temperature above 40.5°C was reported in animals of the treatment group T01 and T03. The highest measured temperature was 41.5°C, whilst the maximal rectal temperature was 40.3°C for animals of the treatment group T02. Global Clinical Score (GCS) was calculated for each animal and varied from 25 – 39 points. According to results, GCS was higher in animals of the treatment groups T01 and T03 than in animals of the treatment group T02.
Conclusion	The challenge model for BTV 3 was verified in this study in sheep.

Challenge model – verification of the infectious dose of challenge strain of BTV3 for efficacy study in calves

Study aim	The evaluation of the challenge dose of virulent strain BTV 3 in cattle. The obtained data were used to assess efficacy of an inactivated BTV 3 vaccine.
Animals and application scheme (study groups)	Four calves at the age of minimally 3 months and seronegative for BTV 3 were utilized in this study. Animals were split into two groups according to the dilution of the challenge strain. Concentrated and 10x diluted challenge strain of BTV 3 was used. Two animals received concentrated virulent BTV 3 strain and they were included in the treatment group T1. The other two animals received 10x diluted virulent BTV 3 strain and they were assigned to the treatment group T2.
Follow-up	Clinical signs, general and body conditions were monitored and anticoagulated blood samples were collected for BTV 3 pathogen detection.
Results	Only one animal (in group T1) developed clinical signs of disease such as nasal discharge and conjunctivitis. Others stayed without any clinical sign development. The increase of the rectal temperature was reported in three animals. Global Clinical Score was calculated for each animal and varied from 0 – 6 points. Except in one animal (group T2), viremia was detected in challenged animals starting from SD 5 and persisting until the termination day of the in-life phase.
Conclusion	The challenge model for BTV 3 was verified in this study in cattle.

Testing of efficacy, onset of immunity against BTV3 in lambs by challenge

Study aim	The evaluation of efficacy of BioBos BTV 3 after the administration of one dose – onset of immunity in lambs.
Animals and application scheme (study groups)	Twenty-four lambs at the age of 26–31 days and seronegative for BTV 3 were utilized in the study for evaluation of efficacy (onset of immunity). Animals were divided into three vaccinated groups (T01, T02 and T03) and one control group (C). Animals in group T01 received one dose of the vaccine containing very low content of BTV 3 antigen (1.53 EU/ml)

	at SD 0, one dose of the vaccine containing medium/standard content of BTV 3 antigen (10.39 EU/ml) was administered to animals of the vaccinated group T02 at SD 0 and finally, animals of the vaccinated group T03 received one dose of the vaccine containing high content of antigen (51.82 EU/ml) at SD 0.
Follow-up	Clinical signs, temperature, body and general conditions were scored and compared within groups. Viremia was measured based on qRT-PCR results and compared within the groups.
Results	Clinical signs of disease were observed only in animals of the control group C (conjunctivitis, nasal discharge, diarrhoea, locomotion troubles and apathy). One animal of the control group C had to be euthanized. All vaccinated animals were protected from development of clinical signs of BTV3 disease after virulent challenge. Hyperthermia was observed in all control animals. In contrast, hyperthermia was not observed in vaccinated animals of groups T01, T02 and T03. Global Clinical Score (GCS) was calculated for all animals and was 0 for all vaccinated animals, whilst it ranged from 19 to 34 points in control animals. A statistically significant difference was demonstrated in GCS between the vaccinated groups and control group C. Presence of BTV 3 RNA was evidenced in blood sample of all control animals and also in two animals of the vaccinated group T01 and in one animal of the vaccinated group T02. Viremia persisted until the end of the in-life phase, but at a much lower level in vaccinated animals from T01 and T02 than in control animals. In vaccinated group T03, viremia was not evidenced in any animal. Viral loads in blood, (AUC) was calculated and compared within groups: a statistically significant difference was found between the vaccinated groups T02 and T03 and the control group C, whilst the statistically significant difference was not determined between the vaccinated groups.
Conclusion	This study verified the required parameters (clinical signs, viremia) of efficacy of the BioBos BTV 3 in accordance with the requirements of the EMA guideline in the target species – sheep. The onset of immunity 21 days after administration of one dose has been established.

Testing of efficacy, onset of immunity against BTV3 in calves by challenge

Study aim	The evaluation of efficacy of BioBos BTV 3 after the administration of the recommended vaccination schedule (two doses administration) – onset of immunity in cattle.
Animals and application scheme (study groups)	Eighteen calves at the age of 21 – 33 days and seronegative for BTV 3 were utilized in the study. The range of the calf age had to be extended from 21 days to cover the number of eighteen animals, but the vaccinated animals were at the age of 23 – 32 days on the day of the first dose administration.

	Animals were distributed in three groups: vaccinated groups T01 and T02 and the control group C, with six animals in each group. Vaccinated animals in group T01 received two doses of the vaccine BULTAVO 3 with medium/standard potency (10.39 EU/ml) at a 21-day interval. Animals of the vaccinated group T02 were vaccinated with two doses of the vaccine BULTAVO 3 with the medium/standard potency (12.6 EU/ml) at a 21-day interval.
Follow-up	Clinical signs, rectal temperatures, body and general conditions were scored and compared between the groups. Viremia was measured based on qRT-PCR results and compared between the groups, also percentage reduction of viral loads was calculated.
Results	Vaccinated animals did not develop any clinical signs after challenge, whilst 4 out of 6 control animals displayed clinical signs as nasal discharge and conjunctivitis. Elevated rectal temperatures were monitored only in control animals. Global clinical score (GCS) calculated for vaccinated animals was 0 and for control animals ranged from 1 to 8 points. A statistically significant difference was observed in GCS between the vaccinated group T01 and control group C and also between the vaccinated group T02 and the control group C. Viremia was measured only in the control animals and persisted until the termination date of in-life phase on animals (SD 63). The maximal arithmetic mean virus titre was measured on SD 53 (4.8 log10 TCID50/ml). Calculated AUCs (viral loads) were statistically compared between groups and the statistically significant difference was confirmed between the vaccinated group T01 and the control group C and between the vaccinated group T02 and control group C.
Conclusion	This study verified the required parameters (clinical signs, viremia) of efficacy of the BioBos BTV 3 in accordance with the requirements of the EMA guideline in target species – cattle. The onset of immunity 21 days after second administration has been established.

Testing of efficacy, duration of immunity against BTV3

Due to the application for registration according to the Article 25 of the Regulation 2019/6, the duration of immunity study has not been performed. It is clearly stated in SPC.
DOI studies are ongoing in both target species. Twelve - month duration of immunity study (DOI) will be prepared by the end of 2025 in cattle and by Q1-Q2 2026 in sheep.

4.C. Clinical trials

Due to the application for registration according to the Article 25 of the Regulation 2019/6, the field studies have not been performed.
The pharmacovigilance surveillance of BioBos BTV 3 (BULTAVO 3) for the period 1. October 2024 - 31. May 2024 (resp. 01 May 2024 – 31 January 2025 - Bultavo 3) demonstrates that there is no indication of safety or efficacy concern. Incidences calculated support the conclusion that this vaccine does not show any disconcerting trend. The safety information remains in line with the cumulative experience to date and SPC.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment are acceptable.

POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC/labelling/package leaflet is/are available in the Union Product Database (UPD).

COMMITMENTS

1. completed and by 30.6.2027 submitted a stability study performed on three batches of the veterinary medicinal product BioBos BTV3 injectable suspension for sheep and cattle during storage for 27 months. In the event that the results of the stability study are not in accordance with the approved specifications, immediately inform the Veterinary Institute of this non-compliance.

2. completed and by 30.6.2027 submitted a stability study after first opening performed on three batches of the veterinary medicinal product BioBos BTV3 injectable suspension for sheep and cattle at the end of the shelf life. In the event that the results of the stability study are not in accordance with the approved specifications, immediately inform the Veterinary Institute of this non-compliance.