



Syva receives a positive opinion for Syvazul BTV 3 vaccine from the CVMP of the European Medicines Agency (EMA).

León – Parque Tecnológico – Spain, 22 januari 2025

On 15 January 2025, the Committee for Medicinal Products for Veterinary Use (CVMP) issued a positive opinion recommending the granting of a marketing authorisation for Syvazul BTV 3 vaccine. This step forward marks an important milestone in the fight against Bluetongue, and Syva is proud to be at the forefront of this innovation.

Protection against Bluetongue serotype 3

Syvazul BTV 3 contains inactivated **Bluetongue** virus serotype 3 (BTV-3/NET2023). The positive opinion of the CVMP concerns, for the time being, **vaccination of sheep**, for which **a single dose of Syvazul BTV3 is required**.

Syva's vaccine currently has **a temporary authorization for use in bovine and ovine species** in accordance with Article 110(2) of Regulation (EU) 2019/6.

This vaccine represents an **essential tool** to protect flocks, especially in regions where **Bluetongue** serotype 3 virus has been identified as a major health threat..

History of Bluetongue serotype 3 (BTV-3) and Syva's commitment

Bluetongue serotype 3 emerged in September 2023 in the Netherlands, severely affecting cattle and sheep herds in the region. From that moment on, Syva has led a rapid and effective response, working closely with the European veterinary authorities.

Through Article 110(2) of Regulation (EU) 2019/6, temporary authorizations for use were achieved in 11 European countries and outside Europe to ensure early availability of the vaccine in areas of greatest need. These key steps have allowed for its progressive distribution while the data necessary for a full marketing authorization were being developed and reviewed. This approach has been key to mitigating the impact of the disease and protecting animal health at the European level..

Key benefits for farmers and animals

- **Significant reduction of the impact of the disease:** Syvazul BTV 3 reduces the harmful effects of Bluetongue, offering effective protection of the animals.
- **Rapid onset of protection:** Active immunity is achieved four weeks after completion of the primary vaccination schedule, allowing rapid protection of herds.
- **Animal welfare benefits:** Vaccination contributes to the reduction of suffering of affected animals, improving their quality of life.
- **Economic sustainability for farmers:** By reducing losses associated with the disease, Syvazul BTV 3 supports the profitability and economic stability of the sector.
- **Importance of an optimal vaccination coverage:** Ensuring **high vaccination coverage** in herds is essential to achieve **mass immunity**, reducing virus circulation and protecting both vaccinated and immunized animals. This strengthens the overall health of herds and minimizes the impact of future outbreaks.

Towards a promising future for animal health

Syva is fully committed to supporting veterinarians and farmers by offering innovative and reliable solutions. The adoption of a positive opinion by the CVMP for Syvazul BTV 3 is a decisive step towards a marketing authorisation and extended protection against the consequences of Bluetongue.

We will continue to collaborate with health authorities and industry stakeholders to ensure sufficient vaccine availability.

ABOUT SYVA

Since its founding in 1941, the Spanish company Laboratorios Syva has been committed to scientific research and development to innovate and provide efficient solutions for the animal health sector. This capacity to adapt drives its growth strategy and the maintenance of state-of-the-art bioengineering and manufacturing facilities to produce vaccines, first-line anti-infectives and other essential medicines for animal health and welfare, which are distributed in almost 70 countries worldwide.

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