

SYVA PRESS RELEASE Syvac® EH Marker, the first DIVA vaccine against EHD to receive emergency use authorization in Belgium

The FAMHP/FAGG has just authorized Syvac® EH Marker, the first and only marker (DIVA) vaccine against the Epizootic Haemorrhagic Disease (EHD) virus.

León – Parque Tecnológico – Spain, 30th Januari, 2025

Syva is pleased to announce that the FAMHP/FAGG has granted emergency use authorization for its marker (DIVA) vaccine against EHD in accordance with Article 110(2) of Regulation (EU) 2019/6 for use in cattle and deer.

SYVAC® EH Marker is the first and only subunit vaccine available on the European market against EHD serotype 8. The "subunit" technology is a major asset for disease control, enabling the implementation of a DIVA strategy that makes it possible to differentiate animals infected by the wild virus from vaccinated animals.

## Why this temporary authorization?

The Belgian authorities have granted this authorization based on the following elements:

- Several reports indicate the presence of **biting midges in France**, and this activity is **highly likely to spread to Belgium**. As a result, large-scale **outbreaks** could emerge starting in spring 2025.
- **Early vaccination is necessary** to prevent the spread of large-scale outbreaks.
- Currently, no vaccine has marketing authorization in Belgium or any other European Union member state.
- Scientific studies show that there is **sufficient data** on the **safety**, **quality**, and **efficacy** of **Syvac® EH Marker** to authorize its temporary use.

As a reminder, vaccination of cattle against serotype 8 of EHD is mandatory since January 1, 2025.

# Why is Syvac® EH Marker different from a conventional vaccine?

The vaccine targets the **VP2 protein**, which plays a key role in the **recognition** and attachment of the **virus** to host cells. Therefore, **antibodies induced against VP2 are able to neutralize the virus**. **VP2** is the only protein of EHDV known to induce a strong response in the form of **virus-neutralizing antibodies**. A **VP2 subunit vaccine** therefore induces a focused protective response while an immune response against other viral proteins (e.g. VP5, VP7) confirms either a previous natural infection or vaccination with a conventional vaccine, without being able to distinguish between infected and vaccinated animals.

## **Epizootic Haemorrhagic Disease: an imminent threat to Europe!**

The first cases of EHD serotype 8 were reported in November 2022, **in Italy**. Outbreaks were then detected in southern **Spain**, in Extremadura and Andalusia, and rapidly spread to many farms across the country. In **September 2023**, **France reported its first outbreaks**. As mentioned above, **although EHD has not yet been detected in Belgium, vaccination has been mandatory there since January 1, 2025**. The virus progression since 2022 suggests that no European country is safe in the future.

EHD does not affect humans. The virus – an Orbivirus – is transmitted by biting midges of the genus Culicoides, whose peak activity occurs primarily from July to October. For **optimal herd protection**, vaccination schedules should be completed **before the Culicoides activity period** and in compliance with **good practices**.

Vaccination is unanimously recognized as the most effective method for controlling the disease. Having a **DIVA vaccine** available for the first time in Europe is a **significant breakthrough and a key innovation for protecting cattle herds.** 

### **ABOUT Syvac® EH Marker**

**Syvac® EH Marker** is the first and only **subunit vaccine** that provides differentiated protection against EHD in cattle and deer. It is currently the only vaccine on the European market that allows differentiation between infected and non-infected animals. Moreover, it is easy to use thanks to its two-dose vaccination schedule, with intramuscular injections of 2 ml given four weeks apart. It is available in 40 ml (20 doses) and 100 ml (50 doses) vials.

For more information, visit the <u>product page on our website</u>

#### **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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