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Dutch authorities approved the use of the vaccine against bluetongue serotype 3 developed by Laboratorios Syva

León - Technology Park – Spain, April 26, 2024

After intensive work performed by our teams in our laboratories, an excellent coordination with the contract research organisations (CRO) which carried out the clinical trials necessary to test the vaccine's safety and efficacy, and an efficient communication with the authorities in the Netherlands, Syva Laboratories is pleased to announce that its vaccine against BTV 3 has been authorised for emergency use in the Netherlands under Article 110 (2) of Regulation (EU) 2019/6.

An emergency situation

The first severe clinical outbreaks of BTV3 were reported at the beginning of September in the region of Amsterdam, and on 18 October 2023, Dairy Global ran the headline "Bluetongue virus outbreak in Netherlands spreading like wildfire". The rate of spread of this new serotype 3 appears to be even faster than that reported during the BTV-8 epidemic in 2006-2008.

Given the severity of the clinical situation and the speed at which this new serotype 3 was spreading in the Netherlands and was starting to spread in neighbouring countries, we could not remain indifferent to the damage caused by this particularly aggressive BTV serotype. According to official reports, on the worst affected farms, especially sheep farms, mortality could reach 40%. And major losses in productivity were reported on cattle farms.

Rapid decision-making and risk-taking

After assessing our production capacity and human resources and consulting our different departments," said César Carnicer, Managing Director of Syva Laboratories, "we decided very quickly to prioritise the development of the BTV3 vaccine. As you can imagine in such a situation, it's very complicated to assess the needs of different countries, and whether the strain we obtained was going to be sufficiently productive to provide the quantity of doses needed to achieve vaccine coverage in what everyone hopes would be a short space of time. Despite the many unknowns, we decided to take the risk...".

At the beginning of December, following a call for action at European level, AnimalHealthEurope organised a meeting with the animal health pharmaceutical laboratories likely to be able to produce a BTV3 vaccine, to assess their capacity to respond to this situation and investigate their intentions. Of course, since 2006, Syva has developed vaccines to protect against the different serotypes of blue tongue, and in 2019 SYVA registered its combined BTV vaccine for serotypes one, four and eight at European level. However, when it comes to developing vaccines, no one can predict success.

A solution before the summer was expected

Contacts were very soon established with the Dutch authorities, who were anxious to reassure the country's sheep and cattle farmers and offer a solution before the new wave of Culicoides, the vector insects that carry BTV. Over time, we have been contacted by other concerned countries. Over the last few months, we have been keen to let our teams work in complete serenity, because the effort we have asked them to make has been extreme.

Clinical trials, a crucial step

"By the end of October, we were in possession of the BTV3 virus strain", commented Hans de Smit, Director of R&D at Syva..."and we could start preparing the registration file by setting up the essential clinical trials required by the European regulatory authorities to enable them to assess the vaccine's safety and efficacy data before granting marketing authorisation. At the time, we were aware about the Article 110 and other emergency procedures. Our reference for complying with the requirements was our experience with the dossier submitted in 2019 for authorisation at European level of our combined BTV vaccine".

Exceptional agility and commitment from everyone

One thing is clear: without the exceptional commitment of all our departments, the development of the vaccine and its launch on the market would not have been achieved with such agility. Our teams were able to assess, communicate and coordinate actions to ensure that we quickly had an effective and safe vaccine. It took just over 6 months to achieve this result. And we'd like to say well done Team and thank you!

Reducing Dutch breeders' anxiety

Syva hopes that this will enable Dutch and even European breeders to look forward to the Culicoides season with less anxiety. SYVA would like to thank the Dutch competent authorities, and the office of the Minister for Agriculture, Nature and Food Quality, Piet Adema, for their care of an efficient process and for respecting our wish not to communicate until Syva was able to provide all the necessary data to ensure the efficacy and safety of the Syva BTV3 vaccine.

ABOUT SYVA

Since its foundation in 1941, the Spanish company Laboratorios Syva has been committed to researching opportunities and to scientific based development to innovate and offer efficient solutions for the animal health sector. This capacity to adapt drives the company's strategy to grow and to maintain 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 nearly 70 countries worldwide.

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