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HIPRA receives positive opinion from the European Medicines Agency for its COVID-19 vaccine adapted to the LP.8.1 variant for this autumn

The adapted vaccine, 100% produced in Spain, aligns with EMA and WHO recommendations

It will be available in a single-dose format

Girona, September 19, 2025 – The biotechnology pharmaceutical company HIPRA has received a positive opinion from the European Medicines Agency (EMA) for its **monovalent recombinant protein adjuvanted vaccine BIMERVAX®** adapted to the LP.8.1 variant. The vaccine, once it receives the decision from the European Commission, will be available for active immunization against COVID-19 for individuals aged 16 years and older. At the same time, the EMA has also announced the extension to expand the indication of the vaccine to individuals aged 12 years and older, which is also pending the decision of the European Commission.

According to the World Health Organization (WHO), the activity of the SARS-CoV-2 virus has shown a global rebound in recent months. The organization notes that "since mid-February 2025, based on available sentinel site data, global SARS-CoV-2 activity has been increasing, with a test positivity rate reaching 11%, levels not observed since July 2024"[1]. Although most detected cases present mild or moderate severity, this increase confirms that the virus continues to circulate significantly and reinforces the need to maintain epidemiological surveillance and vaccination campaigns to protect the most vulnerable groups.

Last July, the Public Health Commission approved the COVID-19 response recommendations document prepared by the vaccine task force, establishing that for the 2025-2026 season there will be availability of mRNA and recombinant protein vaccines. The adaptation of the vaccine follows the recommendations of the EMA's Emergency Task Force (ETF) and the WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) for use in this autumn's vaccination campaign to address current SARS-CoV-2 variants.

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HIPRA's adapted COVID-19 vaccine obtained a favorable opinion from the EMA's Committee for Medicinal Products for Human Use (CHMP) after **demonstrating that it generates a strong immune response against LP.8.1**. In addition, studies confirm a solid presence of neutralizing antibodies against LP.8.1 and other emerging sublineages such as NB.1.8.1 and XFG thanks to the cross-protection offered by the vaccine.

Single-dose format

The new adaptation of the BIMERVAX® vaccine will be available in a single-dose, ready-to-use format. This presentation **will facilitate administration** by healthcare personnel and logistics, thereby helping **improve vaccination rates** and reduce product waste.

It is a vaccine that can be stored refrigerated between **2 °C and 8 °C, with a shelf life of 12 months, facilitating transport and storage logistics**. With the new format and the materials used in the packaging, the use of plastics has been significantly reduced, for example, by using cardboard for blisters. This decision s**trengthens our commitment to sustainability and reducing the carbon footprint of our vaccines**.

Vaccine 100% produced in Spain

HIPRA **began the development** of this adaptation months before the official recommendations were issued thanks to the **continuous epidemiological monitoring** of the virus carried out by its R&D team. In addition, to ensure the supply and availability of doses for vaccination campaigns, **doses of this new adapted vaccine have already been produced**. The vaccine has been manufactured entirely at HIPRA's facilities in the province of Girona, Spain, which integrate all stages of the vaccine's life cycle (from research and development, industrial scaling, production, registration, packaging, and final conditioning).

This comprehensive capacity strengthens HIPRA's role as a **key partner in reinforcing Europe's strategic autonomy in health**. In this context, HIPRA participates in initiatives such as the **EU FAB** project, in which it was selected to ensure flexible production capacity in the face of emergencies, and **SPEEDCELL**, an EU4Health project led by HIPRA group companies, which seeks to provide Europe with greater technological readiness and agility, reducing to 100 days the development of new vaccines in future health emergencies. Another example of the company's

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commitment to global health is its participation in the European project **LWNVIVAT**, focused on researching a vaccine against the West Nile virus, a zoonotic disease with potential to become a threat to human health. Likewise, with the European project **VAX4ASF**, work is underway on the development of a vaccine against African swine fever, one of the main threats to animal health.

About HIPRA

HIPRA is a biotechnology pharmaceutical company focused on prevention for animal and human health (one health), with a wide range of highly innovative vaccines and an advanced diagnostic service. With its claim "Building immunity for a healthier world," HIPRA affirms its commitment to contributing solutions that improve global health. It has a strong international presence with 40 subsidiaries of its own, 3 R&D centers, and 6 production centers strategically located in Europe (Spain) and America (Brazil). In addition, its extensive international distribution network maintains open marketing channels with nearly 100 more countries, thus covering all five continents.

Research and development form the core of its expertise. HIPRA dedicates more than 15% of its annual turnover to R&D activities focused on creating and applying the latest scientific advances to develop innovative vaccines of the highest quality.

HIPRA offers an extensive portfolio of vaccines based on different technological platforms. Its R&D teams work with a wide range of technologies and more than 300 pathogens. To add value to its vaccination expertise, the company also develops medical devices and traceability services for animal health.

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[1] WHO COVID-19 - Global Situation: https://www.who.int/emergencies/disease-outbreak-news/item/2025-DON572?utm_source