MINISTÈRE
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French General Directorate for Food

ACTION PLAN FOR VACCINATION AGAINST HIGHLY PATHOGENIC AVIAN INFLUENZA (HPAI)

Available vaccines effective against circulating HPAI virus

An effective vaccination plan for Highly Pathogenic Avian Influenza (HPAI) entails supply of effective vaccines suitable for use against the viral strain in circulation.

THE REGULATORY FRAMEWORK FOR VACCINE AUTHORISATION

National and EU regulations provide for the possibility of recourse to vaccination against HPAI using a vaccine covered by an authorisation. The regulatory references governing vaccine use are as follows:

- Regulation (EU) 2016/429 on transmissible animal diseases ('Animal Health Law') sets out the criteria in Article 46 for the use of veterinary medicinal products in the context of the prevention and control of animal diseases.
- Delegated regulation (EU) 2023/361 establishes the European regulatory framework for vaccination against category A diseases, HPAI included.
- Regulation (EU) 2019/6 establishes the rules governing the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of veterinary medicinal products.

If it is to be marketed in France, a medicinal product or vaccine manufactured on an industrial basis must be covered by a marketing authorisation issued by the European Medicines Agency (EMA) or, failing this, an authorisation for temporary use (ATU) issued by the French Agency for Veterinary Medicinal Products (ANMV).

In accordance with Article 110.2 of regulation (EU) 2019/6, the ANMV may, in cases of especial urgency and for listed diseases, these being detailed in Article 5 of regulation (EU) 2016/429, authorise the use of a veterinary medicinal product or vaccine not covered by an authorisation at European Union level. For this, the pharmaceutical firm must submit an application for an ATU to the ANMV in accordance with Article L5141-10 of the French public health code. For such an authorisation to be granted, the pharmaceutical quality of the vaccines must be deemed satisfactory, and the outcome of assessments conducted by the ANMV as to their safety for health must be favourable.

MAY 2023

AVAILABLE VACCINES FOR THE HPAI VIRUS

In France, only the Nobilis Influenza H5N2 vaccine distributed by MSD Santé Animale has received a marketing authorisation. However, the vaccine strain used in this solution, which targets *Gallus gallus*, has not been updated since 2006.

In order to obtain supply of vaccines effective against the strain in circulation, an ATU procedure has been initiated for new candidate vaccines.

The list of vaccines covered by an ATU is regularly updated on the ANMV website: https://www.anses.fr/fr/content/médicaments

INITIAL ORDER FOR THE SUPPLY OF VACCINES AGAINST THE HPAI VIRUS

On 17 April 2023, the Ministry of Agriculture and Food Sovereignty of the French Republic published a call for tenders for the supply, storage and delivery of vaccine doses. The purpose of the order for supply is to guarantee, ahead of immediate need, the availability of an initial quantity of vaccines to enable a vaccination campaign to be undertaken if all the conditions are met, beginning in autumn 2023. The call for tenders provides for the supply of up to 80 million doses of authorised vaccines for foie gras ducks (Mulard) and table ducks (Muscovy).

If the decision is taken not to vaccinate in autumn 2023, this initial order for supply will provide the French government with a vaccine stock available for possible use up to the 2024-2025 season, taking account of the satisfactory use-by dates applicable to the ordered vaccines.

For more information:

- **European Medicines Agency website (EMA):** https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/ema_en
- **French Agency for Veterinary Medicinal Products (ANMV) :** https://www.anses.fr/fr/content/l%E2%80%99agence-nationale-du-m%C3%A9dicament-v%C3%A9t%C3%A9rinaire-%E2%80%93-missions-et-actions
- **Regulation (EU) 2016/429** of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02016R0429-20210421&qid=1639515145830&from=EN
- **Commission Delegated Regulation (EU) 2023/361** of 28 November 2022 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council as regards rules for the use of certain veterinary medicinal products for the purpose of prevention and control of certain listed diseases: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R0361&qid=1681975761645&from=EN
- **Regulation (EU) 2019/6** of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0006&qid=1684155706191