



**MINISTÈRE
DE L'AGRICULTURE
ET DE LA SOUVERAINETÉ
ALIMENTAIRE**

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INFORMAL MEETING ON HPAI VACCINES HELD ON 12 JULY IN BRUSSELS

**ATTENDED BY REPRESENTATIVES OF 6 MEMBER STATES (FR, CZ, NL, HU, BE, IT),
COMMISSION, EUROPEAN MEDICINES AGENCY AND 5 PHARMACEUTICAL COMPANIES**



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Introduction

Informal meeting organized by Animal Health Europe

In the frame of the Council Conclusions on avian Influenza (24/05/22) and the operational road map

Paragraphe 10 : *“Invites the Commission and the Member states to collaborate with the pharmaceutical industry”*



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Introduction of the meeting

Experts presented the Conclusions on HPAI

and stressed :

- i) the urgency of the situation
- ii) the intensity and duration of the epizootic season
- iii) the diversity of the strains involved
- iv) the societal concerns regarding mass slaughter



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5 pharmaceutical companies

Then : 5 companies were interviewed separately, in order to respect the confidentiality of their projects and their scientific and economic strategy





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Highlights

- There are varying levels of progress in the reflexion, development and process of authorisation
- The EU approach (based on EFSA advice, field trials,..) is relevant, although time consuming
- Different dynamics and impacts of the disease according to specific sectors (broiler, layer, breeding stock...) and the need to develop specific vaccination strategies for each MS

Laboratories want to understand the EU strategy and need clear signals (strategy, volume, ...) : the Council Conclusions, the trials in different MS and the meeting, are already clear signals



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Technical comments

EMA :

- The vaccines presented will fall under a centralized authorization considering that they are derived from new technologies
- The companies master the procedures and are in connection with the EMA
- Relevance of field trials, considering that the numerous scientific data presented in the MA application do not guarantee efficacy in the field in different situations
- The difference between third country Good Manufacturing Practices (GMPs) (especially US, Mexico, ...) and EU standards, may have an impact on authorizations

Companies :

- Commission delegated act on vaccine banks does not include avian influenza
- Breeders request the implementation of compartmentalization

Thank you for your attention

