



THE VOICE
OF THE ANIMAL
MEDICINES INDUSTRY



Key Factors of Vaccine Availability

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Why do we have or not have vaccines?

Previously unrecognised new disease

Emerging Diseases in Europe

Disease present but no vaccine

Vaccine authorised but not available



New Vaccine Development

For Major livestock species:

- **5-10 years research and development to gain a marketing authorisation**
- **Cost of development around €20M**
- **Both are increasing**



Vaccines to meet Emergency Needs

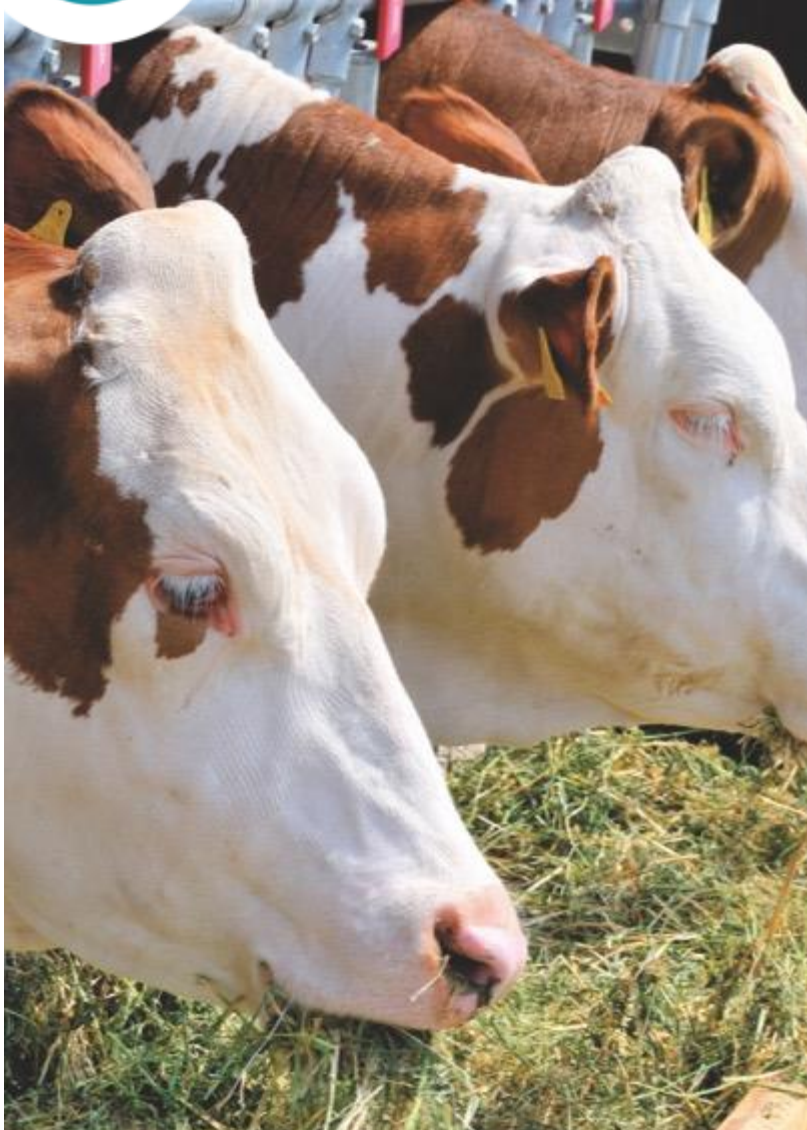
Industry is willing to work with authorities and try to develop vaccines when needed.

We have done successfully:

- Blue Tongue Virus
- Schmallenberg

But not without problems:

- Schmallenberg Vaccine very quickly not used, development costs not recovered
- Blue Tongue, emergency authorisations were needed at each concerned member state in parallel



Vaccines for Emerging Diseases

If Disease is not present in Europe there are various considerations:

- Will the disease enter Europe?
- How far in the future?
- Will vaccination be permitted?
- Maintenance of a Marketing Authorisation has a cost.

Leads to High Uncertainty

- Need for mechanisms to reduce uncertainty and reduce risk



Use of Vaccines from outside Europe

Global market for vaccines

- Many vaccines imported into and exported from Europe.

Real Point: Use of Vaccines not authorised in European Union

- These vaccines are authorised and used in other countries
- Can be a fast and effective way to access vaccines in an emergency, if of sufficient quality
- Currently an average of 1.5 years from dossier submission to approval in the EU
- May be quicker (6-10 months) with Article 8 use
- Additional studies may be required, particularly region specific studies



Some diseases more difficult:

African Swine Fever:

50 years of research by industry and academia

Problems:

- Very large virus - typical virus 10-12 proteins, ASF over 150 proteins
- Very diverse virus - multiple genotypes
- Virus strategies to evade host immune system
- Both Humoral and Cellular immunity needed
- Difficult to grow the virus *in-vitro*
- Vaccine for both domestic and wild pigs needed?
- Vaccine with a concomitant DIVA test?

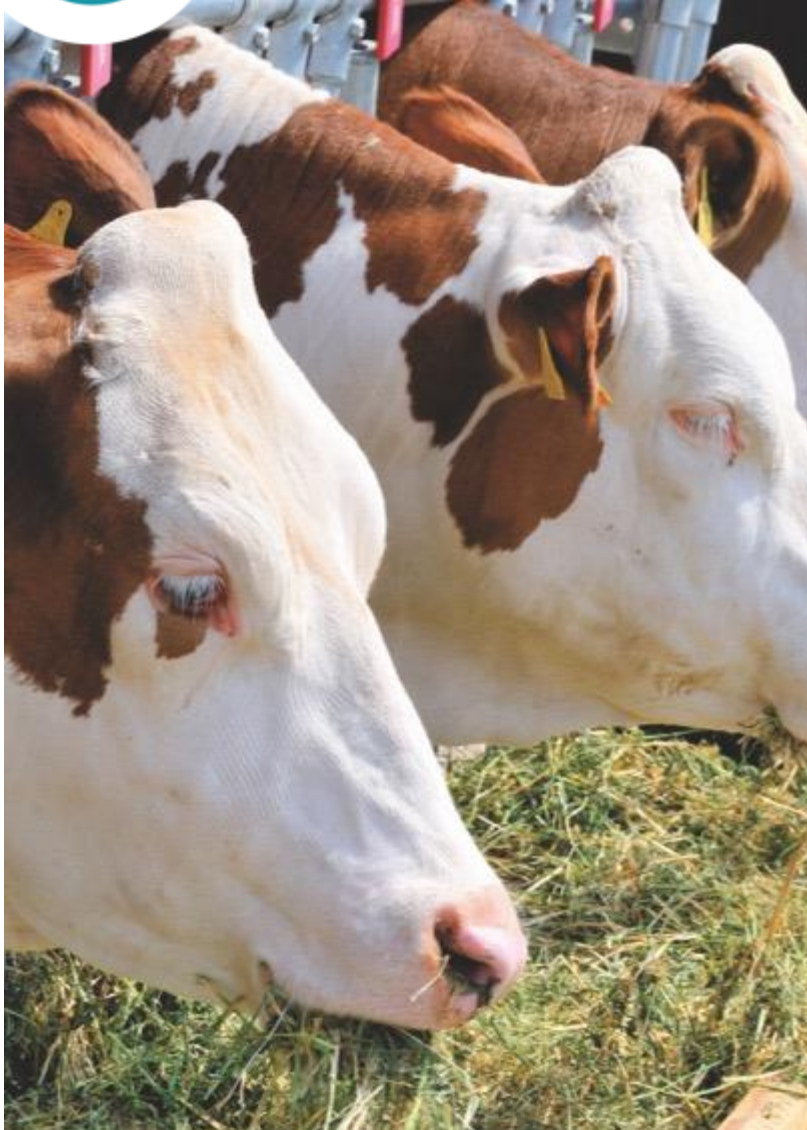


Vaccine Authorised but Unavailable

As an industry we work very hard to avoid this problem.

Reasons include:

- Poor forecast of need for vaccine
- Poor prediction of disease strain in circulation
- Long time for active ingredient production
- Logistics problems
 - Severe Weather, Strikes, Breakdowns



Trade Issues

Important player in decisions to vaccinate.

No point in having a vaccine if you cannot use it in order to protect trade.

Need for DIVA vaccines and international recognition to allow their use.



Conclusions

Need for a vaccine identified as early as possible.

Companies need the clearest possible understanding of the European position on vaccination.

Vaccine Banks/Public Private Partnership

EU exceptional authorisation/permission with

- Agreed initial acceptable data package
- Step-wise development to MA under exceptional circumstances or full MA
- Option to place “on hold”.

A warm, golden-toned photograph of a person's hands gently cradling a white dog's face. The dog's eyes are closed, and the overall mood is peaceful and affectionate. The text "Thank you!" is overlaid in the center in a large, white, sans-serif font.

Thank you!

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