

FESASS' statement on preventive vaccination

Conference on vector-borne diseases

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Introduction

The epidemiological context of the European Union obviously had an important impact on our decision to organise this conference. We had in mind the large scale of bluetongue episodes that Europe is experiencing more and more frequently. We were also thinking about the fight against lumpy skin. For us, there must be no fatality in front of these diseases.

Of course, we are aware that the threat is increasing. But it is out of the question to watch this growing threat without reacting. Therefore we are naturally interested in the use of preventive vaccination. It is a key tool, when available, against vector-borne diseases. It is also an important tool of the new Animal Health Law as Dr Andrea GAVINELLI, the Commission's representative, has just shown. It enables controlling the disease, avoids animal suffering and is an interesting contribution to keep on trade activities.

As farmers' animal health services we have to present our analysis on this crucial topic to establish both individual and collective preventions. But we must be aware that the vaccination answer will differ between diseases and that it is only a part of the response to such threats. In addition, in the context of vector-borne diseases, the strategy must be adapted to the characteristics of the vectors. In particular, it is important to take into account its ability to move quickly and cover long distances.

1°) Focused on preventive vaccination

In this context of vector-borne diseases, I will not speak of all kind of vaccination and I will focus on the preventive use of the vaccination.

There are 3 great possibilities of preventive vaccination:

- At first, the competent authorities can use it in case of emergency. Here, generally, the aim is to establish a kind of buffer zone around the first outbreak's area. It must be decided very quickly in order to vaccinate before the virus

circulates in this area. This buffer zone will protect the rest of the country and the vaccination will also protect the animals inside of the buffer zone. In fact, vaccination here is aimed at both prevention and eradication of the disease. Of course this use of emergency preventive vaccination is always compulsory.

- A second possible use of the preventive vaccination is in case of a growing threat in a neighbouring country to prevent spreading of pathogenic germs in our own countries. Here I would like to point out that this use can only be considered on as a collective approach. The relevant example is the vaccination campaign in Croatia against LSD. It was a success but because it was compulsory and co-financed by the European Commission and the State.
- The third possible use of the preventive vaccination is when the disease became endemic in the territory. In this case vaccination may be carried out on a voluntary or compulsory basis depending on the objective followed by the veterinary authorities and farmers. Indeed if the decision is to live with the disease the vaccination will be voluntary and only necessary for farmers who need to protect animals with a high added value. In this case the decision to vaccinate will be an individual choice of each farmer. It will depend of his awareness of the risk and his own needs. The example of Schmallenberg Virus has shown the limits of such approach. But if the control of the disease seems necessary and feasible, it will be important to collectively decide and use it as a routine vaccination because EFSA has demonstrated that for instance about BTV it would be required to insure a high rate of vaccination for at least 5 years. Here, in the first year, it will no longer be a question of preventive use of vaccination but more of an eradication objective. However, in the following years it will be important to prevent the reappearance of the disease.
- In both cases – individual choice or collective choice - this kind of routine vaccination in front of a permanent risk also means permanent constraints and costs.

I detailed these 3 kinds of possible uses of the vaccination as a preventive tool because we need to determine the legal and practical procedures for the implementation of each of them.

2°) Some key prerequisites

But before to use vaccination there are some important prerequisites:

- The availability of vaccines
- A relevant regulation on vaccination
- The necessity of agreements for international trade,
- And last but not least, the acceptance of consumers and food trade

These prerequisites are essential. Therefore they should be clarified and some suggestions made.

To be able to vaccinate, we need vaccine. This is obvious, but unfortunately, as David has shown, it is not so easy. As a breeders' organisation we support the

demands of the industry and consider that national and European public authorities have an essential role to play here. It is also the case for the international institutions.

The European authorities are aware of the need to have an effective vaccine in sufficient quantities and at the right time. The new regulation on Veterinary Medicinal Products and the Animal Health Law attempt to respond to this issue taking in account the industry requests. The aim is both to encourage investment in research and development of new vaccines and to clarify the strategy and conditions for the use of the vaccine. These two texts are essential, but our concern is about their implementation. The goodwill and competence of the experts from the Commission and the Member States are not in question. Our fear is that the scale of the stakes could lead to an excess of caution. It is true that this work is not easy because it requires both boldness and reasonableness. That is why I urge the Commission and the European Medicines Agency to involve stakeholders in the preparation of the implementation of these fundamental texts. This should also be the case in Member States where Medicines Agencies do not always have the reflex to rely on stakeholder representatives.

Beyond the implementation of these texts, there is a second challenge: the technical requirements for the marketing authorisation process. I would like to acknowledge the work of the European Agency and the network of Heads of National Agencies in the framework of the Veterinary Vaccine Availability Action Plan. For this project these authorities work with the Veterinary medicines Industry to facilitate the process. But here again, particularly with regard to "field trials", it seems desirable to involve practicing veterinarians and farmers in the discussions. In case of an emergency, we won't have time to organize things. The Pharmaceutical Industry is well aware of this. In this regard, I would like to mention Roxane FELLER, the Secretary General of Animal Health Europe, who last week concluded a meeting with Members of the European Parliament, the Commission services and stakeholder representatives by calling for everyone to work together. I am doing the same today.

The availability of the vaccine also means the establishment of vaccine banks at European and international levels. I am aware of the importance of the Commission's investment in this area. The fight against Lumpy Skin testifies to the usefulness of such a mechanism to support effective international cooperation. But this also requires a shared effort by the third countries concerned. Above all, it requires the agreement of all stakeholders on the principle of the use of vaccination.

This brings me to the other prerequisites and, first of all, to the need for regulations that allow for the easy use of preventive vaccination and help for a better availability of vaccines. The aim is to be able to use vaccination both for the protection of areas and for the movement of live animals. I have already mentioned this need because it is a factor that will encourage industry to produce vaccine. But what is important is to place preventive vaccination in the toolbox of the competent authorities. The Animal Health Law opens the door to this strategy but remains rather timid. What

we ask is that, through the delegated and implementing acts, the Commission clarifies the conditions for using this preventive strategy and the main principles for its implementation. Then at national level, the competent authority shall determine the legal basis for the vaccination programme.

This demand is essential in the face of vector-borne diseases, the threat of which is now permanent and for which vaccination is a major tool. For example, and very concretely, European regulations on Bluetongue should enable Member States to agree on how to use vaccination in order to secure trade when the disease is present. For this reason we strongly support the proposal to include inside of the future regulation the use of derogation to adapt the guarantees requirements to the status and needs of the Members States. The requirements of the current bilateral agreements provide a good basis for such derogations.

The other prerequisites are of a commercial nature.

First of all, it concerns the recognition of preventive vaccination against vector-borne diseases in the OIE Code so that its use does not constitute an obstacle to trade. Progress has been made, for example, in the field of Lumpy skin. Preventive vaccination against this disease is now taken into account and provisions are made subject to appropriate surveillance in order to recover rapidly to free status after cessation of vaccination. In addition, the Code has recently been amended to include a specific chapter on vaccination in general.

But for us, it should be possible to go further in order to really encourage the use of preventive vaccination. This means being able to distinguish vaccinated animals from potentially infected animals. It's require DIVA vaccines combined with a surveillance system ensuring that the disease is not present.

The last prerequisite is the acceptance of consumers and food trade. We are all aware of this constraint and especially of its subjective dimension. This is now enhanced by new communication tools such as social networks. It is therefore necessary to properly inform the consumers in order to ensure that they understand the vaccination interest and challenges. This work must be done well in advance of vaccination campaigns and must also target the agri-food industry and retailers. It is a real issue, common to the veterinary medicine industry, farmers and veterinary practitioners. The public authorities are also involved. The two main arguments are certainly that the vaccination in protecting animal health helps to combat the development of antimicrobial resistance and contributes to animal welfare. I think that here too, it is our duty to act all together.

3°) Vaccination management: Compulsory and co-financed

Well, I would now like to present our view about how preventive vaccination against vector-borne diseases should be organized and managed.

Indeed, vector-borne diseases listed in the Animal Health Law have been selected because there is a strong interest to regulate them at the European level and because their public management is necessary as the threat will be very serious for all animals of susceptible species if one of these diseases occurs in a Member State. The answer will depend on the categorisation of the disease but will necessarily be addressed to the concerned farmers' community. We have the experience of recent years with Bluetongue and Contagious Nodular Dermatitis. We clearly know that only a massive and sufficiently long vaccination over time is effective against these diseases. Consequently, for us, if a preventive vaccination policy would be put in place against a vector-borne disease listed at European level, this vaccination must be compulsory for all susceptible animals. It must be supervised by the competent authority. This is the only way to ensure the effectiveness of preventive vaccination, whether to control the persistence or spread of the disease within an area or to protect an area from the risk of introduction.

Three complementary elements must be taken into account. First of all, the fact that with European categorisation, vector-borne diseases will not give rise to identical management, as it is the case, for example, between Lumpy Skin Disease, Bluetongue and West-Nile Fever. However, for us, if the competent authority decides to carry out vaccination then it should be mandatory and massive.

Secondly, insofar as this decision is a matter of public policy, it must be publicly funded. However, it seems logical to us that the cost of these vaccinations should be shared between the public authorities and farmers. This is a shared responsibility that requires the mobilization of everyone. Such a system involving each actor ensures a higher vaccination rate.

Finally, it is necessary to provide for a certain flexibility in the system, in particular according to the specific risks of each disease and each type of farm. For example, we consider that derogations from compulsory vaccination should be provided for animals kept in vector proof establishments. Alternative measures should also be provided to address, for example, the lack of vaccine for many Bluetongue serotypes.

Two other important factors must be taken into account in order to adapt vaccination management to farmers' expectations. The first is the need for vaccination certification for animals intended for trade. In this case we consider it imperative that the vaccination be carried out by a veterinarian.

The second point concerns access to the vaccine in the event of a shortage. In this case, it is up to the competent authority to define priorities in consultation with the representatives of the livestock farmers and with regard to the risks and activities of the holdings or areas. However, everything must be done to avoid such situations. The decision to vaccinate requires anticipating vaccine needs. In this context, and in order to improve anticipation, it is necessary to rely on reinforced epidemiological surveillance and to guarantee transparency regarding the situation in the neighbouring Member States.

Conclusion

In conclusion, preventive vaccination is an important tool in front of the vector-borne disease. The key words are anticipation, preparedness and partnership. We have prepared preventive vaccination policies and adapted regulations to be able to react as soon as possible. One of the most important problems is the availability on time and in volume of efficient and approved vaccine. Here we have to build Public-Private-Partnership to secure the production. I think here also to interesting platforms like Discontools to identify the priorities for vaccines production and EPRUMA to build confidence between stakeholders.

However, we must be aware of preventive vaccination's limits. We need also to work on alternatives like vector proof establishments, use of repellent, natural immunity and control of import into the EU.

Thank you