Food and Agriculture Organization
of the United Nations

Explore options to improve security of vaccine supply against Foot-and-Mouth and other similar transboundary diseases

FAO, Rome, Italy

22-23 January 2020

Report

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Report of a meeting held to explore options to improve security of vaccine supply against Foot-and-mouth and Similar Transboundary (FAST) diseases
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Summary

Over 70 delegates from public and private sectors involved in the security of supply of vaccines for FAST diseases, participated in a meeting held at the FAO headquarters in January 2020. They expressed a high level of support for a Multi-Stakeholder Platform (MSP) that would enable closer co-operation on issues of common interest.

The main actions agreed were

1) further development of an MSP, through consultation between FAO and key private sector associations;

2) working groups on vaccine pre-qualification and vaccine demand;

3) development of a problem statement relating to the Nagoya Protocol;

4) a more systematic approach to engaging private sector in international working meetings relating to surveillance or vaccination strategies and their impacts.

Secretariat and Participation

The meeting was organized under the framework of the FAO-EuFMD Phase V workplan, with the EuFMD (Keith Sumption and David Mackay) as Secretariat for the meeting. The list of participants is given in **Annex 1**. HealthforAnimals and GALVmed sent information on the meeting, inviting registration of interest, to all parties known to be producing FMD vaccines, ensuring a global opportunity to register and participate.

Opening

The Director of the FAO Animal Health Division, Berhe Tekola, opened the meeting on behalf of the Assistant Director General for Animal Health. He welcomed the participants and indicated the importance FAO places on public and private sector working together and how, in the area of vaccine security, ”multi-stakeholder” engagement is essential to address challenges. He underlined that establishing new ways to facilitate this fits strongly with the stated intentions of the new Director General of FAO.

Objectives of the Meeting

The objectives were stated in the pre-meeting information as 1) Share perspectives on the key issues and identify priorities to be given attention; 2) Share and consult on initiatives of common interest and relevance; 3) Explore the feasibility and potential ways setting up and operating a multi-stakeholder [public private] platform (MSP) to improve vaccine security; and 4) Identify and agree a prioritized set of activities for the program work stream.

Stakeholder perspectives on the need and issued to be addressed

In the first session, representatives of stakeholders made short presentations, after an overview by Keith Sumption on the EuFMD workplans in the areas of emergency supply arrangements and on forecasting vaccine demand. Speakers in this session were Carel du Marchie Sarvaas (HealthforAnimals), Matthew Stone (DDG-OIE), Hendrik-Jan Roest (Deputy CVO, The Netherlands), Carolin Schumacher (GALVmed), Felix Njeumi (FAO) and Jean-Jacques Soula (OIE) relating to PPR Global Eradication Plan Secretariat, and Samia Metwally, FAO (GF-TADS Secretariat, Rinderpest post Eradication).

There was broad overall support for cooperation between all stakeholders in the production and use of vaccines against FAST diseases and agreement, in principle, that a MSP coordinated by EuFMD has the potential to be effective way of making progress with aspects of vaccine security that have proven difficult to tackle to date. Close cooperation between OIE, FAO, national control agencies and NGOs is likewise essential to promote in view of the many ongoing and planned initiatives relating to vaccine security. The importance was emphasised of bringing the beneficiaries of disease control programmes, such as the meat production sector, into the dialogue as soon as possible as experience has shown that they are capable of mobilizing extensive financial and logistical resources when presented with a compelling business case.

AgResults Foot and Mouth Disease (FMD) Vaccine Challenge Project

The second session focused on presentations given by AgResults (Rodrigo Ortiz), GALVmed (Caroline Schumacher and Nina Henning), and on the planned laboratory support to enable testing of candidate vaccines against a panel of East African viruses, given by Anna Ludi (WRL-FMD, The Pirbright Institute). The official launch date is planned for 7th February 2020, and the session was briefed on the two phases of the project, of 4.5 and 4 years respectively, and the time-table relevant to entry into the competition and the awarding of the "prize" funding in the second phase. A very active discussion on the two phases followed the presentations, with the majority of comments and questions being on the product profile and how this will be met or demonstrated, in the initial phase. In responding to the questions, Nina Henning introduced the two other project team members (Jef Hammond, Badi Omar) who will be supporting the project. They will work to answer questions arising from the launch from interested companies from the region and across the world, and the potential buyers of FMD vaccine, public and private, in East Africa. In their responses, AgResults (Parasto Hamed) indicated that companies have up to seven years to enter the competition. However, in order to ensure that Phase 2 will occur from 4.5 years into the project, it is expected that at least one company will have taken the steps to register its vaccines in the eligible East African countries by this milestone. If not, AgResults may be forced to terminate the project at this stage. It was recognized, in developing the project, that very relevant new technologies and platforms to improve production and performance of FMD vaccines now exist. The timetable that has been set encourages the development and registration of these for East Africa. The timeframe also encourages those that already have products that use established technologies, to adapt their vaccines to meet the particular requirements of the region and thereby move towards registration. The developers also recognized that the size of the Prize alone may not be sufficient incentive for companies to enter the FMD field for the first time. Furthermore, the unmet demand for FMD vaccine in Eastern Africa is estimated to be much bigger than that that can be subsidised or supported under the programme. The project should therefore be seen as a catalyst for change in which both private and public procurement of vaccines will rise once registrations have been achieved in the region, and confidence in quality as well as supply is demonstrated in Stage 2. Keith Sumption, as Chair of the Session, also drew attention to the likelihood that vaccines that meet the technical requirements for matching 70% of the panel viruses for Eastern Africa, are likely to match well against a significant percentage of the FMDVs in all other regions of Africa. These also represent attractive and developing markets for FMD vaccines. The discussion also focused on duration of immunity and stability requirements. The rationale for the requirement of DIVA compliance was raised; in the answers to this, the prior consultation had elicited that the major potential buyers in both public and private services had indicated they required DIVA vaccines to meet their national export strategies for livestock for which the ability to demonstrate freedom from circulation of virus is important.

Pre-qualification (PQ) of vaccines for use in animal health

Dr Kris de Clercq, Sciensano, chaired the third session which was centred on systems for procurement of vaccines operated by WHO, OIE and FAO. The issue was on the Agenda for the meeting because of the need identified by FAO for moving from case-by-case tenders to long term agreements (LTA) with vaccine suppliers to better meet the need for timely and efficient response to country and programme needs. EuFMD had proposed to explore the potential of this in relation to LTA for emergency reserve mechanisms, such as the "Assured Emergency Supply Options (AESOP)" in which the diversity of vaccine antigens required might only be met by PQ of multiple suppliers.

Mr Olivier Lapujade, WHO, outlined how the system for PQ of vaccine suppliers to WHO (and other UN agencies such as UNICEF) is organized. This PQ system has operated successfully for many years as a key mechanism underpinning the WHO vaccination programmes. He indicated the significant HR investment needed to maintain and operate the system. WHO is able to utilize cost-recovery which facilitates sustainability of the PQ procedure. In addition, the evident 'buy in' to the system by all stakeholders involved, including WHO, manufacturers and national regulatory authorities worldwide, remains a key element of its success. Dr Stephane Renaudin, OIE, summarized the OIE system for vaccine banks and how their tender process has been managed. FAO and others may procure vaccines based on the results of the agreements reached by OIE with suppliers. David Mackay, for EuFMD, then took participants through the principles and potential procedures of a proposed PQ system that could operate within the FAO procurement context. The system proposed is global in scope and based primarily on evaluating vaccines already registered in one or more member countries of FAO, and a key principle is the active involvement of the National Regulatory Authorities (NRAs) as a party in the centrally managed, two-stage review process. The panel composition for the second stage, leading to recommendations to FAO on PQ, would need to be appropriate to the complexity and risk of the decisions. An aptly composed panel would ensure consistency, widespread acceptability of the outcome and a robust mechanism to demonstrate compliance with OIE standards for vaccines. Given the complexity of the review process, the issues relating to Good Manufacturing Practice (GMP) and its application by NRAs, and the different viewpoints and position of independent laboratory testing for NRAs, there is a need to develop solutions by engaging with a wide spectrum of stakeholders in the public and private sectors with the aim of reaching consensus on major points. Participants in the meeting were given the option of joining the sub-group on the second day to address issues and questions raised and over half did so.

Specific issues raised by stakeholders

The last session on the first day focused on issues raised by stakeholders. The main ones were the problem of information availability on vaccines against FAST diseases and the Nagoya protocol and its implications for development and supply of FAST vaccines. The session was chaired by Carolin Schumacher, GALVmed.

Information status and needs: FAST vaccine and emergency reserve availability

David Mackay presented a review of publicly available information sources relevant to FAST vaccines. A number of different sources of information are separately available containing dissimilar types of information. However, there is no single source of information on what vaccines are manufactured against FAST diseases, what are their properties and their actual availability. A number of such sources have been available at different times but have not been maintained or recently updated, because of the resources needed to curate this type of information, and also that funding of these various initiatives was time bound and project-related. At the least, the current EuFMD work in this field can provide a guide to what is available, and the extent to which it provides the type of information needed by key stakeholders such as national FAST disease risk managers (contingency planners). Sally Gaynor, EuFMD, summarized the type of information needed by such managers; from these, priorities need to be made and a way to improve access to the ones of most significance, which may include the key performance parameters for modelling the impact of vaccination upon control. Dr Alf-Eckbert Füssel, for the Commission (DG-SANTE) reviewed the current basis for arrangements for emergency reserves for FMD and other priority FAST diseases (Lumpy Skin Disease, Sheep and Goat pox, PPR and RVF).

The role of reference laboratories in advising on vaccine strain selection

Don King of the World Reference Laboratory for FMD, Pirbright Institute, highlighted the challenge for FMD in terms of matching vaccine strains to field strains. Reference laboratories provide a valuable service to both governments and manufacturers in terms of testing the in-vitro and in-vivo relationship between vaccine and field strains, and supplying new reference virus strains as they emerge. Establishing cut-offs that can reliably predict the likelihood of protection by vaccine strains remains a particular challenge, and the ability of independent laboratories to perform this essential function is greatly enhanced when manufacturers are prepared to share data, strains and reagents.

The Nagoya Protocol (NP) and its implications

As specific issues had been raised by stakeholders, Dr Josef Geoola (CEO, Ingentium) had been invited to present a review of the issues that the NP creates for vaccine manufacturers. Compliance is required if the genetic resource has been sourced from the 123 countries where the NP of the Convention on Biological Diversity has been ratified. Almost all sub-Saharan African countries are members, and most of Asia. Digital sequence information is not expressly included at present, but this is likely to change as many countries adopt a position of implicit inclusion. There are two key steps (Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT)) and tools associated to assist the access-and-benefits processes, to which links were provided. There are also limitations and exemptions relating to emergencies, to enable utilisation of genetic material, provided PIC/MAT are put in place. With respect to emergencies however, it is important to note that emergencies are generally defined as a

WHO Public Health Emergency, which is human-centric. Hence, outbreaks involving non-zoonotic diseases may not benefit from emergency exemptions. Furthermore, under the NP individual provider countries have been left to determine how to implement NP in matters relating to emergencies. Unfortunately, the only evidence of a concrete process seems to have been implemented by the EC, which is technically only legally valid where the country of origin is within the EU. There are a number of human health and seed-tech initiatives looking at manners in which to strengthen the NP, however nothing appears to exist within the realm of animal health. He concluded with guidance on navigating the NP, and urged a due diligence approach to review current and planned developments, and to begin the process for agreeing PIC/MAT before starting work.

Regulatory perspectives

Caroline Guittré (ANSES-ANMV), provided a valuable overview of the regulatory tools in the EU that are relevant to the setting of FAST diseases. These tools are not normally applicable to other types of vaccine authorized in the EU and have been put in place specifically to address the particular challenge related to vaccines such as bluetongue, avian influenza and FMD that have a high level of antigenic diversity. Paul Hauer (CVB-USDA), covered the recent step relating to strengthen preparedness, such as the National Animal Vaccine and Veterinary Countermeasures Bank. The latter will be US-only and will further strengthen the North American Bank agreements. Of note, is the new emphasis (VS Memo 800.213) given to facilitating the licensing of platform products, allowing variants to be included through a simplified procedure after the initial platform vaccine has been issued a full license. The view in the US is that platform-based technologies will become increasingly important in preparedness for FAST diseases in future, as this approach is ideally suited to dealing with sudden antigenic changes in viral pathogens.

Issues and concerns for HealthforAnimals (HFA) members

David John (Animal Health Europe) summarized their position. On PQ, there was general support to move in this direction but the system must be seen to be practical and workable if it is to attract HFA/Animal Health Europe members to participate. Members were fully willing to join into further discussions that could help ensure that PQ develops in such a manner. On the Nagoya Protocol, their proposal would be that “pathogens should be removed from the scope of the NP”. He also raised a general point, that the strategy development for control of FAST diseases in endemic or free countries or regions appears to be developed without a significant engagement with vaccine producers. HFA members are concerned with the impact of the use of their vaccines, not only for reputational reasons, but also the interest of the producers is to see the maximum impact from the quality of their products being realized when vaccines are delivered to the target animals. National capacities to manage cold-chain, and safely deliver to the target animals, matter for all parties. The private sector would like to have a closer association with the technical work of the public bodies in national control strategy development. The same applies to surveillance, where the results generated by public sector laboratories have a direct impact on vaccine producers. The major points raised by HFA were subsequently addressed in the conclusions of the meeting.

In an exchange of views on the Nagoya Protocol, several industry speakers expressed concern that application of the Protocol has the potential to block or delay their access to genetic material such as new variants of viruses that are needed in the event of new disease threats. Other participants pointed out that the Protocol delivers the protections necessary to avoid exploitation of genetic resources without due reward to the countries of origin. It is important to note that protection of genetic resources and scientific progress may not need to be mutually exclusive. It would be worthwhile investigating whether a new, globally accepted guideline on managing PIC/MAT under NP where this is with relation to a transboundary animal disease emergencies, could be beneficial to the overall objective of the NP. OIE considered it would be helpful for industry and others affected, to generate a problem statement on the challenges identified and why the mechanisms built into the Protocol are inadequate to address the need for rapid access to genetic material. Sector-specific guidelines that 'sit on top' of NP e.g. for epizootic diseases agents could be drafted.

Working arrangements with EMA, vaccine performance and estimating demand for FAST vaccines

Stephan Zientara, ANSES, and Ivo Claassen, European Medicines Agency (EMA) chaired the first session. In the first talk, Ivo Claasen covered the EU regulatory framework for FAST diseases, adding that Article 138 of the new regulation on veterinary medicines (Regulation (EU) 2019/6) allowed for provision of a scientific opinion to international organizations relating to VMPs intended for use exclusively outside the EU. The details of how this would work (financial and procedural) are being developed. The approach will be similar to the Article 58 procedure (of Regulation (EC) 726/2004) which facilitates pre-qualification of human medicines for the WHO PQ procedure. This would add a new element to EMA work, in relation to veterinary vaccines used internationally and could assist the work of the vaccine security platform as it develops.

In the second talk, Giancarlo Ferrari (IZSLT, Rome) drew attention to structured training now available on investigation of vaccine failure in the field, and how this has been delivered by online and workshop formats by EuFMD working with The Pirbright Institute. The training provided builds on the FAO/OIE Guidelines on Post-Vaccination Monitoring, and is applicable to a wide range of vaccines in field use. Polly Compston (RVC, London) then gave a short overview of her planned studies on how socioeconomic factories influence demand for FMD vaccination in East Africa and the drivers and disincentives to reporting disease.

Working groups on the proposed prequalification system (PQ) and on estimating global demand for FAST vaccines

Participants selected their preference for working groups, which then met for 90 minutes in facilitated discussions.

Conclusions relating to the proposed PQ system

Discussion focussed on four points with the main conclusions recorded below.

PQ application: content and format

- There needs to be clear separation between the PQ process and the tender process. The PQ process should be an indication of the quality, efficacy/effectiveness and consistency of production and not an evaluation of suitability for use in a specific epidemiological context.
- PQ should not discriminate directly, or indirectly, against smaller manufacturers. Some participants considered that, for example, a weighted tender process might be appropriate.
- PQ should use existing document formats and content where possible.
- Where possible, the PQ process for veterinary vaccines should adapt and use existing tools, such as those developed by WHO, but care needs to be taken in adaptation to ensure that standards are appropriate to the veterinary sector, bearing in mind that the requirements and environment may differ between the human and veterinary domains. WHO technical series exist for certain zoonoses, e.g. rabies, but not for animal-specific diseases.
- The norms and standards to be applied within the PQ process for veterinary vaccines will need to be developed using a transparent consultation process open to all stakeholders, including manufacturers.
- PQ should take into account existing authorisations where these exist and are issued by regulatory authorities recognised as functional and experienced with respect to veterinary vaccines, e.g. EMA, USDA. The existance of such authorisation should allow a reduction within the PQ procedure of the extent and time taken for evaluation.
- OIE standards should apply, but additional guidance will be required with greater detail/ specificity of how to apply these standards to ensure consistency of assessment.
- Industry associations should be consulted and involved in drawing-up proposals for the content and format of PQ applications to ensure the process ultimately represents a practical and attractive opportunity for manufacturers.

Procedures and responsibilities

- PQ manufacturer inspections should be risk based - e.g. degree of inspection can be reduced if other recognized standards are already achieved by manufacturer, (PICs, EU GMP, EU authorisation for third country products under article 138 etc), as inspection is a major drain on resources for manufacturers.
- The model of GAVI (the Global Alliance for Vaccines and Immunisation) should be explored as a model of incentivising vaccine security through managing procurement.

Product (re)testing

- Reference laboratories have a clear role in quality control, which is made complex due to the large number of FMD vaccine strains used in different geographical regions.
- Quality assurance is necessary to ensure the reliability of testing carried out by official control labs / reference labs.

- PQ should minimize the testing required as testing is burdensome and impacts on animal welfare.
- Role of reference centres in testing for the purposes of PQ vs. at the stage of tender needs further discussion.

Implementation and sustainability of the system

- A scheme should incorporate ability for variations to dossier, as requirement for strains will vary over time.

Conclusions of the subgroup on global demand for FAST vaccines

The topic of focus was exploring informatics and understanding demand for FAST vaccines. Bouda Vosough Ahmadi and Fabrizio Rosso, EuFMD, facilitated the session. Two main questions were discussed during the session namely what information are needed to make significant differences in investment decisions for vaccine production, and what are the most practical mechanisms and actions to address the identified gaps?

The main conclusions were:

- There as a strong need for robust quantifications of the size of the market demand for FAST vaccines that support long-term investment decisions by the private sector. The time horizon of any investment by the private sector in vaccine production facilities must be also taken into consideration (e.g. 15 years and beyond) and must be matched with the demand estimation time horizon. There was an agreement that vaccination in endemic countries is the main driver to invest for Industry rather than vaccine banks.
- A deep understanding of the capacity, conditions and infrastructure of the countries is essential. Examples of knowledge needed include an overview of the available resources, level of biosecurity, adoption rates of vaccination, willingness-to-pay (WTP) of the farmers for vaccines, etc. It was emphasized that understanding the commitment and WTP of the farmers for vaccines are key elements to forecast the demand for vaccines.
- It was suggested, because of the variation in policies, structure of the livestock industry and their characteristics in different countries, that better understanding of the actual number of animals per country, the growth or decline projection, as well the vaccination and control strategies are needed per country. This approach and information sharing must be harmonized and coordinated at regional level.
- It was suggested and agreed that a system-dynamic modelling approach must be developed and used for a more dynamic estimation of the demand that will include characteristics of the viruses in the case of FMD such as serotypes, lineages, etc. This approach will help identify gaps, forecast and assess risks. To do this, a structured framework of collection of information and reporting in real time, with enough details to be able to understand the risks (e.g. FMD virus lineage) is essential. This public-private platform could work as a centralized body who will produce strains instead of having the industry producing them individually.

Action points and timeline

Led by EuFMD, the demand-projection mechanism of this public-private platform will conduct the activities below in the course of the next six months:

- Problem definition and explore options and their feasibility.
- Liaise with private sector, experts and economists in FAO and other institutes to describe the best analytical frameworks to be developed, and identify and locate relevant datasets to be used.
- Report the findings, prepare a plan for next steps and estimate the funding needed.

Considerations and conclusions on the way forward

Mr Carel du Marchie Sarvaas, HFA, co-chaired the final plenary on the way forward on the significant issues of the meeting. He proposed six points to the participants, for their comment and validation.

1. The desirability of a multi-stakeholder platform (MSP) for vaccine security to continue to develop a common approach and actions on the major issues. An MSP is desired, needed and welcomed.
2. Greater engagement of the private sector on the issues of national and regional control programmes involving vaccination.
3. The MSP should encourage and support work that will improve forecasting of demand for FAST vaccines.
4. The further development of the potential prequalification (PQ) system for FAST vaccines, with close consultation with the private sector to ensure interest, and sustainability.
5. A position paper, weighing up the risks and benefits of changes or mitigation measures relating to the Nagoya Protocol, would be helpful, and a strategy to follow from this for advocacy.
6. Improved sharing of information and co-ordination of surveillance for FAST diseases.

There was evident support for these points in the discussion that followed, and a number of **action points** agreed.

1. **Multi-stakeholder platform (MSP) for vaccine security**.

   The FAO office for partnerships with the private sector joined the final day and confirmed the strong interest of FAO in the development of an MSP in the vaccine security area. Lara Machuame (PSPS) will be the appointed focal point for this new MSP.
   A poll of participants (through Mentimeter™), showed strong agreement for the MSP creating Action/Working subgroups, development of written procedures behind the MSP, and a robust support for the Agenda of the MSP being co-managed between public and private key stakeholders.
   Action: HFA and FAO/EuFMD are entrusted with the responsibility to identify what is needed for a successful MSP, the feasibility of establishment, what is needed for success and to ensure it can be sustained.

   Timeframe:
   - before the OIE General Session in May 2020.
   - Next face-to-face meeting could be in one year but the October 2020 EuFMD Open Session also provides a good opportunity to meet.

2. **Action groups (working groups)**

Three Action groups were agreed, with leaders responsible for follow-up:

- On Pre-Qualification (Leader: David Mackay, EuFMD).
- On forecasting demand (Leader: Bouda Vosough Ahmadi, EuFMD).
- On the Nagoya protocol (HFA: for industry, to generate an initial problem statement).

Timeframe: progress reports within six months, to be circulated and public consultation at the EuFMD open Session 2020.

3. Greater engagement of the private sector on surveillance and national and regional control programmes involving vaccination

Considering that the role of co-ordination of meetings is currently done by the international organisations present in the room (FAO, OIE, EC and EuFMD), the type of actions that could be taken would include a more systematic effort to ensure information and invitations on relevant regional meetings, or when planning or reviewing surveillance findings for the implications for vaccination. Fabrizio Rosso, EuFMD, drew attention to meetings on vaccination against FAST disease planned with the REMESA countries (North Africa and Mid-East), and the possibility to invite the private sector to these. Samia Metwally (FAO) indicated how private sector is invited to the GF-TADs Regional FMD Roadmaps which are held in two-three regions every year.

Action: the development of a more systematic process of inviting/involving the private sector in international meetings on FAST disease surveillance and vaccination programmes, starting with a review of the meetings planned in 2020 by GF-TADs, and consideration of involving HFA for a more consistent approach to the private sector stakeholders.

Time-frame: by the OIE General Session, 2020.

Annex 1

List of Participants

Meeting held to explore options to improve

security of vaccine supply against

Foot-and-mouth and Similar Transboundary (FAST) diseases

22-23 January 2020

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