Food and Agriculture Organization of the United Nations

european commission for the control of foot-and-mouth disease

Meeting Report

Standing Committee on Pre-Qualification of Vaccine against Foot-and-Mouth and Similar Transboundary animal diseases

15 December 2021

European Commission for the Control of Foot-and-Mouth Disease

Standing Committee on Pre-Qualification of Vaccine

against Foot-and-Mouth and Similar Transboundary animal diseases

Summary

The EUFMD is in the process of establishing a system for pre-qualification of vaccines (PQv) against FAST diseases. Following endorsement of the initiative by the 44th General Session of EuFMD, Member Nations and Partner Organizations were invited to nominate suitably qualified experts to form a Standing Committee on Pre-Qualification of Vaccines (SCPQv) that is intended act as the decision-making and governance committee for the PQv procedure.

The first meeting of the SCPQv was held virtually on the 15thDecember 2021. Successfully nominated members and experts from partner organizations bring with them a wealth of experience from a range of backgrounds to support the activities of the committee. The SCPQv was provided with an overview of the PQv project and the implementation plan for 2022. The terms of reference for the newly created committee were presented and the intention is to elect a Chair and Vice-Chair at the first formal meeting planned for Q1 2022.

Questions from SCPQv members were fielded by EuFMD experts and where necessary responses were followed up in writing (Appendix 1). The membership of the SCPQv can be found in Appendix 2.

Report

The first meeting of the SCPQv was held virtually on the 15th December 202. Successfully nominated members and experts from partner organizations presented an overview of their experience they brought to the committee. SCPQv members have the necessary expertise and skill set to support the aims and objectives of the committee in the fields of FAST diseases, in the development, manufacture and regulation of veterinary vaccines and procurement and financial management of FAO/EuFMD projects.
The first meeting was an informal and the intention is to elect a Chair and Vice-Chair at the first formal meeting planned for the first quarter of 2022. Members were provided with details of the terms of reference of the SCPQv that is intended act as the decision-making and governance committee for the PQv procedure. The SCPQv will play a key role in the functioning of the PQv procedure though formally approving recommendations from expert evaluation teams for the inclusion of veterinary vaccines for FAST disease onto a published list of prequalified vaccines. The SCPQv will also establish guidance on the procedures and data requirements and act as an arbitration body in situations where the evaluation experts are unable to reach a decision or where manufacturers request an appeal. In addition to a scientific and technical role, the SCPQv will provide oversight of the PQv system, providing advice and support to the EuFMD secretariat and ensure coordination and consultation with key stakeholders in its development and maintenance.

The scope of the SCPQv will extend beyond the PQv procedure and encompass more general topics on the quality and long-term supply arrangements of vaccines for Foot-and-mouth and Similar Transboundary animal diseases (AESOPS; Assured Emergency Supply Options).

SCPQv members were presented with an update on the PQv initiative providing key features of the PQv procedure and the timeframe for implementation. The newly formed EuFMD PQv team presented themselves to the committee and provided details of a planned workshop on vaccine security in January 2022, ‘Improving FAST vaccine security through stakeholder engagement’.

PQv aims to provide a level of assurance on the quality of vaccines for FAST diseases to international/OIE standards, thereby facilitating the procurement of vaccines through tenders, reducing both the time frame and workload. The PQv system is not intended, however, to determine whether a 'quality' vaccine evaluated through the PQv procedure is suitable for the epidemiological situation for which the vaccine is being procured and it will remain a responsibility of risk managers to determine the 'fitness-for-purpose. The PQv system will ensure that any label claims are supported by data submitted through the procedure.

SCPQv members raised a number of questions related to the PQv procedure and where necessary written responses were provided (Annex 2). Some of the technical issues would be referred to the Technical Advisory Group on Pre-Qualification of vaccines against Foot-and-Mouth and other transboundary diseases (PQTAG) to further consider the minimum data requirements for the 'Product Summary File' (PSF). This PSF guidance outlines the information required on the vaccine composition, the manufacturing standards, Quality Control testing, stability, clinical and field studies and all available post-marketing pharmacovigilance information

Appendix 1: SCPQV Questions and Responses

Appendix 2. Members of the Standing Committee for the Pre-Qualification of vaccines for FAST diseases

Appendix 1: SCPQV Questions and Responses

Questions raised by members and partners related to the PQ project

Information Session 15/12/2021		
Member/ partner	Question	Response
A. Dekker	Q1. How will the post-vaccination guidelines for FMDV vaccines be included in our future work? Especially data from standardized field studies	Information on studies conducted as part of post vaccination monitoring of which the applicant is aware should be summarised and included within Section 3.E.1 "Clinical studies information (additional laboratory and/or field studies to those provided in sections 3B and 3C)" of the Product Summary File (PSF) submitted as part of the PQv application. At a future stage, once the PQv system is established, it may be possible to consider how a 'feedback loop' could be set up whereby data from PVM studies conducted using PQ vaccines is taken into account as part of the renewal procedure for continued listing.
	Q2. In many countries NSP absence is not that essential, efficacy is more important. NSP serology is still possible in youngstock, Frenkel non-purified vaccine did not induce an NSP response after 1 shot.	As above, any claims made for DIVA properties as part of the SPC/label for a product will be verified in line with the requirements of the OIE Manual as part of the PQ procedure, but inclusion of a DIVA claim is not a requirement for PQ.
	Q3. Fitness for purpose can be evaluated when we have sera from the post-vaccination monitoring standardised study and test the sera against heterologous strains. This will be a separate issue to PQv, but it shows that is very important to stimulate post-vaccination monitoring studies and share sera with FAO reference laboratories.	The project recognizes that information on PQ is only part of the information that risk managers will need. The possibility of creating an information hub would be an interesting option to explore with links to other relevant sources of information such as FAO reference laboratories, national regulatory authorities with authorised FMD vaccines etc.
	Q4. Not claiming NSP absence is the best option. But I would like to see data on shelf-life as vaccines are always stored. Strain suitability. I read stability. But suitability is often not an issue when higher potency vaccines are produced. Still the SAT2 strains are sufficiently different with insufficient cross-protection data to give scientific sound advice	Section 2.G of the PSF requires data on Stability which will be reflected in the shelf life stated on the SPC. Data on a minimum of three lots of final product is required.

D. Paton	Q5. If I understand aim is to verify claims rather than fitness for purpose - but presumably minimum requirements on claims that have to be made relating to fitness - e.g., on strain suitability or NSP purity?	Generally, the principle is that the manufacturer 'owns' the SPC and is responsible for claims made. FMD is almost unique in that efficacy can be demonstrated for the purpose of authorization using the (homologous) vaccine strain and many FMD vaccines are currently authorized on the basis that they protect against the (vaccine) strains listed on the authorization. Manufacturers may choose to make claims for efficacy against strains other than the vaccine strains. Any such claims must be based on data in the authorisation dossier and verified by the regulatory authority. Likewise, many regulatory authorities require evidence of efficacy against local strains (or inclusion of local strains) for vaccine authorized in their country. In other situations, users rely on other sources of information for fitness-for-purpose including reference laboratories or the manufacturers themselves. For PQ, the approach proposed is not to be proscriptive about claims but to ensure that any claims made are justified by the data provided. This applies equally to any claim made for DIVA properties. If a claim is made for DIVA properties this must be justified in line with the OIE Manual by describing the steps taken during manufacture to eliminate NSP from the final product and the evidence that repeated administration of the vaccine does not result in the induction of antibodies to NSP.
	Q6. One option for manufacturers who wish to avoid difficulty in verifying claims might be not to make them. So, my question was more about what is the minimum set of claims required for a vaccine regarding e.g., strain suitability?	This is addressed above. For the purpose of PQ, efficacy must be demonstrated in line with minimum international standards as defined in the OIE Manual so a vaccine must have a potency of at least 3 PD50 against the vaccine strain. If a vaccine claims to be suitable for emergency use or to be of higher potency, then it must have a potency of at least 6 PD50. The OIE Manual is less prescriptive about heterologous protection, but guidance is given how a claim for protection against strains other than the vaccine strain might be supported. PQ is not intended to be proscriptive of any particular 'use case' for a vaccine (emergency, routine prophylaxis etc.). Hence any vaccine that complies with the minimum standard in the OIE Manual will be eligible for PQ and it is up to potential users to ensure they chose a product suitable for their purpose (e.g., 3 vs. 6 PD50).
R. O'Neill	Q7. Clearly in the last 21 months there have been unprecedented research and progress in vaccine	The rapid regulatory approval of new technologies for human vaccines undoubtedly has many lessons that could be applied in the veterinary domain.

	formulation, manufacture and logistics for Covid. Is that likely to lead to cross-fertilize into FMD vaccines and would that mean a busy period ahead in next 2-5 years for new FMD vaccine proposals.	The great majority of authorised FMD vaccines worldwide are based on conventional inactivated vaccine technology. The standards and norms applied to FMD vaccine technology have been developed for conventional vaccines and only some can readily be applied to products of recombinant technology. For this reason, the PQ proposal currently states on page 7 "The procedure will in the first instance be developed for vaccines involving well-established technologies that are already approved by one or more NRA, as these represent the majority of applications expected. As PQ is a peer review of existing information and previous evaluations, applications for vaccines that have not already been authorised by a national regulatory authority cannot be accepted. In addition, evaluation of innovative products with no history of safe use would require specific adaptation of the procedure and considerably greater input of expertise on behalf of EuFMD, including specialist expertise in the technology to which the application relates. Consideration of extending the scope of the PQ procedure to include vaccines that have not previously been authorised and/or that incorporate novel technologies will therefore take place at a second stage"
	Q8. Is it likely that this committee will ever need a fast track or emergency mode, or will it operate independently of any ongoing field situations?	In the first instance PQ is not envisaged as an emergency or fast track procedure. Rather PQ is envisaged as part of emergency preparedness in 'peace time'. Experience at WHO showed that a separate 'emergency use listing' procedure was ultimately required in addition to a PQ procedure to respond to emergency situations but the current EuFMD procedure is focussed on PQ only at the present time.
G. Torres	Q9. What would be role and responsibilities of the different members of the Standing Committee?	All members of the committee have been appointed on the basis of their expertise in relation to one or more aspects of vaccines and their deployment. In line with standard EuFMD rules for scientific committees, the committee will appoint a Chair and Vice-Chair from among its members. The Committee may decide to form working groups on particular topics or for particular activities as its work develops and members will contribute according to their expertise. Partner organizations are responsible for the representatives that they send to meetings of the SCPQv and the committee benefits from the additional expertise that these representatives

		bring. Expert representatives from partner organisations may not vote (although SCPQv is not currently envisaged as a voting committee).
	Q10. Would negative outcomes be communicated to national authorities?	Applications are considered as commercially confidential information. A positive outcome would be publicised by means of inclusion on the list of PQ vaccines, but a negative outcome would be communicated only to the applicant.
F. Berlingieri	Q11. Given that the vaccine would need to be registered at least in one country, does this limit to registration only in EUFMD Member Nations?Q2: manufacturer needs to submit application any idea on who would apply? Already potential candidates? Q3: what happens with rejected vaccines? (If they were approved in a Member Nations but are not good enough for Committee on PQV, what does this entail? – will there be a list of "rejected" applications?)	Q1: The PQ procedure will have an accelerated evaluation procedure for vaccines that have been authorised by a 'functional regulatory authority' (details of which are given on P15 of the proposal) Q2: Several of the larger pharmaceutical companies have expressed interest in principle in submitting applications for PQ. EuFMD intends to conduct a survey in early 2022 to gather more objective data on the level of interest. Q3: The current proposal is that the company will be informed their vaccine did not meet the criteria for listing and a summary of the reasons provided. Companies will have the opportunity to submit a new application in the future with additional data or by demonstrating that they have addressed deficiencies identified and have the evidence to prove this.

Appendix 2: Members of the Standing Committee for the Pre-Qualification of vaccines for FAST diseases

Official Members of the SCPQv nominated by EuFMD Member Nations:

- Dr. Musa Alkan (Turkey)
- Dr. Rosaria Bullido (Spain)
- Dr. Gabor Kulcar (Hungary)
- Dr. Ronan O'Neill (Ireland)
- Dr. Ioana Neghira (Romania)
- Dr. Tamaš Petrović (Serbia)
- Dr. Aldo Dekker (The Netherlands)
- Prof. David Paton (United Kingdom)
- Dr. Caroline Guittre (France)
- Dr. Sharon Reynolds (United Kingdom VMD)

Partner Organization representatives nominated to the SCPQv:

- Dr. Francesco Berlingieri (European Commission)
- Dr.Ivo Claassen (European Medicines Agency)
- WHO: TBC
- Dr. Gregorio Torres (OIE)
- Dr. Samia Metwally (FAO)
- Dr Nick Nwankpa (PANVAC)
- David Blancato (FAO procurement services)
- Sergei Malitsky (FAO procurement service)

EuFMD Committees

Executive Committee, Standing Technical Committee (STC), Special Committee for Surveillance and Applied Research (SCSAR), Special Committee on Biorisk Management (SCBRM), Tripartite Groups.

Hold-FAST tools

AESOP. Assured emergency supply options; **EuFMDiS**, FMD spread model; **GET PREPARED** toolbox. Emergency preparedness; **GVS**. Global Vaccine Security; **Impact Risk Calculator**; **Online Simulation Exercises**; **Outbreak Investigation application**; **Pragmatist**. Prioritization of antigen management with international surveillance management tool; **PCP-FMD**. Progressive Control Pathway for foot-and-mouth disease. **PCP-Support Officers**; **SAT.** PCP Self-Assessment Tool; **RTT**. Real Time Training; **SMS Disease reporting**; **SQRA toolkit**. A method for spatial qualitative risk analysis applied to FMD; **Telegram**; **TOM.** EuFMD training management system; **Global Monthly reports**; **VADEMOS**. Vaccine Demand Estimation Model; **VLC**. Virtual Learning Center. Microlearning.

United Nations Sustainable Development Goals (UN-SDGs)

EuFMD's programme has a main focus on

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Food and Agriculture Organization of the United Nations

Rome, Italy

Thinking of the environmental footprint

Together against wasting resources, think twice before printing.

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