Food and Agriculture Organization of the United Nations

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

EuFMD FMD VACCINE PREQUALIFICATION PUBLIC SUMMARY REPORT

Adopted by the Standing Committee for Prequalification of vaccines against FAST diseases (SCPQv)

Name of Foot-and-Mouth Disease Vaccine
BIOAFTOGEN

Manufacturer/Applicant
Biogénesis Bagó S.A.

Prequalification number
PQv22-001

Date adopted by the SCPQv
13/09/2023

Date added to the list of prequalified FMD vaccines (PQv list):
02/11/2023

The Public Summary Report (PSR) is a modified version of the full Evaluation Report (ER) considered by the SCPQv with all information of a commercially confidential nature removed.

Contents

Background and basis for prequalification listing

This public summary report for **BIOAFTOGEN**, manufactured by **Biogénesis Bagó S.A.** has been produced following evaluation of an application for prequalification in line with the 'Administrative Procedure for Applications for Prequalification (PQv) of Foot-and-Mouth Disease Vaccines'. The technical requirements applied are those described in 'Technical Guidance for Application for Prequalification of Foot-and-Mouth Disease Vaccines and Content of the Prequalification Evidence File' with the aim of assuring compliance with at least minimum international standards i.e., the standards defined in the general and specific chapters of the latest version of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organization for Animal Health (the' WOAH Terrestrial Manual').

The Public Summary Report (PSR) is a modified version of the full Evaluation Report (ER) considered by the Standing Committee on Prequalification of Vaccines against FAST diseases (SCPQv) with all information of a commercially confidential nature removed. Further information on the role of the SCPQv in the governance and decision process for the prequalification of FMD vaccines can be found at: https://www.fao.org/eufmd/who-we-are/structure/scpqv.

PQv uses a risk-based approach to focus the data requirements on critical elements of FMD vaccine manufacture and testing supported by evidence that the vaccine holds a full marketing authorization (MA)/product registration issued by a National Regulatory Authority (NRA). PQv does not attempt to repeat the evaluation performed by the national regulatory authority(ies) specified in Annex 1 for the purposes of marketing authorization but uses the outcome from the national evaluation procedure(s) as part of the evidence for qualification assurance together with additional information on key properties of the vaccine and its manufacture.

PQv provides an independent and internationally recognized source of information on FAST vaccines that can be used by EuFMD member nations and other parties seeking to control FAST diseases through vaccination. Further details of the PQv scheme can be found at https://www.fao.org/eufmd/global-situation/vaccine-prequalification/key-principles/ or by contacting EuFMD at EuFMD-PQv@fao.org.

Introduction

On **15 April 2023**, the applicant **Biogénesis Bagó S.A.** submitted an application for prequalification for BIOAFTOGEN.

The Prequalification Evidence File (PEF) was submitted in line with the requirements of the 'Technical Guidance for Application for Prequalification of Foot-and-Mouth Disease Vaccines and Content of the Prequalification Evidence File'.

The Standing Committee for Prequalification of FAST vaccines (SCPQv) adopted the vaccine for PQv Listing at its meeting on **13 Sep 2023**.

The vaccine is indicated for **bovine, buffaloes, swine, sheep and goats** against **FMD serotypes O & A.**

The route of administration is **intramuscular (all target species)** or **subcutaneous (bovine, buffaloes, sheep and goats). It is recommended that sheep and goats should preferably be administered BIOAFTOGEN by the intramuscular route.**

The vaccine is an **oil emulsion vaccine adjuvanted with mineral oil and saponin.**

The primary vaccination schedule is **one dose**.

A booster dose is recommended **six months after the first vaccination and twelve months after subsequent doses in all species.**
The vaccine is manufactured by **Biogénesis Bagó S.A. in conformity** to the principles of Good Manufacturing Practice (GMP) as certified by the national regulatory authority for GMP **SENASA [Servicio Nacional de Sanidad y Calidad Agroalimentaria, Argentina].**

The manufacturing site meets the relevant standards of biosafety and biosecurity preventing release of pathogens from sites of manufacture into the environment as certified by the national regulatory authority for biosafety/biosecurity **SENASA [Servicio Nacional de Sanidad y Calidad Agroalimentaria, Argentina].**

Antigen production, QC testing, formulation, filling and packaging take place at:

Address of manufacturing site(s):
Biogénesis Bagó S.A.
Ruta Panamericana km 38,5
Garín, Province of Buenos Aires
B1619IEA
Argentina

Annex 1. Summary of evidence provided to support PQv Listing for BIOAFTOGEN

Definitions

Qualification Assurance	Prequalification of vaccines by EuFMD is based on the principle of 'Qualification Assurance'. Qualification of vaccines is performed by national competent authorities through granting a national marketing authorization (also termed product license or registration in some areas) based on a comprehensive evaluation of evidence demonstrating the pharmaceutical quality, safety and efficacy of the product in line with respective national legislation. Only vaccines for which a national marketing authorization has been issued by at least one national competent authority are eligible for PQv. PQv does not attempt to repeat the evaluation carried out by NRA but relies on a risk-based evaluation of evidence provided by the applicant in the prequalification evidence file (PEF) to demonstrate that the vaccine meets at least the minimum standards in the WOAH Terrestrial Manual with respect to the key properties of the vaccine that are essential for its safe and effective use. The outcome of prequalification is an assessment of the level of assurance that can be placed on the qualification that exists for the vaccine. The level of assurance is rated from 'Assurance', through 'Partial Assurance' to 'Insufficient evidence' to recognize that the level of assurance depends on the amount and quality of data provided. In the case of vaccines rated 'Partial Assurance' or 'Insufficient Evidence', the outcome of PQv does not call into question the evaluation performed by a national competent authority in qualifying the vaccine but only reflects that data has not been provided to EuFMD to demonstrate compliance with the minimum standards of the WOAH Manual. The PQv Technical Guidelines clarifies the interpretation of the standards defined in the WOAH Manual that will be applied by the Standing Committee on Prequalification of Vaccines in order to provide certainty to applicants in situations where the Manual is open to interpretation.
Assurance	Prequalification evidence provided assurance that the product meets at least the minimum international standards of the WOAH Terrestrial Manual as further elaborated in the PQv Technical Guideline.
Partial Assurance	Some prequalification evidence was provided to assure that the product meets at least the minimum international standards of the WOAH Terrestrial manual, but the evidence was not sufficient to provide full assurance as elaborated in the PQv

	Technical Guideline. An explanation of the basis for the assignment of this category will be included in the summary of evidence.
Insufficient evidence	Insufficient prequalification evidence was provided to assure that the product meets at least the minimum international standards of WOAH Terrestrial manual as further elaborated in the PQv Technical Guideline. An explanation of the basis for the assignment of this category will be included in the summary of evidence.
N/A	Not applicable.
Additional information	Additional information is provided in this report where evidence is provided to demonstrate that the standards of manufacture and/or testing meet another internationally recognized standard, for example PIC/S or VICH, or that the evidence provided goes beyond the minimum international standards of WOAH Terrestrial manual.

Country/region where Marketing Authorisation/ Product Registration held	Marketing Authorisation/Product Registration Reference number & Date issued	PQv standard
Argentina	SENASA (Servicio Nacional de Sanidad y Calidad Agroalimentaria) 0095/E December 21, 2018	*Assured*
Cambodia	FR02 016-1985/1121 BGC-GDAHP	
Israel	9-308-29-20	
Jordan	*N/A*	
Kuwait	412/2020	
Morocco	AMM N° 2272	
South Korea	403-002	
Thailand	2F 3/66 (B)	
Vietnam	BIB-04	

PEF Heading/ Section		Prequalification evidence to support PQv listing	PQv standard
1.A	Site Master File (SMF) and evidence of GMP.	A valid GMP certificate issued within last three years was provided for the manufacturing site to the standards of WHO. The GMP certificate is valid until 05 April 2025.	*Assured*
	NRA for GMP.	SENASA (Servicio Nacional de Sanidad y Calidad Agroalimentaria), Argentina.	
1.A.1	Biosafety & Biosecurity.	Inspections are conducted by the national regulatory agency to ensure appropriate standards of biosafety & biosecurity at the site of manufacture. A certificate was granted at the request of the Company and issued on the day 26 October 2022.	*Assured*
	NRA for Biosafety & Biosecurity.	SENASA (Servicio Nacional de Sanidad y Calidad Agroalimentaria), Argentina.	
1.B	Summary Product Characteristics (SPC).	A Summary Product Characteristics (SPC) was provided. Label claims are supported by safety and efficacy studies that comply with the WOAH standards for FMD.	*Assured*
1.C	Labelling and package insert.	Labels for 25 and 60 doses and package insert were provided. Information on product label includes the following sections: target species, efficacy claims, dosage, composition, culture system, potency, storage and warning for administration to target species. Label claims are supported by safety and efficacy studies that comply with the WOAH standards for FMD.	*Assured*

1.D.	Lot summary protocol.	A batch protocol of a commercial batch of vaccine released for use in the market in 2022 and presenting production information, in process-controls and the final batch testing is provided.	*Assured*
Chapter 2	Manufacture & Control		
2.A	Composition.	A table of the qualitative and quantitative composition of the vaccine with details of the antigen content, adjuvants, excipients, and preservative, expressed per dose is provided. One dose of 2 mL of Bioaftogen contains three inactivated strains of FMD virus: O1 Campos strain, A24 Cruzeiro strain and A2001 Argentina strain. The vaccine contains saponin and mineral oil as adjuvants and gentamicin sulfate as a preservative.	*Assured*
2.B	Method of Manufacture		
2.B.1	Description of manufacturing process.	A flow chart indicating the steps of manufacture from the Master Seed Virus (MSV) through to the finished product including the in process (IP) and final product (FP) Quality Control tests is provided. The method of manufacture including the inactivation procedure using a two-vessel system is compliant with the requirements for FMDV vaccines described in chapter 3.1.8 WOAH Terrestrial Manual 2021. Binary ethyleneimine (BEI) is used as the inactivant in a two-step process. Chloroform is added after the first BEI addition to promote the precipitation of proteins and cell residues present	*Assured*

		in the culture. After transfer to a second vessel, BEI is added to a target concentration. Every batch is monitored during the inactivation process. At the end of inactivation step, the residual binary ethyleneimine (BEI) is not neutralized but is removed during the downstream ultrafiltration and diafiltration processes with the BEI concentration falling below the quantification limit of the method of detection. Chloroform is partially removed by centrifugation. The concentration is not exceeding 1 percent w/v and total dose not exceeding 20 mg per animal. Test results for three consecutive batches as approved for routine release are provided.	
2.B.1.a	Validation of the inactivation process.	The validation of the inactivation process (inactivation kinetics, inactivation method) and the validation of the test to control the absence of residual live virus are provided. The cultured FMD virus is clarified by an appropriate method and the viral harvest inactivated by the addition of binary ethyleneimine (BEI). After adding the inactivant, the batch/lot of virus is transferred to second sterile vessel where inactivation is completed. The inactivation kinetics is validated for the time period for chemical treatment and temperature at industrial scale with the manufacturing equipment used for routine production. The company did not test all FMDV strains but used the O1 Campos	*Assured*

		strain in the inactivation kinetics studies because it is the strain that on average yields viral suspensions with the highest titers and antigenic mass and therefore is considered the worst-case scenario. Furthermore, every batch of BIOAFTOGEN manufactured is monitored for complete inactivation. The inactivation procedure was shown to be satisfactory with a decrease in virus titer, when plotted logarithmically, that was linear, and extrapolation indicated that there is less than 1 infectious virus unit per 10,000 L of liquid preparation at the end of inactivation. During the production of each manufactured batch, an inactivation test is conducted to confirm the absence of any residual live virus. The strain Argentina A2001 was used to validate the inactivation test because it shows the lowest infectivity and therefore can be considered as the worst case for this validation. After inactivation, residual BEI in the harvest is not neutralized but the downstream process has been validated to demonstrate removal of the inactivant.	
2.B.2	Detailed flowcharts.	A detailed flowchart of the production steps for BIOAFTOGEN was provided from the Master Seeds to filling and labelling of the finished product. The flowchart included the In Process and Final Product quality control tests.	

2.C	Production and Control of Starting Materials		
2.C.1	Starting materials of biological origin		
2.C.1.1	Virus Seed.	For each virus strain that is included in the vaccine, the source of the isolate has been recorded including details of the country of origin, species, and date of isolation, type of material from which virus was isolated. The in vitro passage history of each vaccine strain has been recorded, including details of the ingredients used and any adaptation to growth on a cell line. Details of the preparation and passage of the Master Seed Virus (MSV) and storage conditions are provided. Tests results for the MSV in accordance with 9 CFR 113.55 (identity, titration, absence of bacteria and fungi [sterility test], absence of mycoplasmas and absence of extraneous agents) were provided. The absence of extraneous agents is controlled by culture on different cell lines followed by detection of cytopathic effects and hemadsorption. Some bovine viruses are also controlled by specific detection methods. With regard to managing the risk of transmissible spongiform encephalopathies (TSEs), only bovine starting materials sourced from countries considered negligible bovine spongiform	Assured

		encephalopathy (BSE) risk countries are used during vaccine production. For each vaccine strain, the genotyping of the VP1 region of the viral capsid has been undertaken. The working seed virus is tested for antigenic identity and purity, FMDV infectivity titre and sterility. The controls performed are compliant with the standards for FMDV vaccines described in chapter 3.1.8 WOAH Terrestrial Manual 2023.	
2.C.1.2	Cell seed.	The Master cell bank is controlled for identity, karyology, sterility test, absence of mycoplasma by PCR and by culture on Vero cells and absence of extraneous agents.	Additional information
2.D	In-Process Controls		
2.D	In-Process controls.	***Inactivation kinetics.*** The inactivation kinetics is monitored during the inactivation step and is compliant with chapter 3.1.8 WOAH Terrestrial Manual. The decrease in virus titre, plotted logarithmically, is linear and extrapolation indicates that there is less than 1 infectious virus unit per 10,000 L of liquid preparation at the end of inactivation. **Inactivation control (innocuity test/absence of residual live virus).** The inactivation control is performed at different steps	Assured

		(after viral inactivation, concentration/purification step, on aqueous phase suspension). The Inactivation test method using virus titre is sensitive and reproducible. An antigen sample representing at least 200 doses of vaccine is used for testing for freedom of infectious virus by inoculation of sensitive cell culture monolayers. ***Residues of inactivating agents.*** Not performed as an in-process test as the BEI inactivant is eliminated by a validated process during production. ***FMDV antigen identity and purity test*** Identity and purity are controlled by ELISA after viral inactivation and antigen concentration steps. ***FMDV antigen mass (146S) content*** The 146S FMDV antigen content of each batch of bulk inactivated antigen is determined by size-exclusion-high-performance liquid chromatography (SEC-HPLC) using a validated method. The specifications set for release for each vaccine strain ensures that a batch of final vaccine produced according to the authorised manufacturing process contains at least the minimum amount antigen per dose at the end of shelf life that was used to establish the efficacy of the vaccine.	Assured Assured Assured Additional information

2.E	Controls on Finished Product		
2.E.1	General characteristics of the finished product.	A list of all tests performed, and the release specifications were provided.	Assured
2.E.2	Identification of active substance(s).	A description of the final product identity test performed on each batch of manufactured vaccine is provided. It is performed by ELISA using FMDV strain specific monoclonal antibodies. Validation reports for the identity of each vaccine strain were provided. Presence of the relevant FMD vaccine strains in the bulk or final filled vaccine, and evidence no other serotype could be present in the vaccine is demonstrated.	Assured
2.E.3	Batch Potency.	A description of the final product batch potency test and validation reports for the potency test that established the specifications for release for each vaccine strain were provided. At least one PGP (protection against generalized foot infection) challenge test per FMDV vaccine strain was used to establish efficacy in cattle and demonstrate a percentage of protection of at least 93.8%, corresponding to ≥ 6 PD_{50}/dose. In addition, a PD_{50} test for all vaccine strain of a standard batch of BIOAFTOGEN was performed in pigs. The PD_{50} values for O1 Campos, A24 Cruzeiro and Argentina A2001 were above 6 PD_{50}/dose.	Assured
2.E.4	Identification and assay of adjuvants	No specific tests to identify and quantify the mineral oil and saponin adjuvants are performed but the physicochemical tests	Additional information

		performed on the finished product confirm the presence of adjuvants in the vaccine.	
2.E.6	Safety Tests.	Routine batch safety tests are not conducted by the manufacturer in compliance with the standards of the WOAH Terrestrial manual. Batch release-safety official controls in cattle are performed by some authorities in South America. Local and systemic post-vaccination safety studies are evaluated by administering to cattle a dose of 2 mL by the intramuscular or subcutaneous route. More than 800 million doses were satisfactorily released between 2012 and 2022. Commercial batches destined for Southeast Asia are also subjected to official control and tested in pigs after intramuscular vaccination with 2 mL dose. More than 109 million doses were satisfactorily released between 2016 and 2021.	Additional information
2.E7	Sterility test	Performed on each batch in accordance with chapter 2.6.1. of the Ph. Eur. “sterility”	Additional information
2.E.8	Purity test	During the manufacturing process, purification steps are included to remove foot-and-mouth disease viral NSPs and other impurities. Non reactivity against NSP has been assessed during the stability studies according to Chapter 3.1.8. WOAH Terrestrial Manual	Assured.

		2021 in cattle vaccinated once with satisfactory results. There is not routinely control freedom from NSP for batch release due to assured consistency of production. Tests are performed by SENASA in Argentina in cattle vaccinated once for lot release purposes of vaccine batches produced for local use. All serials systematically pass the tests showing no reactivity for NSP.	
2.E.9	inactivation test	The virus inactivation test is performed on each batch released for use in the market by subcultures on sensitive cells. The test is validated and the limit of detection was established.	Assured.
2.F	Batch consistency		
2.F	Batch consistency – Process validation.	The batch record of three consecutive batches of vaccine produced in 2022 were provided. The different steps of production, the in-process controls and the controls performed on the finished product are detailed. The results are within the specifications and demonstrate the consistency of the production.	Assured
2.G	Stability		
2.G	Stability.	Stability studies of 3 consecutive batches tested for 25 and 60 dose container every 3 months over the claimed shelf life were provided and support a shelf life of 24 months. The stability study demonstrates that the results of the vaccine remain within the specifications for physicochemical, microbial and immunogenic parameters during 24 months of storage at 2-8°C.	Assured

Safety & Efficacy data requirements for the PEF

PEF Heading/ Section		Prequalification evidence to support PQv listing	PQv standards
Chapter 3	Safety & efficacy section – Use in target species		
3.B	Safety Requirements		
3.B.1	Laboratory studies.	A summary of the laboratory safety studies are provided. Laboratory safety studies have been performed in cattle, pigs, sheep and goats after intramuscular vaccination and in cattle after subcutaneous vaccination. The studies are compliant with standards of the WOAH Terrestrial Manual. The safety warnings on the label reflect the reactions observed in the safety studies: "A mild swelling at the injection site may occur, which disappears in a short period of time with no treatment." Safety data are available to demonstrate the absence of impact of vaccination on pregnancy and lactation. Safety and efficacy data are available, which demonstrate that this vaccine can be administered on the same day but not mixed with BIO-CARBOGEN 2 and bovine RABIAPARESIANTE vaccines. The vaccines should be given at different sites.	Assured
3.B.2	Field Studies	Evidence was provided for field trials conducted to demonstrate the safety of BIOAFTOGEN under field conditions.	Additional information

		Among 60 vaccinated calves 4-5 months of age, only a few animals showed local reactions that disappeared over time, confirming the safety profile of BIOAFTOGEN.	
3.B.3	User safety	Users of the vaccine are informed of the safety risk associated with vaccines adjuvanted with mineral oil, with the information described in the package insert accompanying the product.	Additional information
3.B.4	Consumer Safety	Withdrawal period for meat and milk is zero days for BIOAFTOGEN administered to food producing species.	Additional information
3.C	Efficacy requirements (including DIVA claims)		
3.C.1	Laboratory studies.	Efficacy studies were conducted in cattle, sheep and swine with batches of BIOAFTOGEN produced according to the authorized manufacturing process and containing the minimum amount of antigen per dose. The efficacy studies provided can be summarized as follows: **Cattle**: vaccination with 2 mL by IM route **Efficacy of O1 Campos strain**: Onset of immunity of 7 days demonstrated by challenge. **Efficacy of A24 Cruzeiro strain**: Onset of immunity of 7 days demonstrated by challenge with a monovalent vaccine. **Efficacy of Argentina A2001**: Onset of immunity of 7 days demonstrated by challenge. Duration of immunity of 6 months demonstrated by serology after one administration of vaccine. Duration of immunity of 12 months demonstrated by serology after a booster administration 6 months after the first vaccination.	Assured

		Pigs: vaccination with 2 mL by IM route **Efficacy of O1 Campos, A24 Cruzeiro and Argentina A2001 strains**: Onset of immunity of 28 days demonstrated by challenge. Duration of immunity of 6 months demonstrated by serology. **Sheep**: vaccination with 1 mL by IM route Onset of immunity of 10 days demonstrated by serology. Duration of immunity of 6 months demonstrated by serology. For all FMDV vaccine strains tested in the cattle, pigs and sheep, no interference with maternally derived antibodies was detected based on serological studies. Therefore, the minimum age recommended for vaccination is supported: Bovine from 8-12 weeks, Pigs from 4-8 weeks, Sheep from 4-12 weeks old. Duration of immunity has been established using serology. According to chapter 3.1.8 Terrestrial Manual, the efficacy can be estimated by indirect tests provided there is a correlation determined between antibody level and protection against challenge. For cattle, sheep and pigs, the threshold for protective antibody titers was defined on the basis of a publication made by SENASA (Maradei et al. Vaccine 26 (2008) 6577–6586). ***Additional Information***	

		Vaccine matching was tested in cattle by a Virus Neutralization test performed by the Pirbright Institute, designated as the World Reference Laboratory for Foot-and-Mouth Disease by the Food and Agriculture Organization (FAO) of the United Nations and as a reference laboratory for FMD by the World Organisation for Animal Health (WOAH) **Serotype O**: O/Ind2001, O/Panasia2, and EA-3 and O/Mya-98 lineages show titers equal to or greater than 1.5 log_{10} (range 1.82 - 2.88 log_{10}). **Serotype A**: A/ASIA/Iran-05, A/AFRICA, A/ASIA/Sea-97 and A/ASIA/G-VII lineages show titers above 1.5 log_{10} (range 1.6 - 2.29 log_{10}). **In pigs, cross protection against South Korean field isolates** was shown by challenge. The level of protection demonstrated: 9.96 PD_{50} for O/SKR/2014/Mya-980, 9 PD_{50} for A/SKR/4/2018, 12 PD_{50} for A/SKR/2/2010, 16 PD_{50} for A/SKR/3/2017, 16 PD_{50} for O/SKR/1/2019.	Additional information
3.C.2	Field studies.	A field trial was performed on three farms in Argentina. In each farm, seronegative calves 4-5 months of age were divided into vaccinated and control groups and monitored. Blood samples were collected from the vaccinated and control groups at the day of vaccination, 28- and 56-days post vaccination. The sera were tested by Liquid Phase Blocking ELISA (LPBE) and Virus Neutralisation Test (VNT).	Additional information

		The antibody titers against the three vaccine strains demonstrated high levels of protection.	
3.D	Assessment reports.		
3.E.2	Post-marketing pharmacovigilance.	Periodic safety and efficacy update report (PSUR) is provided for the three years 2020-2022. The reports are consistent with the potential adverse reactions described in the product information.	Assured

Production & Distribution data requirements for the PEF

Chapter 4	Production and distribution data	Prequalification evidence to support PQV listing	PQv standards
4.1	Provide information on the quantity of finished product distributed domestically and exported in the previous 3 years.	Information on batches of FMD vaccine suppled as finished product both domestically and internationally is provided for the years 2020-2022.	Assured
4.2	Provide a list of countries where the product is licensed (marketing authorization) and supplied.	The vaccine is licensed in different countries: Argentina, Korea, Vietnam, Kuwait, Jordan, Cambodia, Morocco, Israel and Thailand.	Assured

Update on regulatory actions data requirements for the PEF

Chapter 5	Update on regulatory actions	Prequalification evidence to support PQV listing	PQv standards
5.1	Provide information on post-authorization regulatory actions.	No refusals, withdrawals or suspensions were carried out within the three-year period, from 2020 to 2022.	Assured
5.2	Provide a list of lots rejected by the NRA, if applicable.	No lots were rejected by the National Regulatory Authority within the three-year period, from 2020 to 2022.	Assured

5.3	Describe restrictions on distribution or recalls, including manufacturer-initiated recalls.	No restrictions on distribution or recalls were carried out within the three-year period, from 2020 to 2022.	Assured
5.4	Name clinical trial suspensions, including manufacturer-initiated suspensions.	No clinical trial suspensions were carried out within the three-year period, from 2020 to 2022.	Assured
5.5	Describe dosage or schedule modifications since the initial marketing authorization/product was granted.	No changes in dosage or schedule have been made since the initial marketing authorization was granted.	Assured
5.6	Provide information on changes in target populations or indications since the initial marketing authorization/product was granted.	No changes in target populations or indications were made since the initial marketing authorization was granted.	Assured
5.7	List the GMP and/or Biosafety/Biosecurity inspections conducted by NRAs within the previous 3 years, including the scope of each inspection.	The list of GMP and Biosafety/Biosecurity inspections conducted by the National Regulatory Authority (Argentina) and foreign authorities is provided.	Assured
5.8	List inspections conducted by foreign GMP and/or Biosafety/Biosecurity authorities within the previous 3 years, including the scope of each inspection.	The list of GMP and Biosafety/Biosecurity inspections conducted by foreign authorities is provided.	Assured

Provision of sera from batch release potency tests data requirements for the PEF

6.	Provision of sera from batch release potency tests	Prequalification evidence to support PQV listing	PQv standards
	Manufacturers with PQv listed FMD vaccines should commit to provide sera from batch release potency tests to independent laboratories once the terms for supply and testing have been agreed with stakeholders and published on the PQv website.	The manufacturer has provided a commitment to supply sera from batch potency release tests to independent laboratories.	Assured