Pre-qualification of vaccines against FAST (Foot-and-Mouth and similar transboundary) diseases

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

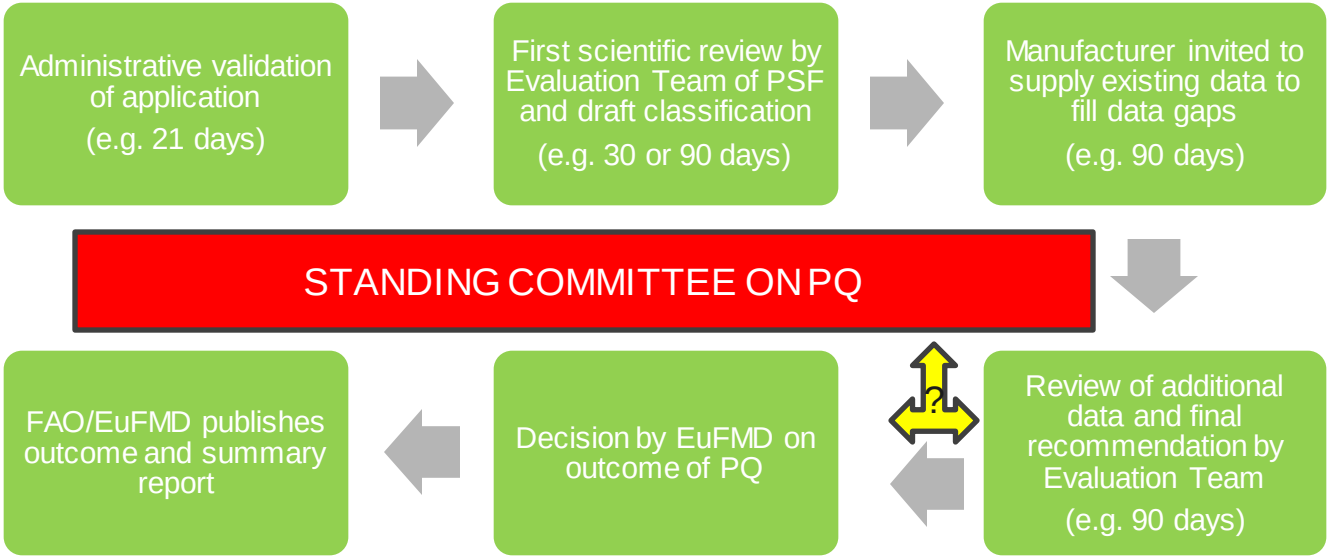
Objectives of pre-qualification

- Ensure that vaccines supplied to EUFMD
  - meet minimal internationally accepted criteria for quality, safety and efficacy
  - can be produced and controlled consistently in manufacturing facilities that operate according to the principles of good manufacturing practice
- Reduce the timescale required for procurement and reduce the risks of procuring vaccines of inadequate quality
- Provide a standardised, transparent, rapid & objective evaluation procedure to suppliers of FAST vaccines to EuFMD
- Provide an independent and internationally recognised source of information for risk managers and other potential purchasers on vaccines against FAST diseases that comply with the requirements for PQ.
- Form one element of a future system for assured emergency supply (AESOP) of FMD vaccines, thereby contributing to vaccine security by promoting predictability for suppliers and assisting vaccine production planning

Approach to pre-qualification

- PQ is a peer review process by independent experts of information, including existing marketing authorisations/licences/registrations, made available by applicants.
- The minimum standards that apply with be those in the relevant general and specific chapters of the International Organisation for Animal Health (OIE) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals ('OIE standards')
- PQ will initially be a documentary review of evidence; the possibility to expand to independent verification will be explored at a later stage of development (e.g. GMP inspection, testing)
- PQ is a separate and distinct activity from procurement. In future, it may be possible to issue restricted tenders, limiting procedures to procurement of that vaccines that are pre-qualified

Outline of key steps in PQ procedure



Beneficiaries of PQ

- EUFMD/FAO by
  - reducing the time and work required to evaluate tenders for supply of FMD vaccines
  - improving the assurance of quality of vaccines procured
- Risk managers by
  - having access to a list of vaccines for which the quality and compliance with international standards has been assured through evaluation by an independent group of experts and overseen by a panel involving the major international organisations responsible for animal health
- Animal health industry by
  - having access to an internationally recognised system of peer review
  - potentially reducing the amount of information and work required during tender procedures
  - helping to sustain viability and predictability of the market for their manufacturers
- Global animal health by
  - improving vaccine security through more ready access to high quality vaccines, thereby

Thank you for your attention

Funded by the European Union

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

FAST
Foot-and-mouth And Similar Transboundary animal diseases

Next steps