



EUFMD

EUROPEAN COMMISSION FOR THE CONTROL OF FOOT-AND-MOUTH DISEASE



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III
3 PILLARS of
the EuFMD



Global FMD vaccine security: progress and directions since the EUFMD Open Session 2018

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With Noel Joseph² and Corissa Miller

²VMD, New Haw, United Kingdom



Why can't livestock owners access FMD vaccines when they need them?

FMD SHOTS
NOW AVAILABLE

Walk in anytime

No appointment necessary

A blue rectangular sign with white text. The top line reads "FMD SHOTS" in large, bold, sans-serif font. The second line reads "NOW AVAILABLE" in a slightly smaller, bold, sans-serif font. A thin white horizontal line separates this from the text below. The third line reads "Walk in anytime" in a bold, sans-serif font. A second thin white horizontal line separates this from the final line, which reads "No appointment necessary" in a bold, sans-serif font.



Money is often NOT the problem. There are other barriers



And
FMD
VACCINES

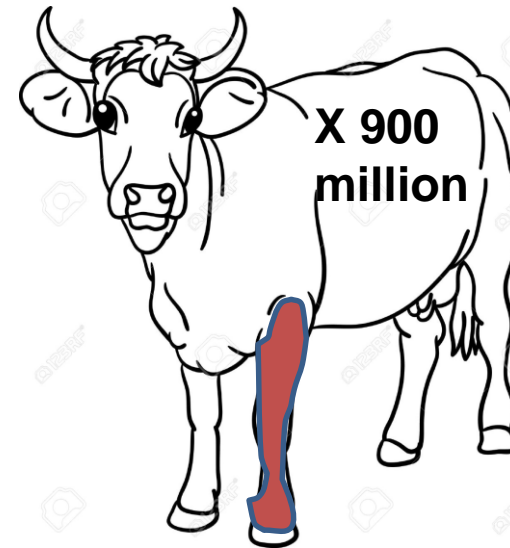


What is the extent of vaccination coverage in large ruminants in non-free countries?

~ 13% at best
(much less in SS Africa)

Assuming:

- 900 million LR (excludes China)
- Bi-annual vaccination (=1.8 billion doses needed)
- All vaccine is used for cattle/LR (unlikely – some pigs/SR)
- Based on C Miller, OS18 paper



Currently
–not even one leg to stand upon = insecurity



FMD CONTEXT (2019)

Non –free (*Endemic*): Africa, Asia, Mid-East

Free countries (70), countries with free zones (19)

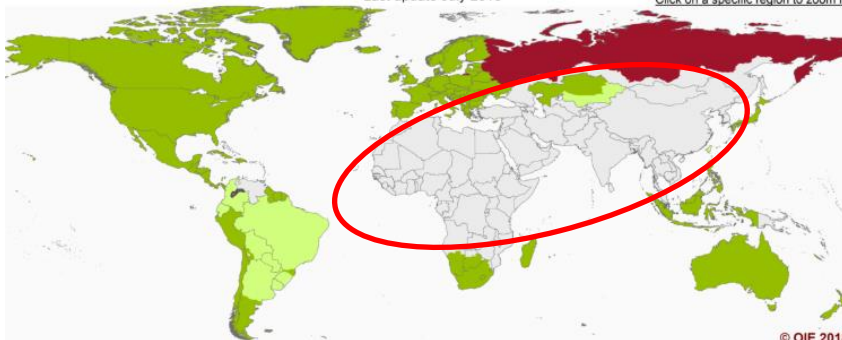
Global large ruminants 1,782 MILLION:

~ **One billion of these are in FMD endemic countries**
[Hundreds of millions of owners]

OIE Members' official FMD status map

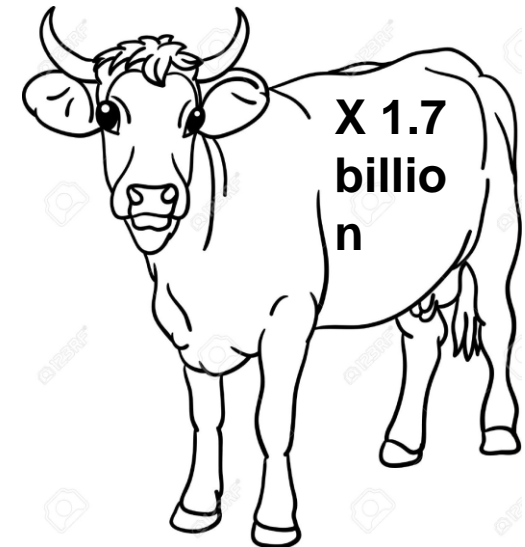
Last update July 2018

Click on a specific region to zoom in



© OIE 2018

- Members and zones recognised as free from FMD without vaccination
- Members and zones recognised as free from FMD with vaccination
- Containment zone within a FMD free zone
- Suspension of FMD free status
- Countries and zones without an OIE official status for FMD



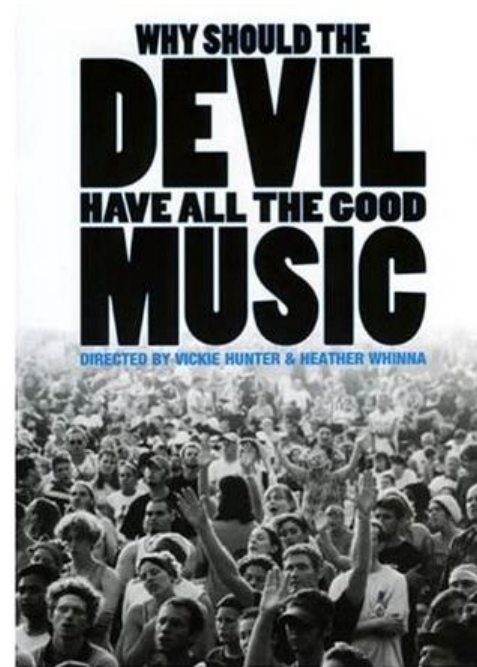


VACCINE Security is not equal

Why should the
**FMD FREE
COUNTRIES**
have the good
VACCINE?

CAN VACCINE BANKS BECOME
PART OF THE GLOBAL SOLUTION?

AESOP

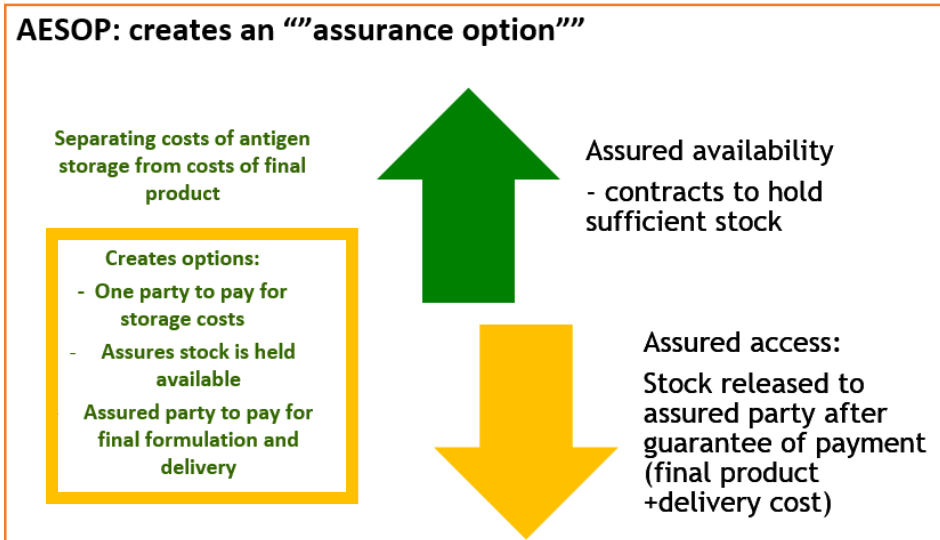




Assured Emergency Supply Options (AESOP)

- addressing need to increase reserves for FMD emergencies

EuFMD Feasibility study -2017/18



But: Needs first a prequalification step to select quality suppliers



GLOBAL VACCINE SECURITY -



OS18



Vaccine security –the concept

"**Food security** exists when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food which meets their dietary needs and food preferences for an active and healthy life. Household food security is the application of this concept to the family level, with individuals within households as the focus of concern (FAO, 2003) "

Vaccine Security

.....people, at all times have physical, social and economic access to sufficient, safe and effective vaccines to meet their needs and of the livestock in their care.....



Vaccine use (2017) in relation to projected trends

Region	2011 ^a		2017 ^b	
	Doses (millions)	%	Doses (millions)	%
China	1600	68.1	1614 ^c	67.8
India	150	6.4	21 ^d	0.9
Rest of Asia	50	2.1	95	4.0
Africa	15	0.6	21	0.9
Middle East	20	0.9	71	3.0
Europe and Turkey	15	0.6	38	1.6
South America	500	21.3	520	21.8
Total	2350	100.0	2380	100.0

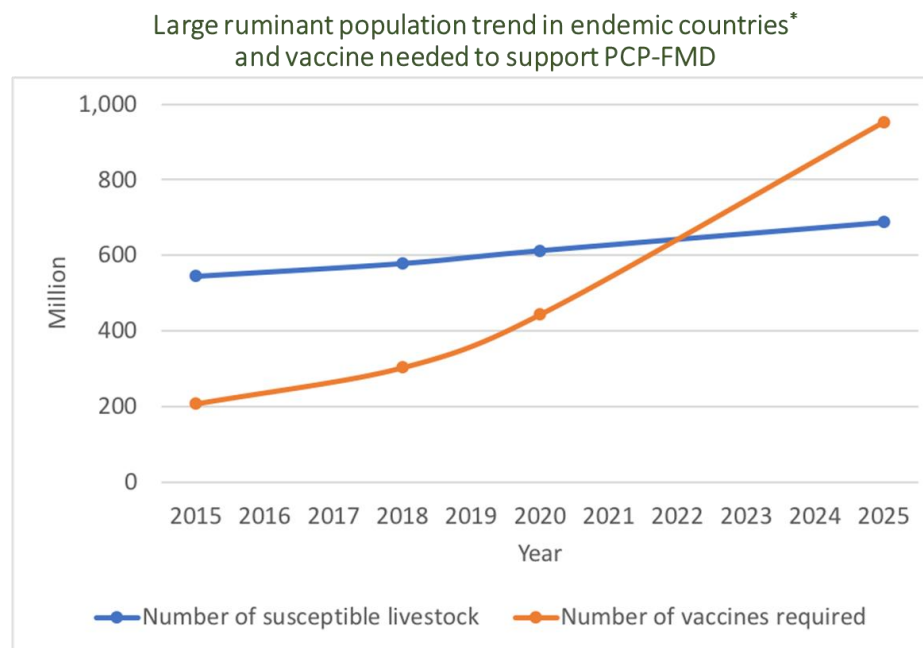
^a Hammond, 2011; Knight-Jones and Rushton, 2013

^b Mean annual use from 2015-2017 unless otherwise stated (OIE WAHIS, 2018)

^c SEACFMD, 2018

^d Reported annual use for 2015 (OIE WAHIS, 2015)

* Work ongoing to validate current estimates



*Excluding China



Vaccine supply challenges

- Inaccessible and/or non-quantified market
 - Lack of sales forecasts
 - Complex supply models: sudden surges
 - Long term and heavy capital investment required
 - Difficulty & costly to produce quality FMD vaccine
 - Constant R&D investment in emerging strains
 - Complex and costly studies for registration
- ➔ Few global manufacturers
- ➔ Shortage of quality FMD vaccine



Since 2012 – global progress *yes*
–but the challenge remains to transform the daily
reality of millions

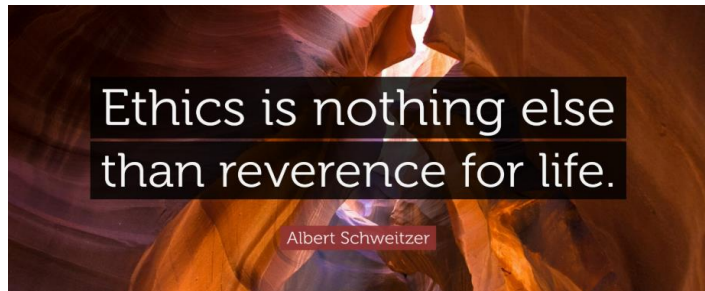
- **Needs**

- a massive upscaling in access to information, services - and vaccine supply
- INNOVATION
- MAJOR private sector investments
- MAJOR public sector policy support for vaccine access
- High level recognition that this is a problem with global impacts affecting multiple, preventable TADS

Vaccine security affects us all!



Why preventing disease matters for welfare, global environment and health



3 additional imperatives for action to make vaccines available

1. Animal disease : the welfare imperative

- Ethics and economics

3. Animal disease and the global environment

3. FMD and AMR – everything is connected



Animal disease : the welfare imperative

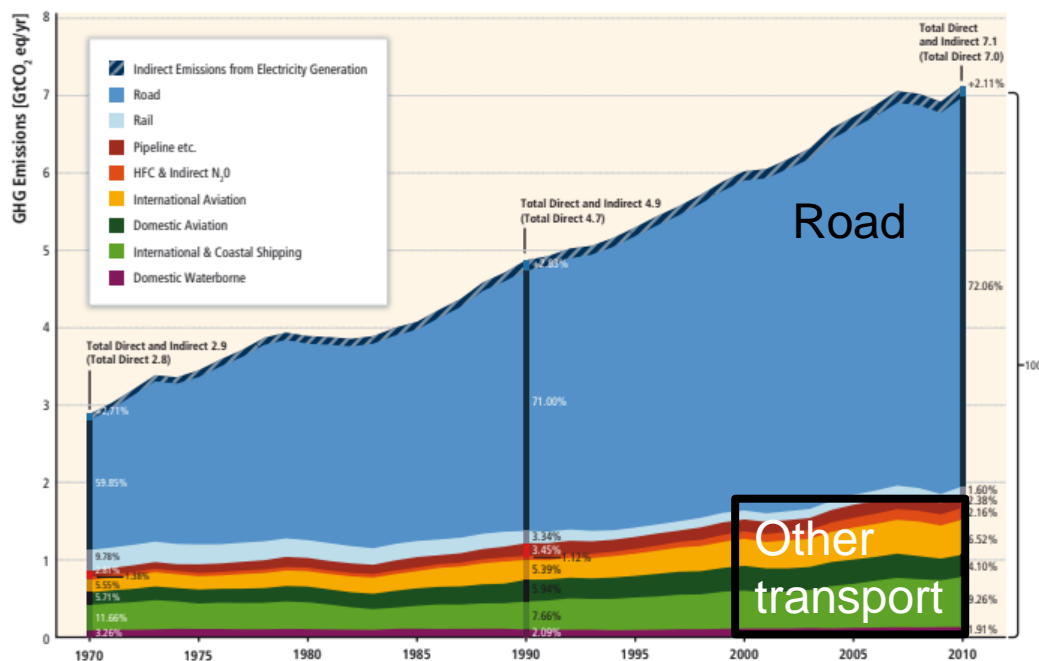
FMD is preventable

- Is it ethical to withhold prevention?
- public policies often constrain vaccine access

Vaccination – its role considering a % of livestock green house gas emission is disease related

Transport

Chapter 8



Livestock:
2.4 GtCO₂

Figure 8.1 | Direct GHG emissions of the transport sector (shown here by transport mode) rose 250% from 2.8 Gt CO₂ eq worldwide in 1970 to 7.0 Gt CO₂ eq in 2010 (IEA, 2012a; JRC/PBL, 2013; see Annex II.8).



FMD and antimicrobial usage – its huge

If we base estimates on 250 million FMD cases per annum

- and 10% of these are treated with AM (Tetracyclines)
- 25 million cases x 12 g OTC/case = 300 tonnes OTC

300 tonnes OTC is greater than the total use of AM by 15 EU countries

(266 tonnes, 15; 7781 tonnes, EU28+SWI)

If 1% are treated: still exceeds total for 6 EU States total AM in livestock

Preventing FMD cases will reduce AM usage. Much more attention needed to this area. Great uncertainty in numbers of cases and AM use; figures simply illustrative for arguments sake





Key Recommendations of OS18

1. Improving vaccine availability
2. Engagement with manufacturers
3. Development of a PPP network to:
 - Create an enabling environment for investment
 - Support R&D for innovative technologies and partnerships
 - Ensuring inclusion of all stakeholders in the value chain
4. Understand the barriers such as registration and legislation
5. Support manufacturers tackling five major challenges: bio-secure facilities; expensive process; constant R&D; registration;
6. Support activities for monitoring of circulating viruses & vaccine matching
7. Pursue right to access effective vaccine for livestock keepers in endemic settings





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GLOBAL VACCINE SECURITY – OUR PARTICIPANTS VIEWS



OS18

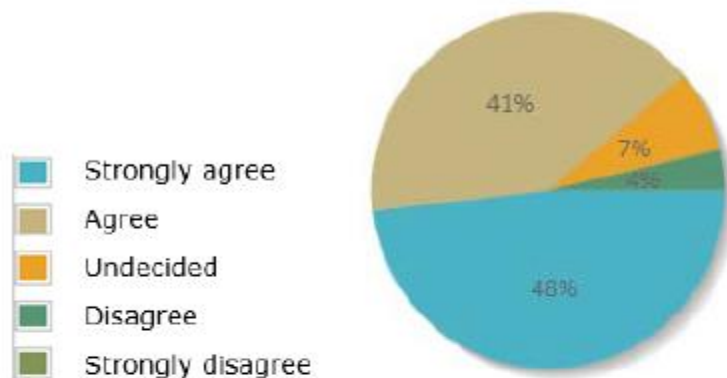
eofmd | **OPEN SESSION** 29-30-31 October 2018 Borgo Egnazia - Puglia, Italy

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

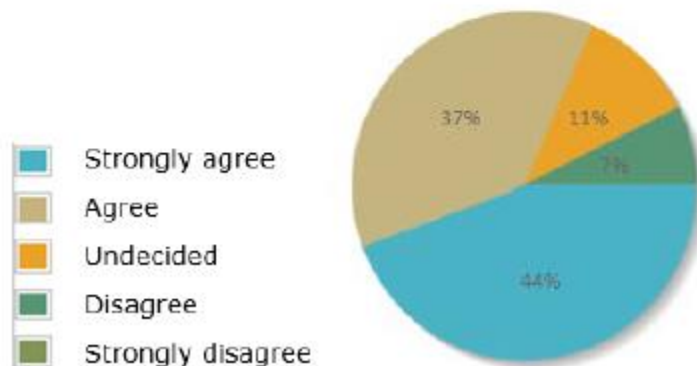


OS18: Overwhelming support for action

Idea 1: Improving vaccine availability needs urgent attention by both the public and private sectors and a new form of partnership is needed to achieve real change in vaccine supply.



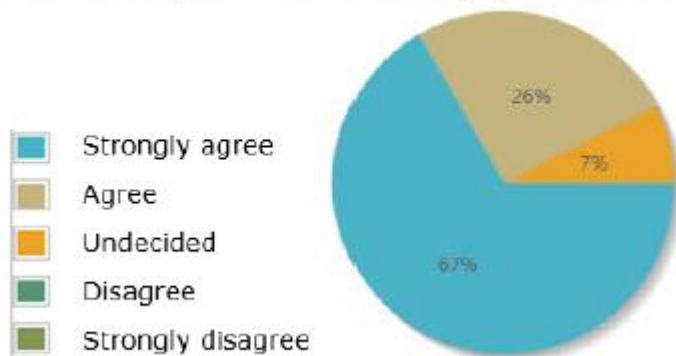
Idea 2: Development of a public-private professional network is needed to increase global security in the supply of effective vaccines.





Almost all believed that barriers to vaccine access must be addressed

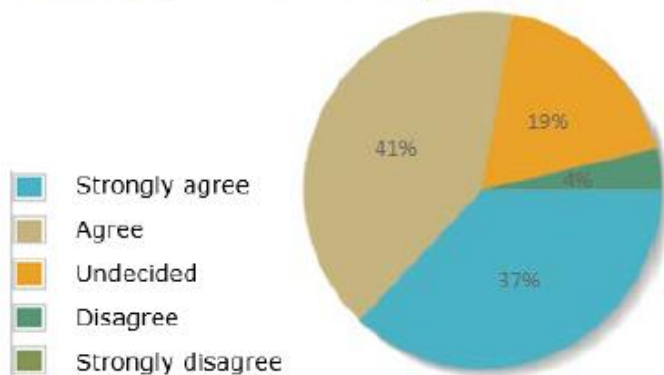
Idea 3: Quality vaccines are not enough, the barriers that prevent their availability must be addressed.



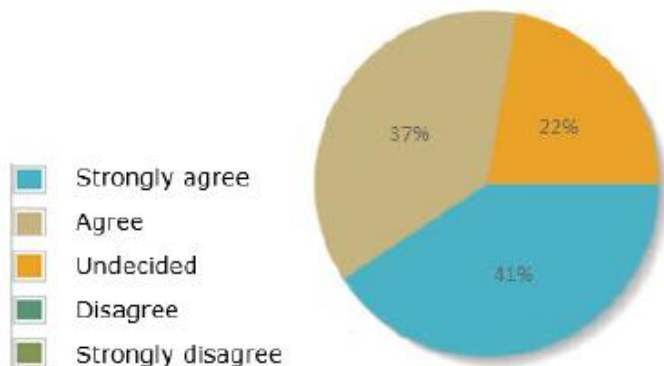


Barriers must be studied, but less support for a “right to access vaccines”

Idea 5: There exists a willingness to pay for vaccine for FMD, but further work is needed to understand the drivers for adoption and barriers to uptake.



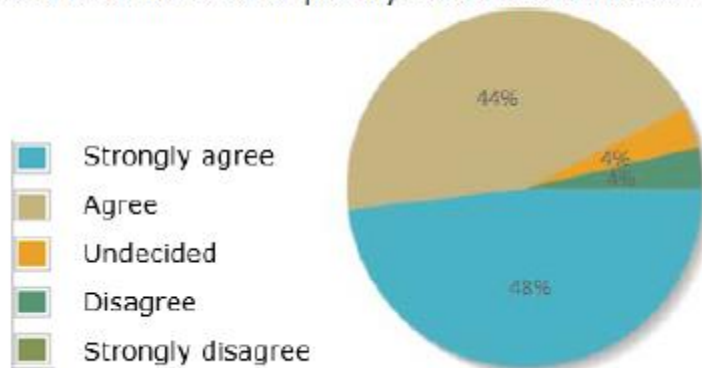
Idea 6: In many endemic settings, livestock keepers should have the right to access effective vaccines to protect their livestock and livelihoods.





Strong support for work to quantify future growth in demand for vaccines (92%)

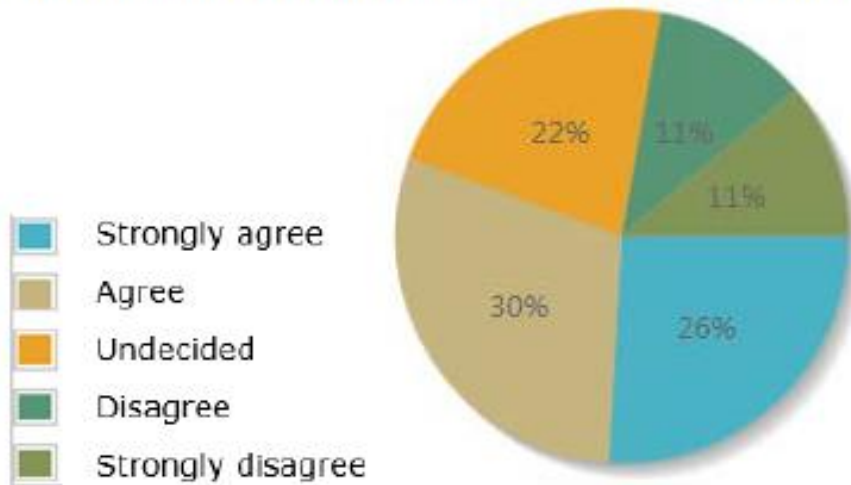
Idea 7: Further work to quantify the unmet demand for vaccines and predict future growth is needed.





Attenuated vaccines: ~50% supported defining a target for safety for use in endemic regions

Idea 10: EuFMD Biorisk Management Committee should examine the question of what level of FMD attenuation would be safe for use as a modified live vaccine in an endemic or free region.





WHAT DID WE DO AFTER?



OS18



Any progress?

1. Improving vaccine availability
 2. Engagement with manufacturers
 3. Development of a PPP network
 4. Understand the barriers such as registration and legislation
 5. Support manufacturers on five major challenges
 6. Support activities for monitoring of circulating viruses & vaccine matching
 7. Pursue access rights - endemic settings
1. New investments and initiatives [GFRA showcase]
 2. PPP network – planned meeting 1/2020, also to address #4,5
 3. Continued funding - global network of FMD reference centres
 4. Access to vaccine – and role of veterinary paraprofessionals – more study needed



Multi-Stakeholder Platform on Vaccine Security

1st PPP –VSP meeting : 23-24th January 2020, Rome

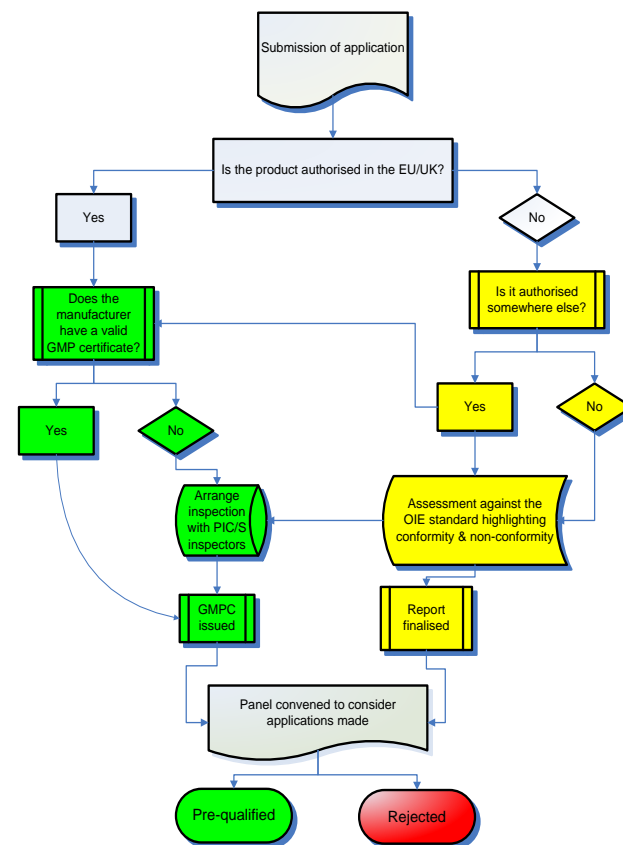
- Public and private stakeholders invited
- Public sector -medicines regulators, emergency managers, key reference centres
- Private sector – focus on vaccine producers
- **to identify priorities for action by the Platform**
- **sharing of new initiatives**

- **Launch of the FMD Vaccine Challenge Initiative (AgResults initiative – managed by GALVmed).**



Consultation on introducing a pre-qualification (PQ) system for FMD vaccines

- to safeguard quality of vaccines procured
- Greater confidence that international standards for FMD vaccines are met
- Enables UN procurement from list of PQ vaccines/producers
- Opens new emergency supply options
- **International Listing as PQ** – will have commercial significance beyond sales to UN agencies?



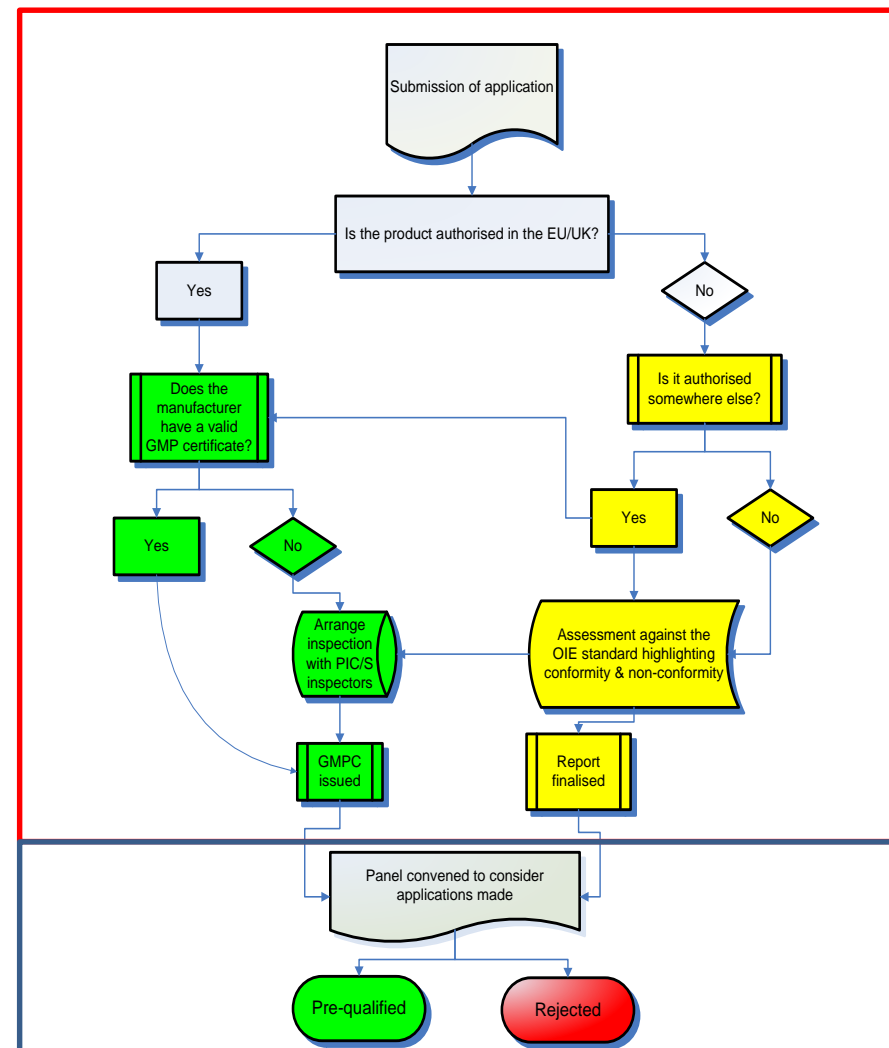


Consultation on FMD vaccine pre-qualification

Guidance paper commissioned – VMD, UK

Key elements:

- Clear process
- Considers evidence from existing authorisations of vaccines
- 1st stage - review of evidence by specialized regulatory assessment agency
- **GMP inspections may be required**
- 2nd stage decision by a Review Panel (FAO-convened) on whether the vaccine can be considered pre-qualified or not



Foot and Mouth Disease (FMD) Vaccine Challenge Project 2020~2028

[to be presented in more detail by Jeremy Salt, GALVmed
@GFRA]



The AgResults initiative is a partnership between:

FMD Vaccine Challenge Project (2020-2028) : Overview

The AgResults FMD Vaccine Challenge Project is a \$17.7 million cost-share mechanism that aims to meet both the technical and market requirements for an FMD vaccine in East Africa.

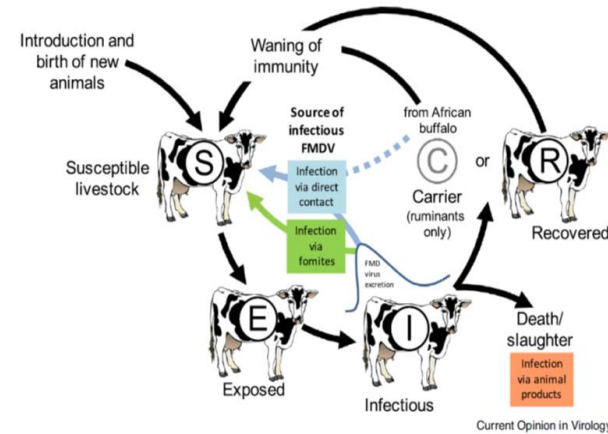
Mechanism Overview

1. The Project will aim to incentivize vaccine manufacturers to develop and produce an improved FMD vaccine tailored to East Africa.
2. It will support government and private sector actors to consistently purchase high volumes of FMD vaccines by **reducing the cost-per-dose**, enabling public and private actors to better combat FMD through higher purchase volumes.
3. The Project will also support the liberalization of the FMD vaccine markets in East Africa by setting aside a minimum volume of vaccines available for purchase by only private sector actors.

Vaccine demand predictions – workplan

(Component 3.4 : 2020-23)

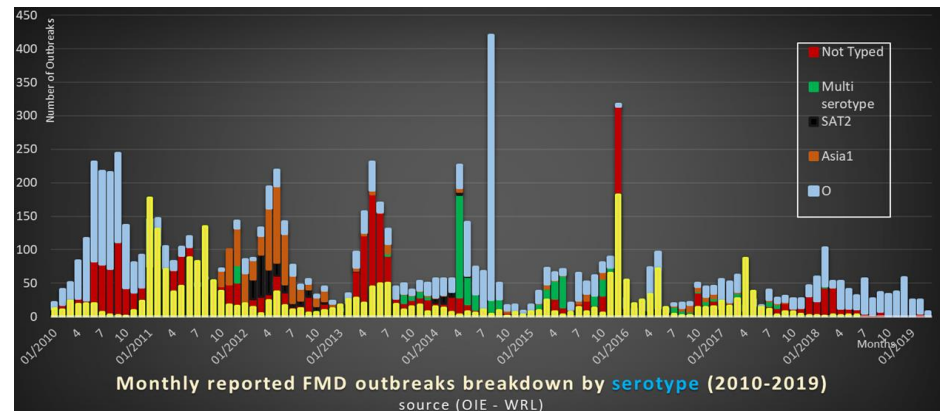
- “Big data” partnerships
- Demographics of animal population and ownership
- Public-private policies
- Control strategies (PCP)



Current Opinion in Virology

FMDV transmission model, Paton et al (2018).

- Many drivers for demand
- Risk - epidemiologic
 - Risk – social risk perceptions
 - Risk -economics & trade strategies
 - Maturity of public –private partnering
 - Political structure (decentralisation)
 - significance of cattle



Monthly reported FMD outbreaks by serotype in the Middle East, North Africa and West Eurasia regions; EuFMD (unpublished), 2019.



Conclusions

1. Since 2012 – global progress on FMD *yes*
–but the challenge remains to transform the daily reality of millions
2. The gap between supply and needs will continue to grow unless significant new production is secured
3. Private sector investment is vital to meet current and future needs
4. New initiatives (AgResults FMD challenge) are extremely significant - potential for increased vaccine security in Africa
5. Need to keep momentum - a public -private platform should assist [platform meeting January 2020]



OS20

Where do you think
the next Open
Session will be held?

Send us an email with
country and city to win
1 free registration

eufmd@fao.org
www.eufmd.info/os20

27th – 30th
October 2020

Save the date!

The largest meeting
on FMD and similar
transboundary
animal diseases

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

