Policy Brief

THE USE OF EXPIRED FMD VACCINE IN LIVESTOCK IN INDONESIA

AUSTRALIA INDONESIA HEALTH SECURITY PARTNERSHIP

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The problem

Substantial stocks of FMD vaccine remain but these are past their expiry date, or shortly will be. There is a proposal to use the remaining FMD stocks and this presents problems of integrity, commitment and sustainability for the FMD control program.

Background

Indonesia experienced its first outbreaks of Foot and Mouth Disease (FMD) for more than 30 years in 2022 ending its status as FMD-free (without vaccination) held since 1990. As there had not been any vaccination for several decades the livestock population was completely susceptible with no immunity to FMD Virus (FMDV). The FMD serotype and lineage was confirmed as O/ME-SA/Ind-2001e.

As soon as the outbreaks were identified, the GoI embarked on a national campaign with large scale FMD vaccine purchases and vaccine delivery to try and control disease spread. Unfortunately, control efforts did not prevent the disease spreading and FMD was declared endemic in 2023.

FMD vaccines were purchased from a number of international manufacturers and held in storage at various locations in Indonesia until required for use. Many millions of vaccine doses were purchased and distributed during 2022-2024, however, several million doses remain unused, and these are now reaching or have passed their recommended expiry date for use.

As the FMD outbreak has now been declared endemic, FMD vaccines can no longer be imported under emergency use procedures and must now be registered in Indonesia before purchase and importation.

The approval process for registering FMD vaccines in the country (for the first time) has proved to be lengthy and complex and is delaying the importation of new batches of vaccine.

The result of this change in policy is that Indonesia will not be able to access new stocks of FMD vaccine before the current stocks of vaccine pass their expiry date. At the same time, several million doses of vaccine are about to reach or have exceeded the expiry dates as set by manufacturers.

There is an obvious need to continue vaccination of cattle to prevent further disease spread while awaiting the delivery of fresh batches of FMD vaccine. To that end, GoI has mandated that expired vaccines be used before any new vaccines are purchased. However, there are a number of risks and practicalities to be considered when deciding to use out of date FMD vaccines, and these are set out below.

Considerations for use of expired FMD vaccines:

The use of expired FMD vaccine is a contentious issue. Many manufacturers suggest that FMD vaccine should be used as soon after production as possible to obtain the most effective protection. The use of expired FMD vaccines is therefore not advised for the following reasons:

1. **Expired Vaccine may no longer have the required FMDV Antigen content necessary for inducing protection**
   - The antigen content of the FMD vaccine begins to deteriorate as soon as the vaccine is formulated and put into bottles for distribution and use. The product does not maintain production antigen levels during storage. Therefore, out of date vaccine may not contain the required level of protective FMDV antigens when taken from prolonged storage for use.
   - Serotype O FMDV vaccines are more unstable than some other serotype FMD vaccines, meaning that there is a good chance the effective antigen content will have significantly decreased over 24 months of storage, even if kept at the required temperature, and will continue to deteriorate post expiry.
   - Antigen integrity has been shown to consistently deteriorate over time in formulated vaccine.
   - Vaccine may not have been stored under the correct conditions (consistent temperature/exposed to light etc) and so antigen may have deteriorated more quickly than documented by manufacturer under ideal conditions.
2. **The manufacturers do not provide any guarantee of efficacy once the expiry date has been passed.**
   - The tests on vaccine longevity are rarely/never carried out on each batch supplied and rely on previous 'grandfather' data to provide shelf-life information. Most vaccine companies suggest a shelf-life of 12 months, with 24 months being the extreme case.
   - Formulated (i.e., in the ready for use bottles) FMD vaccine that has been stored for 24 months is at the very end of its expected/predicted effective life. Biogenesis Bago claim that their vaccine is still effective at 24 months post-production, but there are no data beyond that time point from them and very little to no information from other manufacturers.
3. **There is very little field data reported on use of expired FMD vaccines in the field.**
   - Very little follow up utilising post vaccination monitoring has ever been reported officially, and so efficacy in the field is mostly unknown.
4. **There is no guarantee that the vaccine has been stored under the correct conditions for 24 months.**
   - The cold chain is vital in maintaining FMD vaccine efficacy and fluctuations in storage or transport temperature will adversely affect the vaccines performance.

Potential vaccine failure

If expired FMD vaccine is used, it may not be effective for the following reasons:

- Expired vaccine has no effective antigen content as it has degraded over time.
- Expired vaccine has not been stored under correct conditions and so effective antigen content will have degraded; and/or
- Expired vaccine may be more susceptible to deterioration during transport due to prolonged storage and ineffective cold chain.

If out of date vaccines are used in the field and there are reports of 'vaccine failure' it will be difficult to determine what has caused the failure as all of these factors could have played a role. There also other reasons for vaccine failure and these include:

- Expired vaccine is not administered correctly in the field.
- Cold chain from storage to field is not maintained.
- Vaccinators are not sufficiently trained.
- Cattle being vaccinated are already infected or have a compromised immune system.

Evidence that the vaccine is not effective could be recognised by disease breakthrough in vaccination or new reports of outbreaks in regions where vaccination has been carried out recently.

This apparent failure will be very difficult to follow up and trace if expired vaccine has been used as there will be too many other variables to allow effective troubleshooting of the reason for vaccine failure.
Using poor or ineffective vaccines will increase the risk of the spread of FMD and other diseases as contact with vaccinators and others and animal handling increases the risk of disease spread without the benefit of effective vaccination being provided.

Concerns following reports of vaccine failure:

- Vaccine failure may reduce livestock keepers' confidence in the vaccine, resulting in a reluctance to vaccinate in the future.
- Vaccine failure may reflect badly on the government FMD control program more broadly.
- Vaccine failure may make farmers reluctant to vaccinate their animals against other diseases.

Recommendation on the way forward if use of expired vaccines is unavoidable

Despite all of the above risks, there is an opportunity to use expired FMD vaccine in strictly controlled situations. This use could be in feedlots or on dairy farms which maintain a strict biosecurity environment and are able to carry out careful monitoring of the health of the cattle and serological testing to assess the induced FMDV antibody responses to FMD vaccination in those cattle.

If the importers can guarantee that the FMD vaccine has continually been stored and transported under the correct cold storage conditions of between 2-8° C with no risk of freezing or warming below or above these levels, then it would be possible to use the remaining vaccine under caution, and but the following provisos are made:

1) The vaccine used should be regarded as potentially below the usual expected quality and standard.

2) The vaccine should be closely inspected for colour and consistency to make sure it is still an emulsion.

3) Batches of vaccine should be independently tested in cattle for FMDV antibody production before widespread use, as follows:
   - Samples of each batch should be used to vaccinate a group of 5 FMDV free test cattle (isolated from rest of herd). This requires excellent levels of biosecurity to be maintained throughout the process.
   - The FMDV antibody levels induced should be measured by Virus Neutralisation Test (VNT) and Non-Structural Protein (NSP) ELISA on sera collected at day 0 and day 21 post vaccination.
   - The day 0 and day 21 sera should be sent to a competent FMD reference laboratory for testing. This will provide a serological readout on the antigenic content of the expired vaccine and give an indication of expected protection.

4) Close observation must be maintained on vaccinated cattle and any signs of disease investigated immediately.

5) Subsequent use of the expired vaccine should be closely monitored, and Post Vaccination Monitoring should be carried out in a representative sample of vaccinates.

6) A source of new FMD vaccines should be obtained as soon as possible.

This policy brief was prepared by the Australia Indonesia Health Security Partnership (AIHSP).

The Government of Australia neither endorses the views contained within this publication nor vouches for the accuracy or completeness of the information.

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