

## AVAILABILITY AND USE OF VACCINES FOR FOOT AND MOUTH DISEASE IN DIFFERENT PARTS OF THE WORLD

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The global FMD vaccine market is estimated to be around 700 million doses, of which about 500 million doses is in South America. Excluded from these figures are national markets and market segments, where local manufacturers are protected against the import of FMD vaccines from abroad.

Vaccines against FMD are produced in South America, Africa, Europe, Middle East and Asia. The market for FMD vaccines is very fragmented because of the differences in vaccine strains, composition of the adjuvant and national requirements. In spite of the fragmentation, the leading commercial producers have done significant investments to increase capacity, improve product and processes and, last but not least, to remain in compliance with increasing regulatory requirements.

Of particular importance is the match between field- and vaccine strains. National and OIE Reference Laboratories, including the World Reference Laboratory in Pirbright (UK) study new isolates and advice on the match between new isolates and the existing vaccine strains.

Biosecurity of laboratories and vaccine production facilities is essential. The EUFMD has set detailed requirements on the biosecurity aspects. Laboratories and producers in the EU have to comply with these standards in order to get approval under EU Directive 2003/85 to work with FMD virus. Other parts of the world have similar standards. Compliance with strict biosecurity standards for facilities and for the inactivation and inactivation control procedure is essential to prevent an outbreak of FMD related to vaccine production.

Disease control authorities are keen to get access to new vaccine strains within the shortest possible time. The regulatory authorities put more emphasis on regulatory compliance. The vaccine producer is expected to answer the demand from both sides. FMD vaccine strains might have different properties with regards to influence on potency, production yields, antigenic payload, vaccine stability and purification and concentration. Intensive contact between disease control authorities, regulatory authorities and the vaccine producer is necessary for a proper match between speed of development, regulatory compliance and technical feasibility.

Disease control authorities ask for cheaper vaccines whilst the increase in regulatory requirements increases the R&D and production costs. A responsible balance needs to be determined.

Our common challenge is to maintain and increase the level of investments in research, both at academic as well as industrial level. Within the present generation of inactivated vaccines improvements are still possible in product and processes. Research towards a better understanding of the virus and the interaction with the host and towards new delivery technology will contribute to a more targeted development of vaccines. Vaccines need to be fit for purpose, either for use in endemic setting or for emergency use.

Early involvement of the vaccine industry in research programs will increase the chance that improved products and processes will reach the market.

