Media Release

For Immediate Release

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MEDIA STATEMENT

FOR IMMEDIATE RELEASE

Foot and Mouth Disease Vaccine Development in South Africa

Foot and Mouth Disease (FMD) is a highly contagious viral disease that attacks cloven-hoofed animals, leading to severe production losses. Its significant impact arises from rapid herd-level spread, movement restrictions, and major economic disruption to livestock systems and trade, even when animals recover clinically. As part of dealing with the ongoing devastating outbreaks, the Agricultural Research Council (ARC) wishes to place the following information on record regarding the development, registration, production, and use of FMD vaccines in South Africa. This statement aims to clarify issues currently circulating in the public domain as the country navigates a serious animal health crisis.

For many years, ARC scientists have undertaken long-term research, development, and implementation work in support of the country's agricultural sector and national animal health system. This work has been conducted within established scientific, regulatory, and legal frameworks. The ARC Onderstepoort Veterinary Research (OVR) campus is a World Organisation for Animal Health (WOAH) Reference Laboratory for FMD. WOAH Reference Laboratories are recognised for meeting strict criteria to provide scientific and technical leadership in diagnosis, training, and support to member countries. As part of the WOAH and FAO FMD Reference Laboratory Network, OVR contributes to coordinated global surveillance, standardisation, and data sharing for FMD diagnostics and control. Collaborations, in research and other initiatives, with other members of the network, including the sharing of biological material where necessary, occurs in the normal course of work.

FMD vaccine development is a complex, multi-year process that progresses in defined phases. Research into vaccine strains suitable for use in South Africa has been undertaken by ARC scientists since 2010, from the old factory under adapted systems and processes that meet the modern manufacturing technologies requirements. This work involved identification of new candidate strains, adapting them for cultivation and running several long-term trials to determine strength and longevity of immunity for animals.

The vaccine was registered in South Africa in May 2022 as a stock remedy under the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947). This registration marked an important regulatory milestone and was communicated publicly as such at

the time. The developed vaccine meets all prescribed quality and efficacy standards, with each dose effective for up to one year. However, registration does not constitute manufacturing readiness or large-scale availability. It is therefore incorrect to suggest that the ARC has been in possession of a ready-to-deploy vaccine since 2022. It is also incorrect to characterise the current milestone as the introduction of a “new” or “different” vaccine. It would not be possible to develop a new FMD vaccine in such a short space of time. Vaccine development and production advance through cumulative, phased progress rather than singular events.

Following registration, a proof-of-concept batch was produced at limited scale and deployed in Mpumalanga where it contributed to effective control of the outbreak at the time. It is important to point out that even after a vaccine strain has been developed and registered, scaling FMD vaccine production remains scientifically and technically complex. Increased production scale affects biological processes, not just the volume.

FMD vaccine production is governed by strict legal, regulatory, biosafety, and biosecurity requirements because it often involves handling live FMD virus. Accordingly, no facility in South Africa is authorised to produce the foot and mouth disease vaccine outside of the ARC. While high biocontainment, at least Biosafety Level 3 (BSL-3), is one of the minimum requirements, this does not automatically translate into the ability to produce the FMD vaccine. FMD vaccines must be produced in dedicated, high-biocontainment animal health facilities and cannot be co-manufactured with human vaccines. Production also requires specific skills and long-term investment in research and diagnostics, which the ARC and the Department of Agriculture have made diligently over many years. It is therefore incorrect to suggest that the ARC could simply transfer manufacturing to other parties, in order to meet the current vaccine requirements.

South Africa has relied on imported foot and mouth disease vaccines since 2006 following policy decisions taken at the time, including that of the supply of vaccines supplied by the Botswana Vaccine Institute (BVI). BVI honoured every order from 2006 including the current outbreak period until late 2025, which explains why South Africa has relied on the company for many years, in addition to their vaccine being the most applicable to the strain circulating in South Africa. Until this point, South Africa had not considered any other sources for vaccine, nor was it considered necessary because of the assured supply while national development processes were continuing in the background. Consequently, the 6 February 2026, marks a significant milestone in the journey to restore national capability when the first batch of ARC-produced vaccine was released for use in response to the current devastating outbreaks, marking the first operational use of locally produced vaccine in this context and strengthening national production capability.

The effort to ramp-up of production is well underway, with clearly defined short- to medium-term milestones. Capacity of up to 10 million monovalent doses per year will be established over the next 12 months through capacity enhancements that are currently underway. While imports are flowing in over the next few days and weeks, the ARC will add another 20 000 doses of its vaccine per week to the availability mix from March 2026. With the main factory design complete, South Africa will be able to produce up to 20 million doses per year at full capacity. This will sufficiently cover national herd requirements, as the ARC vaccine provides protection for up to one year. This aligns with the national FMD mass vaccination strategy.

In addition to vaccine development, two other significant functions have been performed by the ARC since the beginning of the outbreaks. Firstly, the provision of diagnostic services remains crucial for monitoring circulating strains, with an unprecedented number of samples processed

during this period. While challenges remain, plans are in place to expand national capacity through activation of the broader laboratory network and the onboarding of additional skilled personnel. Secondly, the ARC conducts vaccine matching for sourcing vaccines from international suppliers to ensure suitability against circulating strains.

The mandate of the Agricultural Research Council, which it continues to discharge diligently, is to undertake scientific research, development, validation, and production of vaccines within its mandate. It is important to note that the distribution, allocation, and rollout of foot and mouth disease vaccines form part of the national disease control programme and fall under the responsibility of the Department of Agriculture, in line with established policy and regulatory frameworks. When technologies have been developed, further decisions relating to deployment, related prioritisation, and field use are managed through the appropriate state-led processes.

The ARC recognises the serious impact that the current foot and mouth disease outbreaks have had on farmers, livestock, livelihoods and the agricultural economy. The organisation remains focused on strengthening national scientific and production capability and supporting South Africa's long-term preparedness and response to animal health challenges, in collaboration with the Department of Agriculture and relevant stakeholders. ARC scientists will continue to perform their work diligently throughout this period. The ARC considers this as a time for coming together around these objectives in support of the national goals and using the structures that have been established for coordination of efforts across government, industry and research.

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Notes to the Editors

About the Agricultural Research Council

The Agricultural Research Council is a premier science institution that conducts research with partners, develops human capital, and fosters innovation in support of the agricultural sector. The ARC provides diagnostic, laboratory, analytical, and agricultural engineering services; post-harvest technology development; agrochemical evaluation; consultation and advisory services; food processing technology services; and various surveys and training interventions. For more information, visit the ARC website at www.arc.agric.za.