MINISTER
AGRICULTURE, LAND REFORM AND RURAL DEVELOPMENT
REPUBLIC OF SOUTH AFRICA

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Response to Parliamentary Question

QUESTION NO.:	**99/NW111E**
TO:	**MINISTER**
FROM:	**DIRECTOR-GENERAL**
SUBJECT:	**QUESTION 99/NW111E FOR WRITTEN REPLY BY MR N P MASIPA (DA) TO ASK THE MINISTER OF AGRICULTURE, LAND REFORM AND RURAL DEVELOPMENT**
CLASSIFICATION:	**CONFIDENTIAL**

NA WRITTEN QUESTION NO 99/NW111E

What are the details of the progress regarding the building of the Foot and Mouth Disease Facility by the Agricultural Research Council in terms of (a) the progress towards completing the building, (b) the (i) delays being experienced and (ii) reasons for the delays, (c) what is the expected completion date and (d) when is the envisaged date for the specified facility to start producing vaccines? NW111E

Enclosed herein is the reply to question 99/NW111E for your approval should you agree with the contents thereof. The information was supplied by the President and CEO of the Agricultural Research Council (ARC).

DALRRD'S RESPONSE:

PQ. 99/NW111E Mr N P Masipa (DA) to ask the Minister of Agriculture, Land Reform and Rural Development:

What are the details of the progress regarding the building of the Foot and Mouth Disease Facility by the Agricultural Research Council in terms of (a) the progress towards completing the building, (b) the (i) delays being experienced and (ii) reasons for the delays, (c) what is the expected completion date and (d) when is the envisaged date for the specified facility to start producing vaccines? NW111E

(a) the progress towards completing the building,

For the project to be properly implemented and brought to its conclusion, the following processes have to be implemented:

1. In 2014 the ARC appointed an engineering firm to provide the layout and concept for architectural design and project manage the construction of the new FMD factory. However, this contract with the appointed external consulting engineers expired in 2016.

2. Once the allocation had been approved by National Treasury and Parliament, the ARC initiated a process to re – engage the architectural consulting engineers. Unfortunately, following lengthy negotiations, the ARC could not utilize the architectural designs due to expired contract and intellectual property claims.

3. In the interim, the ARC has continued to conduct vaccine efficacy and immunogenicity clinical trials within the confines of current old facilities. One of the experimental trials has been to determine the length of vaccine protection.

4. The ARC has trained at least 9 students in vaccine manufacturing through one of the universities. The students successfully obtained Bachelor of Science Honours and have been recruited as employees of the ARC specifically in the FMD vaccine manufacturing facility.

5. The ARC Council (board) has recently approved the following:

    a. ARC to initiate a recruitment process for the specific project manager with expertise in construction and quantity surveying.

    b. ARC to initiate the procurement process for expertise in process design – which will be instrumental towards influencing the architectural design and manufacturing process. A process engineer or expert to develop the design or layout of the infrastructure (piping, bioreactors, purifiers, centrifuges, etc) that will be used in the manufacturing process. A well designed production process is essential for optimization of the factory design, particularly for obtaining qualifications for good manufacturing practice (GMP) which is required not only for export purposes but also by the South African Medicines Control Council to grant the manufacturing license for the factory. And,

    c. ARC to initiate the procurement process for architectural design, facility development (construction) and commissioning. To comply with applicable legislation and regulations the ARC has to proceed with an open process to invite bids for the project from prospective construction and engineering service providers, which, because of the amounts involved.

(b) the delays being experienced –

Delays were caused by negotiations for the use of expired architectural designs. These have impacted on timelines as ARC now has to initiate a new procurement process.

reasons for the delays

Obtaining the services of a process engineer develop the design or layout of the infrastructure (piping, bioreactors, purifiers, centrifuges, etc) that will be used in the manufacturing process and details of the actual production process. This is a scarce skill globally, hence the need for procurement of such expertise from anywhere in the world.

(c) what is the expected completion date

Once recruitment of above key positions is completed, we anticipate at least 3 years for the factory to be completed and commissioned. The project will consist of 3 phases, some of which will run concurrently:

STAGE 1: Design Phase (approximately 449 days)
STAGE 2: Construction (approximately 734)
STAGE 3: Validation (approximately 540 days)
(d) when is the envisaged date for the specified facility to start producing vaccines?
The ARC anticipates that the factory would be operational in 2025. The ARC will be able to produce the first batch within 9 months after commissioning of the factory. Availability of vaccine will be dependent upon regulatory approvals, particularly in terms of the Animal Health Act and Section 21 of the Medicines and Related Substances Act 101 of 1965.