**NATIONAL ASSEMBLY**

**WRITTEN REPLY**

**QUESTION 790**

**INTERNAL QUESTION PAPER [No 9-2022 SIXTH PARLIAMENT]
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**790. Mr N P Masipa (DA) to ask the Minister of Agriculture, Land Reform and Rural Development:**

1. What (a) are the reasons that the upgrade of the new heartwater vaccine has taken five years long to achieve and (b) period longer must farmers wait for the vaccine;

(2) what number of new vaccines have been (a) developed and (b) put on the market by Onderstepoort Biological Products in the past decade? **NW969E**

**THE MINISTER OF AGRICULTURE, LAND REFORM AND RURAL DEVELOPMENT:**

(1)(a) The new heartwater agent was developed by the Agricultural Research Council (ARC) as a proof of concept for further development by OBP into a vaccine following further development of industrial scale manufacturing processes, quality control tests, and validation of clinical efficacy in target animal species. The candidate vaccine failed initial quality control tests necessitating 2 years of further research work to improve the quality of the candidate vaccine seed material. The laboratory scale process developed by the ARC had to be scaled up into an industrial scale, and this was done in 1 and half years. The production process had to be validated, followed by manufacturing of pilot batches that are required to conduct clinical trials in targeted animal species. The candidate vaccine has just undergone 1 and half years of clinical trials to establish the efficacy of the agent as vaccine. Preliminary analysis of the data is not encouraging that the candidate vaccine in its current form is adequately sufficient for registration as vaccine for use to protect animals against the heartwater disease. Further process development and revalidation of the clinical efficacy of the candidate vaccine are required before it can be considered for submission to Act 36 for evaluation as vaccine.

1. Currently, it is impossible to set the timeline within which the product will be available commercially given its observed inadequacy to protect animals from the heartwater diseases in its current form.
2. Below are details on the number of new vaccines developed and put on the market by the Onderstepoort Biological Products:

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| **LIST OF PRODUCTS INTRODUCED IN THE PAST 10YRS** |
| Products | New | Improved | Products introduced |
| LSD |  - | √ | √ |
| Pastuerella cattle |  - | √ | √ |
| Pulpy kidney vaccine |  - | √ | √ |
| B. phemeral |   | √ | √ |
| RVF Clone 13 | √ |  - | √ |
| Chlamysure | √ |  - | √ |
| Respiclos | √ |  - | not |
| Tetanus |   | √ | not |
| Doublesure | √ |  | √ |
| Brucella  | - | √ | √ |