**NATIONAL ASSEMBLY**

**WRITTEN REPLY**

**QUESTION 143**

**INTERNAL QUESTION PAPER [No 1-2022 SIXTH PARLIAMENT]
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**143. Mr J Engelbrecht (DA) to ask the Minister of Agriculture, Land Reform and Rural Development:**

1. On what date did the Onderstepoort Biological Products (OBP) last update the formulation of its African Horse Sickness (AHS) vaccine to ensure that its efficacy levels are maintained;
2. (a) on what dates did OBP conduct efficacy and safety studies on its AHS vaccine (i) in each of the past five financial years and (ii) since 1 April 2021 and (b) what are the details of the outcomes of each efficacy and safety study in each case;
3. whether she will furnish Mr J Engelbrecht with copies of the specified efficacy and safety studies; if not, why not; if so, what are the relevant details;

(4) what has she found to be the reasons for the delay in the approval of the applications in terms of section 20 of the Animal Diseases Act, Act 35 of 1984, for conducting efficacy and safety studies for experimental AHS vaccines already developed by other laboratories in the Republic? **NW147E**

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

1. TheOnderstepoort Biological Products’ (OBP) last update of the African Horse Sickness (AHS) vaccine formulation was done in December 1994. There is no scientific evidence indicating that the AHS viruses in the field have mutated to the extent that it warrants a new formulation. Studies completed that looked at genetic variations of AHS field strains over a period of more than 40 years conclusively indicate that the level of genetic variation in AHS field strains do not warrant a review of the current AHS vaccine formulation.
2. (a)(i) OBP conducts vaccine safety, Innocuity, potency and sterility tests routinely as standard tests for the release of production batches with the option of immunological tests if warranted. The dates when the various batches were released in each of the past five financial years following potency and safety tests were in 02/2017, 06/2017, 08/2017, 10/2017, 12/2017, 02/2018, 04/2018, 07/2018, 09/2018, 10/2018, 12/2018, 03/2019, 05/2019, 06/2019, 07/2019, 10/2019, 02/2020, 05/2020, 06/2020, 08/2020, 09/2020, 02/2021/, 03/2021, 12/2021.

(a)(ii) Since April 2021 there was no production of AHS vaccines and therefore no tests were done between April 2021 and November 2021.

(b) The results obtained in these studies provided evidence that the OBP AHS vaccine generates protective immunity against field strains of AHS viruses and proved to be safe for use in horses.

1. Yes, there are certificates of analyses of all batches released in the past five years to date. Detailed study reports on AHS vaccine safety and efficacy as conducted by OBP are available in each project file for inspection within OBP premises. The OBP AHS vaccine has been evaluated by various authors as published in peer reviewed scientific articles, and the studies demonstrated safety and or efficacy of the OBP AHS vaccine. OBP is also ISO9001:2015 certified giving assurance that all batches passed meet specification for requirements.
2. Due to biosecurity concerns, approval of the applications in terms of section 20 of the Animal Diseases Act, Act 35 of 1984, for conducting efficacy and safety studies for experimental AHS vaccines is dependent on availability of a certified vector protected facility. The Minister has found out that the absence of these facilities is the main reason for the delays in the approval of the applications.