**NATIONAL ASSEMBLY**

**WRITTEN REPLY**

**QUESTION 789**

**INTERNAL QUESTION PAPER [No 9-2022 SIXTH PARLIAMENT]
DATE OF PUBLICATION: 11 MARCH 2022**

**789. Mr N P Masipa (DA) to ask the Minister of Agriculture, Land Reform and Rural Development:**

1. Whether, she will provide Mr N P Masipa with (a) a list of all medical and/or vaccine products currently available for sale including the total number of doses available for immediate sale, (b) a list of all products not available and (c) the expected date for availability; if not, why not; if so, what are the relevant details;
2. whether she will furnish Mr N P Masipa with audited accounts and/or reports of what was achieved with the R500 million that was given eight years ago to the Onderstepoort Biological Products (OBP) to achieve Good Manufacturing Practices (GMP) certification; if not, what is the position in this regard; if so,
3. whether the GMP certification status been achieved; if not, why not; if so, what are the relevant details;

(4) whether the forensic audit, that was requested by the former Chief Executive Officer of OBP has been (a) initiated and/or (b) conducted; if not, why not; if so, what are the relevant details? **NW968E**

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

1. (a) Yes. Please refer to Tables 1 and 2 below for medical and/or vaccine products currently available for sale but excluding the total number of doses available for immediate sale. OBP is unable to disclose the number of doses without compromising its competitive advantage and exposing its business to market competitors and giving them a potentially unfair advantage.

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| **Table 1:** **PRODUCT AVAILABLE IN DISTRIBUTION AND READY FOR SALE** |  | **Table 2:****PRODUCT AVAILABLE AND READY TO BE PACKED** |
| **PRODUCT NAME** | **AVAILABLE** |  | **PRODUCT NAME** | **AVAILABLE** |
| ANTHRAX 100ml | Yes |  | RIFT VALLEY FEVER LIVE 100ml | Yes |
| BLACK QUARTER 100ml | Yes |  | HORSE SICKNESS 12 DOSE PACK | Yes |
| BLUE TONGUE 100ml | Yes |  | LUMPY SKIN DISEASE 50DOS | Yes |
| BOTULISM 100ml | Yes |  | WESSELSBRON DISEASE 1ml | Yes |
| BOTULISM 50ml | Yes |  | RIFT VALLEY FEVER LIVE 50ML | Yes |
| BRUCELLA CFT ANTIGEN 20ml | Yes |  | GASGANGRINE COMPLEX | Yes |
| BRUCELLA MRT ANTIGEN 20ml | Yes |  | BLUE TONGUE A-FinQC | Yes |
| BRUCELLA RB ANTIGEN 20ml | Yes |  | PASTEURELLA (CATTLE) 100ML | Yes |
| BRUCELLA REV 1 100ml 50D | Yes |  | BLUE TONGUE C-FinQC | Yes |
| BRUCELLA STD SERUM 1ml | Yes |  | BOTULISM/BLACK QUARTER  | Yes |
| CALF PARATYPHOID INACT 12x10ml | Yes |  | BLACK QUARTER 100ml | Yes |
| ELEPHANT SKIN DISEASE 10ml | Yes |  | CALF PARATYPHOID INACT 10ml | Yes |
| GASGANGRINE COMPLEX 100 ML | Yes |  | BRUCELLA REV 1 100ml Dos 50 | Yes |
| HORSE SICKNESS 12 DOSE PACK | Yes |  | BOTULISM 100ml | Yes |
| LEUKOPAST 3 (CATTLE) 100ml | Yes |  | GLYCERINE WATER | Yes |
| LUMPY SKIN DISEASE 100ML 50DOS | Yes |  | RIFT VALLEY FEVER INACT 100ml | Yes |
| LUMPY SKIN DISEASE 50ML 25DOS | Yes |  | BOTULISM 50ml | Yes |
| PASTEURELLA (CATTLE) 100ml50do | Yes |  | B-PHEMERAL VACCINE 10 DOSE | Yes |
| PASTEURELLA (SHEEP) 100ml | Yes |  | SWELLED HEAD 100ml | Yes |
| PULPY KIDNEY (ALUM) 100ml | Yes |  | LEUKOPAST 3 (CATTLE) 100ml | Yes |
| REDWATER AFRICA 5ml | Yes |  | BRUCELLA MRT ANTIGEN 20ml | Yes |
| REDWATER ASIATIC 5ml | Yes |  | BRUCELLA MRT ANTIGEN 20ml | Yes |
| RIFT VALLEY FEVER INACT 100ml | Yes |  | BRUCELLA REV 1 100ml Dos 50 | Yes |
| RIFT VALLEY FEVER LIVE 100ml | Yes |  | BRUCELLA REV 1 100ml Dos 50 | Yes |
| SWELLED HEAD 100ml | Yes |  | BRUCELLA MRT ANTIGEN 20ml | Yes |
| TETANUS (2x10ml Botls in 1 DC) | Yes |  |  |  |

(b),(c)

|  |  |
| --- | --- |
| **(b) PRODUCTS NOT AVAILABLE** | **(c) EXPECTED DATE OF AVAILABILITY**  |
| HEARTWATER | End May 2022 |
| ANAPLASMA | End May 2022 |
| BRUCELLA S19 | End May 2022 |

1. Yes. OBP will make the report on the expenditure once available.Expenditure against the R492.5 million government support to OBP to improve its infrastructure to be compliant to the Current Good Manufacturing Practices (cGMPs)in 2014 is a matter of review and investigation by the current Board of OBP. A consulting firm was contracted to conduct this investigation in September 2021. The OBP was not satisfied with the report and is in the process of seeking a second opinion on the expenditure and value for money on what has been spent to-date.
2. No. OBP has a cGMP roadmap as per its Corporate Plan stating that 80% of the activities towards Good Manufacturing Practice (GMP) compliance should be achieved in the 2023/2024 Financial Year. The process of obtaining GMP Certification at OBP has been divided into two parts, namely:
* The building of a GMP facility, and
* Activities and Processes of the organization to comply with cGMP requirements. Progress with respect to GMP facility is a matter of dispute with contractors whilst activities related to complying to cGMP process requirements, gap analysis audit has been conducted and the areas of concern have been highlighted by the creation of a cGMP Roadmap, which is a working document. Training on the fundamentals of cGMP was conducted at various levels within the organization to create awareness within the organization.
1. Yes. OBP’s external auditors (the Auditor-General) issued a management report for Financial Year End March 2019 with findings on some awards specifically aligned to the GMP project.
2. A forensic investigation was initiated because of the report of the Auditor-General.
3. A forensic investigation was conducted, and a report was issued in March 2020 on various matters which included some awards related to GMP. The current Board had requested an initial review to be done by management and a second review has been prompted by further aspects that require a multi-disciplinary team.