# NATIONAL ASSEMBLY

**FOR WRITTEN REPLY**

**QUESTION NO. 2211**

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**(INTERNAL QUESTION PAPER NO. 22)**

**Ms N N Chirwa (EFF) to ask the Minister of Health:**

(1) Following the new data on Pfizer vaccine, what is the current position of (a) his department and (b) SA Health Products Regulatory Authority (SAHPRA) on it being administered;

(2) whether the initial positions of his department and SAHPRA has been altered and/or changed with reference to the safety in light of the current information that is now in the public domain; if not, what is the position in this regard, particularly in view of the fact that there are vaccines that have not been approved on the basis that not all information pertaining to safety were submitted; if not, what is the position in this regard; if so, what are the relevant details?

###### NW2619E

**REPLY:**

(1) (a) The Ministerial Advisory Committee on COVID-19 Vaccines (VMAC) is mandated to advise the Minister regarding COVID-19 vaccines. The VMAC engaged with SAHPRA on the report from the United States of America’s Food and Drug Authority report on the Pfizer Comirnaty COVID-19 vaccine safety. This report that was released was related to the periodic safety update reports that are released by the FDA, and did not identify any new signals for safety concerns. It was also noted that this report contains more than 49 000 adverse events following immunisations (AEFIs). As such, with the lack of new safety signals in the use of Pfizer Comirnaty COVID-19 vaccine, it’s continued use is still viewed as favourable.

(b) SAPHRA released a media statement on the 11th March 2022, which noted the following: “… the safety report received from the United States of America’s Food and Drug Authority in relation to the Pfizer Comirnaty COVID-19 vaccine. SAHPRA indicated that Pfizer indicates all adverse events of special interest (AESIs) during the reporting period. However, not all AESIs included in the report are linked to the vaccine. As these vaccines are still new, their safety profiles are evolving, and investigations are ongoing; hence the need for continuous monitoring. Based on the latest periodically reported safety data reviewed by SAHPRA for Pfizer COVID-19 vaccines, the benefit-risk profile of this vaccine remains favourable and safe to be administered as per the roll-out schedule.” This media release is available on the SAHPRA website.

(2) Neither the Department nor SAHPRA have changed their stance on the use of the Pfizer Comirnaty COVID-19 vaccine, based on the factors noted above, in other words, that no new safety concerns were found in this data. Registration of medicines in the country is the role of SAHPRA, which is mandated to oversee the safety, efficacy and quality of all health products registered in the country, and this includes vaccines. All the COVID-19 vaccines authorised for use in South Africa have been evaluated for safety, quality, and efficacy, and have proven to prevent serious disease and death from COVID-19. Should new safety signals be raised, this product will be reviewed at that time.

END.