# NATIONAL ASSEMBLY

**FOR WRITTEN REPLY**

**QUESTION NO. 2861**

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**(INTERNAL QUESTION PAPER NO. 29)**

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

What (a) total number (i) of adverse effects caused by COVID-19 vaccines have been reported to the Government, (ii) of those have been investigated and (iii) have been found to be related to the specified vaccine and (b) has been the response of Government in instances where adverse effects caused by COVID-19 vaccines have been reported? **NW3460E**

**REPLY:**

An adverse event (not effect) following immunisation (AEFI) is any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended physical sign, abnormal laboratory finding, symptom or disease.

1. From 17 May 2021 to the 8 August 2022 a total number of 6561 AEFIs (total minor and severe) following the use of either the Pfizer (Comirnaty) or J&J (COVID-19 vaccine Janssen) were reported to the South African Health Products Regulatory Authority (SAHPRA).
2. Only severe and serious AEFIs are investigated. A total of 2771 clinical investigations are either concluded or under way.
3. Following investigation, the case files are sent to the National Immunisation Safety Expert Committee (NISEC) for assessment.  For assessments completed up to the 2 September 2022:
	* 81 AEFIs have been linked to the use of a COVID-19 vaccine (Pfizer 52 and J&J 29)
	* these events include immunisation stress related reactions (fear of vaccination) and vaccine product related reaction or were related to the immunisation programme

The causality assessment outcomes are shared with the provincial health departments to provide feedback to the vaccine injured parties, regardless of the outcome.

The purpose of causality assessment is to ensure that high levels of vaccine confidence are maintained in the immunisation programme, and it is therefore essential to identify if an AEFI was causally linked to the use of the vaccine or whether the AEFI was coincidental to vaccination.

Accurate communication about AEFI is essential to prevent misinformation circulating in the community.

END.