# NATIONAL ASSEMBLY

**FOR WRITTEN REPLY**

**QUESTION NO. 3360**

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**(INTERNAL QUESTION PAPER NO. 36)**

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

(a) What number of cases pertaining to the adverse effects of COVID-19 vaccines have been reported since the vaccination programme started, (b) to which vaccines do they relate, (c) what number of the specified reports have been investigated, (d) what is the investigation process and (e) at what point does the investigation conclude whether the cause of adverse effects and/or death is related to the vaccine? **NW4165E**

**REPLY:**

1. From 17th May 2021 up to the 31th August 2022 a total number of  6731 AEFI (total minor and severe) following the use of either the Comirnaty or COVID-19 vaccine Janssen has been reported to the South African Health Products Regulatory Authority (SAHPRA)
2. 5241 (total minor and severe) AEFI related to the Comirnaty vaccine (28274053 doses administered) and 1490 (total minor and severe) AEFI related to the Janssen vaccine (8440418 doses administered)
3. Only severe and serious AEFI is investigated, a total number of 2771 investigations are either concluded or under way.
4. A multi-disciplinary team of health professionals in the district investigate all severe and serious AEFI.The purpose of investigating AEFI/AESI cases are as follows: 1. To confirm the reported diagnosis and/or propose other possible diagnoses as well as clarify the outcome of the medical incident comprising the AEFI. 2. To ascertain the particulars, circumstances and procedures around the vaccine used to immunise the affected recipient. Most importantly, identify any potential vaccine-related link to the given AEFI. 3.To review immunisation practices, logistics and other operational aspects of the programme to ensure programme related issues are not contributing to adverse events following immunisation, even if an event seems to be vaccine product-induced or coincidental.4. To determine whether a reported event was a single incident or one of a cluster and if it is a cluster, confirm that the suspected immunisations were indeed given and the individual vaccines that were used. 5. To determine whether unimmunised people are experiencing the same medical incidents. 6. To gather more information pertaining to the case to inform causality assessment. The process of AEFI investigation thus include visits to the vaccination site, interviews with relevant health care workers, interviews with family, care givers or the vaccine injured party if required. Throughout all relevant clinical records, previous medical history, all relevant lab results and diagnostic test outcomes is collected. In a few cases further clinical assessment or medical treatment may be advised.
5. The investigation is concluded when sufficient information has been collected to conduct causality assessment, or when investigation team confirm no further information is available.

END.