

**Z.16025/02/2018-IMM-Part (1)**  
**Government of India**  
**Ministry of Health & Family Welfare**  
**Immunization Division**

**Nirman Bhawan, New Delhi**  
**Date: 19<sup>th</sup> October 2022**

**Causality assessment results of 257 reported Serious Adverse Events Following Immunization (AEFI) cases following COVID-19 vaccination approved by National AEFI Committee on 29<sup>th</sup>- 30<sup>th</sup> September 2022.**

The Immunization Division, MoHFW has taken several steps to strengthen the national AEFI surveillance system for COVID-19 vaccinations. Considering the importance and critical nature of the task, steps were taken to include medical specialists, cardiologists, neurologists, pulmonary medicine specialists, and obstetrician-gynaecologist as members of the causality assessment sub-committee at the national level. A Special Group has been framed to conduct a causality assessment of AEFIs following COVID-19 vaccination. The results of the causality assessment done by this Special Group is discussed in the national AEFI committee meeting for final approval.

The results of the causality assessment for 257 cases completed on **29<sup>th</sup>- 30<sup>th</sup> September 2022** after a thorough review, deliberation, and approval by the National AEFI Committee is given in the annexure (anonymized line list of the causality assessment done by the National AEFI Committee).

96 out of 257 cases for which Causality assessment has been done were found to have a **consistent causal association to immunization**. Of these 96 cases, 32 cases were vaccine product-related reaction, 50 cases were immunization error related reaction (including a cluster of 46 cases) and 14 cases were anxiety-related reaction. 120 cases have an inconsistent causal association to immunization (**coincidental - not linked to vaccination**), including 67 death cases. There are 6 cases in the indeterminate category. A total of 35 cases were in the unclassifiable category (including 28 death cases)

Vaccine product-related reactions are expected reactions that can be attributed to vaccination based on current scientific evidence. Examples of such reactions are allergic reactions and anaphylaxis, etc.

Indeterminate reactions are reactions that have occurred soon after vaccination but there is no definitive evidence in current literature or clinical trial data that this event could have been caused due to the vaccine. Further observations, analysis, and studies are required.

Unclassifiable events are events that have been investigated but there is not enough evidence for assigning a diagnosis due to missing crucial information. When this relevant information becomes available, the case may be reconsidered for causality assessment.

Coincidental events are events that are reported following immunization but for which a clear cause other than vaccination is found on investigation.

Overall, the benefits of vaccination are overwhelmingly greater than the small risk of harm. However, as a measure of utmost precaution, all emerging signals of harm are being constantly tracked and reviewed periodically.