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Government of India
Ministry of Health & Family Welfare
Immunization Division

Nirman Bhawan, New Delhi
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Causality assessment results of 385 reported Serious Adverse Events Following Immunization (AEFI) cases following COVID-19 vaccination approved by National AEFI Committee on 17th- 18th August 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 385 cases completed on **17th- 18th August 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).

85 out of 385 cases for which Causality assessment has been done were found to have **a consistent causal association to immunization.** Of these 85 cases, 44 cases were vaccine product-related reaction including 04 deaths, 05 cases were immunization error related reaction including 02 deaths, and 36 cases were anxiety-related reaction. 199 cases have an inconsistent causal association to immunization (**coincidental - not linked to vaccination**), including 111 death cases. There are 65 cases in the indeterminate category including 11 death cases. A total of 36 cases were in the unclassifiable category (all 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.