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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 172 reported Serious Adverse Events Following Immunization (AEFI) cases approved by National AEFI Committee on 12th January 2023

The Immunization Division of Ministry of Health & Family Welfare has taken several steps to improve the National AEFI surveillance system, both the quality of investigation of cases at state level and their causality assessment at national level. Considering the importance and critical nature of the task, SOPs for causality assessment (CA) have been laid down as quality assurance. The results of causality assessment done by the CA subcommittee is discussed in the national AEFI committee meeting for final approval.

The results of the causality assessment for 172 cases completed on **12th January 2023** after 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).

128 out of 172 cases for which Causality assessment has been done were found to have **a consistent causal association to immunization**. Of these 128 cases, 91 cases were vaccine product related reaction including 3 deaths, 37 cases were immunization error related reaction. Forty cases have inconsistent causal association to immunization (**coincidental - not linked to vaccination**), including 13 death cases. One case was in indeterminate category and three cases were in 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 which 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 which 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.