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Government of India
Ministry of Health & Family Welfare
Immunization Division

Date: 5th March 2021
Nirman Bhawan, New Delhi

Causality assessment results of 5 reported Serious Adverse Events Following Immunization (AEFI) cases following COVID-19 vaccination approved by National AEFI Committee

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, obstetrician-gynecologist as members of the causality assessment sub-committee at the national level. A Special Group has been framed to conduct causality assessment of AEFIs following COVID-19 vaccination. The results of 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 5 cases completed over the past month 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).

Three of the five cases for which CA has been done have been found to have **consistent causal association to vaccination** and two cases have been found to have **inconsistent casual association to vaccination (coincidental)**. None have been found to be due to the COVID-19 vaccine.

CAUSALITY CLASSIFICATION OF 5 AEFI CASES REVIEWED AND APPROVED BY THE NATIONAL AEFI COMMITTEE
5th February 2021 - (NEW DELHI)

A1 - VACCINE PRODUCT RELATED REACTION
A2 - VACCINE QUALITY DEFECT RELATED REACTION
A3 - IMMUNIZATION ERROR RELATED REACTION
A4 - IMMUNIZATION ANXIETY RELATED REACTION
B1 - TEMPORAL RELATIONSHIP IS CONSISTENT BUT THERE IS INSUFFICIENT DEFINITIVE EVIDENCE FOR VACCINE CAUSING EVENT
B2 - REVIEWING FACTORS RESULT IN CONFLICTING TRENDS OF CONSISTENCY AND INCONSISTENCY WITH CAUSAL ASSOCIATION TO IMMUNIZATION
C - COINCIDENTAL - UNDERLYING OR EMERGING CONDITION(S), OR CONDITIONS CAUSED BY EXPOSURE TO SOMETHING OTHER THAN VACCINE
D - UNCLASSIFIABLE

S. NO.	NATIONAL ID	YEAR	STATE	DISTRICT	Age in years	SEX	REASON FOR REPORTING / OUTCOME	DATE OF VACCINATION (DD/MM/YYYY)	ANTIGENS	ROUTINE, SIA, CAMPAIGN & OTHERS	CLASSIFICATION BY NATIONAL AEFI COMMITTEE	JUSTIFICATION
1	IND(CO-AEFI)RJPLI21002	2021	RAJASTHAN	PALI	21 YRS	FEMALE	HOSPITALIZED AND RECOVERED	19-01-21	COVISHIELD	COVID 19 CAMPAIGN	A1	Brighton level 2 of diagnostic certainty Features of anaphylaxis within 10 minutes of vaccination
2	IND(CO-AEFI)DLSOU21001	2021	DELHI	SOUTH	22 YRS	MALE	HOSPITALIZED AND RECOVERED	16-01-21	COVAXIN	COVID 19 CAMPAIGN	A1	Brighton level 1 of diagnostic certainty Features of anaphylaxis within 15 minutes of vaccination
3	IND(CO-AEFI)DLWES21001	2021	DELHI	WEST	26 YRS	MALE	HOSPITALIZED AND RECOVERED	21-01-21	COVAXIN	COVID 19 CAMPAIGN	A4	History of similar symptoms (sweating, dizziness, anxiety, cold extremities, hypotension) while blood sampling, developed symptoms immediately (within 5 minutes) of vaccination and spontaneous recovery
4	IND(CO-AEFI)KASHI21001	2021	KARNATAKA	SHIVAMOGGA	56 YRS	MALE	DEATH	18-01-21	COVISHIELD	COVID 19 CAMPAIGN	C	Post coronary artery bypass graft (CABG) surgery (2007), recently documented block in one of the coronary artery on coronary arteriogram. Known case of Type II Diabetes mellitus, acute coronary syndrome with non-ST elevation MI, moderate LV dysfunction with ejection fraction of 45%, bilateral lower limb peripheral vascular disease. On anti-arrhythmic medications for NSVT (non-sustained ventricular tachycardia).
5	IND(CO-AEFI)RJCTG21001	2021	RAJASTHAN	CHITTORGARH	55 YRS	MALE	DEATH	16-01-21	COVISHIELD	COVID 19 CAMPAIGN	C	Presented as hypertensive emergency with systolic BP of 240mmHg. Known case of Chronic Kidney disease with underlying hypertension, getting treatment for same