

Z.16025/02/2018-IMM
Government of India
Ministry of Health & Family Welfare
Immunization Division

Date: 17th March 2021
Nirman Bhawan, New Delhi

Causality assessment results of 8 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 8 cases completed on 9th March 2021 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 eight causally assessed cases have been found to have **consistent causal association to vaccination**, four cases have been found to have **inconsistent causal association to vaccination (coincidental)** & one case was found **unclassifiable**. None have been found to be due to the COVID-19 vaccine.

CAUSALITY CLASSIFICATION OF 8 AEFI CASES REVIEWED AND APPROVED BY THE NATIONAL AEFI COMMITTEE
9th Mar 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 YEAR)	SEX	REASON FOR REPORTING / OUTCOME	DATE OF VACCINATION (DD/MM/YYYY)	ANTIGENS	ROUTINE, SIA, CAMPAIGN & OTHERS	CLASSIFICATION BY CA SUBCOMMITTEE	JUSTIFICATION
1	IND(CO-AEFI)MHABD21001	2021	MAHARASHTRA	AURANAGABAD	52	FEMALE	DEATH	29-01-2021	COVISHIELD	COVID 19 CAMPAIGN	COINCIDENTAL	Patient had documented Myocardial infarction (ECG, clinical assessment, post mortem finding of necrotic patch in inferior wall of heart). She had a preceding risk factor of hypertension
2	IND(CO-AEFI)KABLY21001	2021	KARNATAKA	BALLARI	43	MALE	DEATH	16-01-2021	COVISHIELD	COVID 19 CAMPAIGN	COINCIDENTAL	Patient had documented Myocardial infarction (clinical assessment, ECG, ECHO and post mortem finding), he had risk factors for MI including long standing diabetes mellitus and hypertension. Post mortem showed left ventricle wall thickening and hemorrhagic patch in heart and evidence of chronic lung infection.
3	IND(CO-AEFI)TSMCL21001	2021	TELANGANA	MANCHERIAL	52	FEMALE	DEATH	19-01-2021	COVISHIELD	COVID 19 CAMPAIGN	COINCIDENTAL	Patient presented with symptoms of fever with cough and difficulty in breathing, BP of 210/120mmHg. Was clinically diagnosed to have accelerated HTN with LVF with pneumonia. CT chest confirmed pneumonia. She also had underlying kyphoscoliosis and restrictive lung disease
4	IND(CO-AEFI)BISAR21003	2021	BIHAR	SARAN	43	MALE	DEATH	18-01-2021	COVISHIELD	COVID 19 CAMPAIGN	UNCLASSIFIABLE	There was little clinical information and no diagnosis was mentioned in the available treatment records. No investigations were performed. Postmortem was not done. Verbal autopsy also did not contribute towards making a diagnosis
5	IND(CO-AEFI)MHTHN21003	2021	MAHARASHTRA	THANE	61	MALE	DEATH	20-01-2021	COVISHIELD	COVID 19 CAMPAIGN	B1	Patient had sudden cardiac death 11 days after vaccination. He was known case of hypertension on medication. Sudden cardiac death is likely to be due to a cardiovascular event. COVID 19 disease is known to trigger a pro thrombotic state and cardiovascular events. Biological plausibility exists for vaccine triggering these events.
6	IND(CO-AEFI)MPHAR21001	2021	MADHYA PRADESH	HARDA	38	MALE	DEATH	28-01-2021	COVISHIELD	COVID 19 CAMPAIGN	B1	Young patient without any cardiac risk factors, he had COVID 19 infection 2 months (8 weeks and 4 days) back. COVID 19 disease is known to trigger a pro thrombotic state and cardiovascular events.
7	IND(CO-AEFI)KABEL21002	2021	KARNATAKA	BELAGAVI	36	FEMALE	DEATH	22-01-2021	COVISHIELD	COVID 19 CAMPAIGN	B1	Covid disease is known to lead to thrombocytopenia as well as pro-inflammatory & pro-thrombotic state. Biological plausibility exists for vaccine causing acute stroke with severe thrombocytopenia.
8	IND(CO-AEFI)UPPIL21001	2021	UTTAR PRADESH	PILIBHIT	56	MALE	DEATH	28-01-2021	COVISHIELD	COVID 19 CAMPAIGN	COINCIDENTAL	He was a known case of coronary artery disease with PTCA with LV dysfunction with stenting of RCA (2017) and taking medication for the same.