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Government of India
Ministry of Health & Family Welfare
Immunization Division

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Nirman Bhawan, New Delhi

Causality assessment results of 31 reported Serious Adverse Events Following Immunization (AEFI) cases following COVID-19 vaccination approved by National AEFI Committee on 05th Feb, 09th March and 31st March, 2021.

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 formed 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 of 31 cases approved by the National AEFI Committee on 05th February (five cases), 09th March (eight cases) and 31st March 2021 (18 cases) after thorough review and deliberations is given in the annexures attached. As per data in the first week of April 2021, the reporting rate is 2.7 deaths per million vaccine doses administered and 4.8 hospitalizations per million vaccine doses administered. Mere reporting of deaths and hospitalizations as serious adverse events does not automatically imply that the events were caused due to vaccines. Only properly conducted investigations and causality assessments can help in understanding if any causal relationship exists between the event and the vaccine. For causality assessments, priority has been given to death cases.

Of the 31 causally assessed cases, 18 were classified as having **inconsistent causal association to vaccination (coincidental - not linked to vaccination)**, 7 were classified as **indeterminate**, 3 cases were found to be **vaccine product related**, 1 was **anxiety related reaction** and 2 cases were found to be **unclassifiable**.

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.

**Causality assessment results of 31 AEFI cases following COVID 19 vaccination approved by National AEFI Committee on 05 February,
09 March and 31 March 2021**

S. NO.	NATIONAL ID	YEAR	AGE IN YEARS	SEX	REASON FOR REPORTING/ OUTCOME	DATE OF VACCINATION (DD/MM/YYYY)	VACCINE	DIAGNOSIS	CLASSIFICATION* BY NATIONAL AEFI COMMITTEE	DATE OF APPROVAL BY NATIONAL AEFI COMMITTEE
1	IND(CO-AEFI)MHBMC21025	2021	68 YRS	M	DEATH	8/03/21	COVISHIELD	Anaphylaxis	Vaccine product related reaction	31 March 2021
2	IND(CO-AEFI)KETRM21006	2021	50 YRS	F	DEATH	3/02/21	COVISHIELD	Intracranial bleed	Indeterminate	31 March 2021
3	IND(CO-AEFI)MPBRW21001	2021	59 YRS	F	DEATH	23/02/21	COVISHIELD	Acute Myocardial infarction with pulmonary edema	Indeterminate	31 March 2021
4	IND(CO-AEFI)ORAGL21001	2021	55 YRS	F	DEATH	3/02/21	COVISHIELD	Left sided middle cerebral artery ischemic infarct	Indeterminate	31 March 2021
5	IND(CO-AEFI)BIBJR21001	2021	41 YRS	M	DEATH	9/02/21	COVISHIELD	Sudden cardiac death	Indeterminate	31 March 2021
6	IND(CO-AEFI)MHKLP21003	2021	51 YRS	F	DEATH	22/01/21	COVISHIELD	Left sided middle cerebral artery ischemic infarct with underlying co morbidities- diabetes, hypertension and chronic kidney disease	Coincidental	31 March 2021
7	IND(CO-AEFI)APCHT21001	2021	51 YRS	M	DEATH	9/02/21	COVISHIELD	Sudden cardiac death with underlying co morbidities - hypertension	Coincidental	31 March 2021
8	IND(CO-AEFI)KACBP21002	2021	56 YRS	M	DEATH	10/2/21	COVISHIELD	Acute Myocardial infarction with underlying co morbidities - severe aortic stenosis with left ventricle dysfunction	Coincidental	31 March 2021
9	IND(CO-AEFI)JHRNC21004	2021	51 YRS	M	DEATH	1/2/21	COVISHIELD	Sudden cardiac death with underlying co morbidities- left ventricular hypertrophy with congestive cardiac failure	Coincidental	31 March 2021
10	IND(CO-AEFI)HAPNP21002	2021	35 YRS	F	DEATH	4/02/21	COVISHIELD	Septic shock with Acute respiratory distress syndrome with Multi organ dysfunction syndrome ? Dengue Shock syndrome	Coincidental	31 March 2021

11	IND(CO-AEFI)ORPUR21001	2021	55 YRS	M	DEATH	20/02/21	COVISHI ELD	Acute Myocardial infarction with pulmonary edema with underlying co morbidities- diabetes and hypertension	Coincidental	31 March 2021
12	IND(CO-AEFI)UPAGR21003	2021	77 YRS	M	DEATH	28/01/21	COVISHI ELD	Acute coronary syndrome with acute Kidney injury with underlying co morbidities – Coronary artery disease with poor left ventricular function with diabetes	Coincidental	31 March 2021
13	IND(CO-AEFI)WBUDJ21002	2021	52 YRS	M	DEATH	17/02/21	COVISHI ELD	Acute coronary syndrome with acute Kidney injury with COVID 19 infection	Coincidental	31 March 2021
14	IND(CO-AEFI)MPHAR21002	2021	44 YRS	M	DEATH	13/02/21	COVISHI ELD	Sudden cardiac death with underlying co morbidities - coronary artery disease and hypertension	Coincidental	31 March 2021
15	IND(CO-AEFI)APAPR21001	2021	47 YRS	F	DEATH	13/02/21	COVISHI ELD	Anaphylaxis to injection ceftriaxone	Coincidental	31 March 2021
16	IND(CO-AEFI)TRTRS21002	2021	66 YRS	M	DEATH	4/03/21	COVISHI ELD	Chronic obstructive pulmonary disease with acute exacerbation	Coincidental	31 March 2021
17	IND(CO-AEFI)GOGOS21001	2021	41 YRS	M	DEATH	2/02/21	COVISHI ELD	Pneumonia with multisystem dysfunction with congestive heart failure with underlying co morbidities- diabetes and hypertension	Coincidental	31 March 2021
18	IND(CO-AEFI)DLSOU21006	2021	55 YRS	M	DEATH	5/2/21	COVISHI ELD	Unexplained death	Unclassifiable	31 March 2021
19	IND(CO-AEFI)MHABD21001	2021	52 YRS	F	DEATH	29/1/21	COVISHI ELD	Acute inferior wall myocardial infarction with underlying co morbidity - hypertension	Coincidental	09 March 2021
20	IND(CO-AEFI)KABLY21001	2021	43 YRS	M	DEATH	16/1/21	COVISHI ELD	Acute myocardial infarction with underlying co morbidities- diabetes mellitus with hypertension with probable chronic lung infection	Coincidental	09 March 2021
21	IND(CO-AEFI)TSMCL21001	2021	52 YRS	F	DEATH	19/1/21	COVISHI ELD	Acute pneumonia with accelerated hypertension with left ventricle failure with underlying co morbidities- kyphoscoliosis with restrictive lung disease	Coincidental	09 March 2021
22	IND(CO-AEFI)BISAR21003	2021	43 YRS	M	DEATH	18/1/21	COVISHI ELD	Unexplained death	Unclassifiable	09 March

										2021
23	IND(CO-AEFI)MHTHN21003	2021	61 YRS	M	DEATH	20/1/21	COVISHI ELD	Sudden cardiac death with underlying co morbidities hypertension	Indeterminate	09 March 2021
24	IND(CO-AEFI)MPHAR21001	2021	38 YRS	M	DEATH	28/1/21	COVISHI ELD	Acute anterior wall myocardial infarction with severe left ventricular dysfunction	Indeterminate	09 March 2021
25	IND(CO-AEFI)KABEL21002	2021	36 YRS	F	DEATH	22/1/21	COVISHI ELD	Acute right middle cerebral artery infarct with haemorrhagic venous infarct left frontoparietal lobe with severe thrombocytopenia	Indeterminate	09 March 2021
26	IND(CO-AEFI)UPPIL21001	2021	56 YRS	M	DEATH	28/1/21	COVISHI ELD	Sudden cardiac death due to probable acute coronary syndrome with underlying coronary artery disease (post PTCA and stenting) and left ventricular dysfunction	Coincidental	09 March 2021
27	IND(CO-AEFI)RJPLI21002	2021	21 YRS	F	HOSPITALIZED AND RECOVERED	19/1/21	COVISHI ELD	Anaphylaxis	Vaccine product related reaction	05 February 2021
28	IND(CO-AEFI)DLSOU21001	2021	22 YRS	M	HOSPITALIZED AND RECOVERED	16/1/21	COVAXIN	Anaphylaxis	Vaccine product related reaction	05 February 2021
29	IND(CO-AEFI)DLWES21001	2021	26 YRS	M	HOSPITALIZED AND RECOVERED	21/1/21	COVAXIN	Syncope	Immunization anxiety related reaction	05 February 2021
30	IND(CO-AEFI)KASHI21001	2021	56 YRS	M	DEATH	18/1/21	COVISHI ELD	Acute coronary syndrome with ventricular fibrillation with underlying co morbidities coronary artery disease with diabetes with left ventricle dysfunction	Coincidental	05 February 2021
31	IND(CO-AEFI)RJCTG21001	2021	55 YRS	M	DEATH	16/1/21	COVISHI ELD	Hypertensive emergency with intracranial bleed with underlying chronic kidney disease with hypertension	Coincidental	05 February 2021

***COVID19 vaccines are new vaccines. Causality classification may change as more information becomes available .**