

Z-16025/05/2012 Imm p/f
Government of India
Ministry of Health & Family Welfare
Immunization Division

Date: 12th July, 2021
Nirman Bhawan, New Delhi

Causality assessment results of 88 reported Serious Adverse Events Following Immunization (AEFI) cases following COVID-19 vaccination approved by National AEFI Committee on 28th June 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 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 88 cases completed on 28th June 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).

61 out of 88 cases for which Causality assessment has been done found to have consistent causal association to vaccination, of these 61 cases, 37 were vaccine product related reactions 22 cases were immunization anxiety related reactions, and 2 cases were immunization error related reaction. 18 cases have inconsistent causal association to vaccination (coincidental - not linked to vaccination) including 3 death cases. 9 cases were in indeterminate category including 2 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.

CAUSALITY CLASSIFICATION OF 88 AEFI CASES TO BE APPROVED BY THE NATIONAL AEFI COMMITTEE ON 28 JUN 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	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)HAHSR21001	2021	34	FEMALE	HOSPITALIZATION AND RECOVERED	18-01-2021	COVISHIELD	ANAPHYLAXIS	A1	28-06-2021
2	IND(CO-AEFI)JKJAM21001	2021	50	MALE	HOSPITALIZATION AND RECOVERED	16-01-2021	COVISHIELD	ACUTE FEBRILE ILLNESS	A1	28-06-2021
3	IND(CO-AEFI)KABMP21003	2021	39	FEMALE	HOSPITALIZATION AND RECOVERED	18-01-2021	COVISHIELD	OHA INDUCED HYPOGLYCEMIA WITH TYPE 2 DIABETES MELLITUS AND RHEUMATOID ARTHRITIS	C	28-06-2021
4	IND(CO-AEFI)KABMP21004	2021	37	FEMALE	HOSPITALIZATION AND RECOVERED	21-01-2021	COVISHIELD	ANXIETY REACTION WITH RHD	A4	28-06-2021
5	IND(CO-AEFI)MHRTG21001	2021	43	FEMALE	HOSPITALIZATION AND RECOVERED	16-01-2021	COVISHIELD	ACUTE FEBRILE ILLNESS	A1	28-06-2021
6	IND(CO-AEFI)PBBTD21002	2021	35	MALE	HOSPITALIZATION AND RECOVERED	20-01-2021	COVISHIELD	VESTIBULAR NEURITIS	C	28-06-2021
7	IND(CO-AEFI)PBBTD21003	2021	32	MALE	SEVERE AND RECOVERED	19-01-2021	COVISHIELD	FACIAL PALSY	B1	28-06-2021
8	IND(CO-AEFI)TNTNV21001	2021	41	FEMALE	HOSPITALIZATION AND RECOVERED	18-01-2021	COVAXIN	ACUTE FEBRILE ILLNESS	A1	28-06-2021
9	IND(CO-AEFI)WBDJL21018	2021	37	FEMALE	SEVERE AND RECOVERED	03-02-2021	COVISHIELD	VOMITING AND HEADACHE	A1	28-06-2021
10	IND(CO-AEFI)WBMLD21001	2021	49	FEMALE	SEVERE AND RECOVERED	25-01-2021	COVISHIELD	ALLERGIC REACTION	A1	28-06-2021
11	IND(CO-AEFI)MNBPR21001	2021	44	FEMALE	DEATH	12-02-2021	COVISHIELD	PLASMA CELL MYOCARDITIS WITH CHF	B1	28-06-2021
12	IND(CO-AEFI)APKRL21001	2021	55	FEMALE	DEATH	15-02-2021	COVISHIELD	COMPLICATED PLASMODIUM VIVAX MALARIA	C	28-06-2021
13	IND(CO-AEFI)KABEL21005	2021	23	MALE	HOSPITALIZATION AND RECOVERED	19-02-2021	COVISHIELD	FEVER WITH SYNCOPE	A1	28-06-2021
14	IND(CO-AEFI)TNCNI21002	2021	31	FEMALE	HOSPITALIZATION AND RECOVERED	30-01-2021	COVAXIN	ACUTE GASTRITIS	C	28-06-2021
15	DAP	2021	45	FEMALE	HOSPITALIZATION AND RECOVERED	07-02-2021	COVISHIELD	ANXIETY REACTION	A4	28-06-2021
16	RNU	2021	45	FEMALE	SEVERE AND RECOVERED	16-02-2021	COVISHIELD	CELLULITIS	A3	28-06-2021
17	IND(CO-AEFI)APCHT21002	2021	37	MALE	DEATH	16-02-2021	COVISHIELD	ACUTE PANCREATITIS WITH ACUTE KIDNEY INJURY	C	28-06-2021
18	IND(CO-AEFI)WBCAL21018	2021	37	FEMALE	SEVERE AND RECOVERED	23-02-2021	COVISHIELD	ANAPHYLAXIS	A1	28-06-2021
19	IND(CO-AEFI)PBKPT21002	2021	56	MALE	HOSPITALIZATION AND RECOVERED	23-02-2021	COVISHIELD	FACIAL PALSY	B1	28-06-2021
20	IND(CO-AEFI)UPETA21001	2021	42	FEMALE	HOSPITALIZATION AND RECOVERED	16-01-2021	COVISHIELD	URINARY TRACT INFECTION	C	28-06-2021
21	IND(CO-AEFI)TNTRY21001	2021	55	FEMALE	HOSPITALIZATION AND RECOVERED	20-01-2021	COVAXIN	COVID-19 DISEASE	C	28-06-2021
22	IND(CO-AEFI)RJKA21001	2021	62	MALE	DEATH	03-03-2021	COVISHIELD	ACUTE CORONARY SYNDROME	C	28-06-2021
23	IND(CO-AEFI)JHSBE21001	2021	37	FEMALE	HOSPITALIZATION AND RECOVERED	16-01-2021	COVISHIELD	NAUSEA AND VOMITING	A1	28-06-2021
24	IND(CO-AEFI)WBDMD21002	2021	35	FEMALE	HOSPITALIZATION AND RECOVERED	18-01-2021	COVISHIELD	ANXIETY REACTION	A4	28-06-2021
25	IND(CO-AEFI)JHSBE21003	2021	28	FEMALE	HOSPITALIZATION AND RECOVERED	18-01-2021	COVISHIELD	DIZZINESS POST VACCINATION	A1	28-06-2021
26	IND(CO-AEFI)BIDBG21001	2021	45	FEMALE	SEVERE AND RECOVERED	18-01-2021	COVISHIELD	FEVER AND VOMITING	A1	28-06-2021

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27	IND(CO-AEFI)MHKLP21004	2021	48	FEMALE	HOSPITALIZATION AND RECOVERED	16-01-2021	COVISHIELD	FEVER AND BODYACHE	A1	28-06-2021
28	IND(CO-AEFI)PBKPT21001	2021	39	FEMALE	SEVERE AND RECOVERED	21-01-2021	COVISHIELD	PANIC REACTION	A4	28-06-2021
29	IND(CO-AEFI)CGGRB21001	2021	62	FEMALE	HOSPITALIZATION AND RECOVERED	21-01-2021	COVISHIELD	ANXIETY REACTION	A4	28-06-2021
30	IND(CO-AEFI)DLWES21002	2021	43	MALE	HOSPITALIZATION AND RECOVERED	16-01-2021	COVAXIN	RIGHT BASAL GANGLIA HAEMORHAGIC STROKE	B1	28-06-2021
31	IND(CO-AEFI)DLNDL21001	2021	35	FEMALE	HOSPITALIZATION AND RECOVERED	16-01-2021	COVISHIELD	NON CARDIAC CHEST PAIN	C	28-06-2021
32	IND(CO-AEFI)GUJMC21004	2021	26	FEMALE	HOSPITALIZATION AND RECOVERED	23-01-2021	COVISHIELD	FEVER, BODY ACHE, DIARRHEA AND VOMITING	A1	28-06-2021
33	IND(CO-AEFI)TRGMT21001	2021	50	MALE	HOSPITALIZATION AND RECOVERED	19-01-2021	COVISHIELD	RIGHT LUNG CAVITY WITH HEMOPTYSIS WITH HYPERTENSION	C	28-06-2021
34	IND(CO-AEFI)WBCAL21001	2021	25	FEMALE	HOSPITALIZATION AND RECOVERED	25-01-2021	COVISHIELD	FEVER, BODYACHE AND FACIAL PUFFINESS	A1	28-06-2021
35	IND(CO-AEFI)RJPLI21003	2021	36	FEMALE	SEVERE AND RECOVERED	19-01-2021	COVISHIELD	LEFT SIDED PERIPHERAL FACIAL NERVE PALSRY	B2	28-06-2021
36	IND(CO-AEFI)DLWES21003	2021	31	FEMALE	HOSPITALIZATION AND RECOVERED	25-01-2021	COVISHIELD	FEVER, MALAISE AND PAIN ABDOMEN	A1	28-06-2021
37	IND(CO-AEFI)MHBMC21007	2021	40	MALE	SEVERE AND RECOVERED	20-01-2021	COVISHIELD	INJECTION SITE ABSCESS	A3	28-06-2021
38	IND(CO-AEFI)TRTRW21001	2021	41	FEMALE	HOSPITALIZATION AND RECOVERED	19-01-2021	COVISHIELD	FEVER, HEADACHE AND MALAISE	A1	28-06-2021
39	IND(CO-AEFI)MPIDR21001	2021	26	MALE	HOSPITALIZATION AND RECOVERED	27-01-2021	COVISHIELD	ANXIETY REACTION	A4	28-06-2021
40	IND(CO-AEFI)PBLDN21001	2021	55	MALE	SEVERE AND RECOVERED	16-01-2021	COVISHIELD	COVID-19 INFECTION	C	28-06-2021
41	IND(CO-AEFI)MHBMC21004	2021	26	MALE	HOSPITALIZATION AND RECOVERED	06-02-2021	COVISHIELD	FEVER, VOMITING, LOOSE STOOLS AND HEADACHE	A1	28-06-2021
42	IND(CO-AEFI)MHBMC21014	2021	29	MALE	HOSPITALIZATION AND RECOVERED	06-02-2021	COVISHIELD	FEVER, LOOSE MOTION AND VOMITING	A1	28-06-2021
43	IND(CO-AEFI)MHBMC21008	2021	46	MALE	SEVERE AND RECOVERED	09-02-2021	COVISHIELD	ALLERGIC REACTION	A1	28-06-2021
44	IND(CO-AEFI)GUJMC21002	2021	45	MALE	HOSPITALIZATION AND RECOVERED	04-02-2021	COVISHIELD	ANXIETY REACTION	A4	28-06-2021
45	IND(CO-AEFI)GUJMC21001	2021	56	FEMALE	HOSPITALIZATION AND RECOVERED	04-02-2021	COVISHIELD	ANXIETY REACTION	A4	28-06-2021
46	IND(CO-AEFI)GUJMC21007	2021	20	FEMALE	HOSPITALIZATION AND RECOVERED	28-01-2021	COVISHIELD	FEVER, VOMITING, HEADACHE	A1	28-06-2021
47	IND(CO-AEFI)MHABD21002	2021	51	FEMALE	SEVERE AND RECOVERED	30-01-2021	COVAXIN	PANIC REACTION	A4	28-06-2021
48	IND(CO-AEFI)MHBMC21005	2021	20	FEMALE	HOSPITALIZATION AND RECOVERED	05-02-2021	COVISHIELD	FEVER WITH SEIZURE	B1	28-06-2021
49	IND(CO-AEFI)MHBMC21006	2021	20	FEMALE	HOSPITALIZATION AND RECOVERED	05-02-2021	COVISHIELD	VOMITING, DEHYDRATION AND HYPOTENSION	A1	28-06-2021
50	IND(CO-AEFI)MHBMC21010	2021	25	MALE	HOSPITALIZATION AND RECOVERED	12-02-2021	COVISHIELD	ANXIETY REACTION	A4	28-06-2021
51	IND(CO-AEFI)MHBMC21015	2021	44	FEMALE	HOSPITALIZATION AND RECOVERED	22-01-2021	COVISHIELD	FEBRILE REACTION	A1	28-06-2021
52	IND(CO-AEFI)MHBMC21010	2021	34	FEMALE	HOSPITALIZATION AND RECOVERED	29-01-2021	COVISHIELD	ALLERGIC REACTION	A1	28-06-2021

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53	IND(CO-AEFI)WBCAL21008	2021	23	MALE	HOSPITALIZATION AND RECOVERED	25-01-2021	COVISHIELD	ALLERGIC REACTION	A1	28-06-2021
54	IND(CO-AEFI)MHBMC21011	2021	52	FEMALE	HOSPITALIZATION AND RECOVERED	27-01-2021	COVISHIELD	ANXIETY REACTION	A4	28-06-2021
55	IND(CO-AEFI)MHBMC21012	2021	48	FEMALE	SEVERE AND RECOVERED	25-01-2021	COVISHIELD	ALLERGIC REACTION	A1	28-06-2021
56	IND(CO-AEFI)WBCAL21009	2021	26	FEMALE	SEVERE AND RECOVERED	28-01-2021	COVISHIELD	ANXIETY REACTION	A4	28-06-2021
57	IND(CO-AEFI)HAPNP21003	2021	42	FEMALE	HOSPITALIZATION AND RECOVERED	25-01-2021	COVISHIELD	ANXIETY REACTION WITH POORLY CONTROLLED HYPERTENSION	A4	28-06-2021
58	IND(CO-AEFI)BIKHA21003	2021	33	FEMALE	HOSPITALIZATION AND RECOVERED	13-02-2021	COVISHIELD	HEADACHE AND NAUSEA	A1	28-06-2021
59	IND(CO-AEFI)WBCAL21015	2021	28	MALE	SEVERE AND RECOVERED	30-01-2021	COVISHIELD	FEVER AND MYALGIA	A1	28-06-2021
60	IND(CO-AEFI)WBCAL21014	2021	33	FEMALE	SEVERE AND RECOVERED	25-01-2021	COVISHIELD	HEADACHE AND FEVER POST VACCINATION	A1	28-06-2021
61	IND(CO-AEFI)KABEL21003	2021	45	FEMALE	HOSPITALIZATION AND RECOVERED	18-02-2021	COVISHIELD	ALLERGIC REACTION	A1	28-06-2021
62	IND(CO-AEFI)DLSOU21005	2021	33	MALE	HOSPITALIZATION AND RECOVERED	25-01-2021	COVAXIN	ANXIETY DISORDER WITH PANIC ATTACK	A4	28-06-2021
63	IND(CO-AEFI)PBMHL21001	2021	24	FEMALE	SEVERE AND RECOVERED	23-01-2021	COVISHIELD	ALLERGIC REACTION	A1	28-06-2021
64	IND(CO-AEFI)MHBMC21020	2021	37	MALE	HOSPITALIZATION AND RECOVERED	20-02-2021	COVISHIELD	ALLERGIC REACTION	A1	28-06-2021
65	IND(CO-AEFI)UPBRL21009	2021	28	FEMALE	SEVERE AND RECOVERED	26-02-2021	COVISHIELD	ANAPHYLACTOID REACTION	A1	28-06-2021
66	IND(CO-AEFI)WBMBD21007	2021	24	MALE	HOSPITALIZATION AND RECOVERED	27-01-2021	COVISHIELD	ANXIETY REACTION	A4	28-06-2021
67	IND(CO-AEFI)WBMBD21006	2021	59	MALE	HOSPITALIZATION AND RECOVERED	10-02-2021	COVISHIELD	ALLERGIC REACTION	A1	28-06-2021
68	IND(CO-AEFI)CGKRB21001	2021	73	FEMALE	DEATH	05-03-2021	COVISHIELD	ACUTE MYOCARDIAL INFARCTION	B1	28-06-2021
69	IND(CO-AEFI)RJDUP21001	2021	78	MALE	HOSPITALIZATION AND RECOVERED	04-03-2021	COVISHIELD	ACUTE CORONARY SYNDROME WITH HYPERTENSION AND DIABETES MELLITUS	B1	28-06-2021
70	IND(CO-AEFI)KAUDU21001	2021	39	FEMALE	HOSPITALIZATION AND RECOVERED	16-01-2021	COVISHIELD	ANXIETY REACTION	A4	28-06-2021
71	IND(CO-AEFI)TNCN21005	2021	21	MALE	HOSPITALIZATION AND RECOVERED	20-01-2021	COVISHIELD	VOMITING AND GIDDINESS	A1	28-06-2021
72	IND(CO-AEFI)TNCN21007	2021	41	FEMALE	HOSPITALIZATION AND RECOVERED	05-03-2021	COVISHIELD	ANXIETY REACTION	A4	28-06-2021
73	IND(CO-AEFI)WBUDJ21003	2021	24	FEMALE	HOSPITALIZATION AND RECOVERED	09-03-2021	COVAXIN	ANXIETY REACTION	A4	28-06-2021
74	IND(CO-AEFI)UPDOR21002	2021	41	FEMALE	HOSPITALIZATION AND RECOVERED	18-03-2021	COVISHIELD	FEVER AND DIARRHOEA	A1	28-06-2021
75	IND(CO-AEFI)MHBMC21034	2021	37	MALE	HOSPITALIZATION AND RECOVERED	08-03-2021	COVISHIELD	HYPERTENSION	C	28-06-2021
76	IND(CO-AEFI)GOGOS21004	2021	72	MALE	SEVERE AND RECOVERED	11-03-2021	COVISHIELD	CVA (ISCHEMIC) WITH LACUNAR INFARCT WITH DIABETES MELLITUS, HYPERTENSION, CHRONIC	C	28-06-2021
77	IND(CO-AEFI)WBBDN21004	2021	47	FEMALE	HOSPITALIZATION AND RECOVERED	19-03-2021	COVISHIELD	DYSENTERY	C	28-06-2021
78	BNU	2021	22	FEMALE	HOSPITALIZATION AND RECOVERED	18-01-2021	COVISHIELD	ANXIETY REACTION	A4	28-06-2021

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79	IND(CO-AEFI)KACBP21001	2021	37	FEMALE	HOSPITALIZATION AND RECOVERED	19-02-2021	COVISHIELD	DISSOCIATIVE DISORDER	C	28-06-2021
80	IND(CO-AEFI)WBHGL21002	2021	31	FEMALE	HOSPITALIZATION AND RECOVERED	27-01-2021	COVISHIELD	FEBRILE REACTION	A1	28-06-2021
81	IND(CO-AEFI)HAPNP21007	2021	72	MALE	HOSPITALIZATION AND RECOVERED	24-03-2021	COVAXIN	ANXIETY REACTION	A4	28-06-2021
82	IND(CO-AEFI)WBHGL21003	2021	39	FEMALE	SEVERE AND RECOVERED	21-01-2021	COVISHIELD	ANXIETY REACTION	A4	28-06-2021
83	IND(CO-AEFI)KABEL21007	2021	83	FEMALE	HOSPITALIZATION AND RECOVERED	25-03-2021	COVISHIELD	ACUTE CORONARY SYNDROME WITH TYPE 2 DM, HYPERTENSION, DEGENERATIVE HEART DISEASE, DIABETIC NEPHROPATHY	C	28-06-2021
84	IND(CO-AEFI)MPBPL21006	2021	30	MALE	HOSPITALIZATION AND RECOVERED	25-02-2021	COVISHIELD	CVA WITH HYPERTENSION AND HYPOTHYROIDISM	B1	28-06-2021
85	IND(CO-AEFI)WBBDN21007	2021	48	MALE	HOSPITALIZATION AND RECOVERED	26-03-2021	COVISHIELD	FEVER WITH DIARRHOEA	A1	28-06-2021
86	IND(CO-AEFI)MPBPL21007	2021	68	MALE	HOSPITALIZATION AND RECOVERED	22-03-2021	COVISHIELD	CVA (ISCHEMIC) WITH LEFT MCA INFARCT WITH DIABETES MELLITUS AND HYPERTENSION	C	28-06-2021
87	IND(CO-AEFI)WBCAL21024	2021	42	MALE	HOSPITALIZATION AND RECOVERED	30-03-2021	COVAXIN	ANXIETY REACTION	A4	28-06-2021
88	IND(CO-AEFI)KACBP21004	2021	73	MALE	HOSPITALIZATION AND RECOVERED	08-03-2021	COVISHIELD	ACUTE CORONARY SYNDROME WITH HYPERTENSION AND COPD	C	28-06-2021

*Covid vaccine is a new vaccine. The causality may change as more information becomes available,

Verified by Dr Anju Seth and Dr Anil Gurtoo on 1st July 2021