

**Z.16025/02/2018-IMM-Part(1)**  
**Government of India**  
**Ministry of Health & Family Welfare**  
**Immunization Division**

**Nirman Bhawan, New Delhi**  
**Date: 06<sup>th</sup> February 2023**

**Causality assessment results of 73 reported Serious Adverse Events Following Immunization (AEFI) cases following COVID-19 vaccination approved by National AEFI Committee on 12<sup>th</sup> January 2023.**

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, and obstetrician-gynaecologist as members of the causality assessment sub-committee at the national level. A Special Group has been framed to conduct a causality assessment of AEFIs following COVID-19 vaccination. The results of the 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 73 cases completed on **12<sup>th</sup> January 2023** after a 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).

12 out of 73 cases for which Causality assessment has been done were found to have a **consistent causal association to immunization**. Of these 12 cases, 7 cases were vaccine product-related reaction including 03 deaths, and 05 cases were anxiety-related reaction. 47 cases have an inconsistent causal association to immunization (**coincidental - not linked to vaccination**), including 27 death cases. There are 9 cases in the indeterminate category including one death case. A total of 5 cases were in the 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 that 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 that 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 73 AEFI CASES APPROVED BY THE NATIONAL AEFI COMMITTEE 12 JAN 2023

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)KEWYD21001	2021	49	FEMALE	DEATH	2/19/2021	COVISHIELD	ACUTE CORONARY SYNDROME	C	1/12/2022
2	IND(CO-AEFI)KEKZK21026	2021	56	MALE	DEATH	2/16/2021	COVISHIELD	ACUTE CORONARY SYNDROME IN KNOWN CASE OF CORONARY ARTERY DISEASE	C	1/12/2022
3	IND(CO-AEFI)KEPLK21002	2021	70	MALE	DEATH	3/15/2021	COVISHIELD	UNEXPLAINED DEATH	D	1/12/2022
4	IND(CO-AEFI)KEPTM21002	2021	65	MALE	HOSPITALIZED AND RECOVERED	3/18/2021	COVISHIELD	ACUTE CORONARY SYNDROME IN KNOWN CASE OF CAD AND SMOKER	C	1/12/2022
5	IND(CO-AEFI)ASLKR21001	2021	45	MALE	HOSPITALIZED AND RECOVERED	3/5/2021	COVISHIELD	ACUTE GASTROENTERITIS WITH HAEMATEMESIS	C	1/12/2022
6	IND(CO-AEFI)KETRM21002	2021	81	MALE	HOSPITALIZED AND RECOVERED	18-03-2021	COVISHIELD	ACUTE CORONARY SYNDROME IN KNOWN CASE OF OLD CVA, TYPE II DIABETES, HYPERTENSION AND NEPHROPATHY	C	1/12/2022
7	IND(CO-AEFI)KETRM21005	2021	23	MALE	HOSPITALIZED AND RECOVERED	2/4/2021	COVISHIELD	ACUTE MENINGITIS	C	1/12/2022
8	IND(CO-AEFI)SINTH21001	2021	54	MALE	HOSPITALIZED AND RECOVERED	4/1/2021	COVISHIELD	SEIZURES IN KNOWN CASE OF EPILEPSY	C	1/12/2022
9	IND(CO-AEFI)MHBMC21042	2021	42	MALE	HOSPITALIZED AND RECOVERED	22-02-2021	COVISHIELD	ACUTE ST-ELEVATION MYOCARDIAL INFARCTION (STEMI) WITH UNDERLYING TYPE II DIABETES AND HYPERTENSION	C	1/12/2022
10	IND(CO-AEFI)KEAPZ21009	2021	77	MALE	DEATH	22-03-2021	COVISHIELD	ACUTE CORONARY SYNDROME IN KNOWN CASE OF HYPERTENSION	C	1/12/2022
11	IND(CO-AEFI)KETRM21003	2021	71	MALE	HOSPITALIZED AND RECOVERED	16-03-2021	COVISHIELD	INTRACRANIAL BLEED IN KNOWN CASE OF HYPERTENSION AND OLD CVA	C	1/12/2022
12	IND(CO-AEFI)KETRM21011	2021	78	FEMALE	HOSPITALIZED AND RECOVERED	3/12/2021	COVISHIELD	ACUTE FEBRILE REACTION	A1	1/12/2022
13	IND(CO-AEFI)KETRM21012	2021	70	FEMALE	HOSPITALIZED AND RECOVERED	3/27/2021	COVISHIELD	HEAD INJURY WITH INTRACRANIAL HEMORRHAGE IN KNOWN CASE OF HYPERTENSION AND BRONCHIAL ASTHMA	C	1/12/2022
14	IND(CO-AEFI)WBMNP21004	2021	46	FEMALE	HOSPITALIZED AND RECOVERED	19-04-2021	COVISHIELD	EPILEPSY	C	1/12/2022
15	IND(CO-AEFI)KETHR21012	2021	70	FEMALE	DEATH	23-04-2021	COVISHIELD	ACUTE CORONARY SYNDROME IN KNOWN CASE OF DIABETES TYPE II	C	1/12/2022
16	IND(CO-AEFI)KETRM21015	2021	59	MALE	HOSPITALIZED AND RECOVERED	4/10/2021	COVISHIELD	GUILLAIN-BARRE SYNDROME	B1	1/12/2022
17	IND(CO-AEFI)KETHR21016	2021	68	FEMALE	DEATH	17-04-2021	COVISHIELD	SEVERE COVID-19 DISEASE	C	1/12/2022
18	IND(CO-AEFI)KETHR21020	2021	65	MALE	DEATH	21-04-2021	COVISHIELD	COVID 19 DISEASE WITH UNDERLYING DIABETES MELLITUS	C	1/12/2022
19	IND(CO-AEFI)KETHR21021	2021	67	FEMALE	DEATH	5/4/2021	COVISHIELD	COVID 19 PNEUMONIA	C	1/12/2022
20	IND(CO-AEFI)WBDJL21016	2021	48	FEMALE	HOSPITALIZED AND RECOVERED	4/29/2021	COVISHIELD	ACUTE EXACERBATION OF COPD	C	1/12/2022
21	IND(CO-AEFI)WBDJL21017	2021	46	MALE	HOSPITALIZED AND RECOVERED	4/12/2021	COVISHIELD	DYSURIA (UTI)	C	1/12/2022
22	IND(CO-AEFI)KETRM21018	2021	67	MALE	HOSPITALIZED AND RECOVERED	25-06-2021	COVISHIELD	ACUTE CORONARY SYNDROME IN KNOWN CASE OF TYPE II DIABETES AND SMOKER	C	1/12/2022
23	IND(CO-AEFI)KETRM21019	2021	39	MALE	DEATH	6/5/2021	COVISHIELD	THROMBOSIS THROMBOCYTOPENIA SYNDROME	A1	1/12/2022
24	IND(CO-AEFI)WBDJL21023	2021	18	MALE	HOSPITALIZED AND RECOVERED	7/6/2021	SPUTNIK V	PANIC ATTACK	C	1/12/2022
25	IND(CO-AEFI)KETRM21023	2021	66	MALE	DEATH	6/10/2021	COVISHIELD	THROMBOSIS THROMBOCYTOPENIA SYNDROME	A1	1/12/2022
26	IND(CO-AEFI)KETRM21025	2021	69	FEMALE	HOSPITALIZED AND RECOVERED	6/28/2021	COVISHIELD	ACUTE ISCHEMIC STROKE IN KNOWN CASE OF HYPERTENSION	C	1/12/2022
27	IND(CO-AEFI)KEWYD21017	2021	48	MALE	DEATH	7/5/2021	COVISHIELD	RTA WITH INTRACEREBRAL HEMORRHAGE	C	1/12/2022
28	IND(CO-AEFI)KETRM21026	2021	35	FEMALE	HOSPITALIZED AND RECOVERED	6/13/2021	COVISHIELD	CEREBRAL VENOUS SINUS THROMBOSIS	B1	1/12/2022
29	IND(CO-AEFI)KETRM21028	2021	75	FEMALE	HOSPITALIZED AND RECOVERED	6/29/2021	COVISHIELD	MULTI LACUNAR INFARCT STATE	C	1/12/2022

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30	IND(CO-AEFI)KETHR21034	2021	58	MALE	DEATH	6/21/2021	COVISHIELD	UTI WITH SEPSIS IN KNOWN CASE OF TYPE II DIABETES, HYPERTENSION, DIABETIC NEPHROPATHY, PARAPLEGIA AND BED RIDDEN	C	1/12/2022
31	IND(CO-AEFI)KETRM21029	2021	52	FEMALE	HOSPITALIZED AND RECOVERED	7/8/2021	COVISHIELD	ACUTE DEMYELINATING ENCEPHALOMYELITIS (ADEM)	B1	1/12/2022
32	IND(CO-AEFI)MHTHN21020	2021	32	MALE	DEATH	7/27/2021	COVISHIELD	RIGHT ACUTE EXTRADURAL HAEMATOMA	C	1/12/2022
33	IND(CO-AEFI)KEWYD21020	2021	78	MALE	DEATH	8/3/2021	COVISHIELD	CORONARY ARTERY DISEASE	C	1/12/2022
34	IND(CO-AEFI)KETHR21041	2021	58	MALE	DEATH	7/29/2021	COVISHIELD	INFERIOR WALL MYOCARDIAL INFARCTION	C	1/12/2022
35	IND(CO-AEFI)KETHR21045	2021	57	MALE	DEATH	7/10/2021	COVISHIELD	COVID-19 DISEASE	C	1/12/2022
36	IND(CO-AEFI)KETHR21047	2021	78	FEMALE	DEATH	8/3/2021	COVISHIELD	SUDDEN CARDIAC DEATH	C	1/12/2022
37	IND(CO-AEFI)KEPTM21012	2021	39	FEMALE	DEATH	8/2/2021	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPAENIC SYNDROME (TTS)	A1	1/12/2022
38	IND(CO-AEFI)WBJPG21011	2021	38	FEMALE	DEATH	8/16/2021	COVISHIELD	TRAUMATIC BRAIN INJURY	C	1/12/2022
39	IND(CO-AEFI)WBMNP21008	2021	36	FEMALE	HOSPITALIZED AND RECOVERED	8/27/2021	COVISHIELD	FEVER WITH MYALGIA	A1	1/12/2022
40	IND(CO-AEFI)KEMPM21015	2021	46	FEMALE	HOSPITALIZED AND RECOVERED	8/22/2021	COVISHIELD	GUILLAIN-BARRE SYNDROME	B1	1/12/2022
41	IND(CO-AEFI)KETHR21055	2021	51	MALE	DEATH	8/13/2021	COVISHIELD	HAEMORRHAGIC STROKE WITH UNDERLYING HYPERTENSION AND CHRONIC KIDNEY DISEASE	C	1/12/2022
42	IND(CO-AEFI)KETHR21054	2021	84	MALE	DEATH	7/23/2021	COVISHIELD	COVID-19 DISEASE WITH CEREBROVASCULAR ACCIDENT	C	1/12/2022
43	IND(CO-AEFI)KEWYD21025	2021	60	MALE	DEATH	8/26/2021	COVISHIELD	SUDDEN CARDIAC DEATH WITH UNDERLYING CORONARY ARTERY DISEASE	C	1/12/2022
44	IND(CO-AEFI)KETHR21058	2021	60	MALE	DEATH	9/7/2021	COVISHIELD	COVID-19 DISEASE IN A PATIENT WITH ACUTE MYOCARDIAL INFARCTION	C	1/12/2022
45	IND(CO-AEFI)MHNGP21009	2021	42	MALE	DEATH	10/23/2021	COVISHIELD	CORONARY ARTERY SYNDROME LEADING TO SUDDEN CARDIAC DEATH	B1	1/12/2022
46	IND(CO-AEFI)ASKJR21001	2021	53	FEMALE	DEATH	10/10/2021	COVISHIELD	UNEXPLAINED DEATH	D	1/12/2022
47	IND(CO-AEFI)KETHR21075	2021	88	FEMALE	DEATH	10/28/2021	COVAXIN	ACUTE GASTROENTERITIS WITH HYONATREMIA IN KNOWN CASE OF HYPERTENSION	C	1/12/2022
48	IND(CO-AEFI)MHBMC21102	2021	36	MALE	DEATH	10/25/2021	COVISHIELD	SUDDEN UNEXPLAINED DEATH	D	1/12/2022
49	IND(CO-AEFI)MHTHN21025	2021	23	FEMALE	HOSPITALIZED AND RECOVERED	9/21/2021	COVISHIELD	GUILLAIN-BARRE SYNDROME	B1	1/12/2022
50	IND(CO-AEFI)ORNUP21007	2021	47	FEMALE	DEATH	11/24/2021	COVISHIELD	UNEXPLAINED DEATH	D	1/12/2022
51	IND(CO-AEFI)MHBMC21106	2021	50	MALE	DEATH	11/17/2021	COVISHIELD	ALCOHOLIC LIVER DISEASE WITH INTRACRANIAL BLEED IN KNOWN CASE OF HYPERTENSION	C	1/12/2022
52	IND(CO-AEFI)KETHR22007	2022	82	MALE	DEATH	1/15/2022	COVISHIELD	SUDDEN CARDIAC DEATH WITH CARCINOMA STOMACH/ HYPERTENSION AND DIABETES MELLITUS	C	1/12/2022
53	IND(CO-AEFI)KETHR22008	2022	71	MALE	DEATH	1/28/2022	COVISHIELD	SUDDEN CARDIAC DEATH IN KNOWN CASE OF DIABETES AND CAD	C	1/12/2022
54	IND(CO-AEFI)TSMDK21002	2021	73	MALE	DEATH	3/24/2021	COVISHIELD	UNEXPLAINED DEATH	D	1/12/2022
55	IND(CO-AEFI)KETHR22009	2022	72	MALE	DEATH	5/2/2022	COVISHIELD	ACUTE CORONARY SYNDROME WITH ATRIAL FIBRILLATION IN KNOWN CASE OF CAD AND HYPERTENSION	C	1/12/2022
56	IND(CO-AEFI)ASNLB22001	2022	19	FEMALE	HOSPITALIZED AND RECOVERED	6/6/2022	COVAXIN	ANXIETY REACTION	A4	1/12/2022
57	IND(CO-AEFI)WBBSI21001	2021	60	MALE	SEVERE AND RECOVERED	1/16/2021	COVISHIELD	URINARY BLADDER POLYP WITH HEMATURIA	C	1/12/2022
58	IND(CO-AEFI)MHBMC22010	2022	73	FEMALE	DEATH	7/14/2022	COVISHIELD	ACUTE ON CHRONIC KIDNEY DISEASE WITH SEPSIS WITH SEPTIC SHOCK IN KNOWN CASE OF DIABETES MELLITUS AND HYPERTENSION	C	1/12/2022
59	IND(CO-AEFI)HAKNL22002	2022	13	MALE	HOSPITALIZED AND RECOVERED	7/11/2022	CORBEVAX	ADEM	B1	1/12/2022

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60	IND(CO-AEFI)KEKZK22003	2022	14	FEMALE	HOSPITALIZED AND RECOVERED	7/26/2022	CORBEVAX	SYNCOPE	A4	1/12/2022
61	IND(CO-AEFI)KEWYD22002	2022	14	MALE	SEVERE AND RECOVERED	8/2/2022	CORBEVAX	ANXIETY REACTION	A4	1/12/2022
62	IND(CO-AEFI)KARMN21005	2021	67	MALE	DEATH	10/8/2021	COVISHIELD	ACUTE CORONARY SYNDROME IN KNOWN CASE OF TYPE II DIABETES AND HYPERTENSION	C	1/12/2022
63	IND(CO-AEFI)MHBMC21116	2021	56	FEMALE	HOSPITALIZED AND RECOVERED	5/28/2021	COVISHIELD	CEREBROVASCULAR ACCIDENT IN KNOWN CASE OF HYPERTENSION	C	1/12/2022
64	IND(CO-AEFI)KACBP21008	2021	84	MALE	HOSPITALIZED AND RECOVERED	4/1/2021	COVISHIELD	CVA(STROKE)	C	1/12/2022
65	IND(CO-AEFI)KEKOT22003	2022	15	MALE	HOSPITALIZED AND RECOVERED	2/19/2022	COVAXIN	RIGHT MCA & ACA THROMBOTIC STROKE WITH UNDERLYING HYPERTROPHIC CARDIOMYOPATHY	C	1/12/2022
66	IND(CO-AEFI)JHLTH21001	2021	73	FEMALE	DEATH	3/21/2021	COVISHIELD	CEREBROVASCULAR ACCIDENT	C	1/12/2022
67	IND(CO-AEFI)WBMNP21009	2021	19	FEMALE	HOSPITALIZED AND RECOVERED	10/1/2021	COVISHIELD	CONVULSIONS	B1	1/12/2022
68	IND(CO-AEFI)WBMLD22002	2022	14	FEMALE	HOSPITALIZED AND RECOVERED	4/23/2022	CORBEVAX	SYNCOPE	A4	1/12/2022
69	IND(CO-AEFI)WBMLD22003	2022	18	FEMALE	HOSPITALIZED AND RECOVERED	2/15/2022	COVAXIN	ANXIETY REACTION	A4	1/12/2022
70	IND(CO-AEFI)MHYTL21001	2021	39	FEMALE	HOSPITALIZED AND RECOVERED	7/3/2021	COVISHIELD	GUILLAIN-BARRE SYNDROME	B1	1/12/2022
71	IND(CO-AEFI)MHWSM21001	2021	30	FEMALE	HOSPITALIZED AND RECOVERED	3/8/2021	COVISHIELD	PRURITIS	A1	1/12/2022
72	IND(CO-AEFI)KETHR21086	2021	55	MALE	HOSPITALIZED AND RECOVERED	3/13/2021	COVISHIELD	DISSEMINATED TB WITH DIABETES MELLITUS AND STROKE	C	1/12/2022
73	IND(CO-AEFI)KAHAS21003	2021	26	MALE	HOSPITALIZED AND RECOVERED	9/17/2021	COVISHIELD	ANAPHYLAXIS (LEVEL III)	A1	1/12/2022

\*Covid vaccine is a new vaccine. The causality may change as more information become available.

Verified by Dr Anil Gurtoo on 21st Jan 23 and Dr Anju Seth on 23rd Jan 23

Abbreviations:

ADEM- Acute Disseminated Encephalomyelitis

CAD- coronary artery disease

COPD- Chronic Obstructive Pulmonary Disease

CVA - Cerebrovascular Accident

NSTEMI- Non-ST Elevation Myocardial Infarction

UTI- Urinary Tract Infection

RTA- Road Traffic Accident