

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

Date: 08th July, 2021
Nirman Bhawan, New Delhi

Causality assessment results of 60 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 60 cases completed on 27th May 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).

55 out of 60 cases for which Causality assessment has been done found to have **consistent causal association to vaccination**, Of these **36 were anxiety related reactions**, and **18 were vaccine product related reactions** and **one was classified as both vaccine product related and anxiety related reaction**. 5 cases have been found to have **inconsistent causal association to vaccination (coincidental - not linked to vaccination)** of which **one was a death case**.

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 60 AEFI CASES APPROVED BY THE NATIONAL AEFI COMMITTEE 27 MAY 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)CGJHP21001	2021	35	F	HOSPITALIZATION AND RECOVERED	18-01-2021	COVISHIELD	ACUTE GASTROENTERITIS	COINCIDENTAL	27-05-2021
2	IND(CO-AEFI)DLEAS21001	2021	27	F	HOSPITALIZATION AND RECOVERED	18-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
3	IND(CO-AEFI)GUAMC21002	2021	52	M	SEVERE AND RECOVERED	21-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
4	IND(CO-AEFI)GUAMC21003	2021	26	F	SEVERE AND RECOVERED	21-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
5	IND(CO-AEFI)KABMP21007	2021	26	F	HOSPITALIZATION AND RECOVERED	06-02-2021	COVISHIELD	ALLERGIC REACTION	A1	27-05-2021
6	IND(CO-AEFI)PDMAE21002	2021	58	M	SEVERE AND RECOVERED	16-01-2021	COVISHIELD	VASOVAGAL SYNCOPE	A4	27-05-2021
7	IND(CO-AEFI)PBFZP21002	2021	33	F	HOSPITALIZATION AND RECOVERED	19-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
8	IND(CO-AEFI)PBFZP21001	2021	48	F	HOSPITALIZATION AND RECOVERED	03-02-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
9	IND(CO-AEFI)UPBHN21002	2021	29	F	HOSPITALIZATION AND RECOVERED	16-01-2021	COVISHIELD	FEVER & ANXIETY REACTION	A1 & A4	27-05-2021
10	IND(CO-AEFI)UPVRN21001	2021	23	F	HOSPITALIZATION AND RECOVERED	11-02-2021	COVAXIN	ANXIETY REACTION	A4	27-05-2021
11	IND(CO-AEFI)WBRMH21001	2021	30	M	SEVERE AND RECOVERED	16-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
12	IND(CO-AEFI)TRTRW21007	2021	38	M	HOSPITALIZATION AND RECOVERED	15-02-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
13	IND(CO-AEFI)WBCAL21013	2021	65	F	HOSPITALIZATION AND RECOVERED	15-02-2021	COVISHIELD	ACUTE GASTROENTERITIS WITH DYSELECTROLEMIA	COINCIDENTAL	27-05-2021
14	IND(CO-AEFI)HAHSR21002	2021	30	F	HOSPITALIZATION AND RECOVERED	18-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
15	IND(CO-AEFI)HAPNP21004	2021	31	F	HOSPITALIZATION AND RECOVERED	22-02-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
16	IND(CO-AEFI)HAJND21002	2021	34	F	HOSPITALIZATION AND RECOVERED	25-01-2021	COVISHIELD	FEVER WITH BODYACHE WITH VOMITING	A1	27-05-2021
17	IND(CO-AEFI)TNMDU21001	2021	38	F	SEVERE AND RECOVERED	19-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
18	IND(CO-AEFI)MHTHN21008	2021	70	F	SEVERE AND RECOVERED	04-03-2021	COVISHIELD	ANAPHYLAXIS	A1	27-05-2021
19	IND(CO-AEFI)MHTHN21009	2021	77	M	SEVERE AND RECOVERED	04-03-2021	COVISHIELD	ALLERGIC REACTION	A1	27-05-2021
20	IND(CO-AEFI)WBMBD21002	2021	24	M	SEVERE AND RECOVERED	16-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
21	IND(CO-AEFI)PDMAE21001	2021	50	M	SEVERE AND RECOVERED	16-01-2021	COVISHIELD	ALLERGIC REACTION	A1	27-05-2021
22	IND(CO-AEFI)UPBLS21001	2021	37	F	HOSPITALIZATION AND RECOVERED	16-01-2021	COVISHIELD	ALLERGIC REACTION	A1	27-05-2021
23	IND(CO-AEFI)UPBLS21002	2021	55	F	HOSPITALIZATION AND RECOVERED	16-01-2021	COVISHIELD	ALLERGIC REACTION	A1	27-05-2021
24	IND(CO-AEFI)CGMMD21001	2021	41	F	HOSPITALIZATION AND RECOVERED	16-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
25	IND(CO-AEFI)RJPLI21001	2021	20	F	SEVERE AND RECOVERED	19-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021

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26	IND(CO-AEFI)KABEL21001	2021	30	F	HOSPITALIZATION AND RECOVERED	20-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
27	IND(CO-AEFI)WBJPG21001	2021	43	F	SEVERE AND RECOVERED	21-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
28	IND(CO-AEFI)HAPNP21001	2021	30	F	HOSPITALIZATION AND RECOVERED	19-01-2021	COVISHIELD	FEVER AND VOMITING	A1	27-05-2021
29	IND(CO-AEFI)WBDMD21001	2021	48	F	HOSPITALIZATION AND RECOVERED	21-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
30	IND(CO-AEFI)UPGRP21001	2021	33	F	HOSPITALIZATION AND RECOVERED	22-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
31	IND(CO-AEFI)TSSDP21002	2021	49	F	HOSPITALIZATION AND RECOVERED	19-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
32	IND(CO-AEFI)TSSDP21001	2021	36	F	HOSPITALIZATION AND RECOVERED	19-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
33	IND(CO-AEFI)UPSHP21002	2021	46	F	HOSPITALIZATION AND RECOVERED	22-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
34	IND(CO-AEFI)JKJAM21004	2021	29	F	HOSPITALIZATION AND RECOVERED	25-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
35	IND(CO-AEFI)TRTRW21002	2021	36	M	HOSPITALIZATION AND RECOVERED	19-01-2021	COVISHIELD	ACUTE GASTRITIS WITH FEVER	A1	27-05-2021
36	IND(CO-AEFI)MHTHN21001	2021	24	M	HOSPITALIZATION AND RECOVERED	19-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
37	IND(CO-AEFI)RJAJM21001	2021	32	F	HOSPITALIZATION AND RECOVERED	25-01-2021	COVISHIELD	ACUTE GASTRITIS WITH FEVER	A1	27-05-2021
38	IND(CO-AEFI)UPBRC21001	2021	37	F	HOSPITALIZATION AND RECOVERED	22-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
39	IND(CO-AEFI)UPSBD21001	2021	40	F	HOSPITALIZATION AND RECOVERED	28-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
40	IND(CO-AEFI)GUJMC21006	2021	22	F	HOSPITALIZATION AND RECOVERED	28-01-2021	COVISHIELD	ALLERGIC REACTION	A1	27-05-2021
41	IND(CO-AEFI)WBDMD21004	2021	41	F	HOSPITALIZATION AND RECOVERED	16-01-2021	COVISHIELD	ALLERGIC REACTION	A1	27-05-2021
42	IND(CO-AEFI)BIKHA21002	2021	39	F	HOSPITALIZATION AND RECOVERED	28-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
43	IND(CO-AEFI)GURJT21002	2021	21	F	HOSPITALIZATION AND RECOVERED	28-01-2021	COVISHIELD	UPPER RESPIRATORY TRACT INFECTION	COINCIDENTAL	27-05-2021
44	IND(CO-AEFI)TRTRN21001	2021	46	F	HOSPITALIZATION AND RECOVERED	29-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
45	IND(CO-AEFI)UPBJN21002	2021	21	F	SEVERE AND RECOVERED	29-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
46	IND(CO-AEFI)WBCAL21002	2021	53	M	HOSPITALIZATION AND RECOVERED	29-01-2021	COVISHIELD	VOMITTING AND DIZZINESS	A1	27-05-2021
47	IND(CO-AEFI)UPPSN21001	2021	61	F	HOSPITALIZATION AND RECOVERED	28-01-2021	COVISHIELD	ACUTE GASTROENTERITIS	COINCIDENTAL	27-05-2021
48	IND(CO-AEFI)MPRTM21001	2021	61	F	HOSPITALIZATION AND RECOVERED	27-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
49	IND(CO-AEFI)BIMUN21001	2021	39	F	HOSPITALIZATION AND RECOVERED	01-02-2021	COVISHIELD	VOMITING AND PAIN ABDOMEN	A1	27-05-2021
50	IND(CO-AEFI)TRTRW21004	2021	21	F	HOSPITALIZATION AND RECOVERED	02-02-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021

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51	IND(CO-AEFI)UPSHA21001	2021	19	F	HOSPITALIZATION AND RECOVERED	29-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
52	IND(CO-AEFI)WBCAL21003	2021	26	F	HOSPITALIZATION AND RECOVERED	05-02-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
53	IND(CO-AEFI)JHRNC21003	2021	23	F	SEVERE AND RECOVERED	06-02-2021	COVISHIELD	CHILLS	A1	27-05-2021
54	IND(CO-AEFI)WBCAL21004	2021	31	F	HOSPITALIZATION AND RECOVERED	27-01-2021	COVISHIELD	VASOVAGAL SYNCOPE	A4	27-05-2021
55	IND(CO-AEFI)MPIDR21003	2021	21	M	HOSPITALIZATION AND RECOVERED	18-02-2021	COVISHIELD	ALLERGIC REACTION	A1	27-05-2021
56	IND(CO-AEFI)UPBRL21010	2021	28	M	SEVERE AND RECOVERED	18-02-2021	COVAXIN	ALLERGIC REACTION	A1	27-05-2021
57	IND(CO-AEFI)UPAGR21001	2021	48	F	HOSPITALIZATION AND RECOVERED	16-01-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
58	IND(CO-AEFI)HAPNP21005	2021	88	M	SEVERE AND RECOVERED	15-03-2021	COVAXIN	ALLERGIC REACTION	A1	27-05-2021
59	IND(CO-AEFI)WBMBD21011	2021	58	F	SEVERE AND RECOVERED	19-03-2021	COVISHIELD	ANXIETY REACTION	A4	27-05-2021
60	IND(CO-AEFI)DLNWE21001	2021	57	M	DEATH	17-02-2021	COVISHIELD	ACUTE ANTERIOR WALL MI with CORONARY ARTERY DISEASE	COINCIDENTAL	27-05-2021

*Covid vaccine is a new vaccine. The causality may change as more information becomes available, Approved by Dr Anju Seth and Dr Anil Gurtoo on 31st May 2021