Health Canada / Santé Canada

REPORT OF A VACCINE-ASSOCIATED ADVERSE EVENT

Protected when completed

In confidence to: Vaccine Safety Unit
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IDENTIFICATION

PATIENT IDENTIFIER	PROVINCE/TERRITORY	DATE OF BIRTH YEAR MONTH DAY	SEX ☐ Male ☐ Female	DATE OF VACCINE ADMINISTRATION YEAR MONTH DAY

VACCINES

VACCINE(S) GIVEN	NUMBER IN SERIES	SITE	ROUTE	DOSAGE	MANUFACTURER	LOT NUMBER

ADVERSE EVENT(S)

Events marked with an asterisk (*) must be diagnosed by a physician. Report only events which cannot be attributed to co-existing conditions. Additional information for all events should be provided under SUPPLEMENTARY INFORMATION on reverse side. Record interval between vaccine administration and onset of each event in minutes, hours or days.

LOCAL REACTION AT INJECTION SITE

☐ **INFECTED ABSCESS** (tick one or both of the options below) — MIN. | HOURS | DAYS
- (i) positive gram stain or culture ☐
- (ii) existence of purulent discharge with inflammatory signs ☐

☐ **STERILE ABSCESS/NODULE** — MIN. | HOURS | DAYS
No evidence of acute microbiological infection

☐ **SEVERE PAIN AND/OR SEVERE SWELLING** — MIN. | HOURS | DAYS
(tick one or both of the options below)
- (i) lasting 4 days or more ☐
- (ii) extending past nearest joint(s) ☐

☐ **SCREAMING EPISODE/PERSISTENT CRYING** — MIN. | HOURS | DAYS
Inconsolable for 3 hours or more; OR quality of cry definitely abnormal for child and not previously heard by parents

☐ **FEVER** — MIN. | HOURS | DAYS
Highest recorded temperature (Report only **39.0°C** (102.2° F) or above)

Temperature: _____ °C (or _____ °F)

Site: rectal ☐ oral ☐ axilla ☐ skin ☐ tympanic ☐

Temperature believed to be high but not recorded ☐
Should be supported by the presence of other systemic symptoms

☐ **ADENOPATHY** (tick one or both of the options below) — MIN. | HOURS | DAYS
- (i) enlarged lymph node(s) ☐
- (ii) drainage of lymph node(s) ☐

Site(s) _____

☐ **PAROTITIS** — MIN. | HOURS | DAYS
Swelling with pain and/or tenderness of parotid gland(s)

*☐ **ANAPHYLAXIS OR SEVERE SHOCK** — MIN. | HOURS | DAYS
Explosive, occurring within minutes after immunization, and evolving rapidly towards cardiovascular collapse AND requiring resuscitative therapy

☐ **OTHER ALLERGIC REACTIONS** (tick one or more of the options below) — MIN. | HOURS | DAYS
- (i) wheezing or shortness of breath due to bronchospasm ☐
- (ii) swelling of mouth or throat ☐
- (iii) skin manifestations (e.g., hives, eczema, pruritus) ☐
- (iv) facial or generalized edema ☐

☐ **RASHES** (other than hives) — MIN. | HOURS | DAYS
Lasting 4 days or more AND/OR requiring hospitalization

Generalized ☐ Localized (indicate site) ☐ _____

Specify characteristics of rash _____

_____

☐ **ARTHRALGIA/ARTHRITIS** — MIN. | HOURS | DAYS
Joint pain/inflammation lasting at least 24 hours
If condition is an acute exacerbation of a pre-existing diagnosis, give details under **Supplementary Information**

☐ **SEVERE VOMITING AND/OR DIARRHEA** — MIN. | HOURS | DAYS
Must be severe enough to interfere with daily routine

☐ **HYPOTONIC-HYPORESPONSIVE EPISODE** (in children < 2 yrs, only) — MIN. | HOURS | DAYS
Characterised by all the features of: (i) generalized decrease/loss of muscle tone; AND (ii) pallor or cyanosis; AND (iii) decreased level of awareness or loss of consciousness
Should not be mistaken for fainting, a post-convulsion state, or anaphylaxis

☐ **CONVULSION/SEIZURE** — MIN. | HOURS | DAYS
Febrile ☐ Afebrile ☐
Past history of: A) Febrile seizures Yes ☐ No ☐
B) Afebrile seizures Yes ☐ No ☐
Omit fainting, seizures occurring within 30 minutes of immunization, and seizures occurring as part of encephalopathy or meningitis/encephalitis

*☐ **ENCEPHALOPATHY** — MIN. | HOURS | DAYS
Acute onset of major neurological illness characterized by any two or more of: (i) seizures; (ii) distinct change in level of consciousness or mental status (behaviour and/or personality) lasting 24 hours or more; (iii) focal neurological signs which persist for more than 24 hours

*☐ **MENINGITIS AND/OR ENCEPHALITIS** — MIN. | HOURS | DAYS
Abnormal CSF findings AND an acute onset of: (i) fever with neck stiffness or positive meningeal signs; OR (ii) signs and symptoms of encephalopathy (see ENCEPHALOPATHY above)
Results of CSF examination should be provided under **Supplementary Information**

*☐ **ANAESTHESIA/PARAESTHESIA** — MIN. | HOURS | DAYS
Lasting over 24 hours
Generalized ☐ Localized (indicate site) ☐ _____

*☐ **GUILLAIN-BARRÉ SYNDROME** — MIN. | HOURS | DAYS
Progressive subacute weakness of more than one limb (typically symmetrical) with **hyporeflexia/areflexia**

*☐ **PARALYSIS** (Do not code if Guillain-Barré Syndrome is coded) — MIN. | HOURS | DAYS
Limb paralysis ☐ Facial or cranial paralysis ☐

Describe _____

*☐ **THROMBOCYTOPENIA** — MIN. | HOURS | DAYS
Give lab results under **Supplementary Information**

☐ **OTHER SEVERE OR UNUSUAL EVENTS** — MIN. | HOURS | DAYS
Include any adverse event believed to be related to immunization, that does not fit any of the categories listed above and for which no other cause is clearly established
Report events of clinical interest which require medical attention, and particularly events that are (i) fatal, (ii) life-threatening, (iii) require hospitalization, or (iv) result in residual disability

DESCRIPTION

_____
_____
_____
_____
_____

REPORTER'S NAME	TELEPHONE NUMBER ( )	ADDRESS (Institution/No., Street, etc.)
PROFESSIONAL STATUS: MD ☐ RN ☐ OTHER _____		
SIGNATURE DATE Year Month Day		City Province Postal Code

Canada

OUTCOME OF EVENT(S) AT TIME OF REPORT PLEASE FORWARD ANY FOLLOW UP INFORMATION — FULLY RECOVERED ☐ — RESIDUAL EFFECTS (describe) ☐ — FATAL ☐ — LOST TO FOLLOW-UP ☐ — PENDING ☐

SOUGHT MEDICAL ATTENTION (Emergency room, clinic, family physician etc.) NO ☐ YES ☐ (If yes, include relevant details of treatment under **Supplementary Information**)

HOSPITALIZED BECAUSE OF EVENT(S) NO ☐ YES ☐ | **LENGTH OF STAY** (DAYS) ☐ | **DATE ADMITTED** Year Month Day

CONCOMITANT MEDICATIONS (exclude those used to treat the adverse event)
DRUG(S) GIVEN

MEDICAL HISTORY Please provide information on relevant medical history or concurrent illness (See detailed instructions on reverse)

SUPPLEMENTARY INFORMATION

INSTRUCTIONS FOR COMPLETING REPORT OF A VACCINE-ASSOCIATED ADVERSE EVENT

1. Please use dark ink when completing form to improve legibility of copies.
2. Report only events which have a temporal association with a vaccine and which cannot be attributed to co-existing conditions. **A causal relationship does not need to be proven, and submitting a report does not imply causality.**
3. Events marked with an asterisk (*) must be diagnosed by a physician. Supply relevant details in the SUPPLEMENTARY INFORMATION box.
4. Record interval between vaccine administration and onset of each event in minutes, hours or days.
5. Provide relevant information, when appropriate, in the SUPPLEMENTARY INFORMATION box. Includes details of events diagnosed by physician (see 3 above), results of diagnostic or laboratory tests, hospital treatment, and discharge diagnoses where a vaccinee is hospitalised because of a vaccine-associated adverse event. If appropriate, and preferred, photocopies of original records may be submitted.
6. Provide details of medical history that are relevant to the adverse event(s) reported. Examples include a history of allergies in vaccinee, previous adverse event(s), and concurrent illnesses which may be associated with the current adverse event(s).

TO BE COMPLETED BY MEDICAL HEALTH OFFICER RECOMMENDATIONS FOR FURTHER IMMUNIZATION

NAME: _____ **PHONE:** _____

SIGNATURE **DATE** Year Month Day