

– Appendix II –



Health
Canada

Santé
Canada

In confidence to: Division of Immunization
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REPORT OF A VACCINE-ASSOCIATED ADVERSE EVENT

Protected when completed

IDENTIFICATION										
PATIENT IDENTIFIER	PROVINCE/TERRITORY	DATE OF BIRTH	YEAR	MONTH	DAY	SEX	DATE OF VACCINE ADMINISTRATION	YEAR	MONTH	DAY
						<input type="checkbox"/> Male <input type="checkbox"/> Female				

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.*

<p>LOCAL REACTION AT INJECTION SITE</p> <p><input type="checkbox"/> INFECTED ABSCESS (tick one or both of the options below) MIN. HOURS. DAYS (i) positive gram stain or culture <input type="checkbox"/> (ii) existence of purulent discharge with inflammatory signs <input type="checkbox"/></p> <p><input type="checkbox"/> STERILE ABSCESS/NODULE MIN. HOURS. DAYS No evidence of acute microbiological infection</p> <p><input type="checkbox"/> SEVERE PAIN AND/OR SEVERE SWELLING (tick one or both of the options below) MIN. HOURS. DAYS (i) lasting 4 days or more <input type="checkbox"/> (ii) extending past nearest joint(s) <input type="checkbox"/></p> <p><input type="checkbox"/> 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</p> <p><input type="checkbox"/> FEVER MIN. HOURS. DAYS Highest recorded temperature (Report only 38.0°C (100.2° F) or above) Temperature: _____°C (or _____°F) Site: rectal <input type="checkbox"/> oral <input type="checkbox"/> axilla <input type="checkbox"/> skin <input type="checkbox"/> tympanic <input type="checkbox"/> Temperature believed to be high but not recorded <input type="checkbox"/> Should be supported by the presence of other systemic symptoms</p> <p><input type="checkbox"/> ADENOPATHY (tick one or both of the options below) MIN. HOURS. DAYS (i) enlarged lymph node(s) <input type="checkbox"/> (ii) drainage of lymph node(s) <input type="checkbox"/> Site(s) _____</p> <p><input type="checkbox"/> PAROTITIS MIN. HOURS. DAYS Swelling with pain and/or tenderness of parotid gland(s)</p> <p><input checked="" type="checkbox"/> ANAPHYLAXIS OR SEVERE SHOCK MIN. HOURS. DAYS Explosive, occurring within minutes after immunization, and evolving rapidly towards cardiovascular collapse AND requiring resuscitative therapy</p> <p><input type="checkbox"/> OTHER ALLERGIC REACTIONS (tick one or more of the options below) MIN. HOURS. DAYS (i) wheezing or shortness of breath due to bronchospasm <input type="checkbox"/> (ii) swelling of mouth or throat <input type="checkbox"/> (iii) skin manifestations (e.g. hives, eczema, pruritus) <input type="checkbox"/> (iv) facial or generalized edema <input type="checkbox"/></p> <p><input type="checkbox"/> RASHES (other than hives) MIN. HOURS. DAYS Lasting 4 days or more AND/OR requiring hospitalization Generalized <input type="checkbox"/> Localized (indicate site) <input type="checkbox"/> Specify characteristics of rash _____</p> <p><input type="checkbox"/> 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</p>	<p><input type="checkbox"/> SEVERE VOMITING AND/OR DIARRHEA MIN. HOURS. DAYS Must be severe enough to interfere with daily routine</p> <p><input type="checkbox"/> HYPOTONIC-HYPORESPONSIVE EPISODE (in children < 2 yrs. only) MIN. HOURS. DAYS Characterized 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</p> <p><input type="checkbox"/> CONVULSION/SEIZURE MIN. HOURS. DAYS Febrile <input type="checkbox"/> Afebrile <input type="checkbox"/> Past history of: A) Febrile seizures Yes <input type="checkbox"/> No <input type="checkbox"/> B) Afebrile seizures Yes <input type="checkbox"/> No <input type="checkbox"/> Omit fainting, seizures occurring within 30 minutes of immunization, and seizures occurring as part of encephalopathy or meningitis/encephalitis</p> <p><input checked="" type="checkbox"/> 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</p> <p><input checked="" type="checkbox"/> 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</p> <p><input checked="" type="checkbox"/> ANAESTHESIA/PARAESTHESIA MIN. HOURS. DAYS Lasting over 24 hours Generalized <input type="checkbox"/> Localized (indicate site) _____</p> <p><input checked="" type="checkbox"/> GULLAIN-BARRÉ SYNDROME MIN. HOURS. DAYS Progressive subacute weakness of more than one limb (typically symmetrical) with hyporeflexia/areflexia</p> <p><input checked="" type="checkbox"/> PARALYSIS (Do not code if Guillain-Barre Syndrome is coded) MIN. HOURS. DAYS Limb paralysis <input type="checkbox"/> Facial or cranial paralysis <input type="checkbox"/> Describe _____</p> <p><input checked="" type="checkbox"/> THROMBOCYTOPENIA MIN. HOURS. DAYS Give lab results under Supplementary Information</p> <p><input type="checkbox"/> 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</p> <p>DESCRIPTION _____ _____ _____</p>
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REPORTER'S NAME	TELEPHONE NUMBER () _____	ADDRESS (Institution/No., Street, etc.)		
PROFESSIONAL STATUS: MD <input type="checkbox"/> RN <input type="checkbox"/> OTHER <input type="checkbox"/>		City	Province	Postal Code
SIGNATURE	DATE Year Month Day			

HC/SC 4229 (03-96) - 1



