



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><b>LOCAL REACTION AT INJECTION SITE</b></p> <p><input type="checkbox"/> <b>INFECTED ABSCESS</b> (tick one or both of the options below)</p> <p>(i) positive gram stain or culture <input type="checkbox"/></p> <p>(ii) existence of purulent discharge with inflammatory signs <input type="checkbox"/></p> <p>MIN.   HOURS   DAYS</p> <p><input type="checkbox"/> <b>STERILE ABSCESS/NODULE</b> No evidence of acute microbiological infection</p> <p>MIN.   HOURS   DAYS</p> <p><input type="checkbox"/> <b>SEVERE PAIN AND/OR SEVERE SWELLING</b> (tick one or both of the options below)</p> <p>(i) lasting 4 days or more <input type="checkbox"/></p> <p>(ii) extending past nearest joint(s) <input type="checkbox"/></p> <p>MIN.   HOURS   DAYS</p> <p><input type="checkbox"/> <b>SCREAMING EPISODE/PERSISTENT CRYING</b> Inconsolable for 3 hours or more; OR quality of cry definitely abnormal for child and not previously heard by parents</p> <p>MIN.   HOURS   DAYS</p> <p><input type="checkbox"/> <b>FEVER</b> <b>Highest recorded temperature</b> (Report only 39.0°C (102.2° F) or above)</p> <p>Temperature: _____°C (or _____°F)</p> <p>Site: rectal <input type="checkbox"/> oral <input type="checkbox"/> axilla <input type="checkbox"/> skin <input type="checkbox"/> tympanic <input type="checkbox"/></p> <p><input type="checkbox"/> <b>Temperature believed to be high but not recorded</b> Should be supported by the presence of other systemic symptoms</p> <p><input type="checkbox"/> <b>ADENOPATHY</b> (tick one or both of the options below)</p> <p>(i) enlarged lymph node(s) <input type="checkbox"/></p> <p>(ii) drainage of lymph node(s) <input type="checkbox"/></p> <p>Site(s) _____</p> <p>MIN.   HOURS   DAYS</p> <p><input type="checkbox"/> <b>PAROTITIS</b> Swelling with pain and/or tenderness of parotid gland(s)</p> <p>MIN.   HOURS   DAYS</p> <p><input checked="" type="checkbox"/> <b>ANAPHYLAXIS OR SEVERE SHOCK</b> Explosive, occurring within minutes after immunization, and evolving rapidly towards cardiovascular collapse AND requiring resuscitative therapy</p> <p>MIN.   HOURS   DAYS</p> <p><input type="checkbox"/> <b>OTHER ALLERGIC REACTIONS</b> (tick one or more of the options below)</p> <p>(i) wheezing or shortness of breath due to bronchospasm <input type="checkbox"/></p> <p>(ii) swelling of mouth or throat <input type="checkbox"/></p> <p>(iii) skin manifestations (e.g., hives, eczema, pruritus) <input type="checkbox"/></p> <p>(iv) facial or generalized edema <input type="checkbox"/></p> <p>MIN.   HOURS   DAYS</p> <p><input type="checkbox"/> <b>RASHES</b> (other than hives) Lasting 4 days or more AND/OR requiring hospitalization</p> <p>Generalized <input type="checkbox"/> Localized (indicate site) <input type="checkbox"/> _____</p> <p>Specify characteristics of rash _____</p> <p>MIN.   HOURS   DAYS</p> <p><input type="checkbox"/> <b>ARTHRALGIA/ARTHRITIS</b> Joint pain/inflammation lasting at least 24 hours If condition is an acute exacerbation of a pre-existing diagnosis, give details under <b>Supplementary Information</b></p> <p>MIN.   HOURS   DAYS</p>	<p><input type="checkbox"/> <b>SEVERE VOMITING AND/OR DIARRHEA</b> Must be severe enough to interfere with daily routine</p> <p>MIN.   HOURS   DAYS</p> <p><input type="checkbox"/> <b>HYPOTONIC-HYPORESPONSIVE EPISODE</b> (in children &lt; 2 yrs. only) Characterised by <u>all the features</u> 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>MIN.   HOURS   DAYS</p> <p><input type="checkbox"/> <b>CONVULSION/SEIZURE</b></p> <p>Febrile <input type="checkbox"/> Afebrile <input type="checkbox"/></p> <p>Past history of: A) Febrile seizures Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>B) Afebrile seizures Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Omit fainting, seizures occurring within 30 minutes of immunization, and seizures occurring as part of encephalopathy or meningitis/encephalitis</p> <p>MIN.   HOURS   DAYS</p> <p><input checked="" type="checkbox"/> <b>ENCEPHALOPATHY</b> Acute onset of major neurological illness characterized by <u>any two or more</u> 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>MIN.   HOURS   DAYS</p> <p><input checked="" type="checkbox"/> <b>MENINGITIS AND/OR ENCEPHALITIS</b> 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 <b>Supplementary Information</b></p> <p>MIN.   HOURS   DAYS</p> <p><input checked="" type="checkbox"/> <b>ANAESTHESIA/PARAESTHESIA</b> Lasting over 24 hours Generalized <input type="checkbox"/> Localized (indicate site) <input type="checkbox"/> _____</p> <p>MIN.   HOURS   DAYS</p> <p><input checked="" type="checkbox"/> <b>GUILLAIN-BARRÉ SYNDROME</b> Progressive subacute weakness of more than one limb (typically symmetrical) with <b>hyporeflexia/areflexia</b></p> <p>MIN.   HOURS   DAYS</p> <p><input checked="" type="checkbox"/> <b>PARALYSIS</b> (Do not code if Guillain-Barré Syndrome is coded) Limb paralysis <input type="checkbox"/> Facial or cranial paralysis <input type="checkbox"/></p> <p>Describe _____</p> <p>MIN.   HOURS   DAYS</p> <p><input checked="" type="checkbox"/> <b>THROMBOCYTOPENIA</b> Give lab results under <b>Supplementary Information</b></p> <p>MIN.   HOURS   DAYS</p> <p><input type="checkbox"/> <b>OTHER SEVERE OR UNUSUAL EVENTS</b> 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>MIN.   HOURS   DAYS</p> <p><b>DESCRIPTION</b></p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>
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<b>REPORTER'S NAME</b>	<b>TELEPHONE NUMBER</b> ( )	<b>ADDRESS</b> (Institution/No., Street, etc.)		
<b>PROFESSIONAL STATUS:</b> MD <input type="checkbox"/> RN <input type="checkbox"/> OTHER _____		<b>City</b>	<b>Province</b>	<b>Postal Code</b>
<b>SIGNATURE</b>	<b>DATE</b> Year Month Day			

