

Reporting Adverse Events Following  
Immunization (AEFI) in Canada

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# **USER GUIDE TO COMPLETION AND SUBMISSION OF THE AEFI REPORTS**



Public Health  
Agency of Canada

Agence de la santé  
publique du Canada

Canada

**TO PROMOTE AND PROTECT THE HEALTH OF CANADIANS THROUGH LEADERSHIP, PARTNERSHIP,  
INNOVATION AND ACTION IN PUBLIC HEALTH.**

—Public Health Agency of Canada

This guide was developed by the **Vaccine Vigilance Working Group** and the **Public Health Agency of Canada**

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# TABLE OF CONTENTS

<b>ACKNOWLEDGEMENTS</b> .....	<b>1</b>
<b>ACRONYMS AND ABBREVIATIONS</b> .....	<b>2</b>
<b>A} BACKGROUND</b> .....	<b>3</b>
<b>B} GUIDELINES ON HOW TO COMPLETE SECTIONS OF THE AEFI FORM</b> .....	<b>7</b>
SECTION 1. Provincial and Regional Identifying Information .....	7
SECTION 2. Impact Lin (Local Inventory Number) .....	8
SECTION 3. Patient Identification .....	8
SECTION 4. Information at Time Of Immunization and AEFI Onset .....	8
SECTION 5. Immunization Errors .....	11
SECTION 6. Previous AEFI .....	11
SECTION 7. Impact of AEFI, Outcome, and Level of Care Obtained .....	12
SECTION 8. Reporter Information .....	14
SECTION 9. AEFI Details .....	14
SECTION 10. Supplementary Information .....	24
SECTION 11. Recommendations for Future Immunization(S) According to the Federal/Provincial/Territorial Best Practices.....	24
SECTION 12. Follow Up Information for a Subsequent Dose of Same Vaccine(S) .....	25
ANNEX 1. Where to Send a Completed AEFI Report.....	26
ANNEX 2. List of Current Approved Vaccines .....	27
ANNEX 3. Definitions of Mucocutaneous Lesions.....	31
ANNEX 4. Resource Document: Temporal Criteria For Selected Adverse Events Following Immunization (AEFIs).....	32
ANNEX 5. Contact Information for the Health Canada Programs .....	35



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The VSWG is a federal/provincial/territorial (F/P/T) working group with representations from all provinces and territories. The working group also includes liaison members from Immunization Monitoring Program ACTIVE (IMPACT), Health Canada's (HC) regulators [(Biologic and Radiopharmaceutical Drugs Directorate (BRDD), and the Marketed Health Products directorate (MHPD)]. In addition, other federal departments including the Indigenous Services Canada's (ISC) First Nations and Inuit Health Branch-FNIHB), Correctional Services Canada (CSC), Department of National Defense (DND) and the Royal Canadian Mounted Police (RCMP). The VSWG reports to the Canadian Immunization Committee (CIC).

The VSWG was created in keeping with the National Immunization Strategy (NIS), which highlighted the significance of strengthening and expanding vaccine safety surveillance activities and improving the system of public health response within Canada. The working group reports to the Canadian Immunization Committee and it functions as a long term task group that facilitates the development of guidelines, standards, protocols and best practices to improve F/P/T public health post-market vaccine safety surveillance in Canada.

In 2004, as part of the effort to further improve and harmonize the reporting of AEFIs in Canada, VSWG took on the task of revising the national reporting form. And for the first time the working group developed this user guide as a technical reference to provide assistance on accurately complete the new national AEFI reporting form.

The VSWG representatives and the liaison members from the following jurisdictions and organizations contributed to the development of this AEFI user guide:

<b>Alberta</b>	<b>Liaison Members:</b>
<b>British Columbia</b>	<b>IMPACT</b>
<b>Manitoba</b>	<b>MHPD – HC</b>
<b>New Brunswick</b>	<b>BRDD – HC</b>
<b>Newfoundland and Labrador</b>	<b>FNIHB – ISC</b>
<b>Nova Scotia</b>	<b>CSC</b>
<b>Northwest Territories</b>	<b>DND</b>
<b>Nunavut</b>	<b>RCMP</b>
<b>Ontario</b>	<b>PHAC – Vaccine Safety Section</b>
<b>Prince Edward Island</b>	
<b>Quebec</b>	
<b>Saskatchewan</b>	
<b>Yukon</b>	

# ACRONYMS AND ABBREVIATIONS

<b>AEFI</b>	Adverse Events Following Immunization
<b>BRDD</b>	Biologic and Radiopharmaceutical Drugs
<b>BCCD</b>	Brighton Collaboration Case Definition
<b>CAEFISS</b>	Canadian Adverse Events Following Immunization Surveillance System
<b>CIC</b>	Canadian Immunization Committee
<b>CIRID</b>	Centre for Immunization and respiratory Infectious Diseases
<b>CSC</b>	Corrections Services Canada
<b>CVP</b>	Canada Vigilance Program
<b>DND</b>	Department of National Defence
<b>F/P/T</b>	Federal/Provincial/Territorial
<b>FNIHB</b>	First Nations and Inuit Health Branch
<b>HC</b>	Health Canada
<b>ICH</b>	International Conference on Harmonization
<b>IMPACT</b>	Immunization Monitoring Program ACTive
<b>IMPACT LIN</b>	IMPACT Local Inventory Number
<b>LCDC</b>	Laboratory Centre for Disease Control
<b>MHPD</b>	Marketed Health Products Directorate
<b>NIS</b>	National Immunization Strategy
<b>PHAC</b>	Public Health Agency of Canada
<b>RCMP</b>	Royal Canadian Mounted Police
<b>SAP</b>	Special Access Program
<b>WHO</b>	World Health Organization
<b>VVWG</b>	Vaccine Vigilance Working Group

# A} BACKGROUND

## **When did National Vaccine Post Marketing Surveillance begin in Canada?**

National monitoring of adverse events dates back to the 1960s when it was the responsibility of the Laboratory Centre for Disease Control (LCDC) for vaccines as well as for drugs. LCDC's responsibility was limited to human preventive vaccines in 1987. That same year, a computerized database was created to collate adverse event reports from all sources. The current Canadian Adverse Event Following Immunization Surveillance System (CAEFISS) is managed by the Vaccine Safety Section of the Centre for Immunization and Respiratory Infectious Diseases (CIRID) of the Public Health Agency of Canada (PHAC).

## **What is an Adverse Event Following Immunization (AEFI)?**

An AEFI is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO). Definition and Application of Terms for Vaccine Pharmacovigilance. Report of CIOMS/WHO Working group on Vaccine Pharmacovigilance. Geneva: CIOMS and WHO; 2012 [cited 2018 Aug 23]. [www.who.int/vaccine\\_safety/initiative/tools/CIOMS\\_report\\_WG\\_vaccine.pdf](http://www.who.int/vaccine_safety/initiative/tools/CIOMS_report_WG_vaccine.pdf)

## **How is vaccine safety monitored in Canada?**

Vaccine safety assessment and monitoring is a continuum that spans all phases of the vaccine product's 'life cycle' from discovery through market authorization and beyond. The Federal government (HC regulators and the PHAC) and other stakeholders including the F/P/T public health authorities, vaccine industry, health professionals and consumers are involved and contribute at various levels to the safety monitoring of vaccines marketed in Canada.

HC and PHAC share the monitoring of the quality, safety and effectiveness of vaccines marketed in Canada. The Canada Vigilance Program (CVP) managed by HC receives serious AEFI reports from manufacturers, Canadian hospitals, healthcare professionals and consumers. Similarly, CAEFISS, managed by the PHAC, receives AEFI reports from all P/T public health authorities and from federal departments including Department of National Defence, Correctional Services Canada, Indigenous Services Canada and Royal Canadian Mounted Police. CAEFISS includes both passive (spontaneous reports from F/P/Ts) and active surveillance (Immunization Program ACTIVE)

Both HC and the PHAC regularly review AEFI reports submitted to their respective databases and monitor scientific literature, activities of other regulatory agencies, as well as the World Health Organization Global Advisory Committee on Vaccine Safety (WHO GACVS). In addition, HC routinely receives and reviews Periodic Safety Update Reports (PSURs)/Periodic Benefit-Risk Evaluation Reports (PBRERs), Risk Management Plans (RMPs) and other safety assessments for vaccines submitted by manufacturers. Potential safety signals arising from any of the above sources are assessed collaboratively by HC and PHAC. The source of identified safety signal determines the lead investigating agency. HC generally leads on signals arising from the review of AEFIs from the CVP, PBRER's, the literature, and international sources, while the PHAC leads on signals arising from CAEFISS, the provincial network of vaccine safety focal points forming the Vaccine Vigilance Working Group (VVWG) and the Public Health Network and its committees. HC and PHAC will take appropriate action if any new public health risks are identified.

## **Should all AEFIs be reported?**

No. During their development, vaccines undergo rigorous testing for safety, quality and efficacy. During these "pre-licensure trials" efforts are made to capture every single adverse event that follows immunization. By the time a vaccine is authorized for marketing, the safety profile for common

adverse events such as vaccination site reactions or mild fever is well known. It is always important to counsel vaccinees or their guardians regarding the possible occurrence of such reactions, but there is no need to report such expected events unless they are more severe or more frequent than expected.

### What type of AEFI should be reported?

AEFIs should be reported when the event:

- **Has a temporal association with a vaccine**
- **Has no other clear cause at the time of reporting:** A causal relationship between immunization and the event that follows does not need to be proven and submitting a report does not imply or establish causality. Sometimes the vaccinee's medical history, recent disease, concurrent illness/condition and/or concomitant medication(s) can explain the event(s).

Of particular interest are those AEFIs which:

- **Meet one or more of the seriousness criteria:** An adverse event that is life threatening or results in death, requires hospitalization or prolongation of an existing hospitalization, results in residual disability or causes congenital malformation.
- **Are unexpected regardless of seriousness:** An adverse reaction whose nature, severity, or outcome is not consistent with the term or description used in the local/regional product labeling (e.g., Package Insert or Summary of Product Characteristics) should be considered unexpected. For additional information regarding unexpected events, please refer to the ICH Harmonised Tripartite Guideline (E2D 2003): [www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Efficacy/E2D/Step4/E2D\\_Guideline.pdf](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2D/Step4/E2D_Guideline.pdf)

The timeline between vaccination and occurrence of an AEFI is very important as it aids in the assessment of the temporal association. AEFIs which occur outside of these timelines can still be submitted at the reporter's clinical discretion as this may indicate a possible safety signal. For guidance on assessing onset timelines for selected AEFIs, refer to the VVWG Resource Document: Temporal criteria for selected AEFIs table, **ANNEX 4**. If there is any doubt as to whether or not an event should be reported, a conservative approach should be taken and the event should be reported.

### Who reports AEFIs?

AEFI reports originate from multiple sources in Canada. Most of the P/Ts have now enacted mandatory AEFI reporting requirements. However, overall, reports are generally submitted on a voluntary basis by health care professionals.

The usual and preferred reporting flow of AEFI reports to CAEFISS is from local or regional health units to central P/T immunization programs. Reports are forwarded to PHAC electronically, or in hard copy by the P/Ts after all personal identifying information has been removed. On occasion, reports may be submitted directly to PHAC by travel health clinics, pharmacists, physicians or the public. These reports are entered into the national database and a copy and/or the reporter's information are redirected to the P/T health authorities of the reporter through the Vaccine Vigilance Working Group (VVWG) representative.

To enhance timely detection and assessment of serious adverse events involving children, PHAC funds an active paediatric hospital based surveillance system known as the Immunization Monitoring Program ACTive (IMPACT). The network includes 12 paediatric hospitals across Canada which together represents 90% of all paediatric tertiary care admissions in the country. Each IMPACT centre reports directly to PHAC ensuring timely identification of serious adverse events, and the same report is sent to public health at the P/T or local public health unit level depending on the standard practice for a given jurisdiction. As each report has a unique IMPACT identification number, it is only entered once into CAEFISS. Special numbering of reports is done to avoid duplication.



CVP on the other hand receives serious AEFI reports, from the market authorization holders (i.e., the sponsors or manufacturers that have the legal authority to market their drug including vaccine in Canada), health care professionals and consumers as mandated by the *Food and Drugs Act and Regulations*. In addition, as of December 2019, the hospitals are required to report all serious adverse drug reactions according to the *Food and Drug Regulations for adverse drug reactions requirements*. *The mandatory reporting requirements for hospitals includes all serious adverse reactions to vaccines administered under a routine immunization program of a P/T to CVP.*

The information collected enables both HC and PHAC to monitor the safety profile of vaccines to determine if their benefits continue to outweigh their risks in accordance with the requirements of the Food and Drugs Act and the Regulations

### **What is done with AEFI reports at the provincial/territorial level?**

AEFI reports are received at the local/regional level from multiple sources: physicians, nurses, pharmacists, public health, IMPACT, and the public. Recommendations for future immunizations are usually made at the local/regional level. In P/Ts with electronic systems, the data are entered at the local health unit or regional health authority level and are then shared with the P/T. The AEFI data are analyzed and disseminated at the P/T level to their stakeholders. Data are then sent electronically to PHAC. Those provinces and territories with paper based systems either send through a secure data platform, email account or fax this information directly to PHAC and/or enter the information in a provincial database.

#### **Of Note:**

Only AEFI reports with Canadian approved vaccines are to be forwarded to PHAC. Any AEFI reports of non-Canadian vaccines are to be retained at the P/T level.

### **What is done with AEFI reports at the national level?**

Personnel in the Vaccine Safety Section screen all submitted reports, ensure they are entered into the CAEFSS and coded using the international standard Medical Dictionary for Regulatory Activities (MedDRA). Reports are monitored with special attention to serious or unusual events that could signal a concern regarding vaccine safety. Analyses are done regularly to search for vaccine safety signals.

Similarly, personnel from HC process and review serious AEFI reports submitted to CVP. Both HC and PHAC regularly publish vaccine safety summaries and reports received by their respective surveillance systems: CVP (Vaccine safety biannual summary), and CAEFISS (AEFI biannual and Annual report).

In addition, on a monthly basis HC and PHAC meet through the Vaccine Safety Review Working Group (VSR WG). The working group provides a (horizontal) linkage/forum between the two departments to enable regular sharing of information pertaining to vaccine quality, safety and effectiveness issues as well as timely identification and review of vaccine safety concerns when they arise.

### **When, why and how was a national AEFI report form first developed?**

Critical groundwork for the current CAEFISS system was done at the Post Marketing Surveillance of Vaccine Associated Adverse Events workshop in 1990, sponsored by Health Canada's Bureau of Communicable Disease (CDWR 1991; Vol. 17–19:97–98) and attended by F/P/T stakeholders as well as vaccine manufacturers, key non-governmental organizations and expert scientific advisors. The purpose of the workshop was to develop a framework for a coordinated approach to optimize vaccine post marketing surveillance in Canada. At the workshop, post marketing surveillance for vaccines was defined as the coordinated, structured, systematic, ongoing collection of data and their subsequent epidemiologic analysis

and dissemination. It was recommended that passive surveillance be centrally aggregated with input by public health and physicians and supplemented by active surveillance activities.

The first national vaccine adverse event report form was developed through a F/P/T collaborative process during the year following the 1990 workshop. It was agreed that the form would list several adverse events considered to be of public health importance. Reporters could check off the specific event and add written detail. There was also an “other” box so that any adverse event of concern to a reporter could be reported. It was agreed that all P/T AEFI forms would be based on the national form with nothing deleted but items could be added if they were of specific interest to a region. Case definitions were also developed, although many simply specified that a physician diagnosis would be required. In 1996, the AEFI report form was revised and it is that version which has been in use until now. A series of F/P/T workshops held from 2000–2002, led to the development of published functional standards, a minimum core data set and updated data definitions for AEFI reporting (CCDR 2002; 28).

### **Why has the form been revised?**

Priorities to improve vaccine safety surveillance in Canada were established during the development of the National Immunization Strategy (NIS). As a part of the efforts to improve voluntary AEFI reporting, a decision was made to revise the AEFI report form. Another reason to revise the form was to facilitate application of standardized AEFI case definitions developed by the Brighton Collaboration, which is an international voluntary group whose goal is to facilitate the development, evaluation, and dissemination of high quality information about the safety of human vaccines.

### **How is privacy and confidentiality of information ensured?**

Personal health information is confidential. All P/Ts and PHAC take great care to protect personal health information. Health care workers are encouraged to discuss with clients, or the clients’ caregiver, the reason for reporting the AEFI and the confidentiality of all collected information. For further information regarding the protection of personal health information you may contact the privacy representatives at your local public health office. Alternatively, the Privacy Act can be accessed online at the following address: [www.laws-lois.justice.gc.ca/eng](http://www.laws-lois.justice.gc.ca/eng)

### **Where can copies of the AEFI report form be obtained?**

The form itself, along with the User Guide, for completion and submission of an AEFI report are published on the PHAC website.

AEFI form: [www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization.html](http://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization.html)

User Guide: [www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/user-guide-completion-submission-ae-fi-reports.html](http://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/user-guide-completion-submission-ae-fi-reports.html)

In addition, the form is available in the Compendium of Pharmaceuticals and Specialties.

# **B } GUIDELINES ON HOW TO COMPLETE SECTIONS OF THE AEFI FORM**

This guide is intended to be used when completing the Report of AEFI for submission to P/T health authorities as well as to PHAC. Its purpose is to provide assistance on how to accurately complete the reporting form. It is not intended to guide treatment. Treatment of all AEFIs should proceed, as appropriate, prior to completing the AEFI form. Following the immediate care of the vaccine recipient, the AEFI form can be completed with all available information.

Given the variation in practice between each of the provinces and territories, sections of the form may not be applicable to all settings. If in doubt, please contact your local public health unit.

## **REPORT OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)**

Complete each section of the AEFI form as follows:

On the top right hand corner: Indicate whether the AEFI report being submitted is an “**Initial**” or a “**Follow up**” report. For all “**Follow up**” reports, provide the “**Unique episode #**” and/or “**Region #**” of the initial report.

### **SECTION 1. PROVINCIAL AND REGIONAL IDENTIFYING INFORMATION**

#### **SECTION 1A) UNIQUE EPISODE NUMBER**

A unique episode number is a mandatory case identification number and should be assigned to each AEFI report submitted to PHAC. In P/Ts that use electronic reporting systems, this number may be automatically generated by the system. In P/Ts that do not use electronic reporting systems, this number should only be filled in by those persons who are authorized to assign the number at P/T health authorities (e.g., P/T health professionals and/or officials). The unique episode number should be marked on the top of the first three (3) pages of the AEFI form as an identifier to link the pages together. If you are not authorized to assign this number, please leave this field blank.

#### **SECTION 1B) REGION NUMBER**

A region number that corresponds to a given health unit should be entered for those regions that have one. The region number (the number that corresponds to a given health unit) should be marked on the top of the first three (3) pages of the AEFI form as an identifier to link the pages together. This number should only be filled in by those persons who are authorized to assign it and should be left blank if it does not apply to your locale.

## SECTION 2. IMPACT LIN (LOCAL INVENTORY NUMBER)

An IMPACT Local Inventory Number (LIN) is assigned by the IMPACT nurse monitor when an AEFI report is generated from an IMPACT centre. The IMPACT LIN should be marked on the top of the first three (3) pages of the AEFI form. Please leave this section blank if it does not apply to you (e.g., if you are not an IMPACT hospital/centre).

The P/Ts should retain the assigned IMPACT LIN numbers when forwarding their reports to PHAC as they are required for the data quality assurance process.

## SECTION 3. PATIENT IDENTIFICATION

This section is intended to capture patient information for use by regional and/or provincial/territorial health officials. This information is kept confidential and should **NOT** be forwarded to PHAC.

**This section should be completed in keeping with provincial/territorial guidelines.**

**Patient identification information:** Provide the patient's first and last name, health number (if applicable), address of usual residence including City/Town and postal code (with the understanding that this address might be in a different province/territory than where the vaccine(s) was administered or where the AEFI is being reported) and a telephone number (either residential or business or both), where the patient can be reached.

**Information source:** If the source of the information for the AEFI report is a parent, or another care provider, provide their name, relation to the patient and contact information (including their full mailing address and phone number where they can be reached) if it is different from the patient's.

## SECTION 4. INFORMATION AT TIME OF IMMUNIZATION AND AEFI ONSET

### SECTION 4A) AT TIME OF IMMUNIZATION

**Provide all information, as described below, in the space provided on the form:**

**Province/Territory of immunization:** Indicate the P/T where the immunization was received. This may be different from the patient's P/T of residence and/or where the AEFI is being reported.

If the vaccine was administered outside of Canada, indicate the country in which the vaccine(s) was/ were administered in the space to capture P/T and also comment if it was received at a Canadian operated clinic in that country.

Reports of non-Canadian vaccines should be kept at the P/T level and not forwarded to PHAC.

**Date and time vaccine administered:** Indicate the date and time of vaccine administration remembering to specify if the vaccine was administered in the “am” or “pm” by circling the appropriate descriptor. If complete information is unknown, provide as much detail as is available (e.g., month and/ or year) as this is now a mandatory field in CAEFISS.

**Date of birth:** Indicate the patient’s date of birth in the space provided. If the complete date is unknown, please provide as much information as is available (e.g., month and/or year).

**Age:** Indicate the patient’s age at the time of immunization.

Use days for infant’s aged less than 1 week; weeks for infants aged less than 1 month; months for infants aged less than 1 year; and years thereafter. Fractions should be used as appropriate (e.g., 6 weeks should be captured as 1.5 months; 15 months should be captured as 1.25 years). If the patient’s exact age is unknown, please estimate patient’s age.

**Sex:** Refers to sex assigned at birth. Sex is typically assigned based on a person’s reproductive system and other physical characteristics (e.g., male or female). If unknown or ambiguous, please choose “Other”.

**Pregnant at time of immunization:** Indicate by selecting the tick box if the patient is/was pregnant at time of immunization.

**Gestation age in weeks/days:** Indicate in weeks/days how far along the pregnancy is/was at time of immunization.

## **SECTION 4B) MEDICAL HISTORY (UP TO THE TIME OF AEFI ONSET)**

Indicate the patient’s medical history prior to the time of AEFI onset by choosing all that apply from the list provided below. Provide all additional details, when available, in section 10.

**Concomitant medication(s):** Provide the name of all medications, including prescription, over the counter and herbal supplements, which the patient had been taking immediately prior to the time of AEFI onset, including those taken only as needed in section 10. When available, provide the dose, frequency, route of administration and reason for taking each concomitant medication.

**Known medical conditions/allergies:** Indicate all known medical conditions and/or allergies that the patient experienced prior to the time of immunization with a corresponding date of onset in section 10. If an exact date of onset is unknown, please provide the greatest amount of detail that is available (e.g., year of onset). Include any conditions for which the patient is taking a concomitant medication including chronic conditions with intermittent symptoms such as migraine headaches. Also, specify in this section if the subject was pregnant at the time of immunization.

**Acute illness/injury:** Indicate if the patient had an acute illness and/or injury immediately prior to the time of immunization and specify a corresponding date of onset in section 10 if known. If an exact date of onset is unknown, provide the greatest amount of detail that is available (e.g., month and/or year of onset).

## SECTION 4C) IMMUNIZING AGENT

Provide all information pertaining to the immunizing agent(s) administered just prior to the onset of the reported AEFI(s). There is space to record five (5) immunizing agents in section 4c; however, if more than five (5) were administered simultaneously, record the additional vaccines in section 10.

**When completing section 4c, provide all information as outlined below:**

**Immunizing agent(s):** Record the proper name or accepted abbreviation as outlined in **ANNEX 2** for all immunizing agent(s).

**Trade name:** Indicate the trade name of all vaccine(s) received.

**Manufacturer:** Specify the name of the manufacturer/distributor as indicated on the product label.

**Lot number:** Document the complete lot number including all letters and numbers. This information is essential for conducting signal detection or future risk assessments.

**Dose number:** Provide the number in series (1, 2, 3, 4, or 5) or indicate if known. For the Influenza vaccine, unless a patient receives two doses in one season, the “**Dose #**” should be recorded as one.

**Dosage/Unit:** Indicate the dose (e.g., 0.5) and unit (e.g., ml) for each vaccine.

**Route:** Specify the route of administration for each vaccine received. Abbreviations (as described below) are acceptable:

- **Intradermal:** ID
- **Intramuscular:** IM
- **Subcutaneous:** SC
- **Intranasal:** IN
- **Oral:** PO
- **Other:** please specify (no abbreviations)

**Site:** Indicate the site of injection for each vaccine administered. Abbreviations (as described below) are acceptable:

- **Left arm:** LA
- **Right arm:** RA
- **Arm:** Arm
- **Left leg:** LL
- **Right leg:** RL
- **Leg:** Leg
- **Left gluteal:** LG
- **Right gluteal:** RG
- **Gluteal:** Glut
- **Mouth:** Mo
- **Nose:** Nose
- **Multiple sites:** MS
- **Other:** please specify (no abbreviations)

## SECTION 5. IMMUNIZATION ERRORS

Indicate whether the AEFI has followed an incorrect immunization (an immunization error, program error, etc.) by choosing “No”, “Unknown” or “Yes”. If “Yes”, please indicate all that apply in section 5 by checking the box next to the situation that most closely reflects the error (as described below) and provide all known details in section 10.

**Given outside the recommended age limits:** The vaccine was administered to an individual who was not within the recommended age limits for a specific vaccine.

**Product expired:** The vaccine was administered after the expiry date as indicated on the vaccine label by the manufacturer and/or after the recommended amount of time elapsed between the first use of a multi-dose vial and the last use (e.g., as indicated in the product monograph for Fluviral, once entered, the multi-dose vial should be discarded after 28 days).

**Wrong vaccine given:** An unintended vaccine was administered.

**Incorrect route:** The vaccine was administered via a route not recommended for its administration (e.g., subcutaneous vs. intramuscular).

**Dose exceeded that recommended for age:** A larger dose of vaccine was administered than is recommended for the patient’s age group.

**Other:** If an error has occurred that is not accurately reflected in the list of provided errors, please choose “Other” and provide all details.

## SECTION 6. PREVIOUS AEFI

Indicate whether the patient had ever experienced an AEFI following a previous dose of any of the immunizing agents as listed in response to question 4c. Choose only one of the answers provided in section 6, as described below:

**No:** The patient had previously received immunization with one or more of the immunizing agents listed in section 4c and had not experienced a subsequent AEFI.

**Yes:** The patient had previously received immunization with at least one of the immunizing agents listed in section 4c and had subsequently experienced an AEFI.

**Unknown:** It is unknown if the patient had previously received immunization with any of the immunizing agents listed in section 4c **and/or**, if an AEFI followed.

**Not applicable:** The patient had never previously received immunization with any of the immunizing agents listed section 4c.

If the answer is “Yes”, the patient had previously experienced an AEFI following a previous dose of one or more of the immunizing agent(s) listed in section 4c, provide all details of the previous AEFI in section 10, including the corresponding time to onset and duration, when known. Also, when possible, provide information regarding the severity of the AEFI and if the previous AEFI was less or more severe than the currently reported AEFI.

If there is uncertainty regarding which option to choose, or if there is additional information to provide (e.g., multiple vaccines were administered and not all of the information regarding the patient's past AEFI experience can be captured in section 6), please provide additional details in section 10.

## SECTION 7. IMPACT OF AEFI, OUTCOME, AND LEVEL OF CARE OBTAINED

### SECTION 7A) HIGHEST IMPACT OF AEFI

Indicate the highest perceived impact of the AEFI by choosing one of the provided responses in section 7a based on the patient's assessment of the impact on their daily activities:

**Did not interfere with daily activities:** No change, or only minimal change is reported by the patient in relation to their daily activities (e.g., work, exercise, social commitments, etc.).

**Interfered with but did not prevent daily activities:** Moderate change is reported by the patient in relation to their daily activities (e.g., interfered with work, exercise and/or social commitments).

**Prevented daily activities:** Significant change is reported by the patient in relation to their daily activities (e.g., prevented work, exercise and/or social commitments).

For young children (e.g., infants and toddlers), indicate the highest perceived impact of the AEFI on their daily activities as assessed by the child's parent/caregiver according to the following:

**Did not interfere with daily activities:** No change or only minimal change, is observed in the child's daily patterns and/or habits (e.g., eating, sleeping, playing, etc.).

**Interfered with but did not prevent daily activities:** Moderate change is observed in the child's daily patterns and/or habits (e.g., reduced appetite, disrupted sleep, disrupted play, etc.).

**Prevented daily activities:** Significant change is observed in the child's daily patterns and/or habits (e.g., not eating, not sleeping, not playing, etc.).

### SECTION 7B) OUTCOME AT TIME OF REPORT

Indicate the outcome of the AEFI at the time of completion of the report by choosing one of the provided responses in section 7b. If the patient is not yet recovered, provide all available details in section 10 and provide updates as they become available. Similarly, should the event result in permanent disability and/or incapacity or death, provide all available details in section 10.

**When completing section 7b, provide the information as outlined below:**

**Death:** Patient died (record the corresponding date of death in the space provided).

**Permanent disability/incapacity:** An injury which impairs the physical and/or mental ability of a person to perform his/her normal work or non-occupational activities supposedly for the remainder of his/her life.



**Not yet recovered:** Residual signs and/or symptoms remain (at the time of the report).

**Fully recovered:** All signs and symptoms have resolved.

**Unknown:** The outcome of the AEFI is unknown or unclear.

## **SECTION 7C) HIGHEST LEVEL OF CARE OBTAINED**

Indicate the highest level of care obtained for the reported AEFI by choosing one of the provided options in section 7c, described in detail below.

**Unknown:** It is unknown if the patient received care for the reported AEFI.

**None:** No care was received for the reported AEFI.

**Telephone advice from a health professional:** The patient received telephone advice from a health care professional (e.g., nurse, nurse practitioner, physician, etc.) regarding the reported AEFI.

**Non-urgent visit:** The patient was seen by a health care professional (e.g., at a physician's office or walk in clinic) for the assessment and/or treatment of the reported AEFI. Document all investigations conducted in section 10.

**Emergency visit:** The patient was seen by a health care professional for an emergency visit for the assessment and/or treatment of the reported AEFI. Please note that emergency visits are not considered admission to hospital and therefore, admission and discharge dates are not required. Document all investigations conducted in section 10.

**Required hospitalization:** The patient was hospitalized for the assessment and/or treatment of the reported AEFI. Indicate the number of days the patient was hospitalized, the date of admission and the date of discharge. Document all investigations conducted in section 10.

**Resulted in prolongation of existing hospitalization:** If a patient was already in hospital at the time of immunization and the AEFI resulted in a longer hospital stay, please check: "**Resulted in prolongation of existing hospitalization**" and indicate the number of additional days stayed in hospital as a result of the AEFI. Also indicate the date of hospital admission and discharge for the entire period of hospitalization (if known). Document all investigations conducted in section 10.

## **SECTION 7D) TREATMENT RECEIVED**

Indicate whether the patient received any treatment, including self-treatment, for the reported AEFI by choosing "**No**", "**Unknown**" or "**Yes**". Provide details of all treatments received, following the onset of the AEFI in section 10 when applicable.

## SECTION 8. REPORTER INFORMATION

Complete the reporter information section in full including the reporter's first and last names, a phone and fax contact number (including extensions when applicable) and the full mailing address of the institution/setting/centre. Indicate the **setting** in which the reporter is located (e.g., physician office, public health clinic, hospital, workplace clinic, pharmacy) or specify if other. Sign and date the AEFI form in the space provided and specify your professional status (e.g., MD: Medical Doctor; RN: Registered Nurse, Pharmacist) or your affiliation (e.g., IMPACT) by choosing one of the options provided. If your professional status or affiliation is not listed, specify beside "**Other**".

## SECTION 9. AEFI DETAILS

Indicate the details of the AEFI being reported by checking all that apply. All additional pertinent details (e.g., results of medical investigations, laboratory test, treatment, etc.) should be provided in section 10. For convenience and consistency, high level definitions have been provided for most events listed in section 9. However, if an asterisk (\*) is present beside an AEFI term, this specific event **should be diagnosed by a physician**. If not, sufficient information should be provided (in section 10) to support the selection(s). For all AEFIs, indicate the time to onset or interval (time from immunization to onset of first symptom/sign), and the duration (time from onset of first symptom/sign to resolution of all of signs and symptoms). For each AEFI where a Brighton Collaboration Definition (BCCD) exists, the most current published version of the case definition has cited.

**Time to onset/interval and duration of signs and symptoms:** The time to onset/interval and the duration of the signs and symptoms of the specified AEFI should be documented according to the following guidelines for all AEFIs:

- **If the time to onset/interval or the time to resolution is less than one (1) hour, record in minutes.**
- **If the time to onset/interval or the time to resolution is greater than or equal to one (1) hour, but less than one (1) day, record in hours.**
- **If the time to onset/interval or the time to resolution is greater than or equal to one (1) day, record in days.**

### SECTION 9A) LOCAL REACTION AT OR NEAR VACCINATION SITE

Any description of morphological or physiological change at or near the vaccination site. (BCCD: Vaccine 26 (2008) 6800–6813).

**Indicate, by choosing all that apply any local reactions at or near the vaccination site, as described below:**

**Infected abscess:** A localized collection of pus in a cavity formed by the disintegration of tissue, usually caused by microorganisms that invade the tissues. (Note presence of any of the following by ticking the appropriate box on the form: erythema, pain, tenderness, warmth, spontaneous/surgical drainage, palpable fluctuance, fluid collection shown by imaging technique, lymphangitic streaking,

regional lymphadenopathy and microbial results; if fever present check box in section 9d; use section 10 for additional details. If treated with antibiotics indicate if resolution/improvement was temporally related to treatment). (BCCD: Vaccine 25 (2007) 5821–5838).

**Sterile abscess:** An abscess whose contents are not caused by pyogenic bacteria.

**(Note presence of any of the following by ticking the appropriate box on the form:** erythema, pain, tenderness, warmth, spontaneous/surgical drainage, palpable fluctuance, fluid collection shown by imaging technique, lymphangitic streaking, regional lymphadenopathy and microbial results; if fever present check box in section 9d; use section 10 for additional details. If treated with antibiotics indicate if resolution/ improvement were temporally related to treatment). (BCCD: Vaccine 25 (2007) 5821–5838).

**Cellulitis:** A diffuse inflammatory process within solid tissues, characterized by edema, redness, pain, and interference with function, usually caused by infection with streptococci, staphylococci, or similar organisms. (Note presence of any of the following by ticking the appropriate box on the form: swelling, pain, tenderness, erythema, warmth, induration, lymphangitic streaking, regional lymphadenopathy and microbial results; if fever present check box in section 9d; use section 10 for additional details). (BCCD: Vaccine 25 (2007) 5803–5820).

**Nodule:** Discrete, well demarcated soft tissue mass or lump at the vaccination site that has a firm texture and is not accompanied by erythema, warmth or abscess formation. (BCCD: Vaccine 22 (2004) 575–585).

**Reaction crosses joint:** Reaction extending past at least one joint adjacent to the site of vaccine administration.

**Lymphadenitis:** Inflammation of one or more lymph nodes, usually caused by a primary focus of infection elsewhere in the body.

**Other:** Specify all details of the vaccination site reaction in section 10 that are not already captured in section 9a above. Examples of “**Other**” local reactions that may be reported here include necrosis, papule etc.

**For all local reactions at or near the vaccination site, describe the signs and symptoms by checking all that apply from the list below. Provide any additional details in section 10:**

**Swelling:** Visible enlargement of the vaccinated limb that is assessed by any person, with or without objective measurement. (BCCD: Vaccine 25 (2007) 5858–5874)

**Pain:** An unpleasant sensation occurring in varying degrees of severity that could be described as discomfort, distress or agony. (BCCD: Vaccine 30 (2012) 4558–4577)

**Tenderness:** Abnormal sensitivity to touch or release of pressure.

**Erythema:** Abnormal redness of the skin.

**Warmth:** A tactile sensation/perception of an increase in temperature.

**Induration:** Palpable thickening, firmness or hardening of soft tissue (subcutaneous tissue, fat, fascia or muscle) that is assessed by a health care provider. (BCCD: Vaccine 25 (2007) 5839–5857).

**Rash:** A morphologically described change in the appearance of the skin or mucosa at or near vaccination site that consists of one or more clearly identified primary lesion(s) (macule, papule, vesicle, nodule, bulla, cyst, plaque, pustule), and/or secondary skin change(s) (scaling, atrophy, ulcer, fissure, excoriation). (BCCD: Vaccine 25 (2007) 5697–5706).

**Largest diameter of vaccination site reaction:** Indicate the diameter (in centimetres) of the largest vaccination site reaction that is present.

**Site(s) of reaction:** Site(s) of the local reaction being reported if known. (Left arm: LA, Right arm: RA, Arm: Arm, Left leg: LL, Right leg: RL, Leg: Leg, Left gluteal: LG, Right gluteal: RG, Gluteal: Glut, Mouth: Mo, Nose: Nose, Multiple sites: MS, if Other: please specify.

**Palpable fluctuance:** Wavelike motion on palpation due to presence of liquid content. (BCCD: Vaccine 25 (2007) 5821–5838).

**Fluid collection shown by imaging technique:** An imaging device is used in the detection of fluid collection (e.g., ultrasound, Magnetic Resonance Imaging (MRI) and/or X-ray).

**Spontaneous drainage:** Draining of fluid from a site without intervention. When available, describe drainage material (purulent or non-purulent, bloody, etc) and provide all Gram stain/culture results.

**Surgical drainage:** Withdrawal of fluids from the site through needle aspiration or incision which could be complete or partial. When available, describe drainage material (purulent or non-purulent, bloody, etc.) and provide all Gram stain/culture results. (BCCD: Vaccine 25 (2007) 5821–5838).

**Microbial results, *specify*:** Tests that are carried out to identify organisms that can cause disease or infection.

**Lymphangitic streaking:** Red streaks below the skin's surface that follows the path of lymph draining from the site of infection via lymphatic vessels to regional lymph nodes.

**Regional lymphadenopathy:** Abnormal enlargement of the lymph nodes closest to the vaccination site (e.g., inguinal adenopathy when associated with an IM vaccination in the thigh, axillary adenopathy associated with an IM vaccination in the deltoid, etc.).

## SECTION 9B) ALLERGIC AND ALLERGIC-LIKE EVENTS

Choose one of the following events below:

**Anaphylaxis:** An acute hypersensitivity reaction with multi-organ-system involvement that can present as, or rapidly progress to, a severe life-threatening reaction. Check all applicable signs/symptoms referable to skin/mucosal, cardio-vascular, respiratory and/or gastrointestinal systems that were observed during the course of the event and use section 10 for additional details. Provide specific measurements, where available, for pulse, respiratory rate and blood pressure and indicate for each if before or after treatment with epinephrine if given. (BCCD: Vaccine 25 (2007) 5675–5684).

**Oculo-Respiratory Syndrome (ORS):** The presence of “**bilateral red eyes**” plus  $\geq 1$  respiratory symptom (cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness or sore throat) that starts within 24 hours of vaccination, with or without facial oedema.

**Other allergic event:** An event considered by reporter to be allergic in nature but not anaphylaxis, ORS or status asthmaticus. Check all symptoms/signs in section 9b that were present and use section 10 for any additional details.

For a chosen event, describe the signs and symptoms by checking all that apply from the list below. Provide all additional details in section 10.

## SKIN/MUCOSAL

**Choose all that apply from the list provided below, and indicate the site of reaction:**

**Urticaria (hives):** Localized redness of superficial layers of skin that is itchy, raised, sharply demarcated and transient (that is skin changes at any location are usually present for less than 12 hours). Specify site of reaction. (BCCD: Vaccine 28 (2010) 4487–4498)

**Erythema:** Abnormal redness of the skin without any raised skin lesions. Specify site of reaction. (BCCD: Vaccine 28 (2010) 4487–4498).

**Pruritus:** An unpleasant skin sensation that provokes a desire to rub and/or scratch to obtain relief. Specify site of reaction.

**Prickle sensation:** Tingling or smarting (stinging) sensation. Specify site of reaction.

**Flushing:** A transient erythema due to heat, exertion, stress or disease.

**Other rash:** A morphologically described change in the appearance of the skin or mucosa that occurs in the context of and in conjunction with an emerging allergic event that consists of one or more clearly identified primary lesion(s) (macule, papule, vesicle, nodule, bulla, cyst, plaque, or pustule) and/or secondary skin change(s) (scaling, atrophy, ulcer, fissure, or excoriation). Refer to **ANNEX 3** for definitions. (BCCD: Vaccine, 25 (2007) 5697–5706).

**Generalized:** Involving more than one body site i.e.: each limb is counted separately as is the abdomen, back, head and neck.

**Localized (site):** Involving one body site only.

**Angioedema:** Areas of deeper swelling of the skin and/or mucosal tissues in either single or multiple sites which may not be well circumscribed and is usually not itchy (Reported symptoms of 'swelling of the lip' or 'swelling of the tongue or throat' should not be documented as angioedema unless there is visible skin or mucosal swelling.) Check all of the locations where angioedema is seen on the AEFI report form (**tongue, throat, uvula, larynx, lip, eyelids, face, and limbs**) and if "Other" is checked, provide details. (BCCD: Vaccine 28 (2010) 4487–4498).

**Red eyes (bilateral or unilateral):** Redness of the white(s) of the eye (s) (sclera). (BCCD: Vaccine 28 (2010) 4487–4498).

**Itchy eyes:** A sensation that provokes the desire to rub and/or scratch to obtain relief. (BCCD: Vaccine 28 (2010) 4487–4498).

## CARDIO-VASCULAR

### Choose all that apply from the list provided below:

**Measured hypotension:** An abnormally low blood pressure and documented by appropriate measurement. Infants and children: age specific systolic BP of <3–5% percentile or greater than a 30% decrease from that person’s baseline; Adults: systolic BP of <90mm Hg or greater than 30% decrease from that person’s baseline. (BCCD: Vaccine 28 (2010) 4487–4498).

**Decreased central pulse volume:** Absent or decreased pulse in one of the following vessels: carotid, brachial or femoral arteries. (BCCD, Vaccine 28 (2010) 4487–4498).

**Capillary refill time >3 sec:** Capillary refill time is the time required for the normal skin colour to reappear after a blanching pressure is applied. It is usually performed by pressing on the nail bed to cause blanching and then counting the time it takes for the blood to return to the tissue, indicated by a pink colour returning to the nail. Normally it is <3 seconds. (BCCD, Vaccine 28 (2010) 4487–4498).

**Tachycardia:** A heart rate that is abnormally high for age and circumstance (In beats per minute: <1year old: >160; 1–2 yrs: >150; 2–5 yrs: >140; 5–12 yrs: >120; >12 yrs: >100). (BCCD: Vaccine 28 (2010) 4487–4498).

Citation is Physical examination. Don M, Robertson MJ, South, editors. Practical paediatrics. 6<sup>th</sup> ed. Elsevier Health Sciences; 2007.

**Decreased consciousness:** Reduced alertness or awareness of the outside world. Indicate duration of the event.

**Loss of consciousness:** Total suspension of conscious relationship with the outside world demonstrated by the inability to perceive and to respond to verbal, visual, and painful stimulus. Indicate duration of the event. (BCCD: Vaccine 28 (2010) 4487–4498).

## RESPIRATORY

### Choose all that apply from the list provided below:

**Sneezing:**An involuntary (reflex), sudden, violent, and audible expulsion of air through the mouth and nose. (BCCD: Vaccine 28 (2010)4487–4498).

**Rhinorrhea:** Discharge of thin nasal mucus. (BCCD: Vaccine 28 (2010) 4487–4498).

**Hoarse voice:** An unnaturally harsh cry of infant or vocalization in a child or adult. (BCCD: Vaccine 28 (2010) 4487–4498).

**Sensation of throat closure:** Feeling or perception of throat closing with a sensation of difficulty breathing. (BCCD: Vaccine 28 (2010) 4487–4498).

**Stridor:** A harsh and continuous sound made on breathing in. (BCCD: Vaccine 28 (2010) 4487–4498).

**Dry cough:** Rapid expulsion of air from the lungs to clear the lung airways and not accompanied by expectoration (a non-productive cough). (BCCD: Vaccine 28 (2010) 4487–4498).

**Tachypnea:** Rapid breathing which is abnormally high for age and circumstance rapid breathing which is abnormally high for age and circumstance (<1yr: >60; 1–2 yrs: >40; 2–5 yrs: >35; 5–12 yrs: >30; >12 yrs: >16), (same source as tachycardia). (BCCD: Vaccine 28 (2010) 4487–4498).

**Wheezing:** A whistling, squeaking, musical, or puffing sound made by breathing out. (BCCD: Vaccine 28 (2010) 4487–4498).

**Indrawing/retractions:** Inward movement of the muscles between the ribs (inter-costal), in the lower part of the neck (supra-clavicular or tracheal tug) or below the chest (sub-costal). The movements are usually a sign of difficulty with breathing. (BCCD: Vaccine 28 (2010) 4487–4498).

**Grunting:** A sudden and short noise with each breath when breathing out. (BCCD: Vaccine 28 (2010) 4487–4498).

**Cyanosis:** A dark bluish or purplish discolouration of the skin and mucous membrane due to lack of oxygen in the blood. (BCCD, Vaccine 28 (2010) 4487–4498).

**Sore throat:** Discomfort or pain in the throat.

**Difficulty swallowing:** Sensation or feeling of difficulty in the passage of solids and liquids down to the stomach.

**Difficulty breathing:** Sensation of difficult/uncomfortable breathing or a feeling of not getting enough air.

**Chest tightness:** Inability or perception of not being able to move air in or out of the lungs.

## GASTROINTESTINAL

**Choose all that apply from the list provided below:**

**Diarrhea:** Loose or watery stools which may occur more frequently than usual. (BCCD: Vaccine 28 (2011) 4487–4498).

**Abdominal pain:** Sensation of discomfort or pain in the abdominal region. (BCCD: Vaccine 28 (2010) 4487–4498).

**Nausea:** An unpleasant sensation vaguely referred to the upper abdominal region and the abdomen, with a tendency to vomit. (BCCD: Vaccine 28 (2010) 4487–4498).

**Vomiting:** The reflex act of ejecting the contents of the stomach through the mouth. Provide details. (BCCD: Vaccine 28 (2010) 4487–4498).

## SECTION 9C) NEUROLOGIC EVENTS

Indicate, by choosing all that apply from the list provided of all neurologic events. Provide all additional details in section 10.

**Meningitis\*:** Should be diagnosed by a physician. Check all applicable 9c boxes and use section 10 to record all additional pertinent clinical details and test results. (BCCD: Vaccine 25 (2007) 5793–5802).

**Encephalopathy/Encephalitis\*:** Should be diagnosed by a physician. Check all applicable 9c boxes and use section 10 to record all additional pertinent clinical details and test results. (BCCD: Vaccine 25 (2007) 5771–5792).

**Guillain-Barré Syndrome\*:** Should be diagnosed by a physician. Check all applicable 9c boxes and use section 10 to record all additional pertinent clinical details and test results especially Electromyography (EMG) and /or Lumbar Puncture (LP). (BCCD: Vaccine 29 (2011) 599–612).

**Bell's Palsy\*:** Should be diagnosed by a physician. Provide any pertinent details. (BCCD: Vaccine 35 (2017) 1972–1983).

**Other paralysis\*:** Should be diagnosed by a physician. Provide all pertinent details.

**Seizure(s):** Sudden loss of consciousness in conjunction with involuntary generalized motor manifestations. (BCCD: Vaccine 22 (2004) 557–562).

**Anaesthesia:** Loss of sensation resulting from pharmacologic depression of nerve function or from neurogenic dysfunction. (Stedman's Medical Dictionary (2016)).

**Paraesthesia:** A spontaneous abnormal usually nonpainful sensation (e.g., burning, pricking); may be due to lesions of both the central and peripheral nervous systems. (Stedman's Medical Dictionary (2016)).

**Other neurologic diagnosis\*:** Specify and provide all details.

**For all neurologic events above, describe the SIGNS, SYMPTOMS and TEST RESULTS relating to the reported event(s) by checking all that apply from the list below. Provide any additional details in section 10:**

**Depressed/altered level of consciousness:** Impairment of the ability to maintain awareness of self and environment combined with markedly reduced responsiveness to environmental stimuli.

**Lethargy:** A general state of sluggishness, listless, or uninterested, with being tired, and having difficulty concentrating and doing simple tasks.

**Personality changes lasting  $\geq$  24 hours:** Change in personal behaviour-response patterns.

**Focal or multifocal neurologic sign(s):** Neurological impairment which is caused by a lesion

**Fever ( $\geq$  38.0°C):** Endogenous elevation of at least one body temperature, regardless of measurement device, anatomic site, age or environmental conditions. (BCCD: Vaccine 22 (2004) 551–556).

**CSF (Cerebral Spinal Fluid) abnormality:** Alteration in normal CSF visual appearance, measured hydrostatic pressure, chemistry (protein, sugar) and/or cellular content (white blood cells, red blood cells) as well as Gram stain/routine bacterial culture results or other tests for presence of microbes.

**EEG (Electroencephalography) abnormality:** Abnormal EEG as interpreted by a qualified health professional.

**EMG (Electromyography) abnormality:** Abnormal skeletal EMG as interpreted by a qualified health professional.



**Neuroimaging abnormality:** Abnormal results of any test used to detect anomalies or trace pathways of nerve activity in the central nervous system; includes Computed Tomography (CT) scans, Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET) scans.

**Brain/spinal cord histopathologic abnormality:** Microscopic changes of the diseased brain/spinal cord tissues. Abnormalities seen on routine and/or electron microscopy by qualified health professionals using appropriately prepared (e.g., using special stains) tissue samples from brain and/or spinal cord.

**Numbness:** Loss of sensation often accompanies by tingling. Indicate site of reaction.

**Tingling:** Sensation commonly described as 'pins and needles.' Indicate site of reaction.

**Burning:** Sensation of stinging or heat not necessarily accompanied by redness, or physical signs of skin irritation. Indicate site of reaction.

**Formication:** Sensation of insects crawling over or within the skin. Indicate site of reaction.

**Other, Specify:** Specify in section 10.

## TYPES OF SEIZURES

**Partial seizure:** Seizure that originates from a localized area of the cerebral cortex and involves neurologic symptoms specific to the affected area of the brain.

**OR**

**Generalized seizure:** Bilateral, with more than minimal muscle involvement.

**Tonic:** Sustained increase in muscle contraction lasting a few seconds to minutes.

**Clonic:** Sudden, brief (<100 milliseconds) involuntary contractions of the same muscle groups, regularly repetitive at a frequency of about 2 to 3 contractions/second.

**Tonic-clonic:** A sequence consisting of a tonic followed by a clonic phase.

**Atonic:** Sudden loss of tone in postural muscles often preceded by, a myoclonic jerk and precipitated by hyperventilation (in the absence of Hypotonic-Hyporesponsive Episode, syncope, or myoclonic jerks).

**Absence:** The occurrence of an abrupt, transient loss of impairment of consciousness (which may not be remembered), sometimes with light twitching, fluttering eyelids, etc.

**Myoclonic:** Involuntary shock-like contractions, irregular in rhythm and amplitude, followed by relaxation, of a muscle or a group of muscles.

**Seizure details:** Check all that apply and record additional details in section 10. Indicate if the event was witnessed by a health care professional by choosing "Yes", "No" or "Unknown".

**Sudden loss of consciousness:** Sudden total unresponsiveness (suspension of conscious relationship with the outside world, inability to perceive and respond). If "Yes", indicate duration of the event.

**Witnessed by healthcare professional:** A healthcare professional (e.g.: doctor, nurse, etc.) observed the seizure. If “Yes”, provide details.

**Febrile:** With fever of  $\geq 38.0^{\circ}\text{C}$ .

**Afebrile:** Without fever.

**Unknown type:** It is unknown if the seizure was febrile or afebrile. Provide all known details.

**Previous history of seizures:** Individuals who have had seizures at any time prior to this vaccination.

**Febrile:** With fever of  $\geq 38.0^{\circ}\text{C}$ .

**Afebrile:** Without fever.

**Unknown type:** It is unknown if the seizure was febrile or afebrile. Provide all known details.

## SECTION 9D) OTHER EVENTS

For a selected event, describe the signs and symptoms by checking all that apply.

Provide all additional details in section 10.

**Hypotonic-Hyporesponsive Episode (age <2 years):** Sudden onset of two to three of: limpness (reduced muscle tone), change in skin colour (pallor or cyanosis) and/or reduced responsiveness (i.e., less responsive than usual to verbal or other sensorial stimuli). Check each appropriate box in section 9d and use section 10 to indicate if muscle tone, responsiveness or skin colour is known to be normal. Do not use the HHE checkbox if the patient is two (2) years of age or older; instead please check “Other severe or unusual events not listed above” and describe the episode. (BCCD: Vaccine 22 (2004) 563–568).

**Choose all that apply to the reported AEFI from the list provided below:**

**Limpness:** Lacking firmness and strength, no muscle tone.

**Pallor:** Unnatural lack of colour in the skin (abnormal loss of colour from normal skin).

**Cyanosis:** A dark bluish or purplish discolouration of the skin and mucous membrane due to lack of oxygen of the blood. (BCCD: Vaccine 28 (2010) 4487–4498).

**Decreased responsiveness:** Change in usual responsiveness to sensory stimuli.

**Unresponsiveness:** Lack of responsiveness to sensory stimuli.

**Persistent crying:** Crying which is continuous unaltered and lasts for 3 or more hours. (BCCD: Vaccine 28 (2010) 4487–4498).

**Intussusception\*:** The prolapse of one part of the intestine into the lumen of an immediately adjacent part, causing partial or complete intestinal obstruction, and should be diagnosed by a physician. Provide all pertinent details. (BCCD: Vaccine 22 (2004) 569–574).

**Arthritis:** Inflammation of the joint(s). Choose all that apply to the reported AEFI from the list provided, and described, below:

**Joint redness:** Redness of the skin at the joint(s).

**Joint warm to touch:** Sensation of increase in temperature, above body temperature, at the joint(s) to touch.

**Joint pain:** Discomfort, pain or inflammation arising from any part of the joint (Mayo Clinic)

**Joint swelling:** An abnormal increase in the size of the joint(s).

**Inflammatory changes in synovial fluid:** Laboratory synovial or joint fluid analysis indicative of inflammatory response.

**Parotitis:** Swelling with pain and/or tenderness of parotid gland(s). (Previous Cdn def'n—CCDR 1995; 21–13: page F–8)

**Rash:** A skin or mucosal change (either new or an exacerbation of a previous condition) following immunization that consists of clearly identified primary lesion(s) (bulla, cyst, macule, nodule, papule, plaque, pustule, vesicle, wheal), and/or secondary skin change(s) (scaling, atrophy, excoriation, fissure ulcer). Refer to **ANNEX 3** for definitions. When possible provide a written description of the rash, using the terminology provided. (BCCD: Vaccine, 25 (2007) 5697–5706).

**Generalized rash:** Systemic eruption in 2 or more parts of the body.

**Localized at non-vaccination site:** Eruption localized at another part of the body, away from the vaccination site.

**Thrombocytopenia\*:** Should be diagnosed by a physician. Platelets count of less than 150 X 10<sup>9</sup>/litre; accompanied by petechial rash or other clinical signs and/or symptoms of spontaneous bleeding (epistaxis, hematoma, hematemesis, hematochezia, hematuria, hemoptysis, petechia, purpura, ecchymosis). Indicate the lowest platelet count on the AEFI form and provide any additional pertinent details, including the clinical evidence for spontaneous bleeding.

**Severe vomiting:** The reflex act of ejecting the contents of the stomach through the mouth. (Severe enough to interfere with daily routine).

**Severe diarrhoea:** An increase by three or more loose or liquid stools (above normal or baseline) occurring within a 24 hour period. (BCCD: Vaccine 28 (2011) 4487–4498).

**Fever (≥ 38.0°C):** Endogenous elevation of at least one body temperature, regardless of measurement device, anatomic site, age or environmental conditions. (BCCD: Vaccine 22 (2004) 551–556).

**Other serious adverse event:** Is any untoward medical occurrence that at any dose results in: death; is life-threatening; requires inpatient hospitalisation or results in prolongation of existing hospitalisation; results in persistent or significant disability/incapacity; is a congenital anomaly/birth defect; or is a medically important event or reaction.

**Unexpected adverse event:** Is an event that has either not been identified previously or one that has been identified previously but is, at current, being reported at an increased frequency. For additional information regarding unexpected events, refer to [www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Efficacy/E2D/Step4/E2D\\_Guideline.pdf](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2D/Step4/E2D_Guideline.pdf)

## SECTION 10. SUPPLEMENTARY INFORMATION

Section 10 should be used to capture information that is pertinent to the AEFI but that has not been fully captured elsewhere or that needs further explanation. Document all known details of any investigations or treatments for the recorded AEFI. Indicate the section of the AEFI report that the information applies to, if applicable, when recording information in section 10.

## SECTION 11. RECOMMENDATIONS FOR FUTURE IMMUNIZATION(S) ACCORDING TO THE FEDERAL/PROVINCIAL/TERRITORIAL BEST PRACTICES

This section is to be completed by the health professional. In some P/Ts, only the MOH or MD can provide recommendations for future immunizations. In others, RNs have been trained to provide the recommendations as well.

Indicate, by choosing all that apply in section 11, your recommendations for the patient with regard to future vaccinations and specify additional information when requested. A “**Comments**” section has been added for your convenience; however, should you require additional space for your recommendation(s), please capture this information in section 10.

Complete the reporter information section in full providing your full name and professional status (MOH/ MHO: Medical Officer of Health/Medical Health Officer; MD: Medical Doctor; RN: Registered Nurse). If your professional status is not listed, describe under “**Other**”. In addition, indicate a phone number where you can be reached and sign and date the AEFI form in the space provided.

## SECTION 12.

### FOLLOW UP INFORMATION FOR A SUBSEQUENT DOSE OF SAME VACCINE(S)

**Note:** The information in this section is not collected by all provinces/territories.

Complete section 12 when an individual who has previously experienced an AEFI following administration of a vaccine receives a subsequent dose of the same vaccine (vaccines given in series).

Choose one of the responses as defined below to describe the outcome following the administration of the subsequent dose of vaccine and provide all pertinent details in section 10.

**Vaccine administered without AEFI:** A subsequent dose of vaccine was administered without the occurrence of any AEFI.

**Vaccine administered with recurrence of AEFI:** A subsequent dose of vaccine was administered and followed by the occurrence of the same adverse event that was previously experienced by the patient. Fill out a new AEFI form for the subsequent AEFI.

**Vaccine administered, other AEFI observed:** A subsequent dose of vaccine was administered and followed by the occurrence of a different adverse event than was previously experienced by the patient. Fill out a new AEFI form for the subsequent AEFI.

**Vaccine administered without information on AEFI:** A subsequent dose of vaccine was administered and it is unknown if it was followed by the occurrence of any AEFI.

**Vaccine not administered:** A subsequent dose of the vaccine was not administered.

## ANNEX 1.

### WHERE TO SEND A COMPLETED AEFI REPORT

Upon completing an AEFI report, please send it to your federal/provincial/territorial (F/P/T) local health unit/health services.

Contact information, listed by F/P/T on where to send the completed report, and for any other AEFI-related questions can be accessed at: <https://www.canada.ca/en/public-health/services/immunization/federal-provincial-territorial-contact-information-ae-fi-related-questions.html>

## ANNEX 2. LIST OF CURRENT APPROVED VACCINES

VACCINE	TRADE NAME	ABBREVIATION	MAH
Cholera – E.coli – Oral	Dukoral®	Chol-Ecol-O	VAL
Diphtheria and Tetanus Toxoids, Acellular Pertussis vaccine adsorbed	Infanrix™	DTaP	GSK
	Tripacel®		SP
Combined Diphtheria and Tetanus Toxoids, Acellular Pertussis, Hepatitis B (recombinant), Inactivated Poliomyelitis and adsorbed conjugated <i>Haemophilus influenzae</i> type b	Infanrix hexa™	DTaP-HB-IPV-Hib	GSK
Combined Diphtheria and Tetanus Toxoids, acellular Pertussis, Hepatitis B (recombinant), Inactivated Polio	Pediarix™	DTaP-HB-IPV	GSK
Diphtheria and Tetanus Toxoids, acellular Pertussis, <i>Haemophilus influenzae</i> type b	ACTacel®	DTaP-Hib	SP
	ACTacel® Hybrid		GSK
	Infanrix™-Hib		GSK
Diphtheria and Tetanus Toxoids adsorbed, combined with Inactivated Poliomyelitis vaccine	Infanrix™-IPV	DTaP-IPV	GSK
	Quadracel®		SP
Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed, Combined with Inactivated Poliomyelitis Vaccine and <i>Haemophilus influenzae</i> b Conjugate Vaccine	Infanrix™-IPV/Hib	DTaP-IPV-Hib	GSK
	Pediacel®		SP
	Pentacel®		
Hepatitis A	Avaxim®	HA	SP
	Avaxim® – Pediatric		
	Havrix® 1440		GSK
	Havrix® 720 (Junior)		
	Vaqta®		Merck
Hepatitis A and B	Twinrix®	HAHB	GSK
	Twinrix® Junior		
Hepatitis A – Typhoid	ViVAXIM™	HA-Typh-I	SP
Hepatitis B (recombinant), Thimerosal free	Engerix® -B	HB	GSK
	Engerix® -B (Pediatric dose)		
	Recombivax HB®		Merck
	Recombivax HB® (Dialysis)		

VACCINE	TRADE NAME	ABBREVIATION	MAH
<i>Haemophilus influenzae</i> type b conjugate	ACT-HIB®	Hib	SP
	Hiberix®		GSK
Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine	Gardasil®	HPV-4	Merck
Human Papillomavirus 9-valent Vaccine, Recombinant	Gardasil® 9	HPV-9	Merck
Human Papillomavirus (Types 16 and 18)	Cervarix™	HPV-2	GSK
Influenza vaccine – inactivated (Split virus)	Fluviral®	Inf	GSK
	Vaxigrip®		SP
Influenza vaccine – inactivated (Surface antigen subunit)	DInfluvac®	Inf	BGP
	Agriflu®		SEQ
	Fluad Pediatric®		
	Fluad®		
Influenza vaccine, quadrivalent – inactivated (Split virus)	Flulaval® Tetra	Inf	GSK
	Fluzone® Quadrivalent		SP
Influenza vaccine – inactivated (Split virus)	Fluzone® High-Dose	Inf	SP
Influenza Vaccine (live, attenuated)	Flumist® Quadrivalent	Inf	AZC
Inactivated Poliomyelitis	Imovax® Polio	IPV	SP
Japanese Encephalitis	IXIARO®	JE	VAL
Multicomponent Meningococcal B Vaccine (recombinant, adsorbed)	Bexsero	Men-B	GSK
	Trumenba™		Pfizer
Meningococcal – Conjugate	Menjugate®	Men-C-C	GSK
	Neis Vac-C®		Pfizer
	Menactra®	Men-C-ACYW-135	SP
	Menveo™		GSK
	Nimenrix™		Pfizer
Measles, Mumps and Rubella	M-M-R® II	MMR	Merck
	Priorix®		GSK
Measles, Mumps, Rubella and Varicella	Priorix-Tetra™	MMR-Var	GSK
	ProQuad™		Merck
Pneumococcal – Conjugate – valent	Prevnar®	Pneu-C-7	Pfizer
	Synflorix™	Pneu-C-10	GSK
	Prevnar® 13	Pneu-C-13	Pfizer



VACCINE	TRADE NAME	ABBREVIATION	MAH
Pneumococcal – Polysaccharide – valent	Pneumovax® 23	Pneu-P-23	Merck
Rabies	Imovax® Rabies	Rab	SP
	RabAvert®		GSK
Rotavirus	Rotarix™	Rot-1	GSK
	RotaTeq®	Rot-5	Merck
Tetanus Toxoid, diphtheria	Td Adsorbed	Td	SP
Tetanus Toxoid, reduced diphtheria toxoid and Acellular Vaccine Adsorbed	Adacel®	Tdap	SP
	Boostrix™		GSK
Tetanus Toxoid, reduced diphtheria toxoid and Acellular Vaccine adsorbed combined with Inactivated Poliomyelitis Vaccine	Adacel® – Polio	Tdap-IPV	SP
	Boostrix® – Polio		GSK
Tetanus and diphtheria toxoids, Inactivated Poliomyelitis vaccine	Td Polio Adsorbed	Td-IPV	SP
Typhoid – Injection	Typhim Vi®	Typh-I	SP
Typhoid vaccine live oral attenuated TY21A	Vivotif® (capsules)	Typh-O	CV
Varicella	Varilrix®	Var	GSK
	Varivax® III		Merck
Yellow Fever	YF-Vax®	YF	SP
Herpes Zoster vaccine (non-live recombinant)	Shingrix	RVZ	GSK
Live, attenuated virus varicella-zoster vaccine	Zostavax® II	LVZ	Merck

## ACRONYMS

<b>AZC</b>	AstraZeneca Canada
<b>BGP</b>	BGP Pharma Inc.
<b>CV</b>	Crucell Vaccines Inc.
<b>GSK</b>	Glaxo Kline Smith
<b>Merck</b>	Merck Canada Inc.
<b>Pfizer</b>	Pfizer Canada Inc.
<b>SEQ</b>	Seqirus Canada Inc
<b>SP</b>	Sanofi Pasteur
<b>VAL</b>	Valneva Canada Inc.
<b>MAH</b>	Marketing Authorization Holder distributes the vaccine, and maybe different from the manufacturer.

## ANNEX 3.

# DEFINITIONS OF MUCOCUTANEOUS LESIONS

### (VACCINE 25 (2007) 5697–5706)

#### Primary mucocutaneous lesions (morphology):

**Bulla:** A fluid-filled cavity or elevation  $\geq 1$  cm in diameter. Fluid can be clear, serous, hemorrhagic, or pus-filled.

**Cyst:** A closed cavity or sac containing fluid or semisolid material. A cyst may have an epithelial, endothelial, or membranous lining.

**Macule:** A flat, generally  $< 0.5$  cm area of skin or mucous membranes with different color or texture from surrounding tissue.

**Nodule:** A dermal or subcutaneous, firm, well-defined lesion.

**Papule:** A discrete, solid, elevated body usually  $< 0.5$  cm in diameter. Papules are further classified by shape, size, color, and surface change.

**Plaque:** A discrete, solid, elevated body usually broader than it is thick measuring  $> 0.5$  cm in diameter. Plaques may be further classified by shape, size, color, and surface change.

**Pustule:** A superficial vesicle containing a cloudy or purulent fluid. Pustules are usually  $< 0.5$  cm in diameter.

**Vesicle:** Fluid filled cavity or elevation  $< 1$  cm in diameter. Fluid may be clear, serous, or hemorrhagic.

**Wheal (hive):** An edematous, transitory papule or plaque.

#### Secondary mucocutaneous changes:

**Erosion:** A localized loss of the epidermal or mucosal epithelium.

**Crusting:** Dried exudates of plasma.

**Scaling:** Whitish scales or flakes are present on the skin.

**Atrophy:** Thinning or absence of the dermis or subcutaneous fat.

**Excoriations:** Oval or linear depressions in the skin with complete removal of the epidermis, exposing a broad section of red dermis.

**Fissures:** Linear, wedge-shaped cracks in the epidermis which may extend down to the dermis.

**Ulcer:** A circumscribed loss of the epidermis or mucosa extending to dermis.

## ANNEX 4.

### RESOURCE DOCUMENT: TEMPORAL CRITERIA FOR SELECTED ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFIS)

#### Notes:

- These onset timelines (**Table 1**) are for guidance only, and are not considered a mandatory requirement for AEFI reporting.
- The intended use of this document is to provide a tool to support health professionals when reviewing/assessing potential AEFI for reporting.
- Provinces/territories (P/Ts) can adopt the proposed onset timelines or use them as a reference document when reviewing/updating their own guidance document.
- The temporal criteria in this document are not intended for causality assessment. For guidance on causality assessment please refer to the World Health Organization (WHO) document: <http://apps.who.int/iris/bitstream/handle/10665/259959/9789241513654-eng.pdf;jsessionid=F13A6F1576645D0CE92A811D581DA11E?sequence=1>

The complete **VVWG Resource Document: Temporal criteria for selected adverse events following immunization (AEFIs)** is posted on the Canadian Vaccine Safety Network in the Canadian Network for Public Health Intelligence.

**TABLE 1: LIST OF SELECTED AEFIS AND TEMPORAL CRITERIA BY VACCINE TYPE**

#	AEFI	TEMPORAL CRITERIA BY VACCINE TYPE	
		INACTIVATED VACCINES	LIVE VACCINES
1	Acute Encephalitis/Encephalopathy	0–42 days	
2	Anaphylaxis	0–1 day	
3	Arthritis/Arthralgia	0–30 days	0–42 days
4	Bell's Palsy	0–90 days	
5	Brachial Neuritis	0–90 days	NA
6	Disseminated vaccine strain infection following vaccination	NA*	Any
7	Febrile Seizure	0–3 days	0–42 days
8	GBS	0–42 days	
9	HHE	0–2 days	
10	Fever >38°C	0–3 days	0–42 days
11	Injection site abscess	0–7 days	BCG: any Other: 0–7 days
12	Injection site cellulitis	0–7 days	BCG: any Other: 0–7 days
13	Other local Reactions (pain, erythema, swelling, pruritus, etc.)	0–2 days	0–7 days
14	Intussusception in infants (< 1 year)	NA	0–42 days
15	Kawasaki Syndrome & HSP	0–42 days	
16	Lymphadenopathy	0–7 days	BCG: any Other: 0–42 days
17	Meningitis Aseptic	0–15 days	0–42 days
18	Non-febrile seizure	0–3 days	0–42 days
19	Orchitis	NA	0–30 days
20	ORS	0–24 hrs	NA
21	Allergic Skin Reactions	0–2 days	
22	Other paralytic Syndrome: peripheral neuropathy and acute flaccid paralysis	0–42 days	
23	Parotitis	NA	0–30 days
24	Persistent crying	0–3 days	

#	AEFI	TEMPORAL CRITERIA BY VACCINE TYPE	
		INACTIVATED VACCINES	LIVE VACCINES
25	Rash (previously Varicella-like rash)	0–7 days	0–42 days
26	SSPE	NA	Any
27	Thrombocytopenia	0–42 days	
28	Tingling/Numbness	0–42 days	

\* NA = Not applicable

**ABBREVIATIONS:** GBS: Guillain-Barré syndrome, HHE: Hypotonic-hyporesponsive episode, HSP: Henoch-Schonlein purpura, ORS: Oculo-Respiratory Syndrome, SSPE: Subacute sclerosing panencephalitis

## ANNEX 5.

### **CONTACT INFORMATION FOR THE HEALTH CANADA PROGRAMS**

Canada Vigilance Program: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/canada-vigilance-program.html>

Special Access Program: <https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/drugs/special-access-programme-drugs-1.html>