

Pandemic (Swine) Flu ADR template – How to fill in the form?

Data Field	Expected Content
Date of report	The current date will be auto-populated.
Country	Please fill in your country of residence
Source	Check the correct tick-box to indicate whether you are a physician, a pharmacist, a nurse, a patient, a Regulatory Authority (RA) or other (e.g. parent of patient)
Vaccinee Details	
Name (Initials)	<p>Please enter the patient's initials (First Name Initial, Middle Name Initial, Last Name Initial).</p> <p>Do not reflect name prefixes/components like "de", "di", "van", "von" etc.</p> <p>Leave blank if no middle name is available or unknown.</p> <p>Use "S" for the German letter "SCH".</p> <p>In case of vowel with umlaut use the corresponding letter: a for ä, o for ö, u for ü.</p> <p>Examples: Hans Meyer => HM Stefan van Boost => SB Silvia de Moreno => SM Max Schneider => MS Thomas Östern => TO Silke Andrea Muster => SAM</p> <p>Note: For names composed with a hyphen (regardless whether applicable for first or last names), enter only the initial of the first part of composed name. Example: Hans-Peter Meyer => HM; Hans Peter-Meyer => HP; Cave: Hans Peter Meyer => HPM.</p>
Date of birth or Age	<p>Please enter the date of birth of patient involved in the numeric format Days (DD), Months (MM) and Years (YYYY).</p> <p>Example: 10.05.2007</p>

	If date of birth is unknown, enter age if known.
Sex	Check the correct tick-box to indicate whether the patient is male (M) or female (F)
Pregnancy	<p>Check the correct tick-box to indicate whether the patient has been pregnant at date of vaccination.</p> <p>Enter “yes”, if patient has been pregnant. Enter “no”, if patient was known to be not pregnant. Enter “unknown” if information on pregnancy status of patient at date of vaccination is not available/unknown.</p> <p>If Pregnancy “yes” has been checked, please enter the week of pregnancy at the time when the patient was vaccinated in the related field “If Yes, specify gestational age at the time of immunization”.</p>
Pre-existing conditions/Relevant medical history	<p>Check the correct tick-box to indicate whether the patient has pre-existing conditions or relevant medical history (e.g. chronic diseases, present illnesses, known allergies, previous adverse events following any kind of vaccination).</p> <p>Enter “yes”, if patient has known pre-existing conditions or relevant medical history. Enter “no”, if has no known pre-existing conditions or relevant medical history. Enter “unknown” if information on pre-existing conditions or relevant medical history of patient is not available/unknown.</p> <p>If “yes” is checked, please specify the pre-existing condition(s) or relevant medical history in the related field “If YES, specify:”.</p>
Swine Flu Vaccines Administered	
Vaccine (Name) Route of administration	<p>Please select the Novartis swine flu vaccine administered to the patient:</p> <ul style="list-style-type: none"> ▪ Focetria® ▪ Celtura® (cell-culture H1N1 vaccine) ▪ SWH1-Fluvirin (US market) <p>If it is not known which Novartis swine flu vaccine was administered, select</p> <ul style="list-style-type: none"> ▪ Pandemic Influenza Vaccine. <p>Check the correct tick-box to indicate whether</p>

	<p>the vaccine was administered</p> <ul style="list-style-type: none"> ▪ Intramuscularly = IM; ▪ Subcutaneously = SC; ▪ Unknown, if information is not available
Manufacturer	<p>For each vaccine selected in the “Swine Flu Vaccines Administered” section, please select the manufacturer “Novartis” if a Novartis Vaccines and Diagnostics product was administered (either Focetria® or Celtura® or SWH1-Fluvirin).</p> <p>Please select “unknown” if it is not known which vaccine was administered (“Pandemic Influenza Vaccines” selected in “Vaccine (Name)” data field).</p>
Batch N°	<p>For each vaccine selected in the “Swine Flu Vaccines Administered” section enter the batch number of vaccine dose administered to the patient.</p>
Number of Doses	<p>Check the correct tick-box to indicate for each vaccine selected in the “Swine Flu Vaccines Administered” section whether it was the 1st or the 2nd dose.</p> <p>Check “Unknown” if information is not available.</p>
Date given	<p>For each vaccine selected in the “Swine Flu Vaccines Administered” section enter the date when the vaccine dose was administered.</p> <p>Leave blank if information is not available.</p>
Detailed Adverse Event Information	
Adverse event	<p>Enter the adverse event(s) experienced by the patient after administration of a swine flu vaccine. If more than four events occurred, additional space is available at the bottom of the reporting form. Please be as precise in the wording as possible.</p>
Start date	<p>For each adverse event mentioned, enter the date when the adverse event occurred first.</p>
Stop date	<p>For each adverse event mentioned, enter the date when the adverse event occurred for the last time or vanished.</p>
Description of Adverse Event (clinical examinations, lab tests) and treatment, if any	<p>For each adverse event mentioned provide information, if applicable and if available, on clinical examinations or lab tests already performed, and if the patient has received any treatment for the adverse event(s) experienced.</p>
Seriousness	<p>Check the correct tick-box to indicate whether the case should be assessed as serious or not serious.</p> <p>Enter “yes”, if the case has to be assessed as serious, i.e. one of the following criteria is</p>

	<p>applicable:</p> <ul style="list-style-type: none"> ▪ Patient was in a <u>life-threatening</u> situation because of the adverse event (This means: The patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe!). ▪ Patient was <u>hospitalized</u> due to the event or an existing hospital stay was prolonged because of the adverse event (This means: An admission to any hospital, casualty centre, emergency room, or healthcare centre). ▪ The adverse event resulted in <u>permanent disability or incapacity</u>. (This means: A permanent and substantial disruption of a person's ability to conduct normal life functions). ▪ <u>Congenital anomaly/birth defect</u> of a baby delivered by a woman who had been vaccinated with swine flu vaccine. ▪ <u>Other</u> (e.g. <u>medically significant</u>). (Medical judgment should be exercised in deciding whether an adverse event/reaction is serious in other situations. Important adverse events/ reactions that are not immediately life-threatening or do not result in death or hospitalization but may jeopardize the subject or may require intervention to prevent one of the other outcomes above, should also be considered serious). <p>Check "no", if none of the above seriousness criteria are applicable. Check "unknown" if seriousness of case is not clear or information to assess seriousness is not available.</p> <p>If seriousness "YES" is checked, select the correct tick-box to indicate the appropriate seriousness criterion. More than one may be checked to reflect the individual situation of the case.</p>
<p>Outcome</p>	<p>Check the correct tick-box to indicate the patient's status with regard to the adverse event based on information available at date of completing the reporting form.</p> <p>Check "Recovered" if adverse event(s) have disappeared.</p>

	<p>Check "Improving" if adverse event(s) are still persisting, however, have already improved in the course since first onset.</p> <p>Check "Not yet recovered" if adverse event(s) are still persisting without improvement since first onset.</p> <p>Check "Sequelae" if a pathological condition results and persists from an adverse event. If checked, please specify in the "If checked, describe:" field.</p> <p>Check "Fatal" if patient died because of adverse event. If checked, indicate whether an autopsy was performed (= YES) or not (=NO) and indicate the cause in the "Cause of death:" data field.</p>
<p>Reporter (Health Professional or Consumer) <i>Note: Data entry of name and either address or phone or fax or email is mandatory</i></p>	
Name	Please enter your name (first name and last name)
Address	Please enter your address.
Profession (only health professional)	If you are a health professional (e.g. physician, pharmacist, coroner, nurse), please indicate your profession.
Phone	Please enter your phone number
Fax	Please enter your fax number
Email	Please enter your email address