**SCHEDULE 3 TO**
**PROTOCOL FOR AVAT NO FAULT COMPENSATION SCHEME**

**SUPPORTING EVIDENCE FORM**
**UNDER THE AVAT NO FAULT COMPENSATION SCHEME**

**INSTRUCTIONS / IMPORTANT NOTICES FOR APPLICANTS:**

1. **When to Use this Form:** Please use this Supporting Evidence Form to provide the medical evidence that is required pursuant to Section 8(a) of the Application form to file an application for compensation under the Program. You should submit this Supporting Evidence form together with the Application Form (Schedule 2 of the Program's Protocol).

2. **Who should Complete this Form:** Please do not complete this form yourself. As provided below, this form should be completed by one or more Registered Healthcare Professionals.[1]

3. **Waiting period:** Except in the case described below, a waiting period of 30 days following the administration of a Vaccine to the Patient must be observed, before any steps towards initiating an Application for compensation under this Program can be taken. In this regard, please do not complete and submit an Application and do not obtain Supporting Evidence, if less than 30 days have passed since the Vaccine was administered, as in that case the Application will not be accepted or considered.

    - Exception: The 30-day waiting period described above does not apply in case the Patient has died following the administration of a Vaccine, and the Patient's death is considered by a Registered Healthcare Professional to have been caused by this Vaccine or its administration.

4. **Registered Healthcare Professional (Not Applicant) Must Complete this Form:** This Supporting Evidence Form should be completed, signed and dated by at least one Registered Healthcare Professional (as defined in footnote 1 below), although it is also possible for several Registered Healthcare Professionals to complete this form. The Registered Healthcare Professional(s) completing this form should answer all sections/questions in this form, and provide as much detail and information as possible. The Applicant should not complete this Supporting Evidence Form himself.

5. **Attachments to this Form:** You may answer questions in this Supporting Evidence form by referring to documents provided with this form. The information

[1] The term "**Registered Healthcare Professional**" means any healthcare professional, including physicians, surgeons, nurses, midwives, nurse practitioners, physicians' assistants, psychiatrists, physical therapists, occupational therapists, dentists and pharmacists, who is duly licensed or legally authorized to practice the profession in the Participating Member States in which the Patient resides or received the Vaccine or in the case of birth defects, where the Patient's mother resides or received the Vaccine.

contained in the documents provided with this form does not need to be repeated in the answers provided in the form itself.

6. **Name, Signature and Date Required:** Each of the Registered Healthcare Professional(s) completing this Supporting Evidence form should sign, date and insert his or her full name in Section 2 of this form.

7. **Accepted Languages:** This Supporting Evidence Form must be completed and submitted in English at Program outset, and subsequently in French or Portuguese. If this form is completed in any other languages, it will not be accepted or considered. However, any documents required to be provided under this Supporting Evidence Form can be submitted in another language, if they are not available in English at Program outset, and subsequently in French, Portuguese or Arabic.

8. **Failure by the Registered Healthcare Professional(s):** (a) to complete all sections/questions in this Supporting Evidence Form, or (b) to sign, date and insert his/her/their full name(s) in this form, will lead to the rejection of the Applicant's Application or to delays in processing it.

9. **Deadline for Submission:** Once this Supporting Evidence Form has been duly completed, signed and dated by Registered Healthcare Professional(s), the Applicant must submit this Supporting Evidence Form, together with the Application Form and the other documents required by Section 8 of the Application form, to the Program's Administrator before the end of the applicable Reporting Period (as set forth in Schedule 1 to the Program's Protocol). If Applicant submits this Supporting Evidence Form after the end of the applicable Reporting Period, then this Supporting Evidence Form and the Application to which it relates cannot be accepted or considered.

10. **How to Submit this Form:** Once this form has been duly completed, signed and dated by Registered Healthcare Professional(s), the Applicant must submit this Supporting Evidence Form, together with the Application Form and the other documents required by Section 8 of the Application Form, to the Program's Administrator, by any of the following means:

    - By uploading them to the Program's web portal, available at www.avatclaims.com;
    - By emailing them to avatclaims@esis.com; or
    - By sending them by regular mail to one of the Program's Regional Centers, whose addresses appear on Annex 1 (Contact Information of Regional Centers) attached to this Supporting Evidence form and are also available on the Program's website at www.avatclaims.com.

11. **Definitions:** Capitalized terms used but not defined in this Application have the meaning given to them in the Program's Protocol, available at www.avatclaims.com.

## SUPPORTING EVIDENCE FORM

**IMPORTANT NOTE FOR COMPLETING THIS FORM**: You may answer questions in this Supporting Evidence Form by referring to documents provided with this form. The information contained in the documents provided with this form does not need to be repeated in the answers provided in the form itself.

### 1. REPORT OF REGISTERED HEALTH PROFESSIONAL(S)[2]

| **A. INFORMATION ABOUT THE PATIENT[3]** | |
|---|---|
| Full name of the Patient, including any middle names | |
| Mailing address of the Patient (including city, zip code and country) | |
| Date of birth of the Patient (day/month/year) | |
| Sex of the Patient | |
| **B. INFORMATION ABOUT THE REGISTERED HEALTHCARE PROFESSIONAL(S) COMPLETING THIS FORM** | |
| 1. Full name(s), including any middle names, of the Registered Health Professional(s) completing this Supporting Evidence form. | |

[2] The term "**Registered Healthcare Professional**" means any healthcare professional, including physicians, surgeons, nurses, midwives, nurse practitioners, physicians' assistants, psychiatrists, physical therapists, occupational therapists, dentists and pharmacists, who is duly licensed or legally authorized to practice the profession in the Participating Member State in which the Patient resides and received the Vaccine or in the case of birth defects, where the Patient's mother resides and received the Vaccine.

[3] The term "**Patient**" means an individual from a Participating Member State: (i) who was administered a Vaccine (see Schedule 1 to the Program's Protocol), and (ii) who claims or in respect of whom it is claimed that he suffered an Injury associated with this Vaccine or its administration. Injury means a serious bodily injury or illness suffered or sustained by a Patient that:

(i) requires Hospitalization or prolongs an existing Hospitalization; and

(ii) results in permanent total or partial Impairment; or

(iii) is a congenital birth injury or illness in an unborn or new-born child of a woman who received a Vaccine and results in permanent total or partial Impairment; or

(iv) results in death.

2. Name of the hospital, clinic or other place of work of Registered Health Professional(s) completing this form, including: (A) Mailing address(es), (B) Email address(es), and (C) Telephone number(s).

3. Type of registration held by the Registered Health Professional(s) completing this form, together with the registration number(s) or other means to identify the registration(s). For example, if you are a state registered nurse, please state “nurse” and provide your registration number.

**C. INFORMATION ABOUT THE VACCINE ADMINISTERED TO THE PATIENT**

1. Details of the Vaccine administered to the Patient (or in the case of birth defects, to the Patient’s mother), including the Vaccine’s: (A) name, (B) dose, (C) batch or lot numbers, and (D) expiry date.

2. If known, details of diluent (if any) used with the Vaccine administered to the Patient (or in the case of birth defects, to the Patient’s mother), including the diluent’s: (A) name, (B) dose, (C) batch or lot numbers, and (D) expiry date.

3. Date(s) and places(s) the Vaccine was administered to Patient (or in the case of birth defects, to the Patient’s mother). Please state the date(s) as day/month/year.

**D. INFORMATION ABOUT THE INJURY OR ILLNESS SUSTAINED BY THE PATIENT AFTER THE VACCINE WAS ADMINISTERED TO THE PATIENT.**

**<u>IMPORTANT NOTE</u>: IF A PATIENT HAS DIED, PLEASE COMPLETE THIS <u>SECTION D</u> TO THE EXTENT APPLICABLE, IN ADDITION TO COMPLETING <u>SECTION E</u>.**

1. Describe the injury or illness suffered by the Patient after the Vaccine was administered to Patient (or in the case of birth defects, to the Patient's mother). Please include:

   (A) details of all examinations and tests of the Patient in relation to such injury or illness; and

   (B) if applicable, details of any congenital birth injury or illness.

2. Regarding symptoms, please describe the following:

(A) all symptoms experienced by the Patient after the Vaccine was administered to Patient (or in the case of birth defects, to the Patient's mother);

(B) the dates (day / month / year) when the symptoms were first recorded; and

(C) for each symptom, the extent to which that symptom was serious; and

(D) the details of any sequelae.

In particular, please mention:

- any severe local reaction suffered by the Patient after the Vaccine administered to him/her (and whether that reaction extended beyond nearest joint); and

- any seizures (febrile or afebrile), abscess, sepsis, encephalopathy, toxic shock syndrome, thrombocytopenia, anaphylaxis, fever (above 38 degrees centigrade).

3. Did the Patient require any treatment for the injury or illness suffered by the Patient after the Vaccine was administered to him/her (or in the case of birth defects, to the Patient's mother)?

**If yes**, please describe what treatment was provided to the Patient for the injury/illness suffered by the Patient after the Vaccine was administered to him/her (or in the case of birth defects, to the Patient's mother).

4. Please describe to what extent the Patient has or has not (as applicable) recovered from the injury or illness suffered by the Patient after the Vaccine was administered to him/her (or in the case of birth defects, to the Patient's mother).

5. In your opinion, what was the cause of the injury or illness suffered by the Patient?

6. If known, please provide the date (day/month/year) and place when the injury or illness suffered by the Patient was first reported to a Registered Healthcare Professional or to the health system.

7. Describe the extent of any permanent impairment of the Patient and the prognosis for the Patient as a result of such impairment.

| | |
|---|---|
| 8. | What is the functional impact on the Patient of the injury or illness suffered by the Patient after the Vaccine was administered to him/her (or in the case of birth defects, to the Patient's mother)? |

9. Details of any hospitalization, or prolongation of existing hospitalization, of the Patient for more than 24 consecutive hours in connection with the injury or illness suffered by the Patient after the Vaccine was administered to the Patient (or in the case of birth defects, to the Patient's mother), including:

   (A) Date (day/month/year) when the Patient was admitted to the hospital or when the Patient's existing hospitalization was prolonged;

   (B) Date (day/month/year) when the Patient was discharged from the hospital; and

   (C) Type of care/treatment provided to the Patient during the initial hospitalization for the injury or illness suffered by the Patient after the Vaccine was administered to him/her (or in the case of birth defects, to the Patient's mother); and

   (D) If applicable, type of care/treatment provided to the Patient during the prolongation of the hospitalization, if any, for the injury/illness suffered by the Patient after the Vaccine was administered to him/her (or in the case of birth defects, to the Patient's mother).

10. Details of other medication/vaccination, to the extent known:

(A) Details of any medicines taken by, and/or any other vaccines administered to, the Patient after the Vaccine was administered to the Patient and/or during the period of 6 weeks before such administration, including:

- name of each medicine/vaccine;
- dose
- time period taken or /administered (stated as day/month/year)

(B) In the case of birth defects, details of any medicines taken by, and/or any other vaccines administered to, the Patient's mother during the pregnancy and/or 6 weeks before the start of the pregnancy, including:

- name of each medicine/vaccine;
- dose;
- time period taken or /administered (stated as day/month/year)

11. Details of previous long-term medication, to the extent known. Details of any medicines not described above that were taken by the Patient for a consecutive period of more than 3 weeks, during the 24 months before the Vaccine was administered to the Patient, including:

- name of each medicine:
- dose
- time period taken (stated as day/month/year)

12. Details of any known pre-existing medical conditions of the Patient or in the case of birth defects, of the Patient's mother (i.e. medical conditions existing before the period the Vaccine was administered to the Patient or in the case of birth defects, to the Patient's mother)

13. Has the Patient suffered any similar injury or illness before? If yes, please describe the previous similar injury or illness.

14. In the case of birth defects, did the Patient's mother have another unborn or new-born child with a congenital birth injury or illness? If yes, please provide details.

15. In your opinion, is it possible that the injury or illness suffered by the Patient after the Vaccine was administered to the Patient (or in the case of birth defects, to the Patient's mother) was caused by, or resulted from, any previous injury or illness of the Patient (or in the case of birth defects, of the Patient's mother)?

    If yes, please provide details.

16. To the extent known, has a close family member of the Patient, such as brother, sister, parent, child, aunt, uncle, or 1st cousin, suffered any similar injury or illness before?

If yes, please indicate which close family member and describe the similar injury or illness.

17. Have you seen any injury or illness similar to that suffered by the Patient amongst other patients who received (or in the case of birth defects, whose mother received) the same Vaccine?

| E. IF THE PATIENT HAS DIED, INFORMATION ABOUT THE PATIENT'S DEATH: |
| --- |
| 1. If the Patient has died after the Vaccine was administered to Patient, then please:<br><br>a. State date of the Patient's death (day/month/year) and all causes of death stated on the Patient's death certificate; and<br><br>b. Include the details of any autopsy performed on the Patient.<br><br>2. In accordance with Section G below, please provide a copy of the Patient's death certificate and any other documentation available regarding the cause and manner of the Patient's death.<br><br>3. In your opinion, what is/are the causes(s) of the Patient's death?<br><br>4. Have you seen death similar to that suffered by the Patient among other patients who received the same Vaccine as the Patient? If yes, please provide details. |

| F. OTHER INFORMATION: |
| --- |
| Please set out any further information which you consider may be relevant for the Patient's claim for compensation under the Program |
| G. DOCUMENTATION TO BE PROVIDED WITH THIS FORM |
| 1. Please provide documentation confirming that the Vaccine was administered to the Patient (or in the case of birth defects, to the Patient's mother), for example, a copy the immunization card or certificate, a copy of the service point immunization log documenting the administration of the Vaccine, or a copy of the completed national adverse event following immunization investigation form.<br><br>2. Please attach a copy of all available medical documentation and records related to the injury or illness sustained by the Patient after administration of the Vaccine, including case sheet, case notes, discharge summary, laboratory reports, autopsy report, as well as prescriptions for concomitant and/or long-term medication, as referred to above, etc.<br><br>3. If available, please also attach a copy of the adverse event following immunization ("**AEFI**") investigation form, AEFI committee causality assessment, and related documentation.[4] |

[4] AEFI investigations and causality assessments may be conducted by a Ministry of Health, its national immunization program, or associated committees, and documents related to such investigations and assessments may be available from such groups.

In the event of any conflict or inconsistency between the English language version of this Supporting Evidence Form and any translations hereof, the English language version shall control and prevail in all respects.

**2. DECLARATION AND SIGNATURE OF REGISTERED HEALTHCARE PROFESSIONAL(S)**

By signing below, I/we hereby certify that:

- before this Supporting Evidence Form was completed, a waiting period of 30 days has been observed since the Vaccine was administered to the Patient (or in the case of birth defects, to the Patient's mother); and

- the statements and answers contained in this Supporting Evidence Form are true and correct to the best of my/our knowledge and belief.

I/We understand that should these statement or answers not be true, the Administrator shall have the right, where applicable, to refer to the relevant law enforcement authority for further investigation.

Full Name of Registered Healthcare Professional: _____

Title: _____

Signature: _____

Date: _____

Full Name of Registered Healthcare Professional: _____

Title: _____

Signature: _____

Date: _____

**[END OF THE SUPPORTING EVIDENCE FORM]**