**ZUELLIG PHARMA ADVERSE EVENT REPORT FORM**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***For any Adverse Event (AE) report received, kindly fill in this this form and submit to*** [***zpmyPV@zuelligpharma.com***](mailto:zpmyPV@zuelligpharma.com) | | | | | | | | |
| **Country of Occurrence: *{country\_name}*** | | | | **AE Reference Number: *{reference\_no}*** | | | | |
| **Date Report was Received by Zuellig:**  ***{first\_notification\_to\_zpc\_at}*** | | | | **Client Name: *{client\_name}*** | | | | |
| **Mode of Receipt: {mode\_of\_receipt\_telephone} Telephone {mode\_of\_receipt\_email} E-mail {mode\_of\_receipt\_letter} Letter {mode\_of\_receipt\_other} Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | |
| **Section 1: Consent Statement** (*please tick (🗸) the following where applicable* | | | | | | | | |
| **If reporter is the user of the product**  **I, the reporter and the user of the product,** agree that the personal information provided in this form may be shared with the Product Owner / Product Registration Owner / Local Authorised Representative / Marketing Authorization Holder of the product (who may be located outside of the country).  {consent\_user\_yes} YES {consent\_user\_no} NO  I can be contacted for follow-up on this report  {can\_be\_contacted\_for\_follow\_up\_yes} YES {can\_be\_contacted\_for\_follow\_up\_no} NO | | | | **If reporter is NOT the user of the product**  **I, the reporter and not the user of the product,** confirm that I have obtained consent from the user to release his/her personal data to the product Product Owner / Product Registration Owner / Local Authorised Representative/ Marketing Authorization Holder of the product (who may be located outside of the country).  {consent\_non\_user\_yes} YES {consent\_non\_user\_no} NO  I can be contacted for follow-up on this report  {can\_be\_contacted\_for\_follow\_up\_yes} YES {can\_be\_contacted\_for\_follow\_up\_no} NO | | | | |
| **Name and Signature/Date:**  **Verbal consent was given to Zuellig Pharma employee or consent was recorded in the system.**  *For further information on Zuellig Pharma’s privacy policy, please refer to* [*https://www.zuelligpharma.com/privacy-policy*](https://www.zuelligpharma.com/privacy-policy) | | | | | | | | |
| **Section 2: Patient Information** | | | | | | | | |
| **Patient Initials:**  ***{patient\_initials}*** | **Gender: {gender\_male} Male**  **{gender\_female} Female {gender\_unknown} Unknown**  **If Female, is she pregnant?**  **{pregnant\_yes} Yes {pregnant\_no} No**  **{pregnant\_unknown} Unknown** | | | **Age: *{patient\_age}*** | | | **Weight (kg):**  ***{patient\_weight}*** | |
| **Date of Birth:**  **(DD/MM/YYYY)**  ***{patient\_date\_of\_birth}*** | | |
| **Section 3: Reporter’s Information** | | | | | | | | |
| **Reporter Category: {reporter\_consultant\_specialist\_doctor}** Consultant / Specialist / Doctor **{reporter\_pharmacist}** Pharmacist **{reporter\_nurse}** Nurse  **{reporter\_medical\_representative}** Medical Representative **{reporter\_sales\_representative}** Sales Representative **{reporter\_caretaker}** Caretaker  **{reporter\_patient}** Patient **{reporter\_other}** Others (please specify) **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | |
| **Reporter’s Contact Details**  **Name: *{reporter\_name}***  **Address or Institution: *{reporter\_place\_of\_practice}***  **Telephone Number: *{reporter\_contact\_no}* E-mail Address: *{reporter\_email}*** | | | | | | | | |
| **Section 4: Adverse Event (AE) Information** | | | | | | | | |
| **Time to Onset of Reaction:**  ***{reaction\_time\_on\_set}*** | | | | **Date of Start of Reaction:**  ***{reaction\_start\_date}*** | | | | |
| **Date of End of Reaction:**  ***{reaction\_end\_date}*** | | | | |
| **Seriousness of reaction:**  **{seriousness\_death}** Resulted in death **{seriousness\_life\_threatening}** Life-threatening  **{seriousness\_hospitalization}** Involved or prolonged in-patient hospitalization  **{seriousness\_disability}** Involved persistent or significant disability or incapacity **{seriousness\_anomaly}** Congenital anomaly / birth defect  **{seriousness\_other}** Other Medically Important Event (please specify): **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **{seriousness\_non\_serious}** Non-serious **{seriousness\_unknown}** Unknown | | | | | | | | |
| **Adverse Event Description: *{reaction\_description}*** | | | | | | | | |
| **Section 5: Other Medical Information (if applicable)** | | | | | | | | |
| **Relevant Investigation / Laboratory Data:**  ***{reaction\_relevant\_investigation\_laboratory\_data}*** | | | | **Relevant Medical History:**  (e.g. allergies, hepatic / renal dysfunction, other illnesses)  ***{reaction\_relevant\_medical\_history}*** | | | | |
| **Section 6: Product / Device Information** | | | | | | | | |
| **Product Category: {has\_medical\_product}** Medicinal Product (proceed to Section 6.1) **{has\_medical\_device}** Medical Device (proceed to section 6.2)  Others: (please specify) **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** (proceed to section 6.2) | | | | | | | | |
| **Section 6.1 - Medicinal Product** | | | | | | | | |
| **Suspect Drug(s)**  (May add rows or use back page if more space is required) | | | **Dose(s) and Frequency Given** | **Therapy Date(s)** | | **Indication(s) for Use** | | **Action:** *Dose (decreased, increased, interrupted, or not changed), Withdrawn, Unknown, NA* |
| **Start** | **Stop** |
| ***{pp\_generic\_name}*** | | | ***{pp\_dosage}***  ***{pp\_frequency}*** | ***{pp\_start\_date}*** | ***{pp\_stop\_date}*** | ***{pp\_indication}*** | |  |
|  | | |  |  |  |  | |  |
|  | | |  |  |  |  | |  |
| **Concomitant Drug(s)**  (May add rows or use back page if more space is required) | | | **Dose & Frequency Given** | **Therapy Dates** | | **Indication(s) for Use** | | |
| **Start** | **Stop** |
| ***{pp\_cd\_1\_drug\_name}*** | | | ***{pp\_cd\_1\_dosage}***  ***{pp\_cd\_1\_frequency}*** | ***{pp\_cd\_1\_start\_date}*** | ***{pp\_cd\_1\_stop\_date}*** | ***{pp\_cd\_1\_indication}*** | | |
| ***{pp\_cd\_2\_drug\_name}*** | | | ***{pp\_cd\_2\_dosage}***  ***{pp\_cd\_2\_frequency}*** | ***{pp\_cd\_2\_start\_date}*** | ***{pp\_cd\_2\_stop\_date}*** | ***{pp\_cd\_2\_indication}*** | | |
| ***{pp\_cd\_3\_drug\_name}*** | | | ***{pp\_cd\_3\_dosage}***  ***{pp\_cd\_3\_frequency}*** | ***{pp\_cd\_3\_start\_date}*** | ***{pp\_cd\_3\_stop\_date}*** | ***{pp\_cd\_3\_indication}*** | | |
| **Section 6.2 - Medical Device / Other Type of Product** | | | | | | | | |
| **Device or Product Details** | | | | **List of other devices or products involved in the event:**  ***{md\_list\_of\_other\_device}*** | | | | |
| 1. **Brand Name** | | ***{md\_device\_name}*** | |
| 1. **Model or Batch Number** | | ***{md\_model\_no}*** | |
| 1. **Duration of Usage** | | ***{md\_usage\_of\_device}*** | |
| **Section 7: Person who filled up this form (to be filled by Reporter or Zuellig Pharma Employee)** | | | | | | | | |
| **Report Form Filled By:**  ***{consent\_employee\_name}***  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Complete Name** | | | | | ***{current\_date}***  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Date** | | | |
| **Section 8: Status of Reporting (to be filled by Zuellig Pharma)** | | | | | | | | |
| **AE Form was Verified By:**  **Name:**  **Date: *{current\_date}***  **Note: Person who verified and whose name appears above attests that he/she actually performed the verification.** | | | | | **Date of Acknowledgement of Receipt from Product Owner / Marketing Authorization Holder:**  ***{ae\_submission\_date}*** | | | |