Adverse Event Reporting Template



ARR –ASPEN/Egypt- 001/01/015

|  |  |  |
| --- | --- | --- |
| *Internal office use:* | | |
| Local Reference number: | Company Number: | Date received: |

**Patient information:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Initials: | DOB: | Age at onset: | Units: | Years/Days/Hours/Months/Minutes/Decades | Gender: | Female: |

Ethnic origin

**Reporter Information:**

|  |  |
| --- | --- |
| Name: | Profession: □ Consumer □ Health care professional □ Other (please specify): |
| Organisation: | Telephone: |
| Address: | Fax: |
| City/County: | Email: |

**Product Information:**

|  |  |  |
| --- | --- | --- |
| Brand name: | Active Ingredient: | Route of Admin: |
| Dose: | Indication: | |
| Start Date: | Stop Date: | Action taken: |

**Event term:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Adverse Events: | Start Date: \_\_/ /  Start Date: \_\_/ / Start Date: \_\_/ / Start Date: \_\_/ / | | Stop Date: \_\_/ /  Stop Date: \_\_/ / Stop Date: \_\_/ / Stop Date: \_\_/ / | | |  |
| Did the event result in hospitalisation? Yes □ No □ Unknown □ | | Did the event result in death? | Yes □ | No | * Unknown | □ |

|  |  |  |  |
| --- | --- | --- | --- |
| **Outcome:** | | | |
| Recovered: □ |  | Recovered with Sequalae: □ |  |
| Not Recovered: □ |  | Unknown: □ |  |
| Fatal: □ | Date of death: / / | Cause of Death: | Autopsy performed: Yes □ No □ Unknown □ |

**Co-Suspect Medication:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name | Dose  Frequency | Route: | Indication: | Start Date:  / \_/ | Stop Date:  / / |
| Name | Dose  Frequency | Route: | Indication: | Start Date:  / \_/ | Stop Date:  / / |
| Name | Dose  Frequency | Route: | Indication: | Start Date:  / \_/ | Stop Date:  / / |

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**Concomitant Medication:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name | Dose  Frequency | Route: | Start Date: \_\_/ / | Stop Date: \_\_/ / |
| Name | Dose  Frequency | Route: | Start Date: \_\_/ / | Stop Date: \_\_/ / |
| Name | Dose  Frequency | Route: | Start Date: \_\_/ / | Stop Date: \_\_/ / |
| Name | Dose  Frequency | Route: | Start Date: \_\_/ / | Stop Date: \_\_/ / |

**Medical History:**

**Event Description:** *(including relevant Lab results)*

|  |  |  |
| --- | --- | --- |
| **Signature** |  |  |
| Reporter Name: | Signature: | Date: |

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