**Adverse Reaction Report Form for Human Medicines Page 1 of 2**

IN CONFIDENCE

Please complete this form in confidence and return to Freepost, Pharmacovigilance Section, Health Products Regulatory Authority, Earlsfort Centre, Earlsfort Terrace, Dublin 2, D02 XP77. Telephone 353-1-6764971, Fax 353-1-6762517, e-mail medsafety@hpra.ie.

A privacy notice in relation to the personal data collected on this form is available on the HPRA website ([www.hpra.ie](http://www.hpra.ie)) under the ‘Report an Issue’ tab and by clicking on ‘Human Medicines Adverse Reaction’.

|  |  |
| --- | --- |
| Reporter name:  |       |
| Address: |       |
| E-mail:  |       |
| Telephone number: |       |
| If healthcare professional, state profession and area of speciality below:  |
| Profession: |        |
| Area of speciality: |       |

|  |  |  |
| --- | --- | --- |
| Patient initials      | Sex Male [ ]   Female [ ]  | Age:       |
| Reason for treatment:       |
| Suspect drug(s)/vaccine(s)[[1]](#footnote-1) | Daily dose  | Route | Batch no. | Dates/duration of treatment |
|       |       |       |       |       |
| Suspected reaction: *(Brief description of the effects/side effects/interactions, including any information relevant to the circumstances of this reaction, such as in use conditions, medication error, occupational exposure etc.)*      |
| Time to onset (hours/days)      | Onset of reaction (date)      | Duration of reaction      |
| Treatment given/action taken      |
| Outcome of reaction: [ ]  Recovered [ ]  Recovering [ ]  Continuing [ ]  Fatal |

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|  |  |
| --- | --- |
| Drug discontinued: Yes [ ]  No [ ] Improvement on discontinuation Yes [ ]  No [ ] Patient rechallenged Yes [ ]  No [ ] If yes, state outcome       | Do you consider the reaction serious? Yes [ ]  No [ ]  If yes, please indicate the basis for this, ticking all the criteria that apply:[ ]  Fatal[ ]  Life threatening (immediately)[ ]  Patient hospitalised / hospitalisation prolonged [ ]  Persistent or significant disability/incapacity   [ ]  Congenital anomaly or birth defect [ ]  Medically significant *-* provide details:   |
| Any other drugs used over this period?*(Please state below)* | None [ ]  Unknown [ ]  |
| Drug/Vaccine | Daily dose: | Route: | Dates/duration of Treatment: | Reason for treatment: |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
| Relevant medical history *(including significant concomitant illness/previous drug reaction)*: |
| Description | Start Date | End date | Continuing (Y/N) |
|       |       |       |       |
| Additional information |
|       |
| Supply of report cards required Yes [ ]  No [ ]   | Manufacturer notified: Yes [ ]  No [ ]   |

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:

Thank you for taking the time to complete this form.

1. *Please use brand names where possible. Please note that for biological products, including vaccines, it is essential to include the brand name and batch number of the product.* [↑](#footnote-ref-1)