**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](mailto: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: | |
|  |  | |  | | |  | |  | |
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|  |  | |  | | |  | |  | |
|  |  | |  | | |  | |  | |
| 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)