HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Adverse Reaction Report Form for Human Medicines
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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) 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/Record number	Sex Male ☐ Female ☐			Age:
Reason for treatment:				
Suspect drug(s)/vaccine(s)[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				

[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.*

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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.