**Report of side effect (adverse reaction) for COVID-19 vaccines**

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 and/or email 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 ‘privacy and data protection’ and by clicking on ‘privacy notice for reporting of adverse reactions from medicines for human use’.

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| Reporter title and name:  |       |
| Address: |       |
| Eircode: |  |
| Email:  |       |
| Telephone number: |       |
| If healthcare professional, state profession, area of speciality and organisation/department below: |
| Profession: |        |
| Area of speciality: |       |
| Organisation/department: |       |

For patient details, enter a minimum of one of the following: initials, sex, date of birth or age.

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| Patient initials:      | Sex: Male [ ] Female[ ]  | Age when the side effect was experienced:       | Weight:      | Date of birth:      |
| Is the patient pregnant? Yes [ ]  No [ ] If the patient is pregnant, which trimester are they in?       |
| Is the patient breastfeeding?       |
| Relevant medical history/underlying conditions:       |

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| Vaccine brand | Batch no.(s) | Vaccination date(s) |
| [ ]  Comirnaty (BioNTech) Original Strain[ ]  Comirnaty adapted for variant BA.1[ ]  Comirnaty adapted for variant BA.4-5[ ]  Comirnaty adapted for variant XBB.1.5[ ]  Comirnaty adapted for variant JN.1[ ]  Comirnaty adapted for variant KP.2[ ]  Spikevax adapted for variant BA.1[ ]  Spikevax adapted for variant BA.4-5[ ]  Spikevax adapted for variant JN.1[ ]  Spikevax (Moderna) Original Strain[ ]  Spikevax (Moderna) adapted for variant XBB. 1.5[ ]  Vaxzevria (AstraZeneca) [ ]  Jcovden (Janssen)[ ]  Nuvaxovid (Novavax)[ ]  Nuvaxovid adapted for variant XBB.1.5[ ]  VidPrevtyn Beta (Sanofi Pasteur)[ ]  Bimervax (Hipra Human Health S.L.)[ ]  Unknown brand of COVID-19 vaccine |                 | 1st Vaccination:     2nd Vaccination:     3rd Vaccination:     Booster vaccination:      |
| Dose administered (e.g. first, second) |
|                 |

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| Suspected side effect: *(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 of side effect (hours/days):      | Date of onset of side effect:      | Duration of side effect:      |
| Treatment given/action taken in response to the side effect:      |
| Outcome of side effect: [ ]  Recovered [ ]  Unknown [ ]  Symptoms persisting [ ]  Fatal |
| Do you consider the side effect 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 [ ]  Disability/incapacity   [ ]  Congenital anomaly or birth defect [ ]  Medically significant |
| Any other drugs used over this period?Please ensure that you include all medications (including herbals) or vaccines (e.g. influenza or pneumococcal vaccines). *(Please state below)* |
| Drug/vaccine name (as shown on label/package) or active substance: | Daily dosage: | Dose administered (if other COVID-19 vaccine e.g. first, second dose): | How was the medicine taken (e.g. by mouth, injection): | Dates/duration of treatment: | Reason for treatment: |
|       |       |       |       |       |       |
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| Description | Start Date | End date | Continuing (Y/N) |
|       |       |       |       |
| Enter any additional information you wish here:       |
| If you are the patient who experienced the side effect(s), do you provide consent for us to contact a nominated healthcare professional to obtain additional information about your experience? Yes [ ]  No [ ]  |
| If yes, name of healthcare professional:       |
| Address of healthcare professional:       |
| Telephone and/or mobile of healthcare professional:       |
| Email address of healthcare professional:       |
| Additional information:       |

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

Thank you for taking the time to complete this form.