## ANNEX 3 AE/PC/SRS REPORTING FORM TEMPLATE FOR MEDICINES OR MEDICAL DEVICES

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|  | **Adverse Event / Product Complaint / Special Reporting Situation (AE/PC/SRS) Report – GB/NI Market Research (HCPs or non-HCPs)** |  |
| Please complete as many details as possible and **forward within one business day** to your pharmaceutical company contact **even if there is no identifiable patient** |
| **Agency and Project Details** |   |
| Market research agency and address: | Date aware of the AE/PC/SRS: |
| Project title and / or Agency reference no: |
| Agency telephone no: | MAH/Certificate Holder reference number / Company project ID: |
| Agency email: | Respondent ID or AE/PC/SRS no: |
| Researcher's name: | Researcher's signature: |
| **Medicine/Device and Event Details** |   |
| Medicine/Device name(s): |
| Indication (condition medicine(s) prescribed/device used for):Unknown | Adverse Event(s)/Product Complaint/Special Reporting Situation details\*:  |
| Dose:Unknown |
| Was the patient pregnant?Yes No Unknown | Lot/Batch No.: | Unknown |
| Reported to the MHRA: Yes No Unknown | Does the HCP/patient think the event might have been related to the medicine/device?Yes No Unknown |
| **Patient Details**  |   |
| Age or year of birth: | Other:  |
| Sex: Male Female  |
| AE/PC/SRS recorded in: GB (England, Scotland, Wales) Northern Ireland [Grab your reader’s attention with a great quote from the document or use this space to emphasize a key point. To place this text box anywhere on the page, just drag it.] |
| No. of patients: Individual patient Multiple patients State no. of patients if known: (only tick 'multiple patients' if no individual identifying details are available; otherwise please complete separate forms |
| **Respondent Details** |   |
| I agree to my details being passed to the pharmaceutical company's safety team so that they may contact me to discuss this report further?Yes No Respondent signature: |
| If respondent does not agree to their contact details being passed on, just complete the type of respondent |
| Name: | Doctor NursePharmacistPatientCarerOther Please specify: |
| Address: |
| Telephone no: |
| Email address: |
| \* e.g. other medicines taken by the patient, relevant medical history, event outcome, action taken with the medicine, was the patient hospitalised?  |