## 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  Nurse  Pharmacist  Patient  Carer  Other 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? | | | | |