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

abpi Bringing medicines to life

Adverse Event / Product Complaint / Special Reporting Situation (AE/PC/SRS) Report – GB/NI Market Research (HCPs or non-HCPs)

BHBIA

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 ☐	Unknown ☐ Lot/Batch No.:
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 ☐	
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 ☐
Address:	Nurse ☐ Pharmacist ☐
Telephone no:	Patient ☐ Carer ☐
Email address:	Other ☐ Please specify:

* e.g. other medicines taken by the patient, relevant medical history, event outcome, action taken with the medicine, was the patient hospitalised?