Updated -draft changes 10.07.2023

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| **EPHMRA Market Research Adverse Event Reporting Form – TEMPLATE****(Including Adverse Events (AEs), Product Quality Complaints (PQCs) and Special Reporting Situations (SRSs)** For use in reporting AEs arising during Healthcare Market Research with HCPs and/or Non-HCPs[[1]](#endnote-2) where the MAH/CH’s[[2]](#endnote-3) medicine or medical device is mentioned by brand (trademark) name or its generic (International Non-proprietary Name / INN)  |
| Market Research Agency and Project Details |
| Market Research Agency name:Full Address: Country:Zip Code: |  |
| Market Research Agency telephone number:Country Code:Number: |  |
| Market Research Agency – Contact email address: |  |
| Research Interviewer’s name:Title:First name:Surname: |  |
| Research Interviewer’s email address: |  |
| Date aware of AE (\*) |  |
| Agency Market Research Project title/reference number |  |
| Marketing Authorisation Holder or Certificate Holder’sreference number / Company project ID  |  |
| Respondent ID or AE\* number |  |
| **Medicine/Device and Event Details**  |
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| **MEDICINE / MEDICAL DEVICE DETAILS**  |
| Medicine/Medical Device Name  |  |
| Indication/condition for which medicine(s) prescribed/medical device used. for):  |  |
| Description of Adverse Event:*Please describe as fully as possible*  |  |
| DoseFrequency of dose: |  | UNKNOWN  |
| Medicine or Medical Device Lot / Batch number: |  | UNKNOWN  |
| Frequency of dose of Medicine: |  |  UNKNOWN |
| Route of administration/form of Medicine |  |  UNKNOWN |
| Was the patient pregnant? | YES | NO | UNKNOWN |
| Reported to the Regulator? | YES | NO | UNKNOWN |
| Does reporter think event might have been related to the medicine? | YES | NO |  UNKNOWN |
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| **PATIENT DETAILS** |  |
| No. of patients: *\*\* Select 'multiple patients' only if individual identifying details are not available, otherwise please complete separate AE reports)* | No. of patients: Individual patient: Multiple patients\*\*:State **number** of patients if known: [enter number]  |
| Availability of patient information | YES | NO |
| Age or year of birth  |  |
| Sex | FEMALE | MALE |
|  | OTHER | PREFER NOT TO STATE |
| Country AE reported in:Reporting in:Spain: include city and/or region if known.GB (England, Scotland, Wales) Or Northern Ireland  |  |  |  |
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|  **RESPONDENT / REPORTER 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.Note: Not applicable in Germany where respondent details are not permitted to be passed to the MAH/CH | Yes: No: Signature or enter name:  |
| **Respondent details**Preferred title: (Mr, Ms, Mrs, Dr., etc.)First Name:Last Name:Address:Country:Telephone no: Email address: |
| Please select one of the respondent types if the respondent does not agree to their contact details being passed on.  | Doctor NursePharmacistPatientCarerPayerOther Please specify. |
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AE/PC/SRS = Adverse Event, Product Complaint and Special Report Situations

1. HCP = a medically qualified person, such as a physician (e.g., primary, or secondary care), dentist, pharmacist, nurse, or as otherwise specified by local regulations. Non-HCP includes persons such as a patient, relative of a patient or carer, payer who is not a healthcare professional. [↑](#endnote-ref-2)
2. MAH / CH = Marketing Authorisation Holder or Certificate Holder [↑](#endnote-ref-3)