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’s  reference 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* |  | | | | |
| Dose  Frequency 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  Nurse  Pharmacist  Patient  Carer  Payer  Other 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)