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AI-generated content may be incorrect.

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| **EPHMRA Template for Market Research Adverse Event Reporting Form**  **Adverse Events’ is an umbrella term that covers Adverse Events (AE), Special Reporting Situations (SRS), and Product Quality Complaints (PQC).**  This template may be used to report AEs arising during Healthcare Market Research with HCPs or non-HCPs where the commissioning company is the MAH/CH for the medicine or medical device or diagnostic mentioned by brand (trademark) name or its generic (INN) | | | | | |
| Market Research Agency and Project Details | | | | | |
| Market Research Agency name:  Full Address:  Country:  Zip Code: |  | | | | |
| Market Research Agency telephone / mobile (cell) number:  Country Code:  Telephone / Mobile (cell) Number: |  | | | | |
| Market Research Agency – Contact email address: |  | | | | |
| Research Interviewer’s name:  Title:  First name:  Surname: |  | | | | |
| Research Interviewer’s contact email address: |  | | | | |
| Date first aware of Adverse Event (including AE, SRS, PQC) |  | | | | |
| 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 / MEDICAL DEVICE / DIAGNOSTIC DETAILS** | | | | | |
| Name of Medicine / Medical Device / Diagnostic |  | | | | |
| Indication/condition for which medicine(s) prescribed, medical device or diagnostic used.  for): |  | | | | |
| Description of Adverse Event:  *Please describe as fully as possible* |  | | | | |
| Dose  Frequency of dose: |  | | | UNKNOWN | |
| Medicine or Medical Device or Diagnostic Lot / Batch number: |  | | | UNKNOWN | |
| Frequency of dose of Medicine: |  | | | UNKNOWN | |
| Route of administration/form of Medicine |  | | | UNKNOWN | |
| Please provide details of the AE if it relates to a medical device or diagnostic: |  | | |  | |
| Was the patient pregnant? | YES | NO | | | UNKNOWN |
| Has the HCP or Non-HCP reported the AE to the appropriate Regulatory Authority? | YES | NO | | | UNKNOWN |
| Does HCP or Non-HCP reporter think event might have been related to the medicine, medical device or diagnostic? | YES | NO | | | UNKNOWN |
|  |  |  | | |  |
| **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:  Additional details for following:   * Spain: include city and/or region if known. * Great Britain (i.e., England, Scotland, or Wales) * Northern Ireland * Other (if applicable) |  |  | | |  |
| **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.  **Country exception**: In Germany respondent details are not permitted to be passed to the MAH/CH, including for AE reporting. | Yes:  No:  Signature or enter name: | | | | |
| **Respondent details**  Preferred title: (Mr, Ms, Mrs, Dr., Other.)  First Name:  Last Name:  Address:  Pose / Zip Code:  Country:  Contract Telephone or Mobile (cell) number (including country code):  Contact 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 detail. | | | | |

**Note:**

Market Research Agency includes third party such as fieldwork agency, independent moderators, consulting company or other individuals or organisations conducting primary MR interviews with HCPs or Non-HCPs on behalf of a commissioning company who is the MAH/CH for a medicine, medical device or diagnostic in scope of the study.

**Abbreviations**

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| AE | An umbrella term that covers Adverse Events (AE), Special Reporting Situations (SRS), and Product Quality Complaints (PQC) |
| **CH** | Certificate Holder |
| **HCP:** | Any licensed member of the medical, dental, pharmacy or nursing professions or any other person who, during their professional activities, may administer, prescribe, purchase, recommend or supply a medicine and/or medical device. It may include a payer who is an HCP with budgetary responsibilities, or as otherwise specified by local regulations |
| **INN** | International Non-proprietary Name |
| **Non-HCP:** | A patient, sufferer, carer, family member or member of the public. It may include a payer who is not an HCP. |
| **MAH** | Marketing Authorisation Holder |

**If you would like to contact EPHMRA please email** [**generalmanager@ephmra.org**](mailto:generalmanager@ephmra.org)**.**

Our registered address is:

European Pharmaceutical Market Research Association, CH Basel

c/o Streicher & Brotschin Treuhand AG, Gartenstrasse 101, 4052 Basel, Switzerland