ATTACHMENT

RECOMMENDED KEY DATA ELEMENTS FOR INCLUSION IN EXPEDITED REPORTS OF SERIOUS ADVERSE DRUG REACTIONS

Some data elements might not be relevant, depending on the circumstances. Attempts should be made to obtain follow-up information on as many other listed items as are pertinent to the case. Refer to the ICH E2B/M2 guidelines for detailed data elements for electronic transmission of ICSRs.

1. Patient Details

- Initials
- Other relevant identifier (patient number, for example)
- Gender
- Age, age category (e.g., adolescent, adult, elderly), or date of birth
- Concomitant conditions
- Medical history
- Relevant family history

2. Suspected Medicinal Product(s)

- Brand name as reported
- International Non-Proprietary Name (INN)
- Batch/lot number
- Indication(s) for which suspect medicinal product was prescribed or tested
- Dosage form and strength
- Daily dose (specify units - e.g., mg, ml, mg/kg) and regimen
- Route of administration
- Starting date and time
- Stopping date and time, or duration of treatment

3. Other Treatment(s)

The same information as in item 2 should be provided for the following:

- Concomitant medicinal products
  (including non-prescription, over-the-counter medicinal products, herbal remedies, dietary supplements, complementary and alternative therapies, etc.)
- Relevant medical devices

4. Details (all available) of Adverse Drug Reaction(s)

- Full description of reaction(s), including body site and severity
- The criterion (or criteria) for regarding the report as serious
- Description of the reported signs and symptoms
- Specific diagnosis for the reaction
- Onset date (and time) of reaction
- Stop date (and time) or duration of reaction
- Dechallenge and rechallenge information
- Relevant diagnostic test results and laboratory data
- Setting (e.g., hospital, out-patient clinic, home, nursing home)
- Outcome (recovery and any sequelae)
- For a fatal outcome, stated cause of death
- Relevant autopsy or post-mortem findings
- Relatedness of product to reaction(s)/event(s)

5. Details on Reporter of an ADR

- Name
- Mailing address
- Electronic mail address
- Telephone and/or facsimile number
- Reporter type (consumer, healthcare professional, etc.)
- Profession (specialty)

6. Administrative and MAH Details

- Source of report (spontaneous, epidemiological study, patient survey, literature, etc.)
- Date the event report was first received by manufacturer/company
- Country in which the event occurred
- Type (initial or follow-up) and sequence (first, second, etc.) of case information reported to authorities
- Name and address of MAH
- Name, address, electronic mail address, telephone number, and facsimile number of contact person of MAH
- Identifying regulatory code or number for marketing authorisation dossier
- Company/manufacturer's identification number for the case (the same number should be used for the initial and follow-up reports on the same case).