EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

Database structure

The database includes the following fields:

- **Medicinal Product:**
  Brandname of the centrally authorised product

- **Active substance**

- **Date of the SPC**
  Whichever date is most recent: date of first authorisation or date of the latest version of the SPC found on the European Commission website:
  http://ec.europa.eu/health/documents/community-register/html/brand_full.htm

  If the medicinal product is a generic, the date indicated may also be the date when the CHMP issued a positive opinion for a variation type IB. In this case there is no decision by the European Commission and the SPC can be found on the EMA website (www.ema.europa.eu) in the Product information tab.

- **Adverse Drug Reaction**
  Adverse Drug Reaction term as it appears in the SPC

- **MedDRA PT-Text**
  MedDRA Preferred Term (text) corresponding to the Adverse Drug Reaction

- **MedDRA PT-Code**
  MedDRA Preferred Term (code) corresponding to the Adverse Drug Reaction

- **MedDRA SOC-Code**
  MedDRA System Organ Class (SOC) corresponding to the Adverse Drug Reaction

- **Age group**
  Age group, if specified, coded as follows:
  0. Age category not specified or unclear
  1. ADR occurs in children only
  2. ADR occurring in adults only
  3. ADR occurring in the elderly only

- **Gender**
  Gender if ADR is mentioned to be related to gender:
  0. Not specified, unclear or both genders
  1. ADR occurs in women only
  2. ADR occurs in men only

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- **Causality**
  Coding of any additional wording existing in the SPC and providing additional information on the strength of causal association, in four categories:
  0. Established ADR (default value for all ADRs listed in the Table)
  1. Possible relationship
  2. Doubtful relationship
  3. Unassessable or unclear

  If a product is made of more than one substance, and an ADR has occurred with one substance only, the ADR has been listed with a causality of 0 (established ADR) and a comment has been added in the Comment field to indicate which substance has caused the ADR.

- **Frequency**
  The frequency category mentioned in the Table of ADRs, coded as follows:

  0. Unknown, not mentioned or no standard category
  1. Very rare
  2. Rare
  3. Uncommon
  4. Common
  5. Very common.

  The comment "CF" (conflicting frequencies) has been added in the Comment field when an ADR has been observed with two conflicting frequencies for the same product. This could happen in the following cases:
  - when several clinical trials with different results (and sometimes different indications) are reported in the SPC;
  - when ADRs are listed for each individual component of a product.

  If a frequency is described with a percentage rather than with a standard wording (i.e. unknown, very rare, rare, uncommon, common or very common), the category is "0" as figures have not been interpreted.

- **Class warning**
  Does the SPC (section 4.8) indicate that the adverse reaction is observed in the same class of drug or is pharmacological class effect (or is there a similar statement)?
  0. No
  1. Yes.

- **Clinical Trial**
  Is the adverse reaction listed in a table presenting results of clinical trials, or is it mentioned in the context of clinical trials?
  0. No
  1. Yes.

- **Post-marketing surveillance**
  Is the adverse reaction listed in a table presenting data from post-marketing surveillance, or is it mentioned in the context of post-marketing surveillance?
  0. No
  1. Yes.

  If the SPC states that the ADRs have been observed from spontaneous reporting and in clinical trials without specifying which ADRs have been observed in which, then "0" has been entered in both fields "Clinical Trial" and "Post-marketing surveillance".

- **Comment**
  This field has been used to include any additional useful information like ADRs occurring in specific indications or with concomitant drugs, to explain the causality assessment, or to indicate with which individual drug component an ADR has been observed.