EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Electronic Submission of Medicinal Product Information by Marketing Authorisation Holders– Regulation (EC) No 726/2004, Article 57(2), 2nd subparagraph

Second Stakeholders Forum on the implementation of the new Pharmacovigilance legislation, 17 June 2011

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Regulation (EU) 726/2004 Article 57(2), 2nd subparagraph

'For the purposes of the database, the Agency shall set up and maintain a list of all medicinal products for human use authorised in the Union. To this effect the following measures shall be taken:

(a) the Agency shall, by 2 July 2011 at the latest, make public a format for the electronic submission of information on medicinal products for human use;

Regulation (EU) 726/2004 Article 57(2), 2nd subparagraph

(b) marketing authorisation holders shall, by 2 July 2012 at the latest, electronically submit to the Agency information on all medicinal products for human use authorised or registered in the Union, using the format referred to in point (a);

(c) from the date set out in point (b), marketing authorisation holders shall inform the Agency of any new or varied marketing authorisations granted in the Union, using the format referred to in point (a).

Implementation Strategy

- The Agency will publish a format and detailed guidance for the electronic submission of medicinal product information by marketing authorisation holders on 1 July 2011:
  - EudraVigilance Medicinal Product Report Message (EVPRM) will serve as initial format
  - Enhancements introduced to ensure future compatibility of data submitted with ISO Identification of Medicinal Product (IDMP) standards e.g.
    - Expression of strength
    - Attachments of SPC, PL, Annexes for CAPs
    - Detailed description of substance characteristics

Implementation Strategy

- Taking into account the ongoing international harmonisation work and the technical and scientific progress, the Agency will update the format by end of 2014
  - Updated format will refer to the five ISO Identification of Medicinal Products (IDMP) standards
  - These standards are currently Final Draft International Standards in ISO and are expected to become International Standards by end of 2011/beginning of 2012
  - Sufficient implementation time for stakeholders considered by the Agency

Medicinal Product Information

Information to be provided initially will include the following:

- A description of the (invented) name of the medicinal product
- A description of the therapeutic area(s) e.g. ATC Code
- The designation of additional monitoring for biological medicinal products, and all other medicinal products where applicable, after 2 July 2012
- Details of the marketing authorisation holder
- A description of the clinical particulars i.e. therapeutic indication(s)

Medicinal Product Information

- Details of the marketing authorisation and the marketing status including
  - Marketing authorisation procedure
  - Country of marketing authorisation
  - Marketing authorisation number
  - Authorisation date and marketing authorisation status
  - Mutual-recognition procedure number/decentralised-procedure number
  - Orphan drug designation

Medicinal Product Information

- A detailed description of the active substance(s), excipient(s), adjuvant(s) and their specific characteristics
- A description of the strength of the active substance(s)
- A description of the medical device(s) in accordance with Regulation (EC) No 1394/2007 as applicable
- The pharmaceutical dose forms
- The route(s) of administration
- Description of the packaging information
- An electronic copy of the SPC, Package Leaflet (and annexes for CAPs)

Implementation Strategy

- Tools will be provided to facilitate the submission of product information by the Agency
  - Targeted to the needs of SMEs
- Training courses will be organised by the Agency
- Information Day for marketing authorisation holders will be organised on 22 and 23 September 2011 by the Agency
  - Inform about the practical aspects on the submission of medicinal product information
  - Inform about the ISO Identification of Medicinal Product Final Draft International Standards (FDIS)

Discussion

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