EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the European Medicines Agency in accordance with Article 57(2), second subparagraph of Regulation (EC) No. 726/2004

Chapter 1: Introduction

Version 3.0

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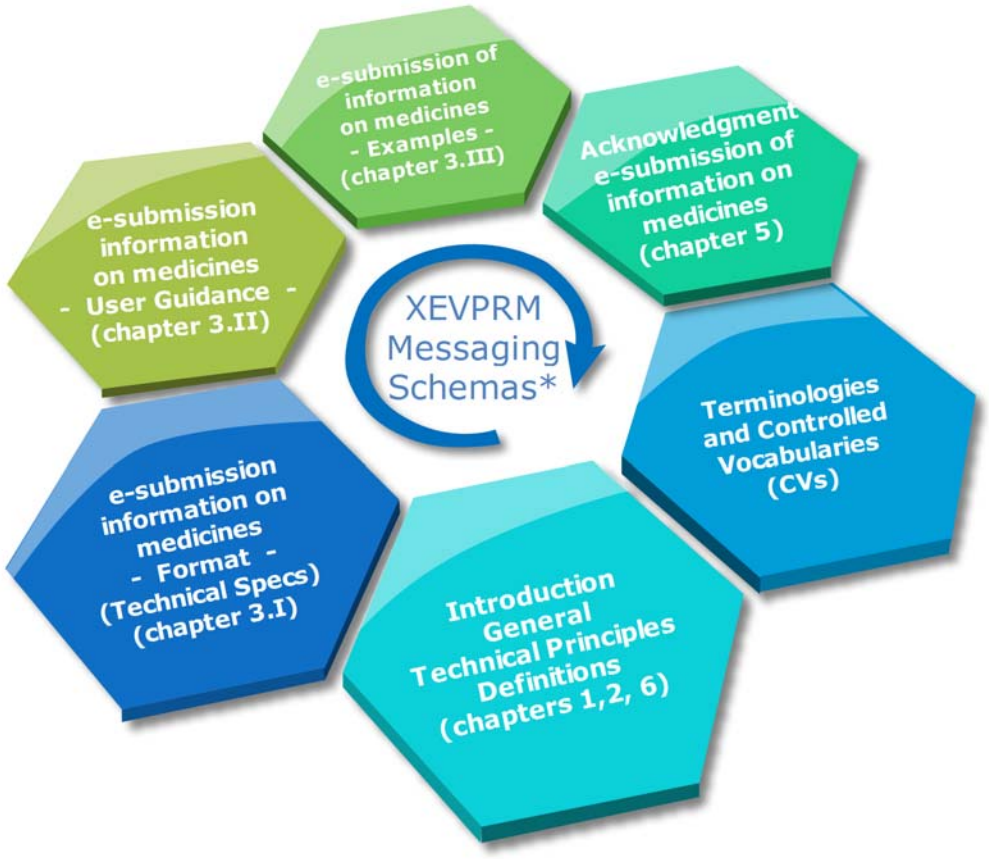
1. Introduction

This Detailed Guidance has been prepared and updated by the European Medicines Agency to comply with the requirements to publish a format for the electronic submission of information on medicinal products for human use authorised in the Union as provided for in Article 57(2), second sub-paragraph of Regulation (EC) No 726/2004 and as referred in to the '*Legal Notice on the Implementation of Article 57(2), second subparagraph of Regulation (EC) No. 726/2004 - Electronic Submission of Information on Medicinal Products for Human Use by Marketing Authorisation Holders to the European Medicines Agency'.*

This guidance together with the terminologies/controlled vocabularies and XEVPRM messaging schemas provide the necessary instructions and tools to start with the electronic submission (e-submission) of information on medicines as follows:



(*) e-submission of information on medicines - Structured Substance Information (SSI) - (chapter 4 currently not applicable)

Detailed Guidance:

- Chapter 1: Introduction to the detailed guidance (Introduction)
- Chapter 2: General technical and electronic submission principles (Technical Principles)
- Chapter 3.I: Electronic submission of information on medicinal products - Technical specifications of the electronic submission format (e-submission information on medicines – Format – Technical Specifications)
- Chapter 3.II: Electronic submission of information on medicinal products – User focused guidance on the use of the data elements of the electronic submission format, language requirements and the handling of Summary of Medicinal Product Characteristics (SmPC) attachments (e-submission information on medicines – User Guidance)
- Chapter 3.III: Electronic submission of information on medicinal products – Practical examples for users (e-submission information on medicines – Examples)
- Chapter 5: Acknowledgement of the electronic submission of information on medicinal products including the notification of EudraVigilance (EV) codes and technical specifications (Acknowledgement e-submission information on medicines)
- Chapter 6: General definitions (Definitions)

Chapter 4 on requirements for structured substance information (SSI) is currently under development. Requirements will be published post-July 2012[1].

Terminologies and Controlled Vocabularies (CVs):

- Controlled Vocabularies (CVs) to be applied for the electronic submission of information on medicinal products and maintained by the Agency can be found on the Agency's website.

In addition to the above CVs maintained by the Agency, further information on terminologies and controlled vocabularies which are maintained by external providers can be obtained from the following websites:

- Medical Dictionary for Regulatory Activities (MedDRA) maintained by the MedDRA Maintenance Support Service Organisation (MSSO): http://www.meddramsso.com/
- Anatomical Therapeutic Chemical (ATC) classification system maintained by the WHO Collaborating Centre for Drug Statistics Methodology: http://www.whocc.no/atc_ddd_index/
- Pharmaceutical forms and routes of administration standard terms maintained by the European Directorate for the Quality of Medicines & HealthCare: http://www.edqm.eu/en/Homepage-628.html
- The Unified Code for Units of Measure (UCUM) maintained by the Regenstrief institute: http://unitsofmeasure.org/
- The official list of ISO 3166-1 country codes maintained by the International Organization for Standardization (ISO): http://www.iso.org/iso/country_codes/iso_3166_code_lists/country_names_and_code_elements.htm

[1] For technical reasons, the electronic messaging format still references the XEVPRM SSI schema for future use. No SSI data should be submitted until Chapter 4 is published post-July 2012.

- The official list of ISO 639-1:2002 codes for the representation of names of languages, Part 1: Alpha-2 code is maintained by the International Organization for Standardization (ISO). http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=22109

eXtended EudraVigilance Product Report Messaging (XEVPRM) Schemas:

- The electronic messaging format referred to as eXtended EudraVigilance Product Report Message (XEVPRM):
  - Extended EudraVigilance product report message (XEVPRM) schema
  - Extended EudraVigilance product report message-structured substance information (XEVPRM_SSI) schema

- The electronic messaging format referred to as eXtended EudraVigilance Product Report Message Acknowledgement (XEVPRM ACK):
  - http://eudravigilance.ema.europa.eu/schema/ackxevmpd.xsd

Frequently Asked Questions & Answers (FAQs):

- Frequently Asked Questions & Answers (FAQs) can be found on the Agency's website.

NOTE 1:

In accordance with Article 57(2), second subparagraph of Regulation (EC) 726/2004 the electronic submission focuses on information on *authorised* medicinal products for human use in the European Union.

This does not include *registrations* of traditional herbal medicinal products (Chapter 2a of Directive 2001/83/EC) and *registrations* of homeopathic medicinal products registered according to the simplified registration procedure (Article 14 of Directive 2001/83/EC).

NOTE 2:

For technical reasons, this guidance also describes the format for the electronic submission of information on Investigational Medicinal Products (IMPs) as defined in Directive 2001/20/EC. The submission of information on IMPs is outside the scope of Article 57(2), second subparagraph of Regulation (EC) No 726/2004.

However, the electronic submission of information on IMPs as required in accordance with the "Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use" ('CT-3') (OJ 2011/C 172/01) published by the Commission on 11 June 2011 should be followed.

1.1. Electronic Submission of Information on Medicinal Products by Marketing Authorisation Holders

The electronic submission of medicinal product information can be achieved in two ways:

- Pharmaceutical companies can use in-house tools to initiate the electronic submission of information on medicinal products in full compliance with the format and the XSD schema as described and referenced in this Detailed Guidance. Electronic submissions of eXtended EudraVigilance Medicinal Product Report Messages (XEVPRMs) should be performed via the EudraVigilance Gateway to the Agency.
- Pharmaceutical companies can use the XEVMPD data entry tool (EVWEB) provided by the Agency; this was specifically developed for Small and Medium Sized Enterprises (SMEs) but can be made available to any pharmaceutical company for the purpose of electronic submission of information on medicinal products to the Agency.

1.2. Registration for submission of information on medicinal products to the Agency

Based on the existing EudraVigilance registration process, which has been operated since the implementation of the electronic transmission of Individual Case Safety Reports (ICSRs) and the establishment of the EudraVigilance Medicinal Product Dictionary (EVMPD), marketing auhtorisation holders need to register for the electronic submission of information on medicines. This is to ensure that proper privacy and security measures are in place and that the principles of data integrity, accountability and availability are adhered to.

To understand how to submit medicinal product data to the Agency and to ensure adequate data quality, at least one marketing authorisation holder user should be trained. The Agency offers training courses with the support of a conference/training organiser focusing on the explanation of the mandatory data elements necessary for the electronic submission of information on medicinal products and the use of the XEVMPD data entry tool (EVWEB). A (X)EVMPD training certificate assists users to register with EudraVigilance.

More information on registration and training can be found on the Agency's website.

1.3. Processing and Validation of the Information on Medicinal Products Submitted to the Agency

Marketing authorisation holders need to ensure that information on all medicinal products, which is submitted electronically to the Agency, is accurate and up to date.

The Agency – with the support of a contractor – will perform an overall review of the quality and integrity of the medicinal product information submitted. Where information is incomplete, missing or erroneous, the Agency will liaise with the marketing authorisation holder to ensure that the information is completed or corrected.