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 3: XEVPRM Technical Specifications, User Guidance and Practical Examples

Version 3.0

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Chapter 3 provides:

- 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)*. Includes also business rules that are applicable as part of the processing and validation of the eXtended Eudravigilance Product Report Messages (XEVPRMs).
- 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)*. Illustrates as how the data elements reflected in chapter 3.I can be used.

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