Internationally agreed terminology, formats and standards for the performance of pharmacovigilance activities
Format and content for electronic reporting of suspected adverse reactions

First Stakeholders Forum on the implementation of the new Pharmacovigilance legislation, 15 April 2011

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New Pharmacovigilance Legislation

Regulation (EC) No 1235/2010
Directive 2010/84/EU
Published 31 December 2010

Amending Regulation (EC) No 726/2004
Amending Directive 2001/83/EC
New Pharmacovigilance Legislation

Regulation (EC) No 1235/2010
Directive 2010/84/EU
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- Implementing Measures
- Good Vigilance Practice
- SOPs, WINs
- ICT Systems
New Pharmacovigilance Legislation

Implementing Measures Pharmacovigilance

Reg. Article 87(a), c
Use of internationally agreed terminology, formats and standards for the performance of pharmacovigilance activities
New Pharmacovigilance Legislation

Implementing Measures
Pharmacovigilance

Reg. Article 87(a), e Format and content of electronic transmission of suspected adverse reactions by Member States and marketing authorisation holders
Objectives (1)

- Support the international dimension of pharmacovigilance to better protect patients
  - Exchange, evaluate and assess suspected adverse reactions related to medicinal products authorised in the EU based on their usage by patients and consumers world-wide
  - Put emphasis on the international harmonisation work at the level of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) allowing for enhanced safety monitoring by regulators and pharmaceutical industry in a resource-efficient manner taking into account scientific and technical progress
Objectives (2)

- Makes use of the ongoing international standardisation work in pharmacovigilance
  - Use of standards and terminologies developed with international Standards Development Organisations (SDOs):
    - European Committee for Standardization (CEN)
    - International Organization for Standardization (ISO)
    - Health Level 7 (HL7)
    - Clinical Data Interchange Standards Consortium (CDISC)
    - International Health Terminology Standards Organisation (IHTSDO)
    - GS1- Barcode & RFID Standards Organisation
Objectives (3)

- Makes use of the ongoing international standardisation work in pharmacovigilance (cont.)

  - Key drivers are:
    - Interoperability especially in the healthcare domain e.g. Electronic Health Records (EHRs)
    - Robustness based on well-defined concepts and models
    - Resources/expertise based on collaboration with an international team of domain experts
Objectives (4)

- Support the operational aspects of the management of pharmacovigilance and medicinal product information with main emphasis on:
  - Classification
  - Retrieval
  - Presentation
  - Benefit-risk evaluation and assessment
  - Electronic exchange
  - Communication

- Key aspects which will benefit also patients, consumers and healthcare professionals
Use of Terminology

- The Medical Dictionary for Regulatory Activities (MedDRA)
  - Developed by ICH as the multidisciplinary topic M1 for the coding, retrieval and analysis of medical information

- Lists of Standard Terms published by the European Pharmacopoeia Commission
  - Developed upon request by the EU Commission for the use in marketing authorisation applications, Summary of Product Characteristics (SmPC), labelling and electronic communications

- The terminology resulting from and supporting the implementation of the ISO Identification of Medicinal Product Standards (IDMP)
Use of Standards (1)

- ISO prEN 11615, Health Informatics, Identification of Medicinal Products (IDMP) standard ‘Data elements and structures for unique identification and exchange of regulated medicinal product information’

- ISO prEN 11616, Health Informatics, Identification of Medicinal Products (IDMP) standard ‘Data elements and structures for unique identification and exchange of regulated pharmaceutical product information’
Use of Standards (2)

- ISO prEN 11238, Health Informatics, Identification of Medicinal Products (IDMP) standard ‘Data elements and structures for unique identification and exchange of regulated information on substances’

- ISO prEN 11239, Health Informatics, Identification of Medicinal Products (IDMP) standard ‘Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation and routes of administration’
Use of Standards (3)

- ISO prEN 11240, Health Informatics, Identification of Medicinal Products (IDMP) standard ‘Data elements and structures for unique identification and exchange of units of measurement’

- ISO prEN 27953-2 Health Informatics ‘Individual Case Safety Reports’ for the electronic transmission of suspected adverse reactions
Use of Standards (4)

- The five ISO IDMP standards the ISO ICSR standard shall be applied as of 1 January 2015
  - Takes into account anticipated finalisation of the:
    - ICSR standard by end of 2011
    - IDMP standards by end of 2012
  - Provides sufficient time for EU regulators and pharmaceutical industry to prepare for the implementation
Use of Formats (1)

- ICH E2B(R2) ‘Maintenance of the ICH guideline on clinical safety data management: data elements for transmission of Individual Case Safety Reports’

- ICH M2 ‘Electronic Transmission of Individual Case Safety Reports Message Specification (ICH ICSR DTD version 2.1)

- These formats shall be applied until superseded by the ISO ICSR standard in January 2015
Use of Formats (2)

- ICH M2 Recommendations ‘Procedure’
- ICH M2 Recommendations ‘ESTRI Gateway’
- ICH M2 Recommendation ‘File Format PDF’
- ICH M2 Recommendation ‘File Format XML’
- ICH M2 Recommendation ‘Information Transfer EDIINT AS1’
Use of Formats (3)

- EudraVigilance Medicinal Product Report Message (EVPRM)

  - Refers to the format for the electronic submission of information on all medicinal products for human use authorised in the Union in accordance with Article 57, paragraph 2, second sub-paragraph of Regulation 726/2004 to be published by the Agency on 2 July 2011

  - This format shall be applied until superseded by the ISO ICSR standard in January 2015
Use of Formats and Terminology

- Instructions for use will be published as part of the Good Vigilance Practice (GVP) (Article 108a(a) of Directive 2001/83/EU)
- Requests for the addition of a new term related to a terminology are to be submitted to the organisation that is responsible for maintaining the terminology
Content for adverse reaction reporting (1)

• Provides further clarification on the definition of adverse reaction as set out in Directive 2001/83/EU:
  – Shall include noxious and unintended effects from the authorised use of a medicinal product but also from:
    – Uses outside the terms of the marketing authorisation including misuse and abuse
    – Medication errors
    – Overdose
    – Occupational exposure

• Provides definition of Individual Case Safety Report (ICSR) as the format for electronic reporting of suspected adverse reactions
Content for adverse reaction reporting (2)

Key principles

• Ensure that individual cases and ICSRs are well documented when transmitted electronically

• ICSRs to provide all information in an accurate and reliable manner, which is available upon initial receipt and any subsequent follow-up with the reporter

• Sufficient details to be included to allow for:
  – The verification of the existence of a patient and the reporter
  – Obtaining further follow-up information from the reporter
  – The medical evaluation of each individual case
  – Auditing of the reported information, if needed
Content for adverse reaction reporting (3)

Defines the minimum criteria for reporting and the key attributes to be provided

- A patient
- A reporter
- At least one suspect medicinal product
- At least one suspected adverse reaction
- A case narrative for all suspected serious adverse reactions with a complete medical description of the case based on the information available at the time of reporting
- Administrative information to facilitate case processing
Content for adverse reaction reporting (4)

- For narrative and textual descriptions a comprehensive English translation is to be provided with the initial verbatim text as reported.
- Further guidance will be provided as part of the Good Vigilance Practice (GVP) (Article 108a(a) of Directive 2001/83/EU)
Questions

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