



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Quality systems for pharmacovigilance

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References

Legislation

Directive 2010/84/EU amending Directive 2001/83/EU

Regulation (EU) No 1235/2010 amending Regulation (EU) No 726/2004

Commission Implementing Regulation (final not yet published)

Guidance

GVP Module I – Pharmacovigilance systems and their quality systems



Directive 2010/84

Article 108

"In order to harmonise the performance of the pharmacovigilance activities provided for in this Directive, the Commission shall adopt implementing measures in the following areas for which pharmacovigilance activities are provided for in Article 8(3), and in Articles 101, 104, 104a, 107, 107a, 107b, 107h, 107n and 107p:

...

(b) the minimum requirements for the quality system for the performance of pharmacovigilance activities by the national competent authorities and the marketing authorisation holder; "



Regulation (EU) No 1235/2010

Article 87a

” In order to harmonise the performance of the pharmacovigilance activities provided for in this Regulation, the Commission shall adopt implementing measures as provided for in Article 108 of Directive 2001/83/EC covering the following areas:

...

(b) the minimum requirements for the quality system for the performance of pharmacovigilance activities by the Agency;”



Commission Implementing Regulation

Article 9 Scope of the quality system

1. *Established and followed quality system that is **adequate and effective for performing pharmacovigilance activities***
2. *Covers organisational structure, responsibilities, procedures, processes and resources and includes appropriate resource management, compliance management and record management*
3. *Based on quality planning, quality control, quality assurance and quality improvements*
4. *Documented in a systematic and orderly manner in the form of written policies and procedures*



Commission Implementing Regulation

Article 10 *Performance indicators*

1. *May be used to continuously monitor the good performance of pharmacovigilance activities*
 - *documentation in an annex to the pharmacovigilance system master file*
2. *The Agency may publish a list of performance indicators on the basis of a recommendation of the Pharmacovigilance Risk Assessment Committee*



Commission Implementing Regulation

Article 11 *Management of human resources*

- 1. A sufficient number of competent and appropriately qualified and trained personnel*

Qualified person responsible for pharmacovigilance has a acquired adequate theoretical and practical knowledge for the performance of the pharmacovigilance activities

- assisted by a medically trained person if not completed basic medical training in accordance with Art. 24 Dir. 2005/36/EC*



Commission Implementing Regulation

Article 11 Management of human resources

2. *Job descriptions defining the duties of the managerial and supervisory staff, including the qualified person responsible for pharmacovigilance*

Organisational chart defining hierarchical relationships

*Qualified person responsible for pharmacovigilance **has sufficient authority to influence the performance of the quality system and the pharmacovigilance activities** of the marketing authorisation holder*



Commission Implementing Regulation

Article 11 *Management of human resources*

3. *Initial and continued training in relation to the role and responsibilities*

Training plans and records for documenting, maintaining and developing competencies and for audit or inspection

4. *Appropriate instructions on processes for dealing with urgent situations, including business continuity*



Commission Implementing Regulation

Article 12 Compliance management

- a) Continuous monitoring of pharmacovigilance data and consideration of options for risk minimisation and prevention*
- b) Scientific evaluation of all information on the risks of medicinal products*
- c) Timely submission of data on adverse reactions to the Eudravigilance*
- d) Effective communication with NCA and Agency*
- e) Up to date product information with current scientific knowledge*
- f) Communication of relevant safety information HCPs and patients*



Commission Implementing Regulation

Article 12 Compliance management

2. *Where a marketing authorisation holder has delegated certain tasks of its pharmacovigilance activities, it shall retain responsibility for ensuring that an effective quality system is applied in relation to those tasks*



Commission Implementing Regulation

Article 13 **Record management and data retention**

1. *For all documents used for pharmacovigilance activities*
 - *Ensuring the retrievability and the traceability of how safety concerns have been investigated, the timelines for these investigations and how and when decisions have been taken*
 - *Allowing accurate reporting, interpretation and verification of the pharmacovigilance information*
 - *Enabling the traceability and follow-up of adverse reaction reports while complying with data protection legislation*
2. *Documents retained at least 5 years (system) or 10 years (product)*
3. *Documentation arrangements documented in PSMF*



Commission Implementing Regulation

Article 14 Audit

1. Risk-based audits at regular intervals

Conducted by individuals who have no direct involvement in or responsibility for the matters being audited

2. Corrective actions and follow-up audit of deficient matters

Audit report of the results of each audit and follow-up audit reviewed by the management responsible for the matters audited



GVP Module I

Pharmacovigilance systems and their quality systems

Guidance for the establishment and maintenance of quality assured pharmacovigilance systems

Marketing authorisation holders

Competent authorities of Member States

Agency

Describes general application of quality management to pharmacovigilance systems and requirements specific to the operation on EU network



Key elements of the Module I

Structures and processes

Overall quality objectives for pharmacovigilance

Principles for good pharmacovigilance practices

Responsibilities

Training

Facilities and equipment

Compliance management



Key elements of the Module I

Structures and processes

Record management

Documentation

Critical pharmacovigilance processes

Monitoring performance and effectiveness

Preparedness planning



Key elements of the Module I Operation of the EU network

Applicant and marketing authorisation holder

Overall pharmacovigilance responsibilities (EU)

Responsibilities in relation to the QPPV

Specific quality system processes

Quality system requirements for delegated pharmacovigilance tasks

Qualified person responsible for pharmacovigilance (QPPV)

Qualifications

Role



Key elements of the Module I Operation of the EU network

EU regulatory network

Competent authorities in Member States

European Commission

European Medicines Agency

Pharmacovigilance Risk Assessment Committee (PRAC)

Committee for Medicinal Products for Human Use (CHMP)

Coordination Group for Mutual Recognition and Decentralised Procedures
(CMDh)



Conclusion

Quality system is to assure the integrity of the pharmacovigilance system and is an integral part of the pharmacovigilance system

Produce visibly good pharmacovigilance

- Public health

- Overall confidence

- Public trust



Thank you !
