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Quality and Safety of Medicines

Union guidance on record keeping and archiving of documents obtained or resulting from pharmacovigilance inspections

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1. Introduction (background)

The standardisation of records management policies and procedures ensures that appropriate attention and protection is given to all records, and that the evidence and information they contain can be retrieved more efficiently, using standard practices and procedures. This guidance was prepared to standardise best practice in records management by setting the minimum requirements for document retention and record keeping for pharmacovigilance inspections.

2. Scope

The scope of this document is to provide high level principles for the record keeping and archiving of documents in relation to EU pharmacovigilance (PhV) inspections of marketing authorisation holders (MAHs) of medicinal products for human and veterinary use carried out by the competent authorities of Member States of the European Union. The principles in this document apply to national competent authorities.

3. Legal basis

Whereas best practice principles are similar for human and veterinary medicines, the legal basis and legal requirements may differ for each domain.

3.1. Human medicinal products

For human medicinal products, Article 16 of Commission Implementing Regulation (EU) No 520/2012 describes the requirements for record management and data retention and constitutes the legal basis for this guidance document. All relevant legal requirements of Directive 2001/83/EC and Regulation (EC) No 726/2004 and Commission Implementing Regulation (EU) No 520/2012, including those relating to the record management described in GVP Module I – Pharmacovigilance systems and their quality systems, Section I.B.10, shall apply without prejudice to the obligations of national competent authorities relating to their processing of personal data under Regulation (EU) 2018/1725.

3.2. Veterinary medicinal products

For veterinary medicinal products, Article 74, Article 123(7) and specifically Article 126(6) of Regulation (EU) 2019/6, constitutes the legal basis for this guidance document. It is noted that Commission Implementing Regulation (EU) 2021/1281 focuses on record keeping and archiving requirements for marketing authorisation holders and their established pharmacovigilance system master files.

All relevant legal requirements of Regulation (EU) 2019/6 and Commission Implementing Regulation (EU) 2021/1281 and the adopted guideline on Veterinary Good Pharmacovigilance Practices (VGVPs) Module: Controls and pharmacovigilance inspections replacing Eudralex Volume 9b Guidelines on Pharmacovigilance for Medicinal Products for Veterinary Use shall apply without prejudice to the obligations of national competent authorities relating to their processing of personal data under Regulation (EU) 2018/1725.

4. Management of inspection files

4.1. Responsibilities

For human medicinal products, national competent authorities and the Agency shall record all pharmacovigilance information and ensure that it is handled and stored so as to allow for accurate

reporting, interpretation and verification of that information. They shall put in place a record management system for all documents used for pharmacovigilance activities that ensures the retrievability of those documents as well as the traceability of the measures taken to investigate safety concerns, of the timelines for those investigations and of decisions on safety concerns, including their date and the decision-making process [IR 520/2012, Art. 16 (1)].

An inspection file is an organized body of records produced or received during the performance of the pharmacovigilance inspection and which contains relevant documentation concerning the inspection.

The lead inspector (LI) and, where applicable, the reporting inspector (RI) should establish the inspection file, immediately after appointment, taking into account legislative requirements, Union procedures and good vigilance practice guidance, as applicable.

For veterinary medicinal products, the reporting/lead inspector is required to include the information on the results of pharmacovigilance inspection, including the inspection report, in the Union pharmacovigilance database [Regulation (EU) 2019/6, Article 126(6). In addition to this legal obligation it is recommended that competent authorities have in place a record management system for all documents used for pharmacovigilance activities, as necessary.

This Union guidance takes precedence over national standard operation procedures (SOPs) concerning the management of documents when the principles of this Union guidance are more stringent.

4.2. Storage

For all pharmacovigilance inspections conducted in the EU, files must be stored under conditions that prevent accidental or premature destruction of the documents in accordance with national requirements. The inspection files should be stored safely in a suitable archive for the whole retention period. It is strongly recommended that only authorised personnel have access to the archives.

Documents may be stored electronically, onto human readable media or other new media as changes in technology demand. If documents are to be stored and archived using electronic or optical media, the methods for transferring the data to these media should be validated. A suitable back up-strategy must be implemented to prevent loss or destruction of data. There must be a possibility to generate hard copies throughout the period of retention.

For human medicinal products, when the inspection reveals critical and/or major findings, the Member State concerned shall share the inspection outcome with the other Member States, the Agency and the Commission in accordance with the second paragraph of Article 111(8) of Directive 2001/83/EC.

For veterinary medicinal products the information on the results of all pharmacovigilance inspections, including the inspection report will be accessible to the other Member States, the Agency and the Commission via the Union pharmacovigilance database.

4.3. Confidentiality and security

Each involved authority is responsible for ensuring observance of applicable data protection requirements.

For human medicinal products, in accordance with Article 122(2) of Directive 2001/83/EC, upon reasoned request, Member States shall send electronically pharmacovigilance inspection report(s) to the competent authorities of another Member State or to the Agency. In accordance with the second paragraph of Article 19(3) of Regulation (EC) No 726/2004, the report of the inspectors shall be made available electronically to the Commission, the Member States and the Agency. The parties in receipt of

the inspection report or translated summary of findings, when the report is not in English, bear full responsibility for ensuring their continued confidentiality.

For veterinary medicinal products, the inspection outcome and inspection report will be made available to other Member States, the Agency and the Commission via the Union pharmacovigilance database.

Access to national inspection reports and inspection files should not be provided to parties other than the Commission, the European Medicines Agency or representatives of the competent authorities, unless otherwise indicated by legislation as e.g. national legislation on freedom of information, or applicable national confidentiality agreements. Whenever an authority grants access to inspection reports, inspection file(s) or parts thereof, this access should be recorded.

For inspection reports for pharmacovigilance inspections requested by the Committee for Medicinal Products for Human Use (CHMP) or the Committee for Veterinary Medicinal Products (CVMP), and conducted in accordance with Union procedures the Agency's policy on access to documents and the rules for the implementation of Regulation (EC) No 1049/2001 apply and these reports may not be released to other parties without the consent of the Agency.

4.4. Retention period and destruction

The national competent authorities and the Agency shall arrange for the essential documents describing their pharmacovigilance system to be kept for at least five years after the system has been formally terminated.

For human medicinal products pharmacovigilance data and documents relating to individual authorised medicinal products shall be retained as long as the product is authorised and for at least 10 years after the marketing authorisation has expired. However, the documents shall be retained for a longer period where Union law or national law so requires [IR 520/2012, Art. 16 (2)]. The same retention period should apply for medicinal product related pharmacovigilance inspection files. Pharmacovigilance data and documents relating to pharmacovigilance systems inspections should preferably be maintained for as long as the pharmacovigilance system is in place and for at least 10 years after the system ceases to exist. After this time, the inspection files could be removed from the archives for destruction. A verified record (i.e. signed by the person responsible) of the decision and the date of the inspection file destruction should be kept, either electronically or as hard copy, in the archives for unlimited time.

For veterinary medicinal products the retention period for related pharmacovigilance inspection files should be in accordance with national procedures and legal requirements, as applicable.

Definitions

For the definition of pharmacovigilance inspection specific terms please refer to the Union procedure on the coordination of EU pharmacovigilance inspections.

References

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, as amended.

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Union code relating to medicinal products for human use, as amended.

REGULATION (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

Commission Implementing Regulation (EU) No 520/2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council.

Guideline on good pharmacovigilance practices (GVP) - Module I – Pharmacovigilance systems and their quality systems.

Guideline on good pharmacovigilance practices (GVP) - Module III – Pharmacovigilance inspections.

Union procedure on the coordination of EU pharmacovigilance inspections.

Union procedure on the preparation, conduct and reporting of EU pharmacovigilance inspections.

Union procedure on the management of pharmacovigilance inspection findings which may impact the robustness of the benefit-risk profile of the concerned medicinal products.

Union procedure on sharing of pharmacovigilance inspection information.

REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.

Commission Implementing Regulation (EU) 2021/1281 of 2 August 2021 laying down rules for the application of Regulation (EU) 2019/6 of the European Parliament and of the Council as regards good pharmacovigilance practice and the format, content and summary of the pharmacovigilance system master file for veterinary medicinal products.

Guideline on Veterinary Good Pharmacovigilance Practices (VGVP) - Module: Controls and pharmacovigilance Inspections.

Guideline on veterinary good pharmacovigilance practices (VGVP) - Module: Pharmacovigilance systems, their quality management systems and pharmacovigilance system master files.