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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 use carried out by the competent authorities of Member States of the European Union.

3. Legal basis

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.

In Union procedures and guidance on pharmacovigilance inspections, any reference to Regulation, Directive and the Implementing Regulation (IR) shall be construed as a reference to Regulation (EC) No 726/2004, Directive 2001/83/EC and Commission Implementing Regulation (EU) No 520/2012 respectively, always including their latest amendments.

All relevant legal requirements of Directive 2001/83/EC, 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 Directive 95/46/EC or the obligations of the Agency relating to its processing of personal data under Regulation (EC) No 45/2001 [IR Art 39].

4. Management of inspection files

4.1. Responsibilities

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 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.

National standard operation procedures (SOPs) concerning the management of documents are not affected by this procedure, except where it is 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 inspections with critical findings 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.

4.3. Confidentiality and security

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

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.

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) 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. 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 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.

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.