THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)

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Data Protection in the Blood Sector

Observations from the Blood Quality Management (B-QM) Programme

EDQM Webinar

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Data Protection

Data protection is a fundamental human right

Article 8(1) of the Charter of Fundamental Rights of the European Union (the 'Charter') and Article 16(1) of the Treaty on the Functioning of the European Union (TFEU) provide that everyone has the right to the protection of personal data concerning him or her.

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Data Protection in the Blood Sector

Blood Donor Personal Data:

- *Demographic Information;*
- *Contact Information;*
- *Photo Identification;*
- *Medical Health Information;*
- *Test Results;*
- *Lifestyle and Sexual Risk Behaviour;*
- *Criminal Offence History;*

Traceability Data;

Quality System Data;

Paper based and Electronic Systems;

What I will cover

- European Data Protection Law (CoE and EU);
- European Blood Legislation, EDQM Blood Guide and Good Practice Guidelines;
- Observations from the Blood Quality Management (B-QM) Audit Programme;
- Anonymous and Pseudonymous data;

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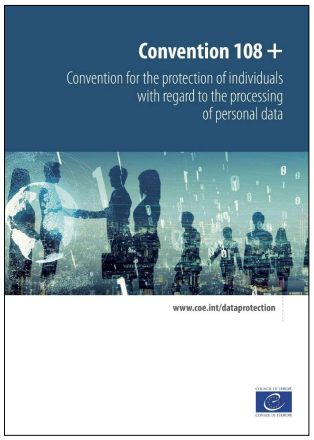
Council of Europe: Convention 108 +

Data Protection Day
2021 - 40th Anniversary of Convention 108



First legally binding international instrument in the data protection field

Ratified by 55 countries (47 CoE MS plus 8 non European countries)

Consultative Committee (T-PD) - 55 Parties, 25 Observers;

2018 - Adoption of the Protocol for Modernisation (Convention 108+)

Recommendation CM/Rec(2019)2 of the Committee of Ministers to member States on the protection of **health-related data**

https://www.coe.int/en/web/data-protection

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General Data Protection Regulation (GDPR)

Under EU law, data protection was regulated for the first time by the **Data Protection Directive** in 1995.

In view of rapid technological developments, the EU adopted new legislation in 2016 to adapt data protection rules to the digital age. The **General Data Protection Regulation** became applicable in May 2018, repealing the Data Protection Directive

Key concepts and principles

Concept of personal data

Sensitive data – Art. 9 – **health data** / genetic / biometric data;

Pseudonymisation and **anonymisation;**

Principles of processing:
-Fair, lawful and transparent processing;
-Purpose limitation;
-Data minimisation;
-Data accuracy;
-Storage limitation;
-Data integrity and confidentiality;
-Accountability;

Principles of processing aligned in Convention 108+ and GDPR

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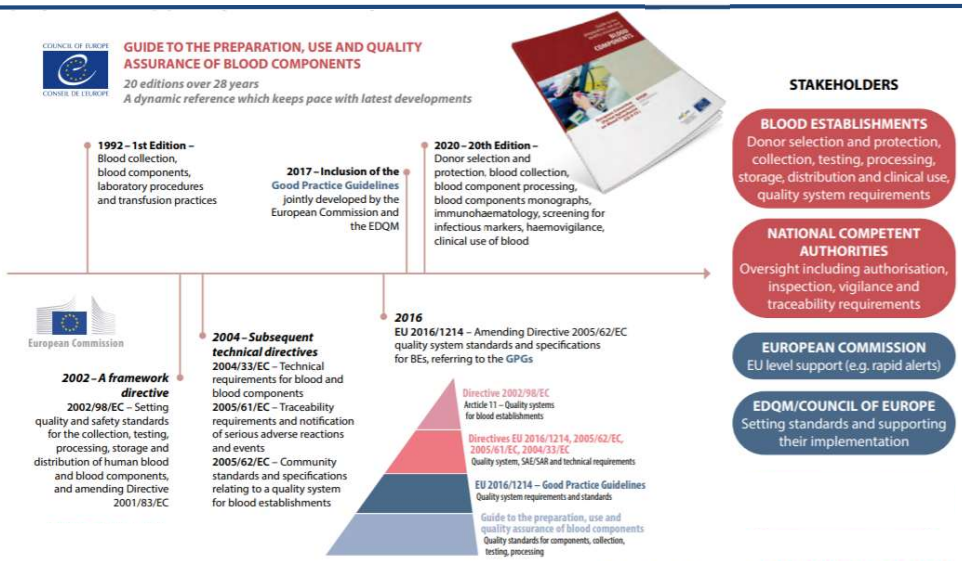
European Blood Legal Framework



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7

European Blood Legislation

EU Blood Legislation

2002/98/EC;

CHAPTER VII

DATA PROTECTION

Article 24

Data protection and confidentiality

Member States shall take all necessary measures to ensure that all data, including genetic information, collated within the scope of this Directive to which third parties have access have been rendered anonymous so that the donor is no longer identifiable.

For that purpose, they shall ensure:

(a) that data security measures are in place as well as safeguards against unauthorised data additions, deletions or modifications to donor files or deferral records, and transfer of information;

(b) that procedures are in place to resolve data discrepancies;

(c) that no unauthorised disclosure of such information occurs, whilst guaranteeing the traceability of donations.

Article 14

Traceability

1. Member States shall take all necessary measures in order to ensure that blood and blood components collected, tested, processed, stored, released and/or distributed on their territory can be traced from donor to recipient and vice versa.

To this end, Member States shall ensure that blood establishments implement a system for identification of each single blood donation and each single blood unit and components thereof enabling full traceability to the donor as well as to the transfusion and the recipient thereof. The system must unmistakably identify each unique donation and type of blood component. This system shall be established in accordance with the requirements referred to in Article 29(a).

With regard to blood and blood components imported from third countries, Member States shall ensure that the donor identification system to be implemented by blood establishments permits an equivalent level of traceability.

2. Member States shall take all necessary measures in order to ensure that the system used for the labelling of blood and blood components collected, tested, processed, stored, released and/or distributed on their territory complies with the identification system referred to in paragraph 1 and the labelling requirements listed in Annex III.

3. Data needed for full traceability in accordance with this Article shall be kept for at least 30 years.

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European Blood Legislation

EU Blood Legislation

2004/33/EC;

COMMISSION DIRECTIVE 2004/33/EC

of 22 March 2004

implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components

(Text with EEA relevance)

ANNEX II

INFORMATION REQUIREMENTS

(as referred to in Articles 2 and 3)

PART A

Information to be provided to prospective donors of blood or blood components

3. Information on the protection of personal data: no unauthorised disclosure of the identity of the donor, of information concerning the donor's health, and of the results of the tests performed.

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European Blood Legislation

EU Blood Legislation

2005/61/EC;

COMMISSION DIRECTIVE 2005/61/EC

of 30 September 2005

implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events

Article 2

Traceability

Article 4

Record of data on traceability

Article 5

Notification of serious adverse reactions

Article 6

Notification of serious adverse events

ANNEX I

Record of data on traceability as provided for in Article 4

BY BLOOD ESTABLISHMENTS

1. Blood establishment identification
2. Blood donor identification
3. Blood unit identification
4. Individual blood component identification
5. Date of collection (year/month/day)
6. Facilities to which blood units or blood components are distributed, or subsequent disposition.

BY FACILITIES

1. Blood component supplier identification
2. Issued blood component identification
3. Transfused recipient identification
4. For blood units not transfused, confirmation of subsequent disposition
5. Date of transfusion or disposition (year/month/day)
6. Lot number of the component, if relevant.

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European Blood Legislation

European Commission

EU Blood Legislation

2005/62/EC;

COMMISSION DIRECTIVE 2005/62/EC

of 30 September 2005

implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments

(Text with EEA relevance)

'computerised system' means a system including the input of data, electronic processing and the output of information to be used either for reporting, automatic control or documentation.

When computerised systems are used, software, hardware and back-up procedures must be checked regularly to ensure reliability, be validated before use, and be maintained in a validated state. Hardware and software shall be protected against unauthorised use or unauthorised changes. The back-up procedure shall prevent loss of or damage to data at expected and unexpected down times or function failures.

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Blood Guide and Good Practice Guidelines

Good Practice Guidelines (GPG)

CoE Blood Guide – 20th Edition

4.2. Appendix 3: Data Processing Systems;

4.3. Qualification and Validation;
4.4. Process Validation;

5.2 Required Good Practice Documentation

Traceability

- **3.5 Labelling**
- **10.1.2 Confidentiality of haemovigilance reporting;**
- **10.6 Reporting of Haemovigilance data;**

5.5. Retention of documents

5.5.1.	It should be clearly defined which record is related to each activity and where this record is located. Secure controls should be in place to ensure the integrity of the record throughout the retention period. These controls should be validated if appropriate.
5.5.2.	Specific retention requirements for certain documentation apply.
5.5.2.1.	Records should be retained for a period according to local, national or EU requirements, as appropriate.
5.5.2.2.	Traceability data (that allow tracing from donor to recipient and vice versa) must be retained for a minimum of 30 years (Directive 2002/98 Article 14.3).
5.5.2.3.	Documentation regarding investigations into serious adverse events and serious adverse reactions should be retained for a minimum of 15 years.
5.5.2.4.	Quality system documentation and associated records should be retained for a minimum of 10 years.
5.5.2.5.	For other types of documentation, the retention period should be defined on the basis of the business activity that the documentation supports. These retention periods should be specified.

Data Protection Principles:
-Storage Limitation
-Data accuracy;
-Data Integrity and Confidentiality
-Accountability;

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BLOOD-QUALITY MANAGEMENT (B-QM) PROGRAMME

► **AIM: Assistance/Educational Programme** to help Blood Establishments in establishing, developing, improving comprehensive and integrated **Quality System**

'Quality System to be in place'

EU Directive 2005/62/EC; Good Practice Guidelines ,Guide to the Preparation, Use and Quality Assurance of Blood Components

Auditing schemes

Blood training visit (B-TV)
On-site visit and training session on technical and QMS issues based on observed non-compliances

Blood mutual joint visit (B-MJV)
Audit to check compliance with requirements
▸ *report and recommendations*

Blood mutual joint audit (B-MJA)
Audit to check compliance with requirements
▸ *report and CAPA follow-up*

Training courses/conferences

Practical guidance

► **Since 2010:** over **30** auditing schemes to date covering **17** European countries **5** training courses/conferences

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B-QM AUDITS – OBSERVATIONS

Identifiable data

Access and Control of Data

Paper based systems and computerised systems

Donor Information and Consent;

"Third party" data processing and control;

Data Integrity

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Anonymised and Pseudonymised Data

EU Blood Legislation

2002/98/EC;

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GDPR

ANONYMISED DATA:

''...information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable.'' - Recital 26, GDPR

The GDPR does not apply to anonymised information.

PSEUDONYMISED DATA:

"…the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person." - Article 4, GDPR

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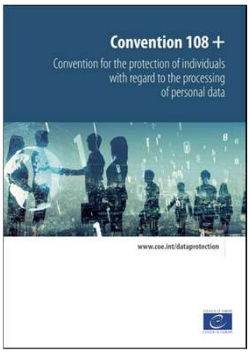

https://www.coe.int/en/web/data-protection

Acknowledgments

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- EDQM PRDD Colleagues

Thank you

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- Moderator, Speakers and Rapporteurs;
- European Committee on Blood Transfusion CD-P-TS;
- EC/DG-SANTE;

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