GDPR – for the pharmaceutical industry

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Cecilia Næssan, PhD

Cluster Safety Lead North Europe, Pfizer

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Outline for today

- GDPR background
- Principles relating to processing of personal data (Art. 5)
- How to follow the principals within Pharmacovigilance
- Rights of the data subject

General Data Protection Regulation (GDPR)

What the is General Data Protection Regulation (GDPR)?

- EU's new data protection / data privacy regulation

GDPR has been created to reform EU data privacy law for the digital age

- Promotes **transparency** so individuals understand what personal data we collect and how we use it
- **Expands privacy rights** and give individuals greater control over the use of their personal data
- **Requires companies** to uphold these privacy rights and imposes **penalties** for non-compliance

Who does GDPR apply to?

- Any organization established in the EU.
- Any organization (regardless of where established)

offering goods or services to or monitoring EU residents

Risks for Non-Compliance

1. Maximum fines of up to 4% of annual global revenue
2. Reputational harm

Definition of personal data and special categories of personal data

- **Personal data is defined as any information that can identify a living person and distinguish a person from others**

- **Name**
- **Email/postal addresses**
- **Telephone number**
- **Government ID number**
- **Email**
- **Picture**
- **Date of Birth**
- **Social Security Number**

- **Criminal Act**
- **Ethnic origin**
- **Genetic Information**
- **Physical or Mental Health Information**
- **Sexual Orientation**
- **Biometric data for the purpose of uniquely identifying a natural person**

- **Dynamic IP address**
- **Sound recording**

Principles relating to processing of personal data (Art. 5)

- Personal data shall be processed lawfully, fairly and in a transparent manner in relation to the data subject

Principles relating to processing of personal data (Art. 5)

Art. 6 Lawfulness of processing

1. Processing shall be lawful only if and to the extent that at least one of the following applies:
   a) the data subject has given consent to the processing of his or her personal data for one or more specific purposes;

   b) processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract;

   c) processing is necessary for compliance with a legal obligation to which the controller is subject;

   d) processing is necessary in order to protect the vital interests of the data subject or of another natural person;

   e) processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;

   f) processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.

Principles relating to processing of personal data (Art. 5)

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Principles relating to processing of personal data (Art. 5)

Art. 9 Processing of special categories of personal data

1. Processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited.

2. Paragraph 1 shall not apply if one of the following applies (listing from (a) to (j)):

(i) processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy;

Principles relating to processing of personal data (Art. 5)

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There is legislation for pharmacovigilance relating to medicinal products, medical devices and cosmetic products

Guidelines on good pharmacovigilance practices (GVP)

Individual case safety reports for food supplements

- the data subject has given consent to the processing of his or her personal data for one or more specific purposes (article 6, paragraph (a) and article 9, paragraph 2 (a))

Principles relating to processing of personal data (Art. 5)

- Personal data can only be processed for specific, explicitly declared and legitimate purposes
  - Markedsføringstillatelsens innehaver skal opprette og forvalte et legemiddelovervåkingssystem med det formål å evaluere mottatt informasjon, vurdere og iverksette nødvendige tiltak for risikoreduksjon og forebygging av bivirkninger (**Legemiddelforskriften § 10-2**)
  - To detect, assess, understand and prevent adverse reactions and to identify, and take actions to reduce the risks of, and increase the benefits from medicinal products for the purpose of safeguarding public health (***GVP module VI.C.6.2.2.10)***

- Personal data cannot be re-used for other purposes

Principles relating to processing of personal data (Art. 5)

- Personal data shall be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed (Dataminimization)
  - Do not collect more personal data than needed
    - What about criminal acts in an ICSR?

- The personal data which are processed should be accurate
  - ***GVP VI.B.3.*** *When first received, the information in suspected adverse reactions reports may be incomplete. These reports should be followed-up as necessary to obtain supplementary detailed information significant for the scientific evaluation of the cases.*

Principles relating to processing of personal data (Art. 5)

- Personal data shall be kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed

  - **GVP VI.C.2.1** Pharmacovigilance data and documents relating to individual authorised medicinal products shall be retained by the national competent authorities in Member States and the Agency 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 [..]

For MAHs, we may need to take into condsideration a legal hold*

*a process that an organization uses to preserve all forms of relevant information when litigation is reasonably anticipated

Principles relating to processing of personal data (Art. 5)

- Personal data shall be processed in a manner that ensures appropriate security of the personal data, including protection against unauthorized or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organizational measures (‘integrity and confidentiality’).

- The pharmacovigilance system should be safeguarded against unauthorized access
  - Technical measures
  - The access to personal data should be restricted

- **GVP VI.B.4 Data management**

Electronic data and paper reports of suspected adverse reactions should be stored and treated in the same way as other medical records with appropriate respect for confidentiality regarding patients' and reporters' identifiability and in accordance with applicable data protection laws. Confidentiality of patients' records including personal identifiers, if provided, should always be maintained. Identifiable personal details of reporting healthcare professionals should be kept in confidence, protected from unauthorized access. With regard to patient's and reporter's identifiability, case report information should be transmitted between stakeholders (marketing authorization holders or competent authorities) in accordance with local data protection laws (see VI.C.6.2.2.10. for guidance on the processing of personal data in the EU).

GDPR Chapter 3 – Rights of the data subject

- The processing of personal data must be fair and transparent
  - The registered individual must be informed of any processing of personal data in an intelligible and easily accessible form, using clear and plain language.

Add this as a requirement in the company Standard Operating Procedures

- Embed this information into your case receipt and follow-up procedures

Personal data	Stored as source document for ICSR	Transfer to competent authority/ other MAH*
Patient initials	Yes	Consider replacing with «PRIVACY» before transfer
Patient birth date	Yes	Consider calculating patient age and only transferring patient age field
Contact information to patient	Yes	No
Special category personal data	Yes, if medically relevant	Yes, if medically relevant
Verbatim from reporter	Yes	Yes, information that can identify the patient/ reporter should be anonymized
Contact information to reporter	Yes	No / *Yes, if reporter ≠ patient

This table is a translated version from the *Guideline for processing personal data in pharmacovigilance* by the Swedish Association of the Pharmacovigilance Industry 15-Feb-2019, version 1.0

Thank you

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