EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The role of privacy and data protection in EU pharmaceutical regulation

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Overview

- **The role of EMA in the EU pharmaceutical regulation**
- **Privacy and Data protection at EMA**
- **Health data**
- **Consent/Legal basis**
- **Pseudonymization/Anonymization**

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The role of EMA in EU pharmaceutical regulation

- European Medicines Agency (**EMA**) was established in 1995 as a decentralised EU agency. It is a networking body pooling together scientific experts from all EU Member States.
- Its main responsibility is the **evaluation of new medicinal products** and the **supervision and safety monitoring of drugs** in the EU.
- It has **7 scientific committees** and a Secretariat of around 900 staff It is currently based in London.

Privacy and data protection at EMA /1

Regulation (EC) 45/2001 on the protection of personal data applies to all the activities of EMA, a special legal framework based on EU data protection law (Directive 95/46/EC and in the future the GDPR)

But

The legal frameworks on **clinical trials** and **pharmacovigilance** give EMA specific responsibilities in processing data.

EMA issues opinions on the basis of scientific evidence, i.e. **data** from trials, observational studies, large-scale database of adverse reactions etc.

It is therefore essential to guarantee **the right balance**: processing of data/ protection of privacy

Privacy and data protection at EMA /2

- A concrete example: the collection and storing of *Individual Case Safety Reports (ICSRs)* in the **Eudravigilance** database used for signal-detection;
- Transfer of ICSRs to EMA from pharmaceutical companies and authorities in Member States; access to the information : "[…] *health-care professionals, marketing authorisation holders and the public shall have appropriate levels of access to these databases,* ***with personal data protection being guaranteed****" (*Article 57 (1) e of Regulation (EC) 726/2004)
- Issues around not only anonymization but also retention/time-limitation

Health data /1

- Definition of **health data** in the GDPR:

"*data concerning health means personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status*"

- Important as health data, together with other sensitive data, are covered by a provision establishing a general prohibition unless an exception applies (Article 9 GDPR)

Health data /2

- In 2015, Article 29 WP clarified that the scope of health data entails also information "where there is scientifically proven or commonly perceived risk of disease in the future".
- This may include cases where the Controller uses any personal data (health data or not) with the purpose of identifying disease risks (such as for example investigating exercise habits) through *lifestyle apps* or the analysis of search engine queries. **This may often be the case in medical research using Big Data.**
- Further to a workshop in November 2016, EMA is part of a Joint task force with HMA on Big Data .

Consent/Legal Basis /1

- **Consent** remains cornerstone of DP law as main legal basis for the processing of personal data, in particular with regard to health data:

"*the data subject has given explicit consent to the processing of those personal data…*"

- Issue in medical research is often on the validity of consent to conduct research activities not explicitly covered by the initial consent i.e. **secondary use of health data/broad consent**:

Recital 33 GDPR: "[…] *Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research*"

Consent/Legal Basis /2

There are legal grounds other than consent for processing health data:

Article 9 (2) (i) GDPR: "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 law or Member States law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subjects, such as professional secrecy".

Particularly relevant for pharmacovigilance, in case of pandemic crisis etc.

Consent/Legal Basis /3

Another important legal basis for processing data in the GDPR, the research derogation :

Article 89 GDPR "*Processing of personal data for...**scientific and historical research or statistical purposes shall be subject to appropriate safeguards, [...]** These safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation*."

These measures may include, depending on whether the purpose can be accomplished with less data, **pseudonymisation** or **anonymization.**

Pseudonymisation/Anonymisation /1

There is a definition of **pseudonymisation** – cfr. Article 4 (5) GDPR e.g. key-coding data from electronic health records.

- "*means the processing of personal data in such a manner that the pesonal data can no longer be attributed to a specific data subject without the use of additional information*"

Recital 26 GDPR: Data which "*has undergone pseudonymisation*", but still could be attributed to a natural person by the use of additional info **should be considered personal data.**

Pseudonymisation/Anonymisation /2

There remains the **challenge of the anonymization** of datasets in particular in the field of health and in order to respect transparency obligations (publication of Clinical Study Reports CSRs).

EMA published an ***External Guidance on anonymisation of clinical reports for the purpose of Policy 70*** non-binding guidance presenting a set of different approaches to the anonymisation of CSR based on masking (redaction) but also other techniques (randomization, generalization) in order to increase the usefulness of published information, preserving the privacy of trial participants.

Establishment of a **Technical Anonymization Group** with experts from different disciplines (law, data science, medical research)

Conclusions

- Importance of striking a **right balance between protection of privacy and ensuring a free flow of information** for public health purposes/medical research.
- Ensuring early dialogue between law and policy-makers and scientists/medical communities in order to avoid “tunnel” visions and aligning common understanding of key concepts
- A good governance of personal data (transparency, supervision) results in better outputs in terms of public health as it generates trust and **accountability**

Thank you for your attention

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