EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA's targeted consultation on data protection and secondary use of data for medicines and public health purposes - **Summary of Stakeholder Input**

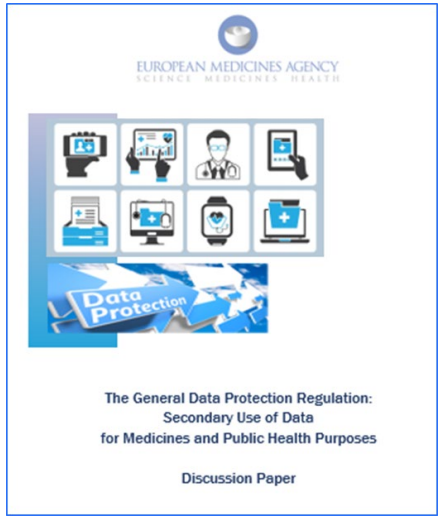
Joint PCWP and HCPWP virtual workshop, 23 September 2020

Sabine Brosch, Data Protection Coordinator Clinical Studies and Manufacturing Task Force (TCS)

Stakeholder Survey

- Ground work was presented at the joint PCWP/HCPWP meeting in June 2020
- Targeted stakeholder consultation (May to July 2020) was conducted based on discussion paper addressed to PCWP/HCPWP members
- Goal was to identify data protection questions focusing on seven key topics

1. Secondary use of health data	5. Transparency
2. Legal basis for processing of personal data	6. Data retention
3. Rights of patients	7. Registries
4. Pseudonymisation	



Stakeholder Survey – Input Received

CPME COMITÉ PERMANENT DES MÉDECINS EUROPÉENS STANDING COMMITTEE OF EUROPEAN DOCTORS

CPME Council on Podiatric Medical Education

eular

EURORDIS RARE DISEASES EUROPE

EPF European Patients Forum

BEUC The European Consumer Organisation

General Remarks

- GDPR is a positive compromise acknowledging the value of data in research and ensuring better rights for patients, yet with some limitations; ensuring harmonisation & proportionality of GDPR application is therefore crucial [EPF]
- Patients' fundamental right to protection of their data concerning health is an important issue in diverse contexts, such as healthcare, care given through eHealth or in a cross-border context, and in research [EPF]
- The smooth sharing of these data is crucial for the good functioning of healthcare services, patient safety, and to advancing research [EPF]
- ***The right balance needs to be reached between ensuring confidentiality of data while allowing their availability and sharing for public health, healthcare and research purposes [EPF]***

General Remarks

Patients are generally comfortable and willing to the secure sharing of their health data recognising its vital importance to advance health research, help other patients and ultimately benefit society [EPF]

EPF's survey on EHRs identified several main purposes for which patients would be willing to share their data:

- collecting data on a specific medicine's safety and efficacy after authorisation
- collecting data on patient-reported outcomes (PROMs), collection of data on adherence to treatment, on lifestyle and demographics
- collecting information on the patient journey to develop measures for patient experience (PREMs)
- linking clinical data to registries for more information on specific diseases for research.

General Remarks

- More cooperation between Member States on minimum security requirements is needed -> ensure equivalent level of protection of personal data shared by patients across the EU and to facilitate cross-border healthcare and research [EPF]
- Key issues to be considered when discussing the use of health data [EPF]:
  - Respecting patients' privacy incl. patient anonymity and possible identification
  - Preventing unauthorised use of data and ensuring its safe transmission, confidentiality and integrity
  - Data control and transparency on how data is used and by whom
  - Ensuring the data is of high enough quality for use in research
  - Addressing any ethical concerns and ensuring human rights are respected
  - Ensuring all data processing is ethical addressing all implications of primary and secondary use, including unintended consequences

General Remarks

- Develop the *Q&As to be comprehensible for lay, non-expert audience* [BEUC, EULAR]
- *Enhancing digital health literacy and data literacy* levels is also crucial to support patients' control of their data and enable them to understand and exercise their rights while realising the societal benefits of data-driven innovation in healthcare
- *Sales or providing shared access to data* that can cause inequalities in healthcare or life decisions to individuals who consented to sharing their data while these companies profit from these details e.g., insurance companies. This *practice should be prohibited* [EULAR] [EURODIS]

1. Secondary Use of Health Data

- Can the *practical details in relation to their data uses* for medicines/public health purposes *be further explained* to patients and consumers? [BEUC]
- Patients generally agree for their data to be re-used for medical or research purposes. *Can the process of re-consent be further explained* e.g., in situations where the new use is really totally different or could cause problems (re-identification risk, risk that someone misuses the data and publishes confusing results) [EURODIS]
- If a patient *does not accept their data to be used for a purpose*, can this affect the research in question, and how? [EURODIS]

1. Secondary Use of Health Data

- Can the *data minimisation principle* be further *explained*? How can a balance be achieved for large data quantities and personal data protection in practice, e.g. in discovery of a new medicine? [BEUC]
- The GDPR provides for research exemption from the principle of purpose limitation, when appropriate safeguards are in place. *Can this be further explained?* [BEUC]

2. Legal Basis for Processing Personal Data

- Is a *separate lawful legal basis (Article 6 of the GDPR) necessary* for further use of patient's data for *secondary purposes, or Article 9(2)(j)* of the GDPR suffice? [CPME]
- What are the *rules for processing genetic data*? [EURODIS]
  Patients' health and genetic data are sensitive information which requires a high level of protection to ensure they are not unnecessarily disclosed [EPF]
- *Clarify legal basis for processing data of vulnerable adults*/people with mental health conditions [EURODIS]

2. Legal Basis for Processing Personal Data

- *Explain* of what constitutes *valid consent* (freely given, specific, informed, and unambiguous) and informed consent under the Clinical Trials Regulation [BEUC, EURODIS]
- *Explain* situations *when an individual's data can be processed without consent* (GDPR derogations for scientific research & other legal basis for data processing) [BEUC]
- *Is consent a contract*? Why am I the only one signing? Why doesn't the controller sign as well, to guarantee my rights will be respected? [EURODIS]
- Can this *consent be used against a patient*? [EURODIS]

2. Legal Basis for Processing Personal Data

- When *consent is digital and the information cannot be understood, who will explain*? Risk of automatic signing to prevent blocking the process [EURODIS]
- In what *situations*, and under which conditions, *are patients' representatives allowed to give consent for further use of the patient's data*? [CPME]
- Is there a possibility of *greater harmonisation of the core elements of informed consent* (in the context of clinical research)? Meaningful informed consent is a concern when patients take decisions on whether or not to allow use of their data [EPF]

2. Legal Basis for Processing Personal Data

- *Is patient's informed consent always required* in order for healthcare professionals, bound by medical confidentiality (professional secrecy), *to disclose patients' data to third parties*? [CPME]
- Can there be *situations where patient's data is disclosed without informed consent*?
  Note: the objective of this question is to reflect on the deontological obligation of obtaining patient's consent before disclosing its data to third parties and frame the discussion in relation to obtaining patients' consent under the GDPR [CPME]

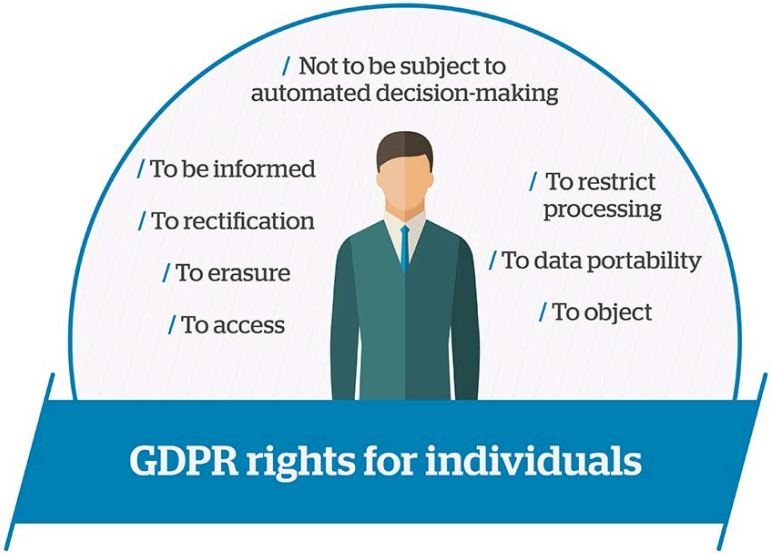
2. Legal Basis for Processing Personal Data

- *Should a hospital now always ask for explicit consent for secondary use*? *Has the hospital an obligation to inform me on who used the data in the past, and what for*? [EURODIS]
- *More reflection is needed on* "broad consent". Patients may be happy to grant blanket permission for use of their data in specific types of research or they may wish to opt out of specific types of research. The *parameters of broad consent should therefore be flexible to consider individual patients' preferences and values* [EPF]

2. Legal Basis for Processing Personal Data – Public Interest

- EPF calls for *more clarity on the definition of re-use of data for public interest*.
  Note: Research and innovation using public data must be driven by public health and societal needs. The investment to facilitate use of publicly generated data, for example for the development of new technologies through public-private partnerships, should be reflected in the output of the innovation process in terms of accessibility and affordability for all [EPF]

3. Patient's Rights – Personal Data Processing



- Can the *individual rights of patients* and their personal data be further explained? [EPF, BEUC, EULAR]
- Can a patient *grant access to their data to a person they trust*? [EURODIS]
- *Can a person* have *access* to their *data in a clinical trial*? [EURODIS]

4. Pseudonymisation & Anonymisation

- EPF calls for *improved and harmonised techniques of pseudonymisation* and, *anonymisation* to ensure data safety, avoid data misuse and increase users' trust
- Pseudonymisation - information should be provided on the *process and procedure depersonalising data*. Who is involved and how is this completed? [EULAR]
- Can healthcare professionals *share data for secondary use in an anonymised format* with third parties, although *keeping patients' data in a pseudonymised format*? [CPME]
- *Does anonymisation of non-aggregated data concerning health exist* in medical research? [CPME]
- For genomic research, *anonymisation might not be possible*. *What safeguards are foreseen for such situations?* [BEUC]

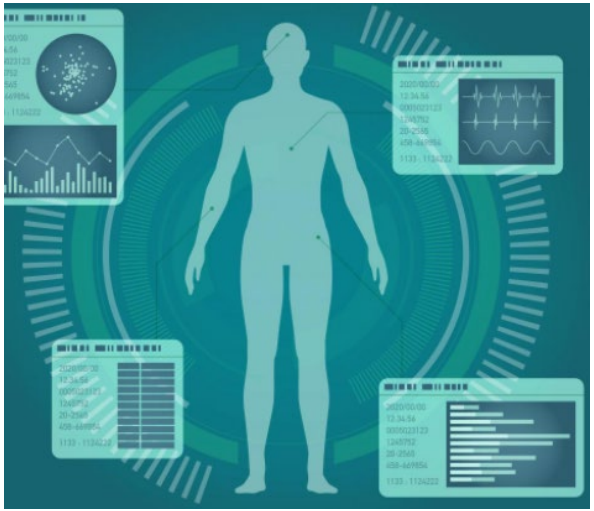
5. Transparency

- *How can additional safe guarding measures be put into place* and *communicated to individuals* around the purpose of collecting this data?
- What is the common good and *who owns the data*? [EULAR]

6. Data Retention

- How c*an I be sure the data will only be kept by the secondary user for a short period*? [EURODIS]
- *How long can data be retained for the purpose of secondary use*? [EURODIS]
- In accordance with Irish health services policy record retention periods differ from A&E, Hospital Admission to clinical trials. *Is it possible to have a better clearer system across the EU*?
  A review of time limits needs to be established across different pieces of legislation to be clear and concise [EULAR]

7. Registries



- *Why are data processing principles different for registries than for other digital records*? On this question, we're waiting for some more feedback.
- Can you *clarify the processing of personal data in the context of COVID 19 and public interest and international registries* and sharing of data and the rules, regulations around GDPR for safeguarding individual's data outside of the EU and governance and legislation for consent to internationals needs? [EULAR]

Thank You

Sabine.brosch@ema.europa.eu

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

Follow us on **@EMA_News**