EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Questions and Answers (Q&As) on data protection and the secondary use of personal data for medicines development and public health purposes

Joint PCWP and HCPWP virtual workshop, 23 September 2020

EMA 25 years

Orsolya Eotvos, Assistant Data Protection Officer, European Medicines Agency

Overview

- Background
- Project need
- Project objective & deliverable
- Structure of the draft Q&As
- Drafting status of the Q&As
- Next steps
- Questions

Background

Health data support pharmaceutical research, development and innovation in various areas:

- Relevance of clinical trial data versus clinical practice
- Safety monitoring and evaluation
- Drug utilisation studies such as use in different age groups (children) and off-label use
- Extrapolation of adult data to children or elderly
- Identification of unmet medical need
- Assessing disease incidence/prevalence

Project Need

Patients
Healthcare professionals
Research performing/supporting infrastructures
Medicines developers

- Implementation of data protection requirements (GDPR)
- How to use personal data for secondary purposes
- Context of medicines development and scientific research

Public health
Regulatory authorities

- Union data protection legislation (GDPR, EUDPR)
- How to use personal data for secondary purposes
- Strengthened evidence base for decision-making, safety monitory and policy making.

Project Objective and Deliverables

Develop a set of Question & Answers (Q&As)

- Clarify compliance with data protection legislation
- Ensure rights and freedoms of patients and consumers
- Facilitate the secondary use of health data for medicines and public health purposes

- Clarify the concept of **scientific research** within the GDPR/EUDPR
- Clarify the concept of **secondary use of data** within the GDPR/EUDPR
- Clarify the specific rules applicable to scientific research and secondary use, e.g. legal basis (consent or other), data erasure and retention period, transparency

Structure of the draft Q&As on SECONDARY USE

KEY PRINCIPLES

- Scope
- Personal data
- Special categories of personal data
- Secondary use
- Applicability
- Data protection principles
- Data retention

ROLES AND LAWFULNESS

- Data controller
- Compatibility
- Legal basis (consent or other)
- Examples: PAES and PASS
- Studies by medicines regulators

Structure of the draft Q&As on SECONDARY USE

RIGHTS OF DATA SUBJECTS

- Impact of different legal bases
- Withdrawal of consent
- Information to be provided to data subjects
- Exceptions from information obligations
- Request to access or a copy of personal data
- Request to rectify or complete personal data
- Restriction of personal data processing
- Right to erasure of their personal data

Drafting status of the Q&As

Phase 1 Drafting of Questions & Answers (Q&As)

- Based on initial key topics discussed with stakeholders
- Operational scenarios (PAES, PASS)

Phase 1 Draft Q&As - Informal Consultation

- EC DG SANTE - completed
- EC DG JUST - ongoing
- European Data Protection Supervisor (EDPS) - ongoing

Targeted Stakeholder Consultation

- Based on Discussion Papers (May to July) - completed
- Consolidation of feedback received - completed

Next Steps

Phase 2 Drafting of Q&As

- Detailed analysis of input received in Targeted Stakeholder Consultation
- Review of comments from EC and EDPS in the informal consultation
- Update of Phase 1 draft Q&As based on the above

Targeted Consultation of Phase 2 draft Q&As

- EMA Stakeholder representatives -> update of draft Q&As
- EMA Scientific Committees -> update of draft Q&As

Formal consultation of draft final Q&As

- Consultation with EC (DG SANTE & JUST) and EDPS

*Publication of final Q&As -> **Q2 2021***

Post-Meeting Note

An adjustment of the timelines may be required to align Q&As with guidance awaited from the European Data Protection Board (EDPB) on the processing of health data for research.

Any questions?

Further information

Orsolya.Eotvos@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**