



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



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 monitoring and policy making.





Project Objective and Deliverables

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

Q&A

➔ 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

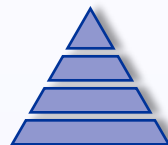


- Clarify the concept of **scientific research** within the GDPR/EUDPR
- Clarify the concept of **secondary use of data** within the GDPR/EUDPR
- Clarify the specific rules applicable to scientific research and secondary use, e.g. legal basis (consent or other), data erasure and retention period, transparency



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

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