EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Brief Introduction to Agency's Survey

Workshop on the application of the General Data Protection Regulation (GDPR) in the area of health and Secondary Use of Data for Medicines and Public Health Purposes, 29 September 2020

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Background

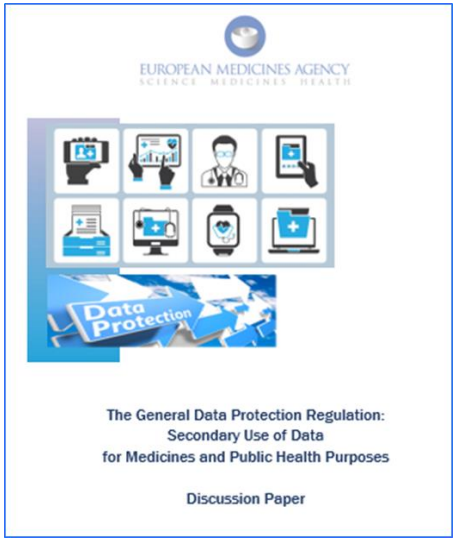
Potential for a strengthened evidence base for decision-making is currently perceived as being hindered by uncertainties about the correct interpretation of the General Data Protection Regulation (GDPR) in the area of the "secondary use" of health and medical data for medicines and public health purposes.

- "***Primary***" purposes are defined as those explicitly stated at the time of data collection, such as patient care, health system administration or research projects named at the time of data collection.
- "***Secondary***" (or further) purposes are those compatible with the primary purpose, that however were not explicitly stated at the time of data collection.

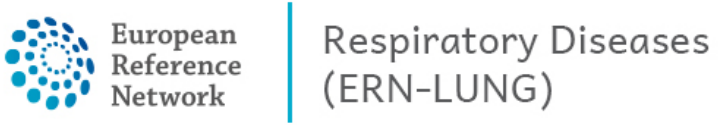
Stakeholder Survey

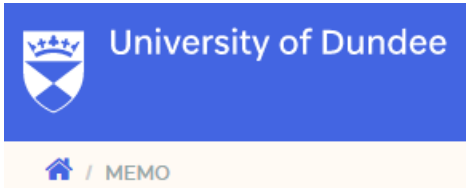
- Targeted stakeholder consultation was conducted (May to July 2020) based on a discussion paper addressed to medicines developers, data providers, research-performing and research-supporting infrastructures
- Goal was to obtain further input on data protection questions focusing on nine key topics and secondary use of health data for medicines and public health purposes

1. Secondary use of health data	6. Data retention
2. Compatibility	7. Data subject's rights
3. Legal basis	8. Registries
4. Pseudonymisation	9. International Transfers
5. Transparency	



Stakeholder Survey – Reponses Received





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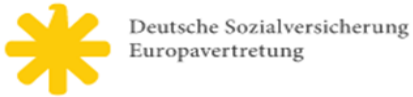

Any questions?

Further information

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