



BEUC The European
Consumer
Organisation

The Consumer Voice in Europe

EU Big Data Stakeholder Forum

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PRIORITIES

- Data governance
- People-centred DARWIN
- Digital & health literacy



DATA GOVERNANCE

Challenge: Multisource personal & non-personal health data combined with the use of advanced analytics is making privacy and data protection a more complex task than just putting in place the standard protection mechanisms foreseen by the existing data protection legal framework.

Solution

In addition to GDPR enforcement, there is need for a legislation establishing:

- Standards for health data anonymisation and pseudonymisation to ensure high protection of patients and consumers data;
- Quality and security standards for all information systems where health data is generated, used or stored to prevent data misuse and unauthorised access;
- Accountability, liability and redress mechanisms in case of data misuse resulting in patient or consumer harm related to health, discrimination and/or other damages;
- Strong public oversight to ensure compliance with data protection rules and other legal standards

When developing a new medicine, real word data – might have an added value for e.g. medicines benefit-risk assessment. However, it should not be the main evidence source to determine safety and efficacy of a drug, as it cannot replace information received through the clinical trial based on established methodology and standards.

Before widely using real world data as an additional data source there is a need to:

- Determine its limitations and possibilities when it comes to generated evidence reliability.
- Develop guidelines on how to ensure quality in the context of different data sources (e.g. patient registries, electronic health records).

DARWIN – DATA ALTRUISM

Challenge: Data altruism is a misleading concept which can lead to malpractice. In situations described as data altruism or data donations in which consumers would grant access to data for research with a public interest the special regime of the GDPR for collecting and controlling health data applies.

Solution:

- If patients and consumers were to provide access to their data for health research under a public purpose research initiative, this should not be for commercial purposes and, if the outcome of the research then contributed to the development of medicines and treatments that are exploited commercially, conditionalities should apply to the use of the research derived from the data supplied by consumers e.g. enabling the research to be used by other parties and not licensed on an exclusive basis.
- Patients and consumers must be legally protected against misleading practices regarding initiatives by the industry which are presented as public purpose research when in reality there is a commercial intent in the exploitation of the data as a result of the commercialisation of the research outputs.

DIGITAL & HEALTH LITERACY

- Healthcare digitalisation must go hand in hand with digital education and raising the level of health literacy of Europeans. 44% of Europeans do not have basic digital skills (EC) , while 47% have poor health literacy (WHO).
- Inadequate knowledge of one's health and a lack of necessary skills, is a public health challenge, as well as an obstacle to a successful and consumer-oriented healthcare digitalisation. Furthermore, lack of digital skills and awareness about data protection tools of the healthcare professionals can easily put the privacy of patients at risk.
- The EU and Member States should put in place mechanisms to ensure professional and educational assistance to both patients and healthcare professionals to better understand use of technologies in healthcare, their rights and obligations and how to manage health data, especially when it comes to its secondary uses.

AREAS OF COLLABORATION

- It is necessary to do the work in a coordinated manner, not only between the EU and Member States, but also within EU institutions & Agencies (e.g. continuous involvement of EMA, ENISA, EDPS is a must)
- It is important to take into account **diverse** interests of civil society groups, HCPs, payers, industry etc.
- Inclusion of consumer/citizens views is crucial, in addition to patient views, as it might differ. E.g. In some situations approach to data sharing can differ tremendously, if health of a person depends on it directly. However, there should never be a trade off between health and privacy.



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Thank you for your attention

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