

The Consumer Voice in Europe

ROLE OF BIG DATA FOR EVALUATION AND SUPERVISION OF MEDICINES IN THE EU

BEUC's reply to EMA public consultation on the summary report of the Heads of Medicines Agencies (HMA) - EMA Joint Big Data task force



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BEUC, The European Consumer Organisation welcomes the core recommendations of the joint EMA-HMA taskforce on big data in health; nonetheless, we call on for a **stronger focus on ethical and practical challenges** related to the use of big data in health in the final set of recommendations.

BEUC agrees with the EMA-HMA taskforce that interoperability, data sharing frameworks, data linkage and use of new analytical approaches and other recommended tools and actions are expected to contribute to a more meaningful use of biomedical big data and could lead to significant progress in medicine. While there are significant expectations of big data in health, it is of key importance to establish common standards and a strong regulatory framework to ensure the benefits of big data materialise in benefit for individual patients and the society as a whole.

Firstly, promoting biomedical big data standards must go hand in hand with the **use of comprehensive and harmonised data protections standards**. We welcome the EMA-HMA recommendations' reference to the European General Data Protection Regulation (GDPR) and the call for a global comprehensive standard on data anonymisation. However, the variety of data sources and use of advanced analytics make privacy protection a more complex task than just putting in place the 'standard' protection mechanisms foreseen by the existing European data protection framework. For example:

- with **user consent** being one of the main means to control personal data, it is important to note that consent alone will not provide all the necessary protection regarding all extensive possibilities of future data uses, especially in the context of health research.
- **data anonymisation techniques**, even when comprehensive, can still leave a possibility for re-identification;
- **IT security** has not proven to be sufficient with a constantly growing number of cases on cyberattacks on health databases.

Undoubtedly, data protection is paramount, however, consumer trust in big data requires not only innovative consent models or guidelines to data anonymisation. In addition, there is a strong need for:

- **quality and safety** standards for all information systems where health data is generated, used or stored.
- **more transparency** of how data is used and by whom through the entire data use process. In the context of the use of AI technology it is of key importance to avoid 'black-box algorithms' use in health and ensure the disclosure of at least basic but meaningful details about the basis of the medical decision, which is also a fundamental rule of medical ethics.
- **more clarity about data access and data control**, especially when it comes to the use of algorithm-based solutions and multiple source data (e.g. data from electronic health data, connected medical device, and social media).
- **more oversight mechanisms** to monitor compliance of all involved in handling of personal biomedical data with privacy protection rules and other ethical norms, and to ensure their accountability in case of data misuse.

- **clear accountability rules** for algorithm-based health-related decisions. Questions of accountability and liability are extremely potent in the context of innovative medical devices. Complex AI-tools make it difficult to determine who is responsible if something goes wrong and current liability rules are not up to date to deal with autonomous products.

In addition, digital health innovation can lead to health benefits only when they are based on the quality of evidence proving the effectiveness of such solutions. Therefore, it is crucial that coherent standards and assessment criteria are developed and widely used during the assessment of digital technologies (e.g. innovative medical devices with embedded software). To this end, we particularly welcome EMA-HMA recommendation to establish **common specifications on analytical and performance requirements for innovative medical devices** within the framework of new regulations for devices and in-vitro diagnostics.

To conclude, big data in health is needed to develop innovative diagnostic, therapeutic tools and to enhance health research. While digital innovation can be beneficial to consumers only when aligned with the current regulatory framework for data protection, it is of key importance to note that the existing legal frameworks do not cover several legal concerns of data subjects and not address the range of ethical issues related to the use of biomedical health data and novel analytical solutions. Thus, to maximise the benefits of biomedical big data for consumers, there may be a need for a **comprehensive regulatory framework setting up clear rules and red lines; oversight mechanisms to protect both consumer and public health interests; as well as accountability mechanisms to also allow public scrutiny of the use of biomedical big data.**

Therefore, we urge the HMA-EMA Joint Big Data taskforce to take the proposed measures into account and prioritise them in the relevant workstreams.

ENDS



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