

COCIR feedback on the Data Act (Inception Impact Assessment) 1

COCIR welcomes the opportunity to provide feedback to the European Commission's inception impact assessment for a Data Act.

COCIR fully endorses the Commission's view that the availability of and access to data holds immense potential for innovation and value creation, and that this will greatly contribute to the recovery and resilience of our society following the COVID-19 pandemic.

Representing the health technology and innovation sector, COCIR is strongly convinced of the positive effects of the use of health data in the public interest. The Data Act can be a valuable tool, complementing other existing frameworks in support of a European Single Market for data and the creation of a European Health Data Space.

With regard to **business-to-government sharing**, first and foremost there should be strong adherence to the GDPR and ePrivacy. Coherence should also be ensured with the ongoing initiatives proposed under the European Health Union package that seek to gather more data linked to health threats.

Requests for data should be reasonable and proportionate. A comprehensive impact assessment should be done before introducing any mandatory data access rights, taking into consideration the sector-specific context, including competition issues and market failures.

At all times it should be made clear for which purposes and to which parties the data will be made available. Sharing mechanisms should take full advantage of automated means to share and exchange data, accommodating bulk transfers or providing data exchange through APIs.

With regard to **business-to-business sharing** it is vital to underscore the voluntary nature of data sharing. Having said that, contractual fairness and clarity should be elemental to any B-2-B agreement. This could be further facilitated and instrumentalised through data sharing template agreements and licenses.

With regard to **rules on data access and usage rights** COCIR fully supports the fair, reasonable, proportionate, transparent and non-discriminatory use of terms. We would like to stress however the legal uncertainty and complexity related to what constitutes personal and non-personal data, and how to deal with any mixed datasets.

With regard to a **competitive cloud market** COCIR appreciates the evaluation of the current industry codes of conduct on data portability and service switching. This should lead to a strengthened framework that will offer European industry the infrastructure and services needed to develop new insights and technologies.

¹ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13045-Data-Act-&-amended-rules-on-the-legal-protection-of-databases_en



With regard to **international access to data** COCIR understands the need for safeguards and trust-building measures. It is however crucial that this does not lead to overly protectionist measures or data localisation measures, as this may inadvertently hamper or block international collaboration on research and innovation. Practical rules on data sharing and free flow of data between trusted parties (also non-EU) should remain the general principle.

COCIR remains fully committed to working with the European Institutions, the Member States and other involved stakeholders in creating a robust European data economy that will foster a competitive and innovative environment, leading to a stronger and more resilient EU economy and society.

COCIR References

COCIR contribution to the public consultation on the Data Governance Act (February 2021)

COCIR response on the European Health Data Space (IIA) (February 2021)

COCIR response on Open Data - Availability of Public Datasets (August 2020)

COCIR response on the data governance framework of common European data spaces (July 2020)

COCIR input on the European Strategy for Data (May 2020)

About COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries.

Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries. www.cocir.org

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