Proposal for a Regulation on European Data Governance - COM(2020) 767

MedTech Europe response to the open public consultation

8 February 2021

MedTech Europe welcomes the opportunity to provide the comments of the medical technology industry to the **proposed European Data Governance Act** (DGA)[1].

MedTech Europe would like to reaffirm its **support for the European data strategy and specifically the sectoral project of the European Health Data Space (EHDS)** and its corresponding initiatives.[2]

Data and the medtech industry

The medical technologies industry ("medtech industry") delivers products, services or solutions that improve prevention, diagnosis, treatment, monitoring and management of health and lifestyle. Digital health and care technologies can innovate and improve access to care and quality of care, and make healthcare delivery more efficient. The medtech industry invests significant resources in research, delivering major advances in areas including cardiac pacemakers, deep brain stimulation, disease screening tests, and glucose monitors. The sharing of (personal) data, with the appropriate safeguards, helps monitoring the safety and effectiveness of existing products on the market, and supports services for medical technologies currently in use. Hence, harnessing the power of health data will advance and accelerate research and innovation in medical technologies and services for the benefit of European citizens.

Therefore, the medtech industry supports the objectives of the proposed DGA to facilitate data sharing across sectors and Member States, and to set a framework for sectoral data spaces.

General comments and recommendations on the DGA commitments

MedTech Europe welcomes the overall architecture of the proposed DGA which presents a compelling balance between advancing opportunities to harness data to advance research and innovation (R&I), and ensuring full respect of data protection rules, including the individuals' control over their personal data.

We believe that for the data governance framework to be successful, it needs to be **based on rules that are trusted by all stakeholders**, while ensuring that individual rights, confidential business information, trade secrets, or intellectual property rights are not undermined.

[1] The proposed Regulation is available here for download: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12491-Legislative-framework-for-the-governance-of-common-European-data-spaces

[2] Recent MedTech Europe expressions of support include the Statement on the European Strategy for Data (May 2020) and the February 2021 response to the EHDS inception impact assessment.

In particular, MedTech Europe **supports the following elements in the proposed DGA:**

- **the creation of data intermediaries and specifically the single contact points in Member States** to assist businesses and researchers in identifying data suitable for re-use. In the healthcare sector, in some Member States such contact points have already demonstrated their effectiveness in connecting data sources and data re-users, and in overcoming silos within countries (health data held in public hospitals, repositories and registries is often difficult to access, or even inaccessible). MedTech Europe would also encourage EU coordination mechanisms and harmonisation in the type of actions that these authorities can undertake.
- **the creation of a 'European Data Innovation Board'** of European experts to facilitate the sharing of Member States best practices, and urges **that relevant stakeholders including the medtech industry be represented**.
- **investment to foster data processing infrastructures**, tools, architectures and mechanisms for data sharing.

In regard to the proposed creation of multiple (regulatory) bodies and authorities, **we would suggest combining these bodies with existing ones or create maximum one body per Member State**, to limit the administrative burden and to avoid fragmentation.

Specific comments and recommendations on the DGA

Potential consequences on contract between companies and public sector bodies

MedTech Europe recommends clarification that the proposed DGA will not **impact, or cause unintended consequences, on the B2G data sharing market** by directly or indirectly affecting contracts between businesses and public sector bodies that involve the supply of data or information. In the health sector, this could for example include contracts between medtech companies and public hospitals.

For example, there are collaborative research agreements between medtech companies and public hospitals that involve licensing data to the hospital for use, but restrict the license to this hospital or this specific use only. From the proposed DGA, it is unclear whether those licensed data would be made available to re-users. Therefore, some of the unintended consequences could be on:

- The established economic model of medtech companies (i.e. the "data suppliers") who would have to factor in new cost of doing business with public sector bodies.
- The collaboration of industry with the public sector, given the possibility of sensitive commercial information having to be made available to third parties, and the possibility that others could receive an unfair advantage by benefitting from significant investment made in generating, collecting and processing data.

Therefore, MedTech Europe recommends clarifications on:

- the **impact on contracts** between businesses and public sector bodies or B2G data sharing.
- the scope of the Regulation, when it comes to **categories of public sector data** available for re-use e.g. whether statistics from health insurers, data collected for public purposes or certain databases (e.g. biobanks) financed with public funds would fall in the scope of the proposal.

The interplay between the DGA & the GDPR

The **General Data Protection Regulation (GDPR)**[3] has been the defining European legal framework on the use of personal data since it went into effect in 2018. The DGA presents **an opportunity** to address some learnings and create a better framework that balances the needs and requirements of individuals with the public interest of the wider society. For example, there is a clear need for legal certainty vis-à-vis the rules related to the processing of personal data, including health data.

The GDPR plays a critical role in protecting the interests of individuals over their data and in establishing clear rules for the processing of personal data. Yet the GDPR leaves it open to the Member States to further regulate certain aspects which have consequently led to legal uncertainties for the medtech industry, especially with regards to the (re-)use of health data, scientific research and R&I.

Therefore, MedTech Europe offers some recommendations below for how the DGA could address **the problem of current European fragmentation in the interpretation and implementation of the GDPR and proposes some solutions with that regard.** Specifically, MedTech Europe recommends that the DGA align with the GDPR, by not imposing additional restrictions and not deepening the already challenging fragmentation under the GDPR. Some identified needs to address would be:

- **Define the concept of 'data' as understood by the DGA** and clarify it is limited to **digital data**. This means that considerable amounts of non-digital, paper-based data would fall out of the scope of the current proposal (e.g. at hospitals), remaining unused. **MedTech Europe supports a broad definition of "data"** (i.e. including other non-digital data and paper based data).
- **Define what is meant by "non-personal data",** contrary to what is stated in the proposed DGA. In addition, MedTech Europe recommends not to restrict any cross-border data transfers to non-personal data: this might preclude sharing of non-personal data and anonymised data, creating new safeguards which go beyond the GDPR.
- With regards to **mixed datasets** (that include personal and non-personal data), provide clarity on how they should be handled and when they can be considered **anonymous** in a way that it can be used and shared for research purposes (including commercial scientific research by medtech companies), and, for example, for testing AI applications.
- When it comes to the **legal basis for processing of personal data**, the GDPR provides multiple bases and grounds to lift the prohibition when it comes to the processing of special categories of data. The DGA seems to suggest consent should be used as a default legal basis for the processing of data. MedTech Europe recommends **aligning the DGA with the wording of the GDPR**. In addition, it should be clarified as to whether data can be shared with a third party based on a compatibility assessment on the initial purpose for which the data was collected, and clarity on the responsibility of the original data recipient in case the third party would use the data beyond the compatible purpose.
- Lastly, **definitions** such as **'pre-processed data', 'main establishment' and 'access'** should be aligned with the GDPR.

[3] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), see https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02016R0679-20160504

Providers of data sharing services

Providers of data sharing services (or "data intermediaries") will serve a critical role in the healthcare sector. We recommend:

- The **role of providers of data sharing services** to be further clarified in the DGA, in particular when it comes to exercising rights of data subjects, in case they would be allowed to manage/exercise consent on behalf of data subjects. More clarity on the terms 'in the exercise of their rights' used in Article 9 (1) (b) and how it interplays with the GDPR is needed.
- With regards to the verification of the results (see art. 5(5) DGA), the public sector body that provides the data 'shall be able to verify any results of processing of data undertaken by the re-user'. MedTech Europe recommends caution in order to not compromise any trade secret or IP rights of the re-user, avoiding a potential public disclosure.
- In the case of cross-border data-sharing services, we would suggest that the cooperation between competent authorities of Member States takes place in the form of a one-stop shop mechanism like the one under the GDPR (Article 13 (6)).
- Data altruism organisations should not be exempted from the requirements for providers of data sharing services as they will be dealing with the same data, with the same sensitivities as other data sharing service providers. Citizens who donate their data should be adequately protected.

Data altruism

MedTech Europe appreciates the potential of data altruism, and will be eager to explore what are the most appropriate mechanisms to make it workable in the health sector. We recommend that special attention is paid to the following risks:

- The proposed DGA risks creating an **additional legal regulatory layer without eliminating existing complexity**, especially when it comes to facilitating the processing of personal data for altruistic purposes. Implementing the DGA may come with an unforeseen administrative burden.
- Under the heading of "data altruism", access to data is to be organised for the common good, and the sharing and processing of data is to be facilitated across sectors. This brings a **risk that the DGA establishes new, additional obligations** that would have to be observed and that would not remain without influence on the GDPR, and on processes that companies have already established for data protection compliance.
- Regarding the planned **European data altruism consent form**, we appreciate that this is planned as a modular form that can be adapted to specific sectors and for different purposes. Despite these provisions, there is a risk this form will not do justice to current and future complexity of cases and purposes, including and especially in healthcare, with its urgent needs for data collection and evaluation in the interest of patients' safety. For example, we take this opportunity to point out certain conflicts with the medical device regulations[4] that arise when individuals revoke their consent for the use of data in the context of machine learning, thereby changing the data basis for AI systems that find application in medical devices.

[4] Medical Devices Regulation (EU) 2017/745 (MDR) and In Vitro Diagnostics Regulation (EU) 2017/746 (IVDR)

- The definition of data altruism should **encompass specifically the possibility of research and development of commercial products and services in medical technology** and the health care industry in general, since this would be to the benefit of citizens, healthcare systems and the European economy.
- With regards to the definition of data altruism and the "purpose of general interest such as scientific research or the improvement of public services", MedTech Europe recommends **confirmation on the concept of research by commercial companies** (especially research in view of developing medical devices and supporting services, but also development of care pathways, to obtain reimbursement, etc.). The GDPR itself says that the research provisions "*should be interpreted in a broad manner*[5]" and therefore, the concept of scientific research should not exclude scientific research done by individual companies. Research by medtech companies to develop and further improve their products, services and therapies should be encouraged, as this scientific research is ultimately aimed at improving patient outcomes, improving access of patients and health care providers to novel therapies, and increasing efficiency and long-term sustainability of the health care system.

Conclusion

The medtech industry supports the new momentum in Europe to harness the power of data. Now is a time of great opportunity for public and private stakeholders to work together to solve complexities, reduce barriers, fill in gaps and lay the ground for a sustainable digital transformation of Europe. Working in silos is no longer an option and we welcome the inclusive approach by all services of the European Commission. The medtech industry stands ready to collaborate with policy-makers and to play its part, especially in the alignment and building of the sectoral initiatives related to the European Health Data Space.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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[5] see GDPR Recital 159