Considerations for Privacy Laws Involving Health Data

About GMTA

The Global Medical Technology Alliance (GMTA) member associations represent companies that produce nearly 85 percent of the health care technology purchased and utilized annually around the world. These technologies are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our companies range from the largest to the smallest innovators and bring medical technology to patients worldwide in every setting. The GMTA is committed to the highest ethical and legal standards for the best interest of patients and public health[1].

Background

Many governments around the world have adopted privacy and/or data protection legislation, and over thirty have pending draft laws or initiatives[2]. As policymakers develop and advance privacy and data protection legislation, we want to raise awareness about the importance of health data and the key role of medical technology companies in patient care to ensure that this data can continue to be utilized to provide the highest levels of care for patients. We welcome any opportunity to work with policymakers in their process of developing privacy and data protection legislation.

Health data & the MedTech industry

The collection, sharing and use of health data is fundamental to advancing healthcare, research and innovation, ensuring the highest levels of safety and quality that also translate to improved health outcomes at lower total cost. As part of the development of new technologies and as part of their roll-out to healthcare systems, the medical technology ("medtech") industry develops and is required to process health data. Over the past years, the medtech industry delivered major advances involving digital components relying on data in areas including cardiac pacemakers, deep brain stimulation, sleep disorders, intravascular ultrasound, artificial hips and knees, disease screening and diagnostics, anti-microbial resistance (AMR) testing, glucose monitors, and also solutions that are helping to fight COVID-19 and strengthening pandemic response and preparedness.

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[1] For more information about GMTA, please see: http://www.globalmedicaltechnologyalliance.org/about.html

[2] *See* Banisar, David, National Comprehensive Data Protection/Privacy Laws and Bills 2021 (August 30, 2021). Available at: https://www.researchgate.net/publication/337060085_National_Comprehensive_Data_ProtectionPrivacy_Laws_and_Bills_Map_-_August_2021_Update

Health data also enables new ways of personal management of one's health and lifestyle. It can be integrated across a variety of platforms to enable better clinical care practice and decision-making. Combining health data from different sources in an appropriate manner can empower people with information to improve their health and deliver more robust evidence for the efficacy of treatments. Data-driven research and innovation has and will continue to deliver benefits across the care spectrum, from diagnosis to cure. In short, the appropriate use of health data brings enormous benefits for people, healthcare professionals, and healthcare systems.

International dimension of data flows

Data flows are critical to the research and development of new technologies, the monitoring of the safety and effectiveness of existing products for providing support services for medical technologies currently in use, and for compliance with regulatory obligations and best practices. In order to be able to effectively and efficiently develop, manufacture, and distribute medical technologies, medtech companies need to be able to operate and collaborate internationally.

The medtech industry is one of the most highly regulated at every stage of device development, from the initial research to the post market surveillance that occurs after the device is on the market. Throughout all stages, numerous safeguards are in place to protect the privacy and confidentiality of the health data, and these safeguards also ensure that data transferred are used only for permissible purposes.

Considerations for policymakers

GMTA supports a coherent approach to data privacy and data protection that takes into account the unique nature and importance of personal health data and deidentified health data used by the medtech industry, and commends policymakers for their attention to this important issue. To support continued research and innovation in healthcare through the responsible use of personal and de-identified health data, GMTA recommends the following considerations when developing privacy and/or data protection legislation:

- **Clear definitions and terminology**: when developing data protection and privacy legislation, we recommend including in the data protection/privacy law clear definitions to avoid terminology which could be confused with similar concepts used in other jurisdictions. For example, the meaning of 'personal data' is different from one jurisdiction to another. In some, it may also include data related to legal persons while others only protect data of natural persons. In addition, the type of personal data falling under that definition can also differ varying from names and contact information of residents in one country, to *any* information related to an individual physically present in another.

- **Consistency with principles, standards and practices** of international organizations and/or international treaties[3]. This will be an important element facilitating market access with other trade partners and advancing the economic growth of the country.

[3] For example, internationally established principles are: Collection Limitation, Data Quality, Purpose Specification, Use Limitation, Security, Transparency, Individual Participation and Accountability.

- **Mechanisms for sharing health data across borders**: the unique nature of health data and its complex use needs to be considered to foster research and innovation and to make healthcare accessible and available across borders.

- **Data localization requirements:** While there are cases where certain data localization requirements might be justified, data localization poses a major barrier to data flow, and add unnecessary cost and delay. Free and secure flow of data contributes significantly to digital innovation, technological advancements, and even the ability to provide healthcare. Regulators should consider adopting a more risk-based regulatory approach to protect data, allow secure and controlled exchange of information while supporting innovation and advancing the competitiveness of the country.

- **Exceptions to individual's right to privacy**: exceptions should only be possible in limited cases and when prescribed by law. We recommend cautiousness when implementing such exceptions mostly in areas of national security, sovereignty and public order. This will ensure improved understanding and more streamlined negotiations when it comes to international personal data transfers as some jurisdictions do not allow the transfer of personal data to countries with very broad exceptions.

- **Mechanisms of redress and independent oversight**: such mechanisms should be available for all the individuals living in the respective country.

In conclusion, GMTA and its members actively call for an unrestricted flow of health data transfers between countries for research and innovation, the monitoring of the safety and effectiveness of existing products for providing support services for medical technologies currently in use, and for compliance with regulatory obligations and best practices, for the interest of patient safety and uninterrupted healthcare delivery.
In addition, GMTA members support countries that seek to set privacy and data protection laws and standards with international alignment of principles and definitions to ensure data can flow from one country to another.
The industry will be a supportive, essential partner in creating and maintaining the highest standards of health data management dedicated to the benefit of patients**.**