

## MedTech Europe welcomes the European Commission's White paper on Artificial Intelligence and the EU Data strategy

Brussels, 21 February 2020 - The medical technology (medtech) industry welcomes the “European Strategy for Data” and the “White Paper on Artificial Intelligence – a European Approach” that were published by the European Commission (EC). The two documents will be tools to unleash the potential of data and artificial intelligence in the health care sector, increasing outcomes for patients with respect for Europe’s values and principles.

MedTech Europe welcomes the European strategy for data as an important commitment of the EC to harnessing the power of data for healthcare, with the EC referring to Health, as “an area where Europe can benefit from the data revolution, increasing the quality of healthcare, while decreasing cost.”. For example, the creation of a European Health Data Space will be a critical enabler of access to high-quality data, which is a fundamental requirement for safe and trustworthy Artificial Intelligence in healthcare, and for increased patient outcomes.

As underlined in our recent [position paper on Artificial Intelligence](#) (AI), we envision an enormous potential for AI in improving the quality and safety of the health care sector, as well as in empowering patients. Above all, the medtech industry agrees with the EC that AI has the potential to make Europe a global champion in health. To pursue this common goal, we are committed to provide sector-specific expertise throughout the building of the future European Health Data Space and the AI strategy in Europe.

The medtech industry agrees, as outlined in the White Paper, that it is necessary to take different types of risk into account when considering the need for any AI-specific regulation. Furthermore, any future legislation on AI should consider existing (sectoral) rules, as well as the specificities of the health sector and ensure that innovative solutions are accessible for patients. In order to maximise the benefits of AI in the health sector, we call on the EC to focus on:

- **Building data and infrastructure for research and AI** – to provide increased access to consistent data with standardised formats and the necessary cybersecurity safeguards. In addition, MedTech Europe calls on the Commission and Member States governments interested in aggregating curated health data across Europe to work collaboratively with all stakeholders to make the European Health Data Space a reality.
- **Establishing a harmonised governance framework based on ethical principles** – taking into account both sector-specific needs of regulation, as well as existing EU legislation and existing institutional structures to reap the benefits of AI.
- **Funding of AI** – investing in research and innovation, but also in resources for implementation and deployment. In addition, the medtech industry calls for a new approach (in the areas of criteria for reimbursement, funding sources, evidence generation and digital health assessment specifics) to the incentives and financing of digital health technologies, including AI in healthcare.

- **Equipping the healthcare workforce and patients with the necessary skills** – providing the EU workforce with the reskilling and continuing learning opportunities required to embrace ongoing technological developments are vital to maximising the positive impact of AI in the EU. This could be done through pre-certification of medical societies and advancement of the AI curricula for healthcare professionals and hospital managers, and learning opportunities for patients.

A multi-stakeholder approach will be the foundation of a forward-looking, sustainable and harmonised AI regulatory landscape and will ensure that policy remains dynamic and flexible, adapting to the evolution of technology.

### **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.

For more information, visit [www.medtecheurope.org](http://www.medtecheurope.org).

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