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## **The Danish Government's response to the public consultation on European Health Data Space**

The Danish Government would like to thank the European Commission for the opportunity to comment on the consultation regarding the upcoming proposal for The European Health Data Space.

The Danish Government welcomes the initiative on a European Health Data Space. We share the goals of benefitting and making the most of digital health in providing high-quality healthcare, reducing inequalities and promoting access to health data for research and innovation on new preventive strategies, diagnosis and treatment. The current COVID-19 pandemic has shown that health data is a crucial element for new and innovative solutions in time of crisis. A shared European ambition in this regard will be a central element in ensuring the future health care in Europe.

The Danish Government has just presented our new life science strategy in which we have seven initiatives on better use of health data. The technological development within health data is rapid, which creates new perspectives in regard of ensuring more value and knowledge from health data. However, this creates new needs for modern, clear defined and secure frameworks for the use of health data. In view of the new life science strategy, the use of data is a central discussion in Denmark and several different authorities and stakeholders are taken into account in the Danish position on health data. Therefore, this consultation response, presents our immediate and overall remarks and points of attention.

### Access to and exchange of health data for healthcare

From a Danish perspective, we see potential in secure data sharing across Member States, for the benefit of patients. It is essential that initiatives on sharing of health data build upon federated models, and Member States' national organizations, such as existing data infrastructure and national initiatives.

The Danish healthcare system has a long tradition of collecting and using healthcare data for the benefit of patient treatment and care. The use of health data across Member States ensures high standard patient treatment by facilitating that patients staying in all Member States can receive data crucial for their treatment. Therefore, Denmark welcomes that we in a European context support, that patients can be treated in other countries and that it is possible to share relevant information for patient treatment a cross borders.

However Denmark would like to state the importance that actions, within data sharing, towards a European Health Data Space build upon EU and Member States' national regulation and principles. For sensitive personal data collected by the public

sector, it is essential that the public authorities in Member States maintain control over the use of data for the purpose of data security and citizens' trust.

Thus, when setting up the European Health Data Space it is important to strike a balance between clearly defined roles, rules and criteria and at the same time make room for innovation and quick responses to new technologies and market demands that change over time. This need for flexibility calls for a decentralised infrastructure. Therefore, The Danish Government encourages the development of data spaces as 'soft infrastructures' based on technical and legal frameworks rather than actual, physical data pools. With this approach data sharing would become much easier for member states to keep the data secure and to ensure control over who accesses what data for what purposes.

#### Access and use of personal health data for research and innovation, policy-making and regulatory decision

Denmark supports access to data for research, innovation, policy-making and regulatory decisions within the EU. There is great potential in being able to combine data from the different Member States. Valuable research and innovation helps to create good opportunities for new treatment methods and quality development for the benefit of patients, as well as to ensure the future health care in Europe. The two data spaces on genetics and cancer-images will be important in setting up pilots for how the broader access and use of health data could look like.

Denmark's collection of health data is unique because many health registers and databases cover the entire population over many years and can be combined across data sources. The Danish population has confidence that their health data is processed and stored securely. In this regard, it is important that new initiatives within the European Health Data Space build upon and support the Member States' local principles and organization, where the individual countries organizes access to data, so that local conditions are taken into account. This is important because the health data area varies with regulatory and administrative legacies among Member States.

#### Digital Health services and products

Denmark is aware of the new possibilities for health data and the possibilities and experiences that lie in common European solutions. Denmark has a well-developed infrastructure where digital welfare solutions are deeply integrated in the health care system. Therefore, we emphasize the need for continued voluntary action at national level for Member States that have well-developed digital health services and thereby ensuring that European solutions can integrate local national solutions.

#### Artificial Intelligence (AI) in healthcare

The development within technology creates new perspectives in relation to getting even more value and knowledge out of European health data. At the same time, however, it creates new needs for modern, clear and secure frameworks for the use of health data. Denmark sees great potential in common European solutions to the new challenges that come with artificial intelligence.

However, we would like to emphasize that there are a number of data protection rules, with regard to artificial intelligence, where Denmark believes it is necessary to take national conditions and rules into account.

### Concluding remarks

In Denmark, health data and general use of data are an integral part of patient care and health research. There is strong public and political attention towards that Danish data are used responsibly and stored securely.

Therefore, Denmark finds it important that the use of health data and particularly sensitive information about citizens' health is shared safely and securely. We emphasise the importance that the European Health Data Space will be in compliance with Union and Member States' privacy and data protection rules, are voluntary in nature and are in line with the division of competences between the Union and the Member States.

Denmark sees great potential in a shared European strategy on health data for the benefit of patients, research and innovation. Therefore, we welcome the cooperation between Member States and the Commission in the work towards European Health Data Space, to ensure continued development of a governance strategy for the use of health data for health care and for the use of research.

In this view, it is essential that a European Health Data Space builds upon Member States' national regulations and principles, as well as upon local conditions, such as existing data infrastructure and national initiatives, and fully respects Member State competences and capacities. For sensitive personal data collected by the public sector, it is essential that the public authorities in Member States maintain control over the use of data to guarantee data security and public trust.

Denmark would again like to thank the Commission for the possibility of consultation. We hope to have a close dialogue with the Commission, since we are currently coordinating a Danish position on the upcoming proposal and would like to present additional remarks and ideas on the European Health Data Space.

Yours sincerely,

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