***PARLIAMENT***
***OF THE CZECH REPUBLIC***
***Chamber of Deputies***
**Ondřej Benešík**
***Chairman***
***Committee on European Affairs***

Prague, 27th June 2022

Dear Ms. President,

I would like to inform you about the opinion of the Committee on European Affairs of the Chamber of Deputies of the Parliament of the Czech Republic

on the Communication from the Commission to the European Parliamentand the Council - A European Health Data Space: harnessing the power of health data for people, patients and innovation /Council Code 8828/22, COM(2022)196/ and

on the Proposal for a Regulation of the European Parliament and of the Council - on the European Health Data Space /Council Code 8751/22, COM(2022)197/

The respective documents were included in the agenda of the 12th session of the Committee on European Affairs and was scrutinized on 22th June 2022. According to the Rules of Procedure the Deputy Minister of Health and the Representative of the Office of the Government of the Czech Republic were present at the session to introduce the preliminary Government's Framework Position.

After the hearing of the rapporteur's review and after the discussion the Committee has adopted the **Resolution No. 75 in the context of the Political Dialogue** which is enclosed to this letter.

Yours sincerely

**Ms. Ursula von der Leyen**
President of the European Commission
B r u s s e l s

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# PARLIAMENT OF THE CZECH REPUBLIC
# Chamber of Deputies
# Committee on European Affairs

Resolution No. 75

**12th Session on 22 June 2022**

**Communication from the Commission to the European Parliamentand the Council - A European Health Data Space: harnessing the power of health data for people, patients and innovation /Council Code 8828/22, COM(2022)196/**

**Proposal for a Regulation of the European Parliament and of the Council - on the European Health Data Space /Council Code 8751/22, COM(2022)197/**

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**Conclusions of the Resolution:**

Committee for European Affairs

1. **takes note of** the documents;
2. **expresses concerns** about the documents:

(a) The documents do not state that a patient or examined person may refuse to record an electronic health record, or refuse to share it in the European Health Data Area after recording within the primary and mainly secondary use of health data. The patient can only deny access to his data to all or some medical facilities, but not to data controllers and secondary use.

(b) Medical facilities would be enormously burdened by the transition to completely new electronic health record systems, both financially, organisationally and educationally. Due to the difficulty of their production and self-certification, multiples of the single cost and higher regular management fees can be expected. This is particularly true for NIS /hospital information systems/, which price is already extremely high at the moment.

Furthermore, medical facilities would be exposed to the threat of high penalty charges for non-compliance with obligations of the Regulation. It is not clear and obvious that this system will be fast enough, user-friendly and intuitive and will make it easier for users to operate. The result would be highly likely leaving of many retired doctors, affecting in this respect the vulnerable expertise of general practitioners for adults and general practitioners for children and youth, or other compromised medical expertise.

In the course of their work, most doctors or other healthcare professionals would be forced to devote an even larger portion of their work to digital communication at the expense of face-to-face communication with the patient, leading to a further deepening of the dehumanization of healthcare.

(c) Products used from smaller medical software manufacturers may be excluded from use as they will not be able to ensure a staffing and financial transition to the new interoperability format, even if these products are currently fully operational and are fully exploited and the users are satisfied with them.

(d) It is not clear from those documents how the European Health Data System will be backed up for the case of a long-term failure of its functionality, so that medical facilities can continue their activities after its failure.

(e) It is not clear from the documents referred how the transfer of health information will be ensured in other form than through the European Health Data Area, not to exclude from

healthcare those who refuse to share their health data with other health establishments or refuse to make their data available in the European Health Data Area.

f) Centralized storage of personalized medical data /even though maximum security/ opens the way for their misuse due to their importance and the value for many subjects, mainly related to genetic, genomic and protheonic data of our population and genomic data of pathogenic organisms and micro-organisms. The acquisition and misuse of this data can have a major negative impact on the future of entire populations, populations and individuals.

(g)It is very difficult to distinguish research for social well-being from research for the potentially or deliberately dangerous, mainly in the fields of genetics, genomics, molecular biology, synthetic biology and artificial intelligence.

(h) Unrestricted disclosure of sensitive personal health data may result in harm to the patient or medical facilities if misinterpreted. It is not possible to recommend unrestricted patient‘s access to all of their health data, especially when it relates to information about severe, untreatable and deadly diseases.

(i) The decision on the possibility of adding information by patients without proper validation filtration also appears to be questionable. It can lead to overloading of the system with ballast and misleading information.

(j) The financial expenses will have to be paid (except the EU and the Member States) by the software manufacturers and subsequently by medical facilities and health insurance systems. The same is true for manufacturers of software and medical devices for the risk of discouraging financial penalties. The financial benefits are uncertain and cannot be clearly predicted due to the complexity of the system created by the European Health Data Area.

(k) The documents do not define the parameters that will evaluate the benefits and efficiency of the system.

(l) The documents do not define who will be directly responsible and what the sanctioning arrangements will be if the system does not achieve its objectives and on the contrary will lead to harm to the Member States citizens‘ interests.

(m) It is unclear how healthcare facilities and patients will directly benefit financially from the sale of secondary use data as the source and producers.

3. **requests** the Government to inform the Committee of further progress of the discussion about these documents in the EU institutions;

4. **authorizes** the Chairman of the Committee on European Affairs to forward this resolution to the President of the European Commission **in the framework of the political dialogue**.