

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

Members' Conference on European Health Data Space: What will it mean in practice?

On 24 March 2023, the Croatian Medical Chamber (CMC) and the Standing Committee of European Doctors (CPME) co-organised a conference titled "European Health Data Space: What will it mean in practice?" in Dubrovnik, Croatia. The conference coincided with the CPME General Assembly. The objective of the conference was to examine the practical implementation of the European Health Data Space (EHDS), specifically focusing on its primary use regime known as MyHealth@EU. The speakers shared their experiences and advice, discussing topics such as training and raising awareness among healthcare professionals, data quality protocols and codes, and the types of data to be used.



Mr. Alexander Jäkel, Chair of the CPME Digital Health Working Group, opened the event explaining that the EHDS draft regulation introduced a new legal framework for accessing and sharing health data in Europe. It aimed to facilitate the access and transmission of electronic health data for diagnosis and treatment (primary use) by establishing patients' rights and a common infrastructure for data exchange called MyHealth@EU.

Mr Jäkel raised CPME's concerns about the draft regulation definition of "data holders," which implied that small medical practices fell within its scope, potentially imposing additional obligations on healthcare professionals. He emphasised the value of the EHDS in improving medical diagnoses, facilitating cross-border collaboration, and supporting decision-making and patient care. Mr Jäkel stressed the need for detailed national discussions to ensure that the system was suitable for doctors, without creating an excessive administrative burden given the strains caused by the COVID-19 pandemic and staff shortages. He highlighted the importance of financial support for those doctors willing to digitise their practices and connect to the EHDS. Digitalisation should be voluntary and bring no additional costs.

Dr Tomislav Sokol, the co-rapporteur of the EHDS file in the European Parliament Committee on Environment, Public Health and Food Safety (ENVI), delivered the keynote speech. MEP Sokol underlined the positive impact the EHDS would have in facilitating cross-border healthcare, free movement and sharing of data between Member States in a secure processing environment. He explained that the EHDS comprised two main functions: primary use, which involved using data for diagnosis and treatment, and secondary use, which focused on re-using data for research, innovation and policy -making. He added that the political discussions focused mainly on the challenges related to the secondary use regime, such as intellectual property rights, permissible purposes, and patient involvement.



He praised the CMC and CPME for organising a conference dedicated to discussing the primary use of the EHDS, which was deemed essential due to the increasing digitalisation of healthcare systems in Europe. MEP Sokol highlighted the lack of interoperability and data sharing, not only between Member States but also within the same Member State. He acknowledged the limitations on EU harmonisation of national healthcare systems, as it fell under national competence.

MEP Sokol explained that the proposal specified the priority data categories to be included in the electronic health record and the creation of a harmonised electronic health record (the so-called EHRxF) to enhance healthcare professionals' access to patients' health data. Member States had the option to decide whether to digitise all or part of the health data before the regulation's implementation, but once in force, health data would need to be available in electronic format. MEP Sokol highlighted the crucial role of medical professionals in this transition. He emphasised that information could only be considered a clinical fact if validated by healthcare professionals. Data introduced by patients would not be valued the same way to avoid confusion.

During the questions and answers exchange, several topics of concern were raised by CPME Members. These included the automatic translation of health data to ensure cross-country understanding, exempting small medical practices from the secondary use regime, medical liability for misleading or overwhelming information in the EHR, the regulation of wellness apps and its connection to the EHR, patients' reluctance to share data for unknown or commercial purposes, the implementation timeline of the EHDS and insufficient EU funding, the use of health data for educational purposes and medical students' access, patient confidentiality, and completion of EHDS discussions within the parliamentary term. The discussions shed some light on the complexity of the EHDS implementation, from data management practices, system security, and stakeholder involvement and collaboration.

The expert panel discussion provided valuable insights into different aspects of the EHDS and its practical implementation. Moderated by Mr Jäkel, the panel included speakers from the French Ministry of Health, the Portuguese Ministry of Health, the KPMG, the Danish Medical Association, and the Cyprus Medical Association.

Ms Isabelle Zablitz-Schmitz (FR) highlighted the significance of the EHDS in addressing European healthcare challenges and the need for secure handling of health data. She presented the French initiatives, such as "Mon espace santé" and the French Health Data Hub, which aligned with the EHDS goals, and the [TESTA](#) infrastructure. Ms Zablitz-Schmitz emphasised the importance of individual control over health data in the primary use regime and manufacturers compliance with technical requirements. The EHR needed to be integrated into the software healthcare professionals were using to avoid time loss.



Dr Cátia Pinto (PT) discussed the primary use of data component, known as MyHealth@EU, and its role in bridging the gap between data and healthcare in the digital era. She stressed the importance of assembling high-quality, standardised data to enable personalised medicine and improve healthcare efficiency. Dr Pinto highlighted the EHDS's potential to create a single market for digital health services, enhance data interoperability, ensure security, provide the portability of health data for citizens and unlock the economic potential of health data. Dr Pinto shared 2 videos on these topics – please see [patient summary](#) and [e-prescriptions and e-dispensations](#) demonstrations.

Mr Hylke Kingma presented the financial impact assessment conducted in the Netherlands and discussed the status of health information exchange in the country. He emphasised the need for identification, authentication, and permission services to establish a well-functioning nationwide infrastructure for health data exchange. The debate pointed towards connected data platforms, where regional data platforms connect different healthcare providers and then connect on a more nationwide level. Mr Kingma outlined the costs and uncertainties associated with implementing the EHDS in the Netherlands, considering existing legislation and ongoing initiatives. He mentioned that in 2017 the government funded healthcare providers from different care segments to implement a unified language and elements of healthcare information exchange. This funding would need to be rerouted towards the elements which were being implemented by the EHDS.

Dr Camilla Noelle Rathcke shared insights into the Danish healthcare system and its experience with electronic health records. At present, none of the Danish systems could be easily integrated with the European system, and there was no immediate answer on how to integrate them. Dr Rathcke emphasised



that training of healthcare professionals had been substantial and could be very time-consuming working with electronic systems. Although it was very easy to access data, the time spent entering data into the system was significant. As a doctor, she used to see more patients before the EHR system was introduced. There had also been a substantial change in the division of labour, she was

doing more secretarial work than before. Speech recognition was not yet easily accessible in these systems. General Practitioners shared data into the national clinical quality databases and health registers, but not all health data was shared (e.g. data from municipalities and elder care). Dr Rathcke added that according to Danish patient organisations, patients were eager to share their data for primary use and partly keen for secondary use (research). However, patients were very reluctant to share data for commercial purposes ('tertiary use'). She feared a possible spillover effect of patients' reluctance for sharing data for primary use due to the developments brought by the EHDS. She concluded by mentioning that the focus of the EHDS should be supporting the primary use of data and patient treatment.

Dr Marios Karaiskakis presented the national eHealth law in Cyprus and its aims to create a national electronic health record, a single and central database for EHR for all citizens, standards compatible with the EHDS and a national contact point for cross-border healthcare. He discussed the challenges from fragmented



patient data and the benefits of a unified system, including detailed data sets with essential information gathered by all specialties. He called for the use of international standards for coding, medical terminology, and mature technologies. It was essential to avoid futuristic technologies and complexity. Interoperability was a must. Cyprus opted for a hybrid model, where the government owned the source code but would buy services from the industry to accelerate the process. If a provider was not delivering well, the government could easily change. Dr Karaiskakis concluded by explaining Cyprus' implementation plan and costs, as well as the potential financial savings and improvements in healthcare delivery.

Dr Keijzer concluded the EHDS Conference by noting that it was very important to learn from the practical examples introduced by the panellists. The speakers emphasised the importance of individual control over health data, standardisation, interoperability, security, and the potential benefits of the EHDS in improving healthcare across Europe. There was still a huge amount of work to be done before the EHDS could be implemented in Europe. Dr Keijzer thanked all speakers for their contribution and their clear presentations.
