



HEALTH POLICY PERSPECTIVES

Insights on the challenges facing the health policy agenda

Digital Health – An Ever Closer eHealth Union?



An ever-increasing eHealth landscape across the EU

The past few years have seen an ever-increasing focus on digital health political initiatives, with a sense of urgency as governments and payers seek to address the changing landscape of an ageing demographic placing growing pressure on healthcare systems. At EU level, the shift can be seen with numerous communications, action plans, EU-funded projects, events, platforms and in more recent years, policies which focus on developing an interoperable framework across Europe.

“I believe that eHealth has the potential to make European health systems more accessible and sustainable and to empower patients to manage their own health.”

Vytenis Andriukaitis, EU Commissioner for Health and Food Safety



‘Digital health’ as a term at EU level includes a wide area of fields, topics, processes and technologies, including: eHealth, mHealth, teleHealth, telemedicine, wearables, personalised medicine, interoperability of health systems, the internet of things, and health information technology to name but a few.

Moving towards better use of patient data?

One of the biggest changes we will see is the implementation of the new General Data Protection Regulation, (GDPR) by May 2018. The new [Regulation on the Protection of Personal Data and on the Free Movement of Such Data](#) (2016) covers such sensitive topics as: informing patients how and for what purposes will personal data be used; limiting the purposes for data collection, and how it can be re-used for research purposes; minimising the amount of data collected (ensuring it is pertinent to the needs, ensuring accuracy, limitations on period for data storage); ensuring confidentiality and integrity of the data; and finally, making data controllers are accountable for their conduct.

In effect, the GDPR allows for greater flexibility in the processing of patients’ data. This means Health Care Professionals (HCPs) and health institutions need not consent systematically before using the data, on the condition that the processor maintains professional secrecy. The Regulation also allows patients the rights to: access their own personal data, to transfer it from one data controller to another, to object to the processing of the personal data, to rectify or erase personal data, to be ‘forgotten’, to be informed in the event of a security breach, to lodge a complaint and seek legal redress if there is a complaint, and the right to be informed and transparency from the data controller.

What does this mean in real-terms?

The Regulation will allow greater flexibility in the use and collation of data for research and innovation. It will be applicable to processors in the EU, regardless of whether the processing will take place within the EU. If goods or services are offered to an EU citizen, the processor, irrespective of their territorial base, will also have to comply with the Regulation. The new Regulation also covers areas such as new protocols, data

breach notification and the creation of a European Data Protection Board. [The European Patients Forum's \(EPF\) position on eHealth](#) notes that for patients, consent is required to collect and use patients' data, except if it is part of the provision of care. The new Regulation requires that consent must be informed, specific, freely given, and unambiguous. Consent for processing of data must be presented clearly and separately from other issues.

Whilst there is much recognition from the World Health Organization (WHO) on the huge potential impact of eHealth for universal health coverage, Dr Zsuzsanna Jakab, Director of the World Health Organization Regional Office for Europe, at 2017 eHealth Week in Malta [urged caution](#) regarding the use of big data: "...These approaches however raise a number of ethical and moral concerns. We also know that countries still have quite a way to go before they are appropriately prepared to adopt such innovations. In fact, only six countries in the European Region have a national policy or strategy regulating the use of big data in the health sector, and only four countries have a national policy or strategy regulating the use of big data by private companies. How can we have the freedom to use this data to innovate without running risks that we have not yet envisaged?"

More broadly, the European Commission has also launched this year a cross-departmental [Task Force on Digital Health](#) which will look at further developing technology for pan-EU cooperation networks for genetic research, supporting continued patient feedback and improving services. Through the new [European Interoperability Framework](#) (2017) there will also be an emphasis on openness and information management, data portability, interoperability governance and integrated service delivery, especially in digital public services. In practice, patients should be able to access their records across EU Member States and use prescriptions seamlessly.

So where are we today?



Currently the European Commission is holding a [Consultation on the High Performance Computing initiative](#) to gain input from stakeholders for a new funding instrument on for HCP in Europe. In parallel there is a [Consultation on Transformation of Health and Care in the Digital Single Market](#) with the view of bringing forward a Communication on the subject at the end of this year. The latter Consultation seeks input on cross-border access and portability of personal health data, sharing of resources that will accelerate research and advance prevention, treatment and personalised medicine, and measures to ensure widespread uptake of digital innovations, enabling more patient centred and integrated healthcare, and allowing for feedback and interaction between patients and healthcare providers.

The Estonian Presidency of the EU placed the issue of [free and secure cross-border movement of health data](#) for discussion amongst Health Ministers, first at an informal meeting in July and on the agenda of the upcoming [Estonian Presidency High-Level Conference on e-Health](#) 16-18 October in Tallinn. Currently the Presidency and [European Connected Health Alliance](#) (EHCAIalliance) are inviting stakeholders to contribute to the [Digital Health Society \(DHS\) consultation process](#) which will lead to a [Declaration on DHS](#) to be co-signed at the High-Level Conference. The Presidency aims to publish Council Conclusions – agreed by all 28 EU Health Ministers – at the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) December meeting in Brussels. In recent days, the EU Commissioner for Competition, Margrethe Vestager, along with some EU national governments, has been looking at companies' ownership of personal data.

Whilst so many efforts have been made to enhance eHealth across the EU, as [EPF notes](#), eHealth is intermittently spread through the Union, with internet access still limited or not possible for some citizens; also older generations and lower income persons do not have the same gains as others. However, through new technologies with the use of apps, the spread of eHealth may be a vehicle for younger generations that can help address issues such as mental health. In addition, eHealth could help bridge the gap for those living in rural areas or who require assisted living support through technologies for remote access.

These changes mean governments and payers can increasingly seek to integrate digital solutions for health systems. For some industries, an ever-increasing eHealth landscape can lead to new technologies, further research and innovation, more and better data and a greater understanding of the end-user. For patients whilst there are numerous advantages including greater access to their own data, new technologies for self-management and more ease of cross-border care, there are concerns over privacy as well as the patch-work application of eHealth across the Union which echoes health and social inequalities. These developments need to be taken into mind noting the application of the new GDPR which will have a notable impact on businesses, especially SMEs.

With greater focus on the use of data and the implementation of the new GDPR in May 2018 as well as pressure on the EU and national governments to take further action by civil society, the debate on data privacy, interoperability and further harmonisation will continue to dominate future discussions in the area. The EU is cautiously moving towards a greater eHealth Union although with numerous questions remaining on big data use, security and ethical implications, EU and national policymakers alike will need to work together to ensure the patient remains at the centre of any future eHealth initiatives.



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Health Policy Perspectives has been initiated by Anna Dé and Neha Dave, independent health policy consultants in London and Brussels, to provide overviews / updates on various Global and European health policy related topics.

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