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GDPR and the secondary use of health data

Report from EMA workshop held with the EMA Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP) on 23 September 2020

Introduction

The introduction of the [General Data Protection Regulation](#) (GDPR) in 2018 has created a new framework for the protection of personal data in the European Union. It is particularly relevant to healthcare, where technological advances and the increasing availability of data from a range of sources offer many opportunities for the further processing (or secondary use) of data in scientific research, medicine development and policy making. However, with these opportunities come legal, technological and digital skills challenges.

This workshop was set up to discuss these challenges and opportunities with patients, consumers, and healthcare professionals and to present the development of an EU-wide governance framework and a future code of conduct on processing personal data in the health sector. These and other initiatives such as EMA's Questions and Answers (Q&A) on the GDPR in secondary use of health data will ensure the full potential of big data in the health arena can be harnessed in a way that benefits EU citizens, while at the same time protecting their privacy. This report offers a high-level summary of the output from the workshop.

'Healthcare professionals have long been advocating the use of big data in the interest of our patients', Ulrich Jaeger, Co-Chair of HCPWP

Session 1 - Towards the European health data space

The workshop started with an overview of the various initiatives underway at EU level, including the European Health Data Space and the Joint Action to support the Health Data Space.

The [European Health Data Space](#) forms part of the European Commission's broader European Strategy for Data. Martin Dorazil from the European Commission explained that it will provide a GDPR-based framework to facilitate the exchange and use of health data and ultimately improve healthcare and research, innovation and policy making. The European Health Data Space will establish measures to guide data governance and data quality. It will also build an infrastructure to allow sharing of health

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data within the EU, by expanding existing initiatives such as the [European Reference Networks](#) for rare diseases and the eHealth Digital Service Infrastructure, and by launching new initiatives such as DARWIN EU. Finally, capacity-building will be pursued in various areas, such as digitisation of healthcare systems and boosting digital skills.

Mr Dorazil also informed participants about the EU4Health programme. Drawing on lessons learned from the COVID-19 crisis, EU4Health will ensure resilient health systems in the EU going forwards. The EU4Health proposal includes digital transformation and digital tools and services to support the European Health Data Space in building capacity and infrastructure.

Another EU project, the Joint Action on the European Health Data Space, was presented by Markus Kalliola from the Finnish Innovation Fund, SITRA. Due to start in February 2021, the mission of this proposal is to ensure that, in the future, EU citizens, communities and companies benefit from protected and secure access to health data, regardless of where the data are stored.

The Joint Action will propose a data governance framework for the European Health Data Space which will include guidelines on health data use in research and policy making, as well as on ethical, legal and social issues. It will also produce a data quality framework. Dialogue with stakeholders will be an important part of the strategy, providing insight into how to strengthen EU citizens' trust in data sharing and increase their capacity to engage with data.

'We need to demonstrate the added value of data sharing for patients and citizens', Nick Schneider, German Federal Ministry of Health

GDPR has put data protection high on the agenda. In terms of secondary use of health data and research, challenges exist due to the legal intricacies and differences in its interpretation between Member States. Nick Schneider from the German Federal Ministry of Health presented some of the work already done to examine these issues and to identify areas for European action, such as a study carried out by the EUHealthSupport consortium in consultation with stakeholders.

Acknowledging the importance of involving all stakeholders as early as possible, Dr Schneider emphasised the German EU Council Presidency's commitment to keeping up the momentum and moving the European Health Data Space forwards. As well as being involved in the preparation of the Joint Action on the European Health Data Space, the German Presidency is supporting the development of codes of conduct to facilitate cooperation between Member States. Such codes of conduct should minimise differences in GDPR interpretation and implementation and increase data quality, making the data 'findable, accessible, interoperable, and reusable' (FAIR). Finally, Dr Schneider flagged another important initiative open to stakeholders, namely a high-level conference '[Digital Health 2020 – EU on the Move](#)' on 11 November 2020.

The discussion following the first session highlighted the important contribution of patient, consumer and healthcare professional organisations in forming many of these EU initiatives. It was confirmed that pharmacies will play a key role in the further expansion of the eHealth Digital infrastructure. In addition, the eHealth Stakeholder Group has been set up as a forum for organisations to provide input into the discussion on the European Health Data Space. There will also be a new study into regulatory gaps which will include surveys of key stakeholders, including patient and healthcare professional organisations. Finally, there will be open and targeted stakeholder consultations when the legislative proposal for the European Health Data Space is prepared next year.

Session 2 - Update from the Big Data Steering Group

In the second session of the workshop, Nikolai Brun from the Danish Medicines Agency and co-chair of the Big Data Task Force presented the background to the workplan for the Big Data Steering Group, a joint collaboration between EMA and Heads of Medicines Agencies (HMA).

The Big Data Task Force was established to map the big data landscape, identify challenges and make recommendations on how to tackle these challenges. The [Big Data Steering Group](#) was subsequently set up to prioritise and implement these recommendations, as well as secure financing through the EC for these initiatives.

The first of these recommendations is the implementation of the DARWIN EU platform. Others focus on data quality and representativeness, data discoverability, EU network skills, and the capability of the network to analyse big data.

Dr Brun also underlined the vital role of collaboration in implementing the Big Data Steering Group recommendations, for example by working with international colleagues in other regulatory settings, such as the United States and Japan, but also with stakeholders such as patient and healthcare professional organisations, industry, and innovators.

'DARWIN EU should enable a learning healthcare system', Peter Arlett (EMA)

In his presentation, Peter Arlett of the EMA took the audience on a deep dive into the first of the recommendations of the Big Data Task Force, the DARWIN EU platform.

DARWIN EU stands for Data Analytics and Real-World Interrogation Network. It involves real world data, which are routinely collected health data from a variety of sources other than clinical trials. It is not a database but a network that will be supported by a third-party coordination centre and will link together researchers, public health organisations and other bodies that hold data. Key features are that the data will stay local and be queried remotely and exchanged data will be anonymous.

In the future, DARWIN EU should enable a 'learning' healthcare system, allowing almost real-time monitoring of the use, safety and effectiveness of medicines on the market. The main aim of the network is to support national and EU regulation of medicines, so that patients have faster access to innovative medicines to meet unmet medical needs, and to ensure safer and more effective use of medicines on the market.

Dr Arlett ended his presentation by highlighting how important close engagement with EU patient, consumer and healthcare professional organisations will be in developing DARWIN EU, promising to share further details of this collaboration in the coming months.

'Co-creation is key!', Marilena Vrana (European Heart Network)

Marilena Vrana from the European Heart Network presented the patients' perspective on big data. Patients generally have a high level of awareness of the potential of digital technologies and understand the benefits of data sharing. However, research funded by the European Heart Network has also identified a number of reasons why patients may not share their health data, such as concerns relating to privacy and data security and poor digital literacy.

The solution, suggested Ms Vrana, is co-creation. Patients and healthcare professionals should be involved from the outset to build trust and to ensure the data use is relevant, effective and adds value.

It is also vital that digitisation does not increase existing inequalities. Therefore, efforts should be made to address structural barriers by improving access to internet, increasing connectivity and boosting digital literacy to empower patients and the wider public to use digital innovations more confidently.

Challenges also exist at the level of academic research, according to the last speaker of the session, Ioana Agache, representing the European Academy of Allergy and Clinical Immunology. As an example, Dr Agache highlighted that patient-centred questions are addressed non-systematically and often only in the post-approval stage of a medicine's lifecycle.

Dr Agache also noted that a vast amount of data will become available in the near future, such as data from biometric sensors, genomic profiling, and medication use. Faced with the four Vs of big data (volume, velocity, variety and veracity), the challenge will be to pick the right data and ensure the research remains relevant and allows good clinical management.

The discussion at the end of session 2 underlined the importance of international collaboration in all the initiatives presented in the workshop. A 'road map' for international collaboration on real world evidence in medicines regulation is being developed and an international summit will be held next summer to reach agreement on guidelines and data quality principles at an international level.

Finally, the discussion highlighted the essential collaboration with patient and healthcare professional communities, and their involvement in the governance and access of data going forwards. Emphasis was also placed on the importance of co-creation and early involvement of public and patients to ensure that the tools are easy to use for people with different levels of digital skills and education.

Session 3 – EMA's survey on GDPR secondary use of data for medicines and public health purposes

EMA's initiative to develop a Q&A document aims to help those using healthcare data for secondary purposes to better navigate the GDPR. In preparation, a targeted stakeholder consultation was held earlier this year to gain greater insight into the concerns and questions relating to GDPR that patient and healthcare professional organisations may have. Sabine Brosch, EMA's Data Protection Coordinator for the Data Analytics and Methods Task Force, took the workshop participants through some of the key input provided by stakeholders.

In general, patients recognise the importance of data in advancing health research, and they appear to accept the secure sharing of their data. However, it is important to achieve the right balance between protecting confidentiality and sharing data. Stakeholders also stressed the importance of the Q&A being comprehensible for a lay, non-expert audience.

The survey further identified specific questions relating to the following key topics: secondary use of health data, the legal basis for processing personal data, patient rights, pseudonymisation, transparency, data retention and registries. In particular, there were many questions on anonymisation and pseudonymisation. Other key areas flagged by the survey respondents included how long data will be stored and how the GDPR applies to patient registries.

EMA's Assistant Data Protection Officer, Orsolya Eotvos, took the audience through the background to the draft Q&A and discussed its aims and the next steps, which will be closely coordinated with the European Commission's ongoing initiatives.

During the discussion session, many comments emphasised the need to clarify the various meanings of consent. Furthermore, the need to balance accessibility and clarity of information for a lay audience was highlighted.

Conclusion

'The protection of patient rights is critical to ensure patients can trust the system put in place', Kaisa Immonen, Co-Chair of PCWP

The workshop provided valuable insight into the European Commission's work on the EU Health Data Space and the development of an EU governance framework and codes of conduct. Participants also learnt more about EMA's work on the DARWIN EU initiative and the [joint Big Data Taskforce](#) recommendations to ensure data are managed and analysed within a secure and ethical governance framework. Finally, throughout the presentations, it was clear that efforts are being made on all fronts to hear and heed the voices of patients, consumers and healthcare professionals from the outset. The important contributions made by participants during the discussion sessions further ensured that this was an informative and useful workshop.