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LIFE SCIENCE LECTURES

EVENT RECAP

EPISODE EIGHT – "THE EUROPEAN HEALTH DATA SPACE (EHDS): YOUR JOURNEY FROM REGULATION TO IMPLEMENTATION''

On 2 September, EUCOPE – the European Confederation of Pharmaceutical Entrepreneurs hosted **the eighth episode of its Life Science Lectures webinar series**. The focus of the webinar, titled: *"Implementing the European* Health *Data Space"* was to delve into the implications of the secondary use of health data outlined in the EHDS legislative text, with the aim to shed light on how these provisions could impact pharmaceutical companies and what is to expect from its implementation phase.

The EHDS Regulation aims to establish the first of its kind health-specific data-sharing ecosystem that sets out rules, common standards and practices, infrastructures and governance framework for the use of electronic health data. It should empower individuals through increased digital access to and control of their electronic personal health data, at national level and EU-wide. In doing so, it also fosters a single market for electronic health record systems. In addition, it also provides a trustworthy and efficient set-up for the use of health data for research, innovationand policymaking.

After the opening remarks provided by **Alexander Natz**, **Secretary General at EUCOPE**, the discussion was kicked off by **Leander Vranken, Senior Policy Officer at EUCOPE**, who underscored that the basic set-up behind the EHDS remained unchanged after EU lawmakers agreed on a legislative text. Health data holders of electronic health data are required to make their data available to health data access bodies (HDABs), who will make it available in a secure platform to data users obtaining a permit. Only data users with a permit can download anonymous data from the secured platform.

Leander elaborated on a variety of shared objectives of the secondary use of health data in the EHDS such as fostering innovation to develop new healthcare solutions. He emphasized that ''*high quality data sets can now be accessed for research and innovation purposes*''. Especially small and medium sized enterprises should benefit from the secondary use, but also the rare disease community. He explained that ''*rare disease data is already rare by default and having one common access point to rare disease data will hopefully also boost research being done on the basis of rare disease data*''. Next to facilitating the collection of real-world data (RWD) for real world evidence generation, it was also underlined that by enhancing access to health data for

R&D purposes can also increase a competitive advantage internationally. How the great promise of EHDS will be realised will largely depend on its implementation.

While **Zinovia Chatzidimitriadou**, **Senior Managing Associate at Sidley Austin**, elaborated on the data sets in scope for secondary purposes such as electronic health records (EHRs), registry data, genomic data and clinical trials data, and what exactly constitutes a 'data holder' and 'data user', she also acknowledged the importance of having a common understanding of how these data categories are defined and whether certain data sets are even in scope. According to Zina, this is particularly important regarding the obligations on non-European electronic health records which may not be permitted to be shared with EU regulators or other EU parties. This could be so especially with mixed data sets from, e.g. biobanks containing data from non-EU subjects. She adds that it is equally unclear whether and to which extent the regulation applies to drug sponsors or data holders outside the EU. On the topic of anonymisation, there was uncertainty expressed whether data holders or HDABs are responsible and who bares the cost.

Zina continued to explain that the pharmaceutical industry was relieved to see a new article in the final text that sets out provisions about how IP rights and trade secrets could be identified and protected. But she also underscored the important role of the HDABs and their responsibilities to protect relevant data. ''*HDABs act as gatekeepers to assess what constitutes commercial and confidential information, and data holders do not have the final say or ability to refuse assess to their data*'', she concluded.

On this topic**, Federico Pisani, Senior Government Affairs and Policy Specialist at Illumina**, replied that ''*striking the right balance between innovation and trust in the framework is one of the most difficult things that has been tried during the legislative process*''. He emphasized the importance of Commission guidance on still a number of confusing grey areas and continued to explain that enough means and resources should be allocated to develop capabilities and capacity for both technical and legal levels to be able to address the volume of requests that the HDABs will face in the future. However, Federico Pisani underlined that if the improvements will amount to enough IP rights and trade secret safeguards, it can represent an incentive for companies to share high value sensitive data and accelerate the entire engine of drug development, personalized medicines, AI and healthcare solutions.

Throughout the discussion, there was a shared recognition for Commission guidance. The participants also discussed the new provision added to the legislative text that allows natural persons to opt out at any time from the processing of personal electronic health data relating to secondary use. However, concerns were expressed regarding the possibility for Member States to introduce stricter measures and safeguards for the data categories referred to in Article 33(1) points (e), (ea), (fa) and (m) (genomics / genetics data etc) and that this could potentially lead to an ''opt-in" through the back door, risking scientifically biased data sets. In addition, uncertainties were also expressed regarding data transfers to third countries as the storage and processing of personal health data must take place on EU territory.

On implementation of the EHDS Regulation, **Owe Langfeldt, Policy Officer at the European Commission, Directorate-General for Health and Food Safety, Digital Health Unit**, recognized that the regulation is written "*in a quite high-level way*" and that there is a lot of implementation work and guidance needed. He underscored the importance of the TEHDAS2 Joint Action Initiative that will be key in providing further guidelines and technical specifications. It will also be the key platform to generate input, as many details regarding the implementing or delegated acts will be informed by TEHDAS2 (and other projects / joint actions).

On the legal side of the discussion, Owe Langfeldt continued to explain that there are numerous empowerments highlighted in the legislative text for the Commission. 13 implementing acts (of which 5 with deadline), 2 delegated acts regarding the secondary use of health data alone. He underscored that some implementing acts regarding the secondary use need to be set out by two years from entry into force already, which would then leave two additional years before the secondary use of health data in EHDS becomes applicable. Those two years will then be the time for actually building the necessary infrastructures, processes etc.

As to the question *"how can the industry feed into the process?"*, Owe Langfeldt explained TEHDAS2 will organize public consultations on the milestones leading to their deliverables. There will be three waves of public consultations, and more information will be provided in due course on how the industry can contribute. However, the first TEHDAS2 stakeholder forum is already scheduled on 31/01/2025 and on the implementing and delegated acts, he confirmed the usual upcoming public consultations on draft acts.

Regarding previous remarks made on the functioning of HDABs by Federico Pisani, Owe Langfeldt confirmed that although Member States will have to set up their own national HDABs following national acts, the European Commission will support capacity building in the Member States. The Commission will monitor the setting up of HDABs when issuing the progress reports.

Concluding on a positive note, Federico Pisani underlined the potential benefits of putting in place an initiative such as the EHDS. Especially in terms of rising awareness in Europe regarding the need of greater competitiveness for the European Union. He underlined the importance of ambitious initiatives that can provide a competitive advantage for companies and researchers operating in Europe, but he also stressed the key challenge of insuring harmonized implementation. EUCOPE believes it is essential that the EU remains globally attractive for investments, to encourage innovation and access. Achieving this goal requires a harmonized approach to the implementation of the EHDS regulatory framework.

Watch the full recording on EUCOPE YouTube Channel here