ENC
NEWS FROM BRUSSELS

- **HERA signs agreement with ECDC and with EMA to strengthen cooperation on health emergency preparedness and response.**
- **Commissioner Kyriakides welcomes Council vote on Medical Device Regulation extension.**
- **Czech stakeholders: Secondary use of health data still needs fine-tuning**
- **WHO Europe's Upcoming Webinar**

HERA SIGNS AGREEMENT WITH ECDC AND WITH EMA TO STRENGTHEN COOPERATION ON HEALTH EMERGENCY PREPAREDNESS AND RESPONSE

The COVID-19 pandemic demonstrated how essential it was for all key players to work together fast, to prepare and respond to health-care related threats. **The European Commission's Health Emergency Preparedness and Response Authority (HERA) was created to become a crucial centrepiece of a strong European Health Union and ensure the exchange of information on threat assessment, advanced research and development, and other priorities relevant for medical countermeasures.**

On 14th March, HERA and the European Centre for Disease Prevention and Control (ECDC), as well as the European Medicines Agency (EMA), have agreed to strengthen cooperation and to coordinate their work in support of health emergency preparedness and response in the area of medical countermeasures. **The agreed working arrangements will help ensure that there are no unnecessary overlaps and that resources are used more efficiently.**

HERA and ECDC identified the following areas of collaboration:

- **Intelligence gathering and assessment of health threats** relevant to medical countermeasures
- **Modelling, forecasts and foresight activities** relevant to medical countermeasures
- **Promoting advanced research and development** of medical countermeasures and related technologies
- **Strengthening knowledge in preparedness and response** related to medical countermeasures
- Contribution to **reinforcing the global health emergency preparedness and response architecture**.

HERA and EMA identified the following collaboration areas:

- **Assessment of serious cross-border threats to health** relevant to medical countermeasures
- **Identification of medical countermeasures and priority research areas**
- **Identification of vulnerabilities and strategic dependencies within the Union related to the development, production, procurement, stockpiling and distribution of medical countermeasures**
- **Coordination,** in relation to medical countermeasures, in the event of recognition of a public health emergency
- Contribution to **reinforcing the global health emergency preparedness and response architecture.**

You may find more information here.

COMMISSIONER KYRIAKIDES WELCOMES COUNCIL VOTE ON MEDICAL DEVICE REGULATION EXTENSION

The Medical Devices Regulation entered in force the 26 May 2021. It provides for a transition period until 26 May 2024. This transition up to now has been slower than anticipated and healthcare systems in the EU are facing a risk of shortages. At the EPSCO Council on 9 December 2022, EU Health Ministers called on the Commission to swiftly submit a proposal to extend the transition period of the Medical Devices Regulation.

On March 7th, **the Council of the European Union has adopted the Commission's proposal to give notified bodies and manufacturers more time to certify medical devices and thereby mitigate the risk of shortages.** This follows the positive vote by the European Parliament last month. The legislative proposal provides a longer transition period to adapt to new rules foreseen under the Medical Devices Regulation, ensuring continued access to medical devices for patients in need.

Welcoming the adoption by the Council, **Commissioner for Health and Food Safety, Stella Kyriakides**, said:

> *"I would like to express my gratitude to the European Parliament, the Council, and the Swedish Presidency in particular for swiftly agreeing on our proposal to extend the transitional periods of the Medical Devices Regulation. This is an important step that will help address the short-term difficulties Member States are facing and ensure a continued access to needed medical devices for patients in the EU.*
>
> *This revised timeline will provide more flexibility to industry for the ongoing certification of needed medical devices and reduce short-term risks of shortages. This will ensure access for patients most in need without jeopardising their safety. It is important to recall that only devices that are safe and for which manufacturers have already taken steps to transition to the Medical Devices Regulation can benefit from this additional time. Patient safety will always be paramount.*
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> *The Commission, together with Member States, notified bodies and the medical industry will continue to work on additional measures to address the structural problems and identify medium and long-term solutions. Ensuring the transition to the new Regulations must be our collective priority to safeguard patient safety and foster innovation in Europe."*

Following the Council's positive vote, the proposed amendment to the Medical Devices Regulation was expected to be formally adopted by both the European Parliament and the Council on 15 March 2023. It will be soon published in the Official Journal and enter into force on the day of its publication.

The Commission will work together with Member States and all stakeholders to provide the necessary support to implement this legislative amendment.

You may find more information here.

BENEFITING FROM THE CZECH EXPERIENCE: SECONDARY USE OF HEALTH DATA

Re-using health data for 'secondary use' is a crucial component of the European Health Data Space (EHDS), which is the proposed legislative framework to govern health data across the bloc. **Secondary use includes health records, public registries, clinical studies, research questionnaires, and social, administrative, genetic, genomic or biomedical data such as biobanks.** For its advocates, secondary use of health data could make it easier to develop new drugs, set policy goals, manage epidemics or improve healthcare quality. However, concerns remain over patients' consent and access. **This form of 'data recycling' is already up and running in the Czech Republic.**

One example is the 'Vitakarta' project of the Czech Occupational health insurance company (OZP) which uses an app and a smartwatch to help insured people collect their health data and use it for various purposes.

> *"The app monitors prevention, allows us to check the reported care and reward the quality of care. It automatically watches for inappropriate drug interactions and can identify chronic conditions,"* said **Eva Švecová, head of the OZP's strategies department**, during a recent debate.

Jaroslav Dušek, director of the Institute of Health Information and Statistics of the Czech Republic (IHIS) added that anyone who meets the conditions can apply for available statistical data, i.e. research centres, companies and other entities. Dušek also emphasised that the Czech Republic is said to be the most advanced in sharing laboratory data on COVID-19.

But many things have yet to be fine-tuned, especially the completion of the National Health Information System (NHIS) and the lack of usable data, which remains a significant challenge.

> *"We are talking about data sharing, and we are located in a country that can share only 30% of the data because it has no more than that collected centrally in a parametric way,"* **Dušek pointed out.**

Paper documentation is still prevalent in Czech clinics, for instance, leaving room for more efficient standardisation and data collection in the country's healthcare sector.

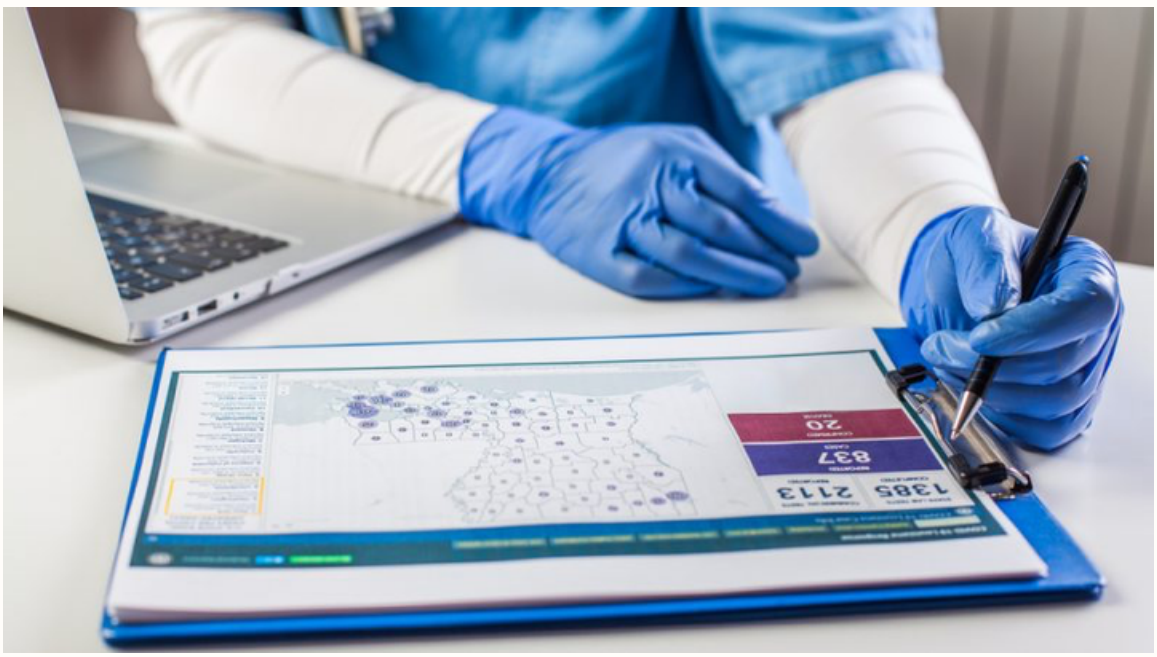
According to **Ladislav Švec, director of the Health Insurance Office, the EU's initiative focusing on data** – the **EHDS** – could "push" the Czech Republic forward and grow its IT sector. Moreover, EU funds could support the creation of the necessary infrastructure. **The EHDS is backed by a budget of €800 million coming from different EU funding programmes such as the EU4Health, Digital Europe, and Horizon Europe.**

The advantage of pan-European data sharing is noticeable – more data from more countries means a better picture of overall trends. While the Commission presented the EHDS proposal in May 2022, talks between EU ministers and MEPs have yet to start. There are several points on which the states have different views, according to **Petr Čermák, who has been involved in the negotiations since the beginning on behalf of the Czech Permanent Representation to the EU.**

The nature and extent of the powers of the Health Data Access Body, which will grant and control access to the data, has not been decided yet. **Data for secondary use would only be shared in aggregated, anonymised and pseudonymised forms.**

For liberal Czech MEP Ondřej Knotek (ANO, Renew Europe) some lawmakers in the European Parliament are "opportunistically calling, in the name of fighting for freedom" for some amendment where the patients are supposed to give their consent before sharing data. Debate speakers responded that this would limit the volume of data collected, and as such risk undermining the point of secondary uses. Another outstanding issue is who should have access to the data, apart from researchers. **Manufacturers of novel drugs, represented in the Czech Republic by the Association of Innovative Pharmaceutical Industry (AIFP), argue that their data from clinical trials is no longer enough and that without access to other statistical data, they will lose out in the global competition.**

But the industry is not the only one interested in data. **Jakub Dvořáček, Czech deputy health minister, believes that no one should be barred from accessing the data, whether it is academics, patients, hospitals, insurers or industry – once the purpose of using the data is made clear.** However, even secure data sharing is not without risk regarding misinterpretation of such data. According to **Dvořáček**, raw data without a verified interpretation can be misused, which he cautioned is something to watch out for in the EHDS.



You may find further information here.

W.H.O EUROPE'S UPCOMING WEBINAR

The World Health Organization (WHO) Europe has announced an interesting webinar opportunity to be held the 17th of April on the subject: **"COVID-19 Vaccination: Why it Matters Now More Than Ever."** As we all know, the COVID-19 pandemic has impacted the world in unprecedented ways, and vaccination has been identified as one of the key tools to bring the pandemic under control. This webinar will provide an in-depth analysis of the current state of COVID-19 vaccination efforts and will explore the challenges and opportunities that lie ahead.

The webinar is open to anyone who is interested in learning more about COVID-19 vaccination efforts. It is particularly relevant for healthcare professionals, policymakers, researchers, and other stakeholders who are involved in the fight against COVID-19.

The webinar will take place on April 17th at 14:00-15:00 CEST. To register, participants can visit the WHO Europe website or follow the registration link provided by WHO Europe: bit.ly/DDH-equity.