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WEEKLY EU HEALTHCARE NEWS UPDATE

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EUROPEAN COMMISSION TO PROPOSE DELAY TO MDR IMPLEMENTATION AMID SUPPLY SHORTAGES

During the meeting of the Employment, Social Policy, Health and Consumer Affairs Council on 09 December, EU Health Commissioner, Stella Kyriakides, informed that proposals to prolong the transition period for the implementation of the European Union's (EU) Medical Device Regulation (MDR) will be submitted in early 2023. The extension will require an amendment to the law, which the Council and Parliament should approve.

Commissioner suggested extending the deadline for higher-risk class III and class IIb devices to 2027, and the deadline for lower-risk class I and class IIa devices to 2028. In the EU market, the MDR first came into effect in 2021 with an initial three-year transition period, which was delayed by one year in 2020 due to the COVID-19 pandemic. According to her, the transition to the new rules was slower than expected. Additionally, there were supply shortages of life-saving medical devices for patients on the global market, affected both by the pandemic and the war in Ukraine. Despite those efforts, Kyriakides warned that around 23,000 devices and 1,500 IVDs certified under the previous directive have not yet transitioned to the new regulation and most probably would expire in May 2024/ May 2025, respectively.

“Patients rightly expect to have safe and high-quality medical devices, Kyriakides stated. European Council members expressed support for a proposal by the EC to delay the transitional deadlines for medical devices under the Medical Devices Regulation (MDR).

Source: https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_22_7627

PACT FOR SKILLS: A NEW PARTNERSHIP IN THE HEALTH SECTOR

With the support of the Commission, the European Health Management Association (EHMA) and other health-related partners have initiated a large-scale skills partnership to improve the skills of the EU health workforce, as well as equip them with new capacities. The Pact for Skills is one of the main initiatives under the European Skills Agenda under which 14 large-scale partnership initiatives in different industrial sectors are implemented.

The data demonstrate that 15 million people work in health occupations, representing over 7% of the EU workforce and almost 4% of the EU population. Hence, this partnership will develop and implement a European skills strategy for these health workers and pilot training for health professionals, with a particular focus on green and digital skills.

As Commissioner for Jobs and Social Rights, Nicolas Schmit said: “The new partnership brings together different actors to map out the skills that are in demand”. In his opinion, a solid investment in continuous professional development is required to upskill the existing workforce and support the training of the next generation of health workers. In her turn, Commissioner for Health and Food Safety Stella Kyriakides opined that „health professionals are the beating heart of our health systems”. The tough pandemic has been continuously proving it.

Source: <https://ec.europa.eu/social/main.jsp?langId=en&catId=89&furtherNews=yes&newsId=10484>

CYBER EUROPE 2022: IS THE EU HEALTHCARE SECTOR CYBER HEALTHY?

The European Union Agency for Cybersecurity (ENISA) releases the after-action report of the 2022 edition of Cyber Europe, the cybersecurity exercise testing the resilience of the European Healthcare sector.

‘Cyber Europe’ exercises simulate significant cybersecurity incidents that develop into pan-EU crises. These simulations allow for the in-depth analysis of cybersecurity issues, as well as the handling of challenging business continuity and crisis management situations. The technical and operational cooperation mechanisms at the EU level were successfully tested by participants. The response and resilience plans were also put to test locally. Furthermore, the exercise provided an opportunity for stakeholders to receive technical skills training. Participants gained high-level engagement in the multiple elements of cooperation required to resolve the problems presented in the scenario.

More than 900 cybersecurity experts from over 29 countries both from the EU and the European Free Trade Association (EFTA), were in action to monitor the availability and integrity of the system. EU agencies and institutions, including ENISA, the European Commission, the CERT of EU Institutions, bodies and agencies (CERT-EU), Europol, and the European Medicine Agency (EMA) were among the participants. Since 2010 ENISA has already organized five pan-European cyber exercises. It normally takes place every two years; however, the 2020 edition was canceled because of the pandemic.

Source: <https://www.enisa.europa.eu/news/is-the-eu-healthcare-sector-cyber-healthy-the-conclusions-of-cyber-europe-2022>

Thank you for your attention!

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