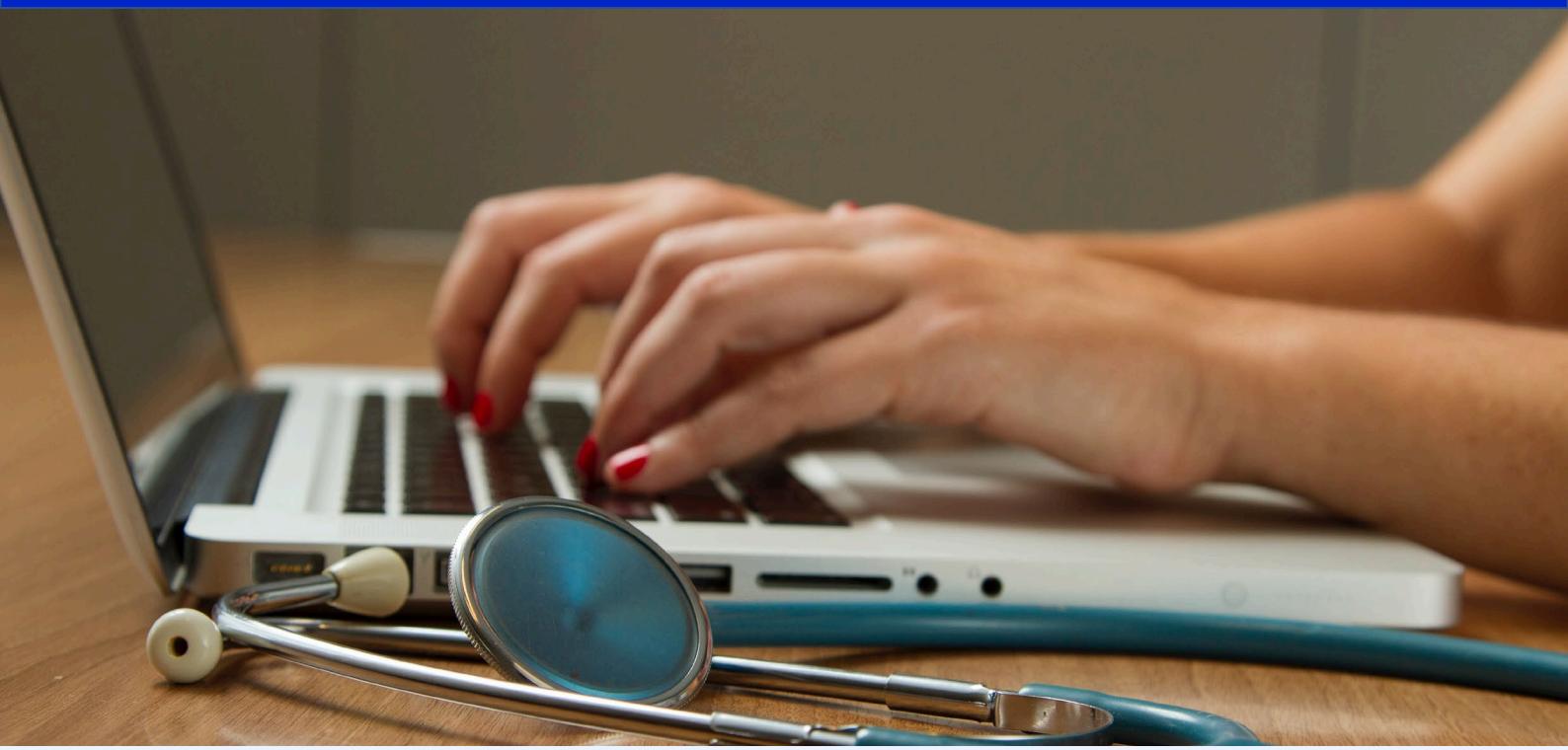

Dear colleagues

We are pleased to share with you the November edition our Monthly Bulletin with the outcomes of the Board of Directors meeting on 17 November 2022. This was first meeting of the Board, previously the Executive Committee, following the adoption of our updated statutes last month.

The Board adopted a letter to the European Commission on the EU's Medical Devices Regulation and received an update on the situation of President of the Turkish Medical Association, Prof. Dr Şebnem Korur Fincancı, who remains in pre-trial detention following a media interview calling for an investigation of the possible use of chemical weapons. We continue to ask you to take action to raise awareness among your national governments and especially the ministries of health.

We invite you to read about this and much more in this month's Bulletin.

Dr Christiaan Keijzer
CPME President

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Board of Directors meeting – 17 November 2022

CPME News

Monitoring

Internal Affairs

Dates for General Assembly November 2024

- The Board approved the dates of 7-9 November 2024 for the General Assembly which will take place in the Netherlands.

Policies

Global Alliance for Tobacco Control (GATC)

- The Board decided to choose the free Network Participant membership category in the rebranded Global Alliance for Tobacco Control (GATC), formerly known as the Framework Convention Alliance (FCA).

The rebranding has made some modifications to the strategic direction, governance, and membership structure. This means that not all the membership categories will be free anymore.

Rome Declaration

- The Board decided to defer a decision on endorsement of the Rome Declaration on access to affordable medicines to the next Board meeting in December.

Medical Devices Regulation

- The Board decided to adopt a letter to the European Commission and make it public.

More details about the letter are provided on Page 9.

Digital Health projects

- The Board agreed to politely decline an invitation to join the health professionals' advisory group of Label2Enable project

The Board was informed that following CPME's decision not to join the project at an earlier stage, the invitation was extended to join in an advisory function. The Board reviewed the high workload on digital health and took note of the fact that EJD was involved in the project. Doctors would therefore be represented, even in absence of CPME.

CPME Statement on Climate Change

- The Board took note that the CPME statement on climate change and health has been published and already cited by the key Brussels news website Politico.

It will be shared among the membership, who may wish to share it in their respective countries. The draft CPME policy on climate change and health has been re-opened for comments and will be on the Board agenda again in March 2023.

Arrest of TMA President Prof. Dr. Şebnem Korur Fincancı

- The Board was updated on the situation of President of the Turkish Medical Association, Prof. Dr Şebnem Korur Fincancı, who remains in pre-trial detention..

A first hearing is planned for early December at which she may be released. However, there is also action to replace the Executive Committee of the TMA. CPME continues to disseminate its statement at EU level and coordinate action in a forum coordinated by Physicans for Human Rights, including WMA and the Norwegian Medical Association. Several CPME members have brought the issue to the attention of national policymakers.

Digital leadership course

- The EC took note of a proposal to continue with the leadership course in 2023 in cooperation with EJD and the Copenhagen Institute on Futures Studies (CIFS).

The Board confirmed that there is general interest for CPME to act as a portal to facilitate members' participation, however there should be no financing commitment from CPME. If this is feasible for the partners, the proposal can be further elaborated.

The European Health Data Space must respect medical ethics and national competence

CPME has published a position on the European Commission's proposal for the European Health Data Space (EHDS), raising concerns about medical ethics, the burden on doctors and the national competence of Member States.

CPME believes that the EHDS can help improve the quality of healthcare to patients and stimulate the availability of health data for scientific research. At the same time, the proposal will touch upon the very core of the patient-doctor relationship, defining the framework for patient-doctor confidentiality, patient privacy and patient-doctor trust.

In order to respect existing structures in Member States, European doctors urge that there should be national discretion with regard to the implementation of ethical safeguards. This includes ethical requirements in relation to the secondary use of health data, such as the duty to obtain patients' consent or to involve ethics committees.

CPME is also concerned about the implementation costs of the proposal, and whether the EHDS can maintain a high level of protection of fundamental rights, including personal data, with sound procedures that respect human dignity, autonomy, and privacy of individuals. Strong obligations for software manufacturers for interoperability and usability must be made mandatory. A better assessment of the legal, social, technical, and financial consequences for doctors, other healthcare professionals, patients and the provision of healthcare is needed.

Importantly, legal accountability on the EHDS must not go beyond the doctors' competency or responsibility.

Action on climate change is a necessary and immediate priority for the healthcare sector

CPME published statement on climate change. These are European doctors' key recommendations to the EU, its member states, and local level policymakers, as healthcare systems must become carbon neutral in the future:

1. Ensure that the targets of the EU climate law will be met by reducing emissions of greenhouse gases through more sustainable energy management, transport, and food choices which also result in improved health.
2. Update the EU ambient air quality standards to fully align the new WHO guidelines and the latest scientific evidence on the health effects of air pollution by 2030 at the latest.
3. Strengthen the climate resilience of health systems, preparing for consequences of extreme weather events and rising numbers of migrants, increased need for mental health support and health inequalities.
4. Introduce regulatory requirements to promote sustainable procurement of pharmaceutical products, food, medical devices, and other hospital equipment, ensuring low-carbon, sustainable supply chains.
5. Increase awareness on the link between climate change and health risks in all policy areas.
6. Ensure that current and future healthcare professionals are trained to inform about the health impacts of environmental and climate change and treat patients affected by the consequences of climate change, including changing disease panoramas.

Finally, we call on all European doctors to lead by example on climate issues.

European doctors urge EU to restore balance in pharmaceutical sector

CPME has published a position on the revision of the European Union's general pharmaceutical legislation, urging the EU to restore balance to the pharmaceutical sector in the interest of patients.

Our position outlines four areas which the European Commission should give priority to:

- improve availability and ensure affordability of medicines;
- ensure more resilient supply chains;
- review current system of incentives to address unmet medical needs;
- ensure safety and quality of medicines.

Given the unequal access to medicines in the European Union, European doctors propose that pharmaceutical companies should be obliged to launch their products in all Member States. Linked to this, there is a need for a balanced and proportionate system of conditional incentives. The current system based on intellectual property rights needs to be reshaped in the public interest to be truly patient-centred. A high degree of transparency should be a prerequisite for obtaining or benefiting from any form of incentives.

To avoid the increasing number of advanced medicinal products entering the market with limited information on safety and effectiveness, the revised legislation should limit the use of accelerated and conditional procedures. They should apply only when no other alternative is available, or when quality of life is severely affected. To benefit from faster approval, medicine producers should be subject to strict obligations and requirements.

For the effective tackling of antimicrobial resistance and development of new antibiotics, CPME believes that market-based regulatory incentives, such as transferable exclusivity extensions, should be avoided.

Letter asking European Commission to ensure availability of medical devices in Europe

CPME has sent a letter to the European Commission urging it to consider all necessary measures to avoid putting the health of European patients at risk. An internal survey showed that doctors are already struggling with shortages that could become much more serious in the near future.

One of the main reasons for these disturbances is the slow implementation of the Medical Devices Regulation (MDR) 2017/745 and the limited capacity, or even lack, of notified bodies.

If no other solution to increase the capacity of Notified Bodies and to make economic operators comply with MDR rules can be found, CPME urges that legislative steps must be considered. This includes permitting continued use, beyond what is currently foreseen in the Regulation, of selected classes of medical devices which do not present unacceptable health risks under the Council Directives 90/385/EEC and 93/42/EEC certificates. This may be permitted for a limited period of time until the MDR certification is processed.

At the same time, recognising that high risk and invasive devices should remain subject to the more stringent certification foreseen by the new Regulation, a blanket extension for all classes should be avoided.

e-Evidence proposal: CPME joins call to improve fundamental rights protections

CPME together with EDRi (European Digital Rights) and twenty-two other organisations, belonging to European civil society groups, associations of media, journalists and of internet service providers, professional and healthcare associations, partnered up in an informal coalition to urge the co-legislator to revise the latest compromise amendments on the proposal for an e-Evidence Regulation.

The Coalition Letter stresses that, without substantial improvements, the system of cross-border access to data in criminal matters foreseen by the latest political trilogues risks to severely undermine fundamental rights, including press and media freedom, the rights of the defence, the right to privacy and medical patients' rights. It would also fail to provide legal certainty for all stakeholders involved in the process.

CPME's key concern relates to immunity and privileges [Article 5(6c) of the compromise]. This provision allows a European Production Order to produce traffic and content data without a mandatory requirement to waive privileges according to national law. This basic safeguard cannot be jeopardised in a democratic state. This requirement – need to waive privileges according to national law before producing traffic and content data - cannot be made optional.

European Doctors and Veterinarians tackle antimicrobial resistance together

To mark European Antibiotic Awareness Day 2022, CPME and the Federation of Veterinarians of Europe (FVE) highlighted their continuous commitment to spearhead the fight against antimicrobial resistance together. Data released by the ECDC on 17 November estimates that AMR is the direct cause of an increasing 35,000 deaths annually in the EU/EEA. Full press release is available here.

Awareness week on alcohol related harm 2022

On 28 November – 2 December, CPME supports and participates in the European awareness week on alcohol related harm. It aims to remind policymakers that two people a minute die in Europe because of the region's uniquely high level of alcohol consumption, while millions more suffer ill-health, violence, injury, job loss, and countless other harms. It will also offer them some policy recommendations. Please find more about the annual campaign here.

Coalition for Vaccination conference

On 17 January, CPME and the other Coalition for Vaccination co-chairs will organise a conference in Brussels to present the results of the EU co-funded IMMUNION project which is coming to an end in March 2023. The event also aims to discuss the future of the Coalition with the European institutions.

Registration is available here.

Patients, Principles and Ethics

Meeting of the Subcommittee on Human Rights discusses case of Şebnem Korur Fincanci

On 14 November, the European Parliament's Sub-Committee on Human Rights heard Mr Yaman Akdeniz, Professor of Law at the Human Rights Law Research Center, Faculty of Law and Pro Rector for the Istanbul Bilgi University, who mentioned the case of Şebnem Korur Fincanci, the President of the Turkish Medical Association, as an example of the pressure faced by civil society. Prior to the meeting, the CPME statement was sent to MEPs. A recording of the meeting is available here.

UK new initiative: NHS pays for patients' energy bills in winter pilot to cut hospital admissions

The new initiative of the National Health Service of the UK targets low-income patients with respiratory conditions and aims to save the NHS money by taking pre-emptive action and paying patients' winter energy bills in a bid to cut hospital admissions.

EU Political Outlook

EU Budget for 2023 adopted

The EU Budget for 2023 totalling €186.6 billion was adopted by the European Parliament on 23 November following intense negotiations between the Parliament, Commission and the Council. The 2023 Work Programme of the EU4Health programme has a budget of €735,8 million, including €242 million for Health Emergency Preparedness and Response Authority (HERA) and €26 million for the infrastructure and governance of the EHDS. Funding for research and innovation was among the disagreements between the institutions. The Parliament defended €663 million in cuts to the R&I programme Horizon Europe proposed by the member states.

G20 Bali Leaders' Declaration

The Leaders of the G20 met in Bali on 15-16 November and reaffirmed their commitment to cooperate and address serious global challenges and multidimensional crises. In the field of health, the Leaders of the G20 committed to implement the One Health approach, to promote a healthy and sustainable recovery which builds towards achieving and sustaining Universal Health Coverage under the SDGs, and to continue collaboration between Finance and Health Ministries for pandemic prevention, preparedness and response measures and capabilities.

The Pact for Skills expands to 1,000 members as it marks its second anniversary

On the second anniversary of its launch, the Pact for Skills achieves an important milestone growing to 1,000 members, including large multinational companies, SMEs, local training providers, and chambers of commerce. The Pact is a central element of the European Skills Agenda and aims to empower people to make the most of the green and digital transitions and the economic recovery through reskilling and upskilling strategies.

Enforcing EU law for a Europe that delivers

The European Commission presented the 'Enforcing EU law for a Europe that delivers' Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. In the field of health, it shows that:

- Regarding the Health Technology Assessment Regulation to improve EU patients' access to innovative technologies in the area of health, the Commission published a rolling plan to support national authorities, health technology developers and stakeholders in implementation of this legislation once it starts to apply in 2025.
- Regarding cross-border healthcare and since some Member States incorrectly transposed EU rules on patients' rights into national legislation, the Commission opened EU Pilot processes to swiftly improve the access to safe and high-quality cross-border healthcare in these countries.

Professional Practice and Health Systems

WHO, members of the World Health Professions Alliance sign new memorandum of understanding on health workforce priorities

The World Health Organization (WHO) signed a memorandum of understanding with the five members of the World Health Professions Alliance (WHPA): FDI World Dental Federation (FDI), International Pharmaceutical Federation (FIP), International Council of Nurses (ICN), World Physiotherapy, and World Medical Association (WMA). The new MoU reflects the importance of investing in the health workforce and universal health coverage through a multi-stakeholder integrated approach and provides a framework for joint action between the five organizations and the WHO to contribute to reinforcing national and regional health systems and services.

Health system performance assessment: A primer for policymakers

The European Observatory on Health Systems and Policies, together with WHO, launched a new Policy Brief during the European Public Health Conference in Berlin on 11 November. This new policy brief highlights the importance of assessing the performance of a health system effectively through the Health System Performance Assessment Framework for Universal Health Coverage.

EC Conference on Health Security in the EU

On 22-23 November, the European Commission brought policymakers, public health experts, healthcare professionals and patient representatives together in Luxembourg to discuss COVID-19 lessons learned and how to ensure a stronger EU Health Security Framework to be prepared for future health threats. Recordings are available here.

Pharmaceuticals and Healthcare

EP Debate on medical devices

The European Parliament discussed the review of the Medical Devices Regulation in the presence of Health Commissioner Stella Kyriakides. MEPs praised the objectives of the MDR and its importance in ensuring high standards of patient safety in Europe. They recognized that other factors, apart from the implementation of MDR, such as Brexit, the COVID-19 pandemic and supply dependencies, may contribute to the current problems with the availability of medical devices in Europe.

Some raised the issue of the impact of MDR not only on patient safety, but also on the economy and the med tech industry in Europe. Most called for pragmatic solutions to ensure the continuity of healthcare provision and the safety of citizens and patients. The Health Commissioner said the European Commission is currently examining legislative measures, including amendments to the MDR, and will present them to EU health ministers at the next EPSCO Council meeting on 9 December. Commissioner Kyriakides added that the situation is indeed very worrying and that the actions being taken were in direct response to calls from MEPs, Member States and stakeholders, including doctors.

CPME has made available to MEPs a letter sent to the President of the European Commission ahead of the debate, and MEP Schwab and MEP Clune directly referred to CPME's position.

EMA updates

- A new report published by the International Coalition of Medicines Regulatory Authorities (ICMRA) highlights successful regulatory and non-regulatory interventions and best practices used in different countries to address the growing public health problem of antimicrobial resistance.
- A new Quality Innovation Expert Group (QIG) has been established by EMA to support innovative approaches for the development, manufacture, and quality control of medicines for the benefit of patients in the European Union.

Prescriptions for pediatric antibiotics are on the rise in France

Antibiotics prescriptions, especially for children, are on the rise in France, the country's public health agency announced. Despite a continuous decline for 10 years in the consumption of antibiotics, France remains the 4th most consuming European country behind Greece, Romania and Bulgaria. A report by the agency showed there were some 700 outpatient prescriptions for antibiotics per 1,000 inhabitants in 2021. The figure marks a resurgence in antibiotic use in the country, after a decade of steady decline.

Almost 3.5 million COVID-19 treatments secured through joint procurement contract

A new Joint Procurement Framework contract for the supply of Paxlovid, a SARS-CoV-2 protease inhibitor oral treatment for patients with COVID-19 at risk of developing severe disease, has been signed by HERA. The contract is signed with the pharmaceutical company Pfizer and will run for an initial period of 12 months.

HERA secures up to 2 million doses of the monkeypox vaccine

The Commission's Health Preparedness and Response Authority (HERA) has signed a Joint Procurement Framework contract with the company Bavarian Nordic, for the supply of up to 2 million doses of the monkeypox vaccine for 2023 and 2024, starting the first deliveries in the second quarter of 2023. This will allow 14 participating countries to purchase doses to build stockpiles and address their medium- and long-term needs.

AMR updates

- 1 in 3 people use antibiotics without prescription, a new WHO/Europe's study shows.
- The second "Surveillance of antimicrobial resistance in Europe" report, published jointly by the WHO/Europe and the European Centre for Disease Prevention and Control (ECDC), finds high percentages of resistance to last-line antibiotics.

Switzerland to examine dispensing of antibiotics

Switzerland's Federal Council wants to examine the idea of people getting exactly the number of antibiotic pills they need to complete their course of treatment. Studies showed that the number of pills in the package does not correspond to the prescribed or recommended treatment course nearly in half of cases. The announcement was made by the Federal Office of Public Health.

WHO/Europe providing monkeypox diagnosis support to countries that need it most

WHO/Europe procured and delivered US$ 1.2m worth of supplies, helping strengthen the health systems of 18 identified priority Member States and territories that were not able to provide an adequate response to the monkeypox outbreak due to a lack of either capacity or supplies, in order to these countries and territories for dealing with monkeypox. 57 000 PCR tests have now been distributed and the correct use of these will be supported through a new training programme being delivered both on-site and remotely.

New antibiotic for urinary infection proved effective

A collaboration between GSK, the U.S. BARDA and DTRA brought long-awaited results. A new antibiotic – gepotidacin – clearly demonstrated superiority over an existing therapy (nitrofurantoin). There has been no new class of oral antibiotics for uncomplicated urinary tract infections for over 20 years. GSK plans to submit a new drug application to the US FDA in the first half of 2023.

European Antibiotic Awareness Day

Use of antibiotics in the EU decreases but more needs to be done

On the occasion of the European Antibiotics Awareness Day, a pan-European survey on antimicrobial resistance shows that half of Europeans still incorrectly believe that antibiotics kill viruses. However, only a 23% of respondents have taken antibiotics over the past year. This is clearly the lowest figure since 2009 and shows that the work of Member States and the Commission to help raise awareness among citizens on the risks of excessive use of antibiotics is having a positive impact, although much more needs to be done.

DG SANTE's Overview report: Member States' One Health National Action Plans against Antimicrobial Resistance

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) presented a new report summarising a review of European Union Member States' One Health antimicrobial resistance (AMR) national action plans (NAPs) as of 1 September 2021. It was conducted by DG SANTE between 1 September 2021 and 31 May 2022. The report also lists the Commission's actions to assist Member States in their fight against AMR.

DG SANTE's Opinion: Managing Antimicrobial Resistance across the health system

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) published the opinion of the Expert Panel on effective ways of investing in health (EXPH) on 'Managing Antimicrobial Resistance across the health system' which explores the global and European impact of AMR and offers an extensive analysis of factors contributing to its spread. The EXPH adopted this opinion at the 13th plenary on 26 October 2022.

Public Health and Disease Prevention

Premature deaths due to air pollution continue to fall in the EU

On 24 November, the European Environment Agency's (EEA) published its full 'Air quality in Europe 2022' assessment, presenting the status of air quality in Europe, assessing the impacts of air pollution on health and ecosystems, and identifying sources of emissions to air. According to the EEA analysis, air pollution continues to pose significant risks to health but the number of people dying early or suffering illness due to air pollution is in decline.

EU's ban on flavored heated tobacco products starts

On 23 November, the EU's ban on flavored heated tobacco products kicked off as part of the Europe's Beating Cancer Plan, with the aim to cut tobacco use in the EU to less than 5 percent of the population by 2040. According to a recent European Commission report, sales of heated tobacco products grew by more than 2,000 percent between 2018 and 2020. EU countries have now eight months to transpose the directive into national law, followed by a three-month transition period. The new rules will be fully applicable starting on 23 October 2023.

New EU report on vaccine confidence among general population and healthcare professionals

On 21 November, the European Commission published the 2022 State of Vaccine Confidence in the European Union report. It shows that 82% of Europeans agree that vaccines are important, 86% agree they are effective and 82% agree that they are safe. Following fluctuations during the pandemic, perceptions have generally returned to their 2018 levels (the report was published also in 2018 and 2020). The new report shows however that differences between countries and vaccine types persist, and that the 18-34-year-olds became less confident between 2018 and 2022. Moreover, the report contains a chapter on healthcare professionals' confidence which demonstrates that among them perceptions towards vaccines are extremely high across the EU, though HCPs across most countries are less likely to recommend vaccines to pregnant women.

Premature deaths due to air pollution continue to fall in the EU, more efforts needed to deliver a toxic-free environment

Europe's air quality keeps improving and the number of people dying early or suffering illness due to air pollution is in decline. However, according to European Environment Agency's (EEA) analysis, published today, air pollution is still the largest environmental health risk in Europe, and more ambitious measures are needed to meet the health-based guidelines of the World Health Organization (WHO).

WHO to identify pathogens that could cause future outbreaks and pandemics

WHO launched a global scientific process to update the list of 25 priority pathogens that can cause outbreaks or pandemics to guide global investment, research and development, especially in vaccines, tests and treatments. The process will include both scientific and public health criteria, as well as criteria related to socioeconomic impact, access, and equity.

Digital Health

Presentation of the European Health Data Space Regulation

The Committee on the Environment, Public Health and Food Safety and the Committee on Civil Liberties, Justice and Home Affairs held their first joint debate on the Commission's European Health Data Space (EHDS) proposal on 8 November. EHDS aims to create a common space where natural persons can control their electronic health data and will be an integral part of building a European Health Union. In this regard, MEPs from both Committees agreed that there is a balance to be struck between protecting sensitive health data and making the data available for primary and secondary use. For further information please see the meeting report.

The European Parliament key dates:
• Deadline for sending draft report to translation: 3 February 2023
• ENVI/LIBE: Presentation of draft report in committee: 1 March 2023
• Deadline for tabling amendments: 23 March 2023
• Vote in ENVI/LIBE: 6 July 2023
• Plenary vote: September 2023

Parliament adopts Digital decade 2030 roadmap

On 24 November, legislation setting up the Digital Decade Policy Programme, a roadmap for digital skills, infrastructure, businesses and public services was adopted by the European Parliament. The aim of this programme, already agreed upon with Council, is to shape Europe's digital transition by setting EU-wide digital targets to be achieved by 2030, through a joint effort by member states and the EU, as well as through joint investment. During the debate, MEPs advocated that at least 75% of European enterprises should use cloud computing services, big data and Artificial Intelligence, and that more than 90% of European SMEs should reach at least a basic level of digital intensity.

AI Act – Council negotiations

The Czech presidency proposed a final compromise text on 11 November which will be submitted to the upcoming Telecommunications Council on 6 December for a possible General Approach. Life and health insurance has been added to the list of high-risk AI use cases in Annex III, and this is in line with CPME policy. Many of the requirements for high-risk AI systems provided in Chapter 2 of Title III of the proposal have been adjusted to be less burdensome for stakeholders to comply with, for example as regards the quality of data, or in relation to the technical documentation that should be drawn up by SMEs to demonstrate that their high-risk AI systems comply with the requirements. In the European Parliament the discussions are still progressing, and a common position is not expected before March 2023 which could push the start of negotiations to April.

DARWIN EU welcomes first data partners

On 23 November, EMA selected the first data partners to collaborate with DARWIN EU, the Data Analysis and Real-World Interrogation Network. The data available will be used for studies to generate real-world evidence that will support scientific evaluations and regulatory decision making. One study will focus on the epidemiology of rare blood cancers to inform on their prevalence in Europe. The second study is on drug use of valproate and the third one is looking at the use of antibiotics to inform future work on antimicrobial resistance. The common feature from these partners (both public and private) is that they all have access to real-world healthcare data from one or more sources such as hospitals, primary care, health insurance, biobanks, or disease-specific patient registries.

EDPS published TechSonar

This report analyses the technological developments that challenge the community of data protection regulators in foresight practice (wider approach with analysis of possible future scenarios). This forward-looking approach addressed federated learning, synthetic data, metaverse, among others.

Interoperable Europe Act

On 21 November, the European Commission adopted the Interoperable Europe Act (IEA) proposal and an accompanying Communication to strengthen cross-border interoperability and cooperation in the public sector across the EU. The Act will support the creation of a network of sovereign and interconnected digital public administrations (the Interoperable Europe Board) and intends to accelerate the digital transformation of Europe's public sector. Feedback is open until 16 January 2023.

CNIL on Health Data Processing

On 14 November, the CNIL (French Data Protection Authority) published a legal analysis on the conditions under which health data can be transferred to complementary health insurance organisations (OCAM) to justify medical treatment in order for the insurer to be reimbursed. The CNIL notes that the information transmitted directly by health professionals to OCAM is covered by medical secrecy and that a derogation to medical secrecy is therefore required. The derogation should be foreseen explicitly by law drawing up necessary safeguards, and cannot be implicit (or inexistant) as currently.

EDPS published Opinion on Cybersecurity Requirements

On 9 November, the EDPS issued an opinion on cybersecurity requirements to protect privacy and personal data in products with remote data processing solutions, these include browsers, operating systems, firewalls, network management systems, smart meters or routers. The EDPS notes that while the NIS2 Directive applied to operators of essential services and digital services providers, the current Proposal introduces common cybersecurity rules for manufacturers and developers of products with digital elements, covering both hardware and software. The EDPS is mostly positive about the Proposal, proposing nine recommendations. Further information here.

EDPS published Opinion on the Council of Europe's AI Convention

On 13 October, the EDPS published and Opinion for a Council of Europe convention on artificial intelligence, human rights, democracy and the rule of law. The EDPS considers the Convention as an important opportunity to complement the European Artificial Intelligence Act by strengthening the protection of individuals' fundamental rights, such as the rights to privacy and to the protection of personal data.

The EDPS provides six key recommendations, among which the need to have minimum procedural safeguards to protect individuals affected by the use of AI systems (e.g. transparent use of AI, clearly explainable to oversight authorities and individuals, and audited regularly to limit risks); the prohibition of AI systems that pose unacceptable risks to individuals (e.g. the categorisation of individuals according to their perceived emotions, should be prohibited by default and AI systems affecting human dignity); and the adoption of a data protection by design and by default approach at every step of AI systems' lifecycle. Further information here.

Court of Justice judgements

On 22 November, CJEU issue a judgment on case C-69/21 on the use of cannabis as a medical treatment. A third country national who is suffering from a serious illness may not be removed if, in the absence of appropriate medical treatment in the receiving country, that national risks being exposed to a real risk of a rapid, significant and permanent increase in the pain linked to that illness. Further information here.

On 27 October, CJEU issued a judgement on case C-129/21 in relation to right of erasure of personal data from directories. A data controller is required to ensure that reasonable steps are taken (appropriate technical and organisational measures) to inform search engine providers of requests for erasure of his or her personal data. Further information here.

DONATE TO THE UKRAINE MEDICAL HELP FUND

European Doctors stand in solidarity with Ukraine

The World Medical Association has set up a bank account to serve these common efforts and you may transfer your donations to the following account:

Bank & Domiciliation

SOCIETE GENERALE
ANNEMASSE ENTERPRISES (04335)

International Banking Account &
Bank Identification Code

IBAN: FR76 30003 04335 00050005353 78
BIC: SOGEFRPP

Account Owner

ASSO MEDICALE MONDIALE
13A Chemin du Levant
01210 FERNEY-VOLTAIRE
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