

CPME

# CPME Newsletter

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Issue 36: December 2021

# MESSAGE FROM THE CPME PRESIDENT



Dear Colleagues and friends,

As 2021 draws to a close, my three-year term as President of CPME is coming to an end and this is my final message as President. I feel honoured and privileged to have served as the President of a such a special organisation of national associations, colleagues and friends.

When I started my three-year term in 2019, no-one could have predicted the onset of the global COVID-19 pandemic that has likely been the greatest challenge we have faced in our careers as doctors. The special recognition award presented to CMPE on behalf of all doctors in Europe by the European Parliament (see report on page 4) is testament to the gratitude of the European public for the extraordinary efforts made by the medical community over the past two years.

As I highlighted in my acceptance speech during the ceremony, one of the sources of encouragement has been the spirit of solidarity. Within CPME and throughout the medical community as a whole, doctors have reached out to each other across borders, both in Europe and worldwide. In this collaborative spirit, we can look ahead to the coming months and years with hope.

Whilst the pandemic has taken centre stage in recent times, CPME has increased its visibility at the European level in a wide range of policy topics. Artificial Intelligence is a key focus in this edition, with a feature on the state of play of the AI Act and its impact on the medical profession. Antimicrobial resistance is another area where we have been very active, and we include an article on perspectives in preserving antimicrobials for human use. Furthermore, we include articles on vaccination, outlining the need for additional vaccination training as well as the importance of vaccinating healthcare professionals against influenza this year.

Our collaborative activities would not be possible without our member associations and the invaluable work of volunteers and leaders who have dedicated their time to our activities. In this edition we hear from the Hungarian Medical Chamber, the Polish Chamber of Physicians and Dentists, as well as the Royal Dutch Medical Association.

We have also continued to build bridges with our partners and stakeholders. In our guest section, the European Commission provides an update on the Healthylifestyle4all campaign and the Health and Environment Alliance (HEAL) outlines the importance of aligning European air quality guidelines with those proposed by the World Health Organization (WHO). In the same section, European Digital Rights (EDRi) provide an on the e-Evidence regulation and its implication for physicians as well as an article from European Junior Doctors on the impact of COVID-19.

From January, I am pleased to hand over the Presidency to my successor, Dr Christiaan Keijzer of the Netherlands (see report of the election on page 3). Our organisation is growing from strength to strength and I look forward to continuing to advance our <u>mission and vision</u> by working closely with my colleagues in the Executive Committee 2022-2024 in my future role as Immediate Past President.

Prof. Dr Frank Ulrich Montgomery CPME President

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### CHRISTIAAN KEIJZER ELECTED NEW PRESIDENT

We are delighted to announce that Dr Christiaan Keijzer has been elected as our President for a three-year term from 2022 to 2024. Dr Keijzer has served as Vice-President since 2019 and succeeds Prof. Dr Frank Ulrich Mont-gomery (Germany) who will complete his highly-successful term at the end of the year and will continue to support CPME as Immediate Past President for the next three years.

Dr Keijzer will chair our Executive Committee 2022-2024, which welcomes two newly elected Vice-Presidents in Dr Marily Passakiotou (Greece) and Dr Jacqueline Rossant-Lumbroso (France), who will join the continuing Vice-Presidents Dr Ole Johan Bakke (Norway) and Dr Ray Walley (Ireland), and Dr Marjo Parkkila-Harju (Finland) as Treasurer.

We extend our gratitude to our departing Vice-President Dr Daiva Brogienė (Lithuania) and departing Immediate Past President Dr Jacques de Haller (Switzerland) for their commitment and hard work over the past three years.

During the CPME meetings in Oslo, Norway, the CPME Board also adopted a <u>policy on the healthcare work-</u> <u>force</u> and responses to the European Commission public consultations on <u>air quality</u> and the <u>revision of the gen-</u> <u>eral pharmaceutical legislation</u>.

Dr Keijzer said "It is an honour to be elected as President of CPME and I aim to build on the excellent work of the outgoing Executive Committee in increasing the visibility of our association at the European level. I also look forward to strengthening our cooperation with our partner European Medical Organisations."





Dr Christiaan Keijzer (Netherlands)



VICE PRESIDENT Dr Ole Johan Bakke (Norway)

VICE PRESIDENT Prof. Dr Ray Walley (Ireland)



Dr Marily Passakiotou (Greece)



TREASURER





VICE PRESIDENT Dr Jacqueline Rossant-Lumbroso (France)



IMMEDIATE PAST PRESIDENT

Prof. Dr Frank Ulrich Montgomery (Germany)

Calum MacKichan, Communication Officer

# EUROPEAN DOCTORS RECEIVE SPECIAL RECOGNITION FROM EUROPEAN PARLIAMENT

On 9 November, CPME was honoured to receive a special recognition award from the European Parliament on behalf of all doctors in Europe for their efforts during the Covid-19 pandemic.

Every year the European Parliament awards the <u>European Citizen's Prize</u> to selected projects or groups to strengthen citizenship in the member states. Last month, a special award was given to the European medical profession and nurses for their outstanding commitment during the Covid-19 crisis.

The President of CPME, Prof. Dr. Frank Ulrich Montgomery, received the certificate from <u>Dita Charanzová</u>, Vice-President of the European Parliament, in a solemn ceremony in the plenary hall. The certificate honours the extraordinary commitment to the high values of humanity, solidarity, selflessness and compassion that the medical profession made during the Corona crisis.

Upon presenting the award MEP Charanzová said "Many Europeans in the health sector undertook heroic efforts to fight the pandemic and help those in need. While many of us were kept at home, our doctors and nurses were sent to the frontline. To acknowledge these heroic efforts, the chancellery and the president decided to honour all European doctors and nurses by offering a special recognition award to their umbrella organisations."

In his acceptance speech, Prof. Dr. Montgomery said "*I am honoured and humbled to accept this recognition on behalf of every doctor who has worked to provide patients with the best possible care throughout this crisis. For the medical community, this virus has likely been the most extreme challenge we have had to face in our careers as doctors.* 

"One of the sources of encouragement in this time has been the spirit of solidarity. Doctors have reached out to each other across borders, both in Europe and worldwide. Among all the negative experiences during the pandemic, we have seen scientific progress at an unprecedented speed, innovation in all areas of society and resilience in the citizens of Europe. All these efforts are allowing us to slowly find a way out of the emergency."

A recording of CPME receiving the award is available on our YouTube channel: https://youtu.be/Gy53Yqi3gHo



Calum MacKichan, Communication Officer

#### THE 2021 REPORT OF THE LANCET COUNTDOWN **ON** HEALTH AND CLIMATE CHANGE

The annual report of the Lancet Countdown to track the progress on health and climate change was published in October. It concludes that a rapid decarbonisation could prevent most of the 3.3 million deaths from air pollution that occur globally each year, the 842,000 deaths associated with excessive red meat consumption, and result in better physical and mental health from higher exposure to nature and more physical activity.

CPME was collaborating again with the Lancet Countdown Policy Brief for Europe which was published simultaneously with the global report. This year's EU policy brief focuses on data and policy recommendations on heat and health, urban green space, and energy systems, air pollution and health.

Moreover, CPME recently responded to the European Commission's public consultation on the revision of the EU Ambient Air Quality Directives, highlighting that the new EU standards must be fully aligned with the latest science and the WHO guidelines which were updated in September. The Commission aims to deliver a legislative proposal to revise the directives in 2022.

**Europe Policy Brief Recommendations** 

Protect human health from the adverse impacts of heatwaves and high

# LATEST NEWS

1	temperatures by adopting appropriate adaptation strategies and implement heat-health action plans.	A AND
2	Enhance city-level climate change adaptation and mitigation, address urbanisation challenges and promote mental and physical health by increasing urban green spaces	Europe Policy Brief Launch: 2 December
3	Fully align the revision of the EU Ambient Air Quality Directive standards with the 2021 WHO Global Air Quality Guidelines levels in a legally binding manner	
4	Develop policies based on integrative thinking, aimed at tackling the sources of GHG emissions and air pollution.	LANCET COUNTDO TRACKING PROG ON HEALT NO CLIMATE CHANGE





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Markus Kujawa, EU Policy Advisor

# NEED FOR ADDITIONAL VACCINATION TRAINING EXPRESSED BY HEALTHCARE PROFESSIONALS

#### There is a need for additional vaccination training for many healthcare professionals.





In the summer of 2021, the EU co-

funded IMMUNION project ("Improving IMMunisation cooperation in the European UNION") conducted a pan-European survey among healthcare professionals which discovered that, while most nurses, doctors, pharmacists and other professionals feel confident to respond to their patients' questions about vaccinations, this is not always the case for all professionals.

All healthcare professionals across Europe should be equipped with the knowledge and tools they need to be able to adequately inform their patients. The survey showed that the majority of healthcare professionals would be willing to attend extra courses on vaccination if they were provided, preferably in an online format.

CPME is one of the three co-chairs of the Coalition for Vaccination, which brings together European associations of healthcare professionals and relevant student associations in the field. It was convened by the European Commission in 2019. CPME is also a partner in the two-year-long IMMUNION project, which aims to strengthen this Coalition and increase vaccine confidence and uptake, especially among healthcare professionals.

The new <u>Coalition for Vaccination website</u> will provide invaluable support as it will serve as a gateway to training materials on vaccine communication, safety, fighting misinformation, and other critical topics, which will increase healthcare professionals' confidence in talking about vaccines with patients, parents and the general public.

The IMMUNION survey results also reveal that healthcare professionals use various sources to look for information on vaccines. Among these, sources provided by healthcare professional organisations were seen as one of the most preferred and trusted. As the Coalition for Vaccination brings together European associations of healthcare professionals, the new Coalition website has great potential to reach different healthcare professionals and increase their knowledge on vaccination.

When asked about what they would like to see on this new website, survey respondents highlighted that it should provide educational materials such as explanatory videos, fact sheets, short articles, scientific publications, frequently asked questions (FAQ) pages, webinars, and recorded lectures. These materials should address questions related to vaccine safety, adverse events and the side effects of vaccines, as well as their effectiveness and working mechanisms. The survey results indicate that these are the most frequent questions respondents received in the past year. In addition, healthcare professionals also received questions on national and regional vaccination



schedules, specific vaccines, and catch-up vaccinations. With regards to vaccine specific questions, the vast majority of responses were related to COVID-19 and influenza vaccines.

Moreover, the survey respondents emphasised that training materials should generally take a positive approach and highlight the benefits and effectiveness of vaccines.

3,300 healthcare professionals across Europe responded to the survey, with a high proportion of respondents from countries which are involved in the IM-MUNION project, such as Romania and Greece. The survey results will be taken into account when developing the new Coalition for Vaccination website as well as the SEKI platform (Strengthening Education and Knowledge on Immunisation), which will provide training materials for healthcare professionals and which will feature on the Coalition website.

Please find a summary of the survey results <u>here</u>. Furthermore, please subscribe to the IMMUNION newsletter <u>here</u>.

Markus Kujawa, EU Policy Advisor

# EUROPEAN HEALTHCARE PROFESSIONALS RECOMMEND GETTING VACCINATED AGAINST INFLUENZA THIS YEAR

In 2020-21, the influenza activity in Europe remained at a low level throughout the flu season, due to various public health and social measures implemented to reduce transmission of SARS-CoV-2. However, it is expected that the seasonal influenza virus will circulate much more in the forthcoming winter, as social mixing and social contact now return in many European countries. In addition, because of the low incidence of flu last year, a lower level of natural population immunity against influenza is expected for the 2021-22 season, which could increase transmission and the burden of disease in people.

Therefore, European healthcare professionals highly recommend people, especially those belonging to an at-risk group, to adequately protect themselves from potential serious illness by getting an influenza vaccine also this year. Moreover, it is crucial that people maintain hygiene measures and avoid unnecessary physical crowding.

In order to secure sufficient protection against the influenza across Europe, the Coalition for Vaccination specifically reminds healthcare professionals to:

- Lead by example and make sure they are vaccinated against the influenza also this year;
- Be vigilant for potential lower uptake of influenza vaccination among their at-risk patients and encourage them pro-actively to take the flu vaccine;
- Provide credible and reliable information on vaccinations while discussing possible questions patients may have.



It is crucial that vulnerable populations and healthcare workers get vaccinated for COVID-19 and flu before the winter months.



Vaccination against COVID-19 and flu provides good protection against severe disease.

The Coalition for Vaccination also calls on the EU, national and regional health authorities to:

- Ensure timely supply of influenza vaccines and adequate support to healthcare professionals who give them;
- Involve and support healthcare professionals as trusted sources for the public in communication on influenza vaccination to secure sufficient uptake;
- Strengthen collaboration with healthcare professionals' organisations as key partners to help increasing trust in vaccines, fighting vaccine hesitancy and achieving higher uptake overall within local communities.

This statement is launched on the occasion of the Flu Awareness Week, organised by WHO/Europe. The European Centre for Disease Prevention and Control (ECDC) provides useful information on flu vaccination <u>here</u>.

The Coalition for Vaccination brings together European associations of healthcare professionals and relevant student associations in the field. It was convened by the European Commission in 2019 with an aim to support delivering accurate information to the public, combating myths around vaccines and vaccination, and exchanging best practices on vaccination. More information about the Coalition for Vaccination can be found <u>here</u>.



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# WHICH ANTIMICROBIALS SHOULD BE RESERVED FOR HUMAN USE ONLY?

Over the past year, the EU has been preparing guidance on how to identify antimicrobials that should be legally banned for use in animals in order to preserve their efficacy for humans. The last step before finalising the guidance was to discuss the <u>criteria</u> proposed for this purpose by members of the European Parliament.

Whereas the two conditions of high importance to human health and risk of resistance transmission were uncontroversial, the third condition, i.e. that an antimicrobial must not be essential for animal health, was met with opposition across political groups, as well as from healthcare professional and civil society organisations.

European doctors, on their part, disagreed with the proposed approach, concerned that it would fail to safeguard



critical antimicrobials of last resort, contain the spread of antimicrobial resistance, and, as a result, inadequately protect human health and life.

From our perspective, the Commission's proposal also does not best serve individual animals, but leaves enough room for industrial farming to continue overusing critical antibiotics to compensate for poor husbandry practices and in metaphylaxis.

Instead, CPME proposed allowing for individual treatment of individual animals after verifying that no less potent antibiotic is available and after a valid antibiogram has been performed.

Although this reasoning convinced the Committee on the Environment, Public Health and Food Safety (ENVI) to <u>object</u> to the Commission's proposal in July, health considerations seemed to give way to other interests in the Parliament's plenary session, which eventually supported the proposal in September.

Following this decision, the Commission is now applying the agreed criteria to determine which particular antimicrobials should be placed on the list prohibiting their use in animals.

Although aware that the unfavourably stringent conditions set the bar very high for doing so, European doctors will continue in their efforts to safeguard the efficacy of as many of the critical antimicrobials of last resort as possible by advocating for their inclusion on the list.

The next opportunity for doing so should arise in the coming weeks when the European Medicines Agency will submit its advice to the Commission. Subsequently, once the Commission proposes the list, we should have another chance to provide our input on its composition before it is finalised.

CPME will certainly not be alone in this endeavour as other stakeholders have already begun calling for a ban on the use of specific antimicrobials in animals e.g., <u>colistin</u>.

The new Veterinary Medicinal Products Regulation, which the criteria for identifying critical antimicrobials supplements, enters into force on 28 January 2022. The list of antimicrobials reserved exclusively for human use is expected to be published shortly thereafter.

# CPME SESSIONS AT INTERNATIONAL BIOETHICS CONFER-ENCE TO HIGHLIGHT AI AND DEFENSIVE MEDICINE



#### 14<sup>TH</sup> WORLD CONFERENCE ON BIOETHICS, MEDICAL ETHICS AND MEDICAL LAW

#### 7-10 MARCH, 2022 PORTO, PORTUGAL

On 7-10 March 2022, the 14th World Conference on Bioethics, Medical Ethics and Medical Law will take place in Porto. Having originally been scheduled for May 2020, the opportunity to have an in-person discussion of ethical questions facing healthcare system will be valued now more than ever.

In panel sessions scheduled for 9 March, CPME will focus on two of its policies with representatives of national medical associations and international experts. The first session will showcase the <u>CPME Policy on Al in Health</u> <u>Care</u> adopted in 2019, and look at regulatory challenges, as well as approaches to 'Humanising Al in healthcare'. Alongside CPME Rapporteur on Al Prof. Christian Lovis, WMA Secretary General Dr Otmar Kloiber and Dr Bogi Eliasen, Director of Health at the Copenhagen Institute for Futures Studies, will present their views for further discussion.

In a second session, the 2019 <u>'CPME Position Paper on Defensive Medicine'</u> will be introduced by CPME Vice-President Daiva Brogienė, who will also share her experience of recent reforms in Lithuania. This will be complemented by presentations on patient-centred care for chronic pain patients by Dr Catarina Matias, and the 'Choosing Wisely' initiative by Dr Stefan Hjørleifsson.

We look forward to this opportunity to present CPME's work to an international audience. More information on the conference including registration options can be found <u>here</u>.

Sarada Das, Deputy Secretary General

# CALL TO ACTION TO PROTECT CHILDREN FROM THE MARKETING OF NUTRITIONALLY POOR FOOD

In November, 20 European organisations, including CPME, launched a <u>call to action</u> to protect children from the marketing of nutritionally poor food. It calls on the European Union to assume responsibility and tackle the exposure of young people to the promotion of nutritionally poor food because there is clear evidence that unhealthy food marketing affects what children eat and ultimately, their health and well-being. The call to action was launched simultaneously with a blueprint Directive presenting how the EU can use its powers to regulate cross-border marketing.



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# Call to protect children from the marketing of nutritionally poor food

KEY DEMANDS FOR EU ACTION

- We call for the adoption of legislation by the European Union (EU) to improve public health, prevent non-communicable diseases and promote children's rights, by effectively protecting children from the harmful impact of the widespread, ubiquitous and insidious marketing of nutritionally poor food.
- The EU has extensive powers to regulate all forms of cross-border marketing to improve the functioning of the internal market, whilst ensuring a high level of public health, consumer and children's rights protection, in line with the EU Treaties and the EU Charter of Fundamental Rights.
- We call on the EU to regulate the cross-border marketing of food and minimise the exposure of children to nutritionally poor food marketing by:
  - ending the marketing of nutritionally poor food between 6am and 11pm on broadcast media, including television and radio;
  - ending the marketing of nutritionally poor food on digital media, including social media and video sharing platforms;
  - ending the sponsorship by food brands of events with cross-border effects, including sports and cultural events, such as festivals, unless brands can prove that such sponsorship is not associated with nutritionally poor food; and
  - ending the use of marketing techniques appealing to children for the promotion of nutritionally poor food, including on food packages. In particular, influencers and other personalities shall not promote nutritionally poor food.
- All children, including adolescents, must be protected from harmful marketing. A child is defined as any person below the age of 18, in line with the UN Convention on the Rights of the Child that all EU Member States have ratified.
- The definition of nutritionally poor food should be based on the WHO Europe nutrient profile model.
- We consider that action to create sustainable, empowering environments conducive to the good health and well-being of future generations is not only warranted, but also feasible. We therefore present a blueprint Food Marketing Directive as a discussion document to relaunch the debate on the protection by the EU of children from the harmful impact that the marketing of nutritionally poor food has on their health and on their rights.

Markus Kujawa, EU Policy Advisor

### THE ARTIFICIAL INTELLIGENCE ACT - STATE OF PLAY

On 21 April 2021, the European Commission presented a <u>draft Regulation on Artificial Intelligence</u> laying down harmonised rules for the development, marketing and use of artificial intelligence (AI), the so-called AI Act. The rules intend to ensure that AI systems are safe, respect EU values and fundamental rights, offer legal certainty to facilitate investment and innovation in AI, prevent market fragmentation and enhance governance and effective enforcement.

The proposal follows a risk-based approach, differentiating between uses that create:

• (i) an unacceptable risk (prohibited);



- (ii) a high-risk, and therefore subject to compliance with certain mandatory requirements and an ex-ante conformity assessment; and,
- (iii) low or minimal risk, which the majority of current AI systems would be classified as.

The proposal introduces transparency obligations for certain AI systems, as well as codes of conduct aimed at encouraging providers of non-high-risk AI systems to (voluntarily) apply the same requirements which are mandatory for high-risk AI systems. The Act sets up governance systems at EU and national level, including a European Artificial Intelligence Board. Monitoring would be facilitated by an EU-wide database, to be operated by the Commission, for stand-alone high-risk AI systems with mainly fundamental rights implications.

In the <u>first in-depth debate</u> in October 2021, the Council agreed that there is a need to set out a unified and systematic approach to trustworthy AI in the EU in order to protect health, safety and fundamental rights. Ministers strongly supported the need to ensure legal certainty and consistency for developers and users, as well as consistency with other legislation. The new law needed to be future-proof and foster innovation, and its provisions flexible enough to adapt to the fast-evolving technologies.

The risk-based approach of the proposal was welcomed, but indicated that many issues require further discussion, in particular regarding the scope of the Act, law enforcement aspects and definitions of key terms. Clarity on these was considered essential for legal certainty and smooth implementation of the Act. Standardisation and availability of high-quality data needed to be promoted. The effective enforcement and supervision, especially human oversight, was also mentioned. The governance structure should be light, and the administrative and financial burden for operators, in particular SMEs and start-ups, should be kept to a minimum. Special support should be offered to SMEs to ensure that they can easily comply with the new rules.

More recently, many Member States expressed the need to extend the prohibitions of 'unacceptable' Al to private companies, and to exclude from the scope of the Al Act those Al systems developed or used for law enforcement. The discussions on the proposal will continue in the Council's Telecommunications Working Party. On 29 November, the EU Slovenian Presidency released a <u>compromise text on the draft Al Act</u>. CPME is currently analysing the document in view of preparing specific amendments.

In the European Parliament, the <u>AI Act file</u> was provisionally assigned to the Committee on Internal Market and Consumer Protection (IMCO), where Brando Benifei (S&D, Italy) is the appointed rapporteur. Other committees, in particular Legal Affairs (IURI) and Civil Liberties, Justice and Home (LIBE), are claiming competence on the AI Act. A resolution of this conflict of competences is pending.

Meanwhile, the European Data Protection Board (EDPB) issued a statement on 18 November 2021 expressing growing concerns about the impact that the legislative panorama on digital and data strategies will have on the rights to privacy and personal data protection of EU citizens, as well as on legal certainty<sup>1</sup>. The EDPB is calling for a phase-out, leading to a ban, of targeted advertising which relies on 'pervasive tracking', a ban on the profiling of children and on facial recognition in public spaces.

The EDPB also expressed significant concern about the potential overlap in competences, creating "a risk of parallel supervision structures where different competent authorities supervise the same entities having regard to the same (processing) activities without structured cooperation between them." For the EDPB, the proposals do not clearly indicate how new supervisory bodies (and the accompanying European Boards) will cooperate with data protection supervisory authorities (and the EDPB). CPME had signalled in its <u>Feedback to the Commission's proposal on Al</u> (August 2021) that agreements and collaborations would be required to determine roles and responsibilities in healthcare oversight of the Al system. European Doctors strongly advocate that medical obligations resulting from the use of Al in healthcare need to be supervised by medical regulators to guarantee the quality of healthcare.

The accompanying article below explains our position on the AI Act and its impact on the medical profession.

Sara Roda, EU Senior Policy Advisor

<sup>1.</sup> EDPB Statement on the Digital Services Package and Data Strategy, 18 November 2021. The legislative proposals concern the Digital Services ACT (DSA), the Digital Markets Act (DMA), the Data Governance Act (DGA), the AI Act, the upcoming Data Act and the European Health Data Space.

# THE ARTIFICIAL INTELLIGENCE ACT – WHAT IMPACT FOR THE MEDICAL PROFESSION?

#### THE ASSISTIVE ROLE OF AI IN HEALTHCARE

Al has the capability to increase the accuracy of diagnosis and efficiency of treatments. In robotics, it can be helpful for complex surgeries. In medicine development or pharmacovigilance it can lead to a more personalised medicine. It can also improve management of workflow so that physicians can devote more time to focusing on patients.

For CPME, however, **AI should have an assistive role**. European Doctors prefer to use the term 'augmented intelligence' in healthcare, as AI exists to enhance physicians' expertise and leverage decision making and cognitive power.



© Alexander Sinn

However, there is a real shift with the digitalisation of healthcare. The way healthcare is delivered (e.g. with telemedicine), medical practice (e.g. with new digital competences), and the patient-doctor relationship, transferred to the virtual environment or where an electronic device assumes an important role (e.g. to retrieve a patient's medical history and examination results, to collect data from patients or to store further information), is changing.

Doctors will need to manage new digital obligations, different perceptions and ways of communicating, while maintaining trust and without losing sight of the humanity in the patient-doctor relationship. To this end, it will be paramount to maintain professional oversight over AI clinical validation.

As the challenges to medical practice increase, while innovations and advances in scientific knowledge bear fruit, CPME hopes that the <u>draft Regulation on Artificial Intelligence (AI Act)</u> has the same positive impact around the world as the General Data Protection Regulation (GDPR) had. Much will depend on the final provisions and on the civil liability regime that will be put in place.

#### CPME'S POSITION ON THE AI ACT

In August, CPME provided its <u>Feedback to the Commis-</u> <u>sion's proposal on AI.</u> CPME recognises that it is a ground breaking piece of legislation and welcomes the risk-based approach proposed by the Commission. CPME also welcomed the creation of the European Artificial Intelligence Board, the development of the EU data base for high-risk AI and the proposed risk management system.

In relation to the proposed AI definition, European Doctors identify three areas that should be included in the Annex III list, namely:



- the use of AI for determining insurance premiums (risk assessment for health insurance);
- the use of AI for medicine development or pharmacovigilance;
- the use of AI for health research.

One of the key challenges for AI systems is that they need to demonstrate compliance with data protection law. This is particularly relevant in healthcare settings when using health data. However, compliance with the EU data protection framework is not clearly considered in the AI Act. For CPME, the AI Act should be more ambitious and stipulate that the CE marking should only be given to those systems that comply with data protection. Moreover, in order to provide legal certainty to the industry, the AI Act could foresee as the minimum threshold:

- the need to conduct a data protection impact assessment for high-risk AI;
- that self-learning algorithms protect personal data from conception; and,
- only certify AI systems that comply with data protection by design and by default.

In relation to the use of AI systems that infer or recognise emotions, CPME agrees that emotion recognition is a serious problem, unreliable, biased and potentially leading to serious infringements. However, as in nuclear medicine, there should be some exceptions for medicine, including research, prevention, assessment, prognosis, diagnosis, therapy and follow up. Some evidence has been identified for the <u>detection of suicidal risk or relapse risk in</u> <u>adolescents</u><sup>1</sup> and for <u>persons with physical disabilities</u>.<sup>23</sup>

European Doctors also note that medical obligations resulting from the use of AI in healthcare need to be supervised by medical regulators in order to guarantee the quality of healthcare. In light of this, agreements and collaborations will be required to determine roles and responsibilities in healthcare oversight of the AI system. The intersections between the Medical Devices Regulation and the AI Act, in particular in relation to the remits of national competent authorities and national supervisory authorities, need to be further clarified.

In addition, in healthcare, 'instructions for use' will need to be clear and complete, so that doctors can understand and manage the implications of high-risk AI. For example, a doctor should be aware how the AI provides for human oversight (and what aspects), how the AI changes (and what aspects) and how he/she (as a human) can control the change, adjust the system and understand the system's trustworthiness and errors. Doctors and students will need to learn about AI's capabilities and limitations in their daily activity, and they will need to develop the necessary digital competences, avoiding over-reliance on the system.<sup>4</sup>

CPME also stresses that human oversight should be of 'high quality', meaning that the individual needs to have the necessary competences and the provider is appropriately resourced for the effective performance of the task.

#### LIABILITY FRAMEWORKS

A system of redress should be developed for the Al user. If a doctor uses an Al system according to the training provided and in adherence with the instructions and guidelines, he/she should be fully indemnified against adverse outcomes. The provider of Al needs to be accountable for what is delivered. In case of a self-learning algorithm, the employer (hospital) or the insurance should come into play, not the doctor, otherwise the legislation would be creating a barrier to using this technology.



Moreover, it may be very difficult for a doctor to know and prove that a malfunction has occurred or that an AI system is defec-

tive. This will depend on the information that he/she has access to. CPME is preparing its response to the Commission's public consultation<sup>5</sup> in this area and intends to further reflect on different case scenarios along with its members.

#### GOVERNMENT AND NMA'S ROLE

The AI Act will be quite important to establish ground rules for the use of AI, but it will not be sufficient. National health systems will need to provide incentives for doctors to use AI. Governments should invest in equipment and software where there is evidence that they are useful and efficient to improve the quality of care, patient safety and patient-doctor relationship – not everything available on the market is acceptable!

With the support and collaboration of National Medical Associations (NMAs), governments should also invest in programmes that enhance digital health literacy skills for doctors, while supporting the emergence of digital leaders so that they become an example for others to follow.<sup>6</sup>

Finally, a new generation of ICT professionals (20 million)<sup>7</sup> is expected. Those managing health data must be properly trained. The healthcare community should require that ICT professionals working in healthcare meet high ethical standards and comply with professional obligations<sup>8</sup>. These professionals will be (and already are) key guarantors of the technical infrastructure of health systems and of granting access to health data in those systems. These specialists should therefore abide by ethical codes of conduct and be subject to disciplinary sanctions. This would ensure that they have up-to-date competences, relevant to their field, creating more trust in ICT - a win-win policy approach.

Sara Roda, EU Senior Policy Advisor

<sup>1</sup> Seymour KE, Jones RN, Cushman GK, Galvan T, Puzia ME, Kim KL, Spirito A, Dickstein DP. Emotional face recognition in adolescent suicide attempters and adolescents engaging in non-suicidal self-injury. Eur Child Adolesc Psychiatry. 2016 Mar;25(3):247-59. doi: 10.1007/s00787-015-0733-1. Epub 2015 Jun 6. PMID: 26048103; PMCID: PMC6642805.

<sup>2</sup>Nagarajan R, Hariharan M, Satiyan M. Luminance sticker based facial expression recognition using discrete wavelet transform for physically disabled persons. J Med Syst. 2012 Aug;36(4):2225-34. doi: 10.1007/s10916-011-9690-5. Epub 2011 Apr 5. PMID: 21465183. For further information see also <a href="https://pubmed.ncbi.nlm.nih.gov/?term=artificial%20intelligence%20facial%20recognition&sort=pubdate">https://pubmed.ncbi.nlm.nih.gov/?term=artificial%20intelligence%20facial%20recognition&sort=pubdate</a>>.

<sup>3</sup>See also the <u>EDPS TechDispatch #1/2021 - Facial Emotion Recognition</u> which mentions the use of facial recognition to detect <u>autism</u> or <u>neurodegenerative diseas-</u> es; to predict <u>psychotic disorders</u> or <u>depression</u> to identify users in need of assistance; to <u>suicide prevention</u>; to <u>detect depression in elderly people</u>; and to <u>observe</u> <u>patients conditions during treatment</u>

<sup>4</sup> See <u>CPME Policy on Digital Competencies for Doctors</u>, adopted on 21 November 2020. Medical education and CPD should reflect the changing roles of Doctors and the new skills they require. These skills include data analytics in healthcare, genomics and bioinformatics, AI in health, telemedicine, smart health devices and mHealth, training with digital health technologies, such as virtual reality (VR) and augmented reality (AR), ethical considerations, communication skills with patients, relatives and healthcare team, and legal implications of digital health tools.

<sup>5</sup> Commission's public consultation on adapting liability rules to the digital age and artificial intelligence, <a href="https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Civil-liability-adapting-liability-rules-to-the-digital-age-and-artificial-intelligence\_en>">https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Civil-liability-adapting-liability-rules-to-the-digital-age-and-artificial-intelligence\_en>">https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Civil-liability-adapting-liability-rules-to-the-digital-age-and-artificial-intelligence\_en>">https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Civil-liability-adapting-liability-rules-to-the-digital-age-and-artificial-intelligence\_en>">https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Civil-liability-adapting-liability-rules-to-the-digital-age-and-artificial-intelligence\_en>">https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Civil-liability-adapting-liability-rules-to-the-digital-age-and-artificial-intelligence\_en>">https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Civil-liability-rules-to-the-digital-age-and-artificial-intelligence\_en>">https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Civil-liability-rules-to-the-digital-age-and-artificial-intelligence\_en>">https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Civil-liability-rules-to-the-digital-age-and-artificial-intelligence\_en>">https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Civil-liability-rules-to-the-digital-age-and-artificial-intelligence\_en>">https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Civil-liability-rules-to-the-digital-age-and-artificial-intelligence\_en>">https://ec.europa.eu/initiatives/12979-Civil-liability-rules-to-the-digital-age-and-artificial-intelligence\_en>">htt

<sup>6</sup> CPME launched, together with the European Junior Doctors Association (EJD), a first digital leadership course: "Health trends & Applications of Futures Thinking – How to develop and adapt your current strategies to face the digital health transformation and prepare digital health leaders?". The course, taking place in December, will be facilitated by the Copenhagen Institute for Futures Studies (CIFS).

<sup>7</sup> See Commission's proposal for a Decision establishing the 2030 Policy Programme "Path to the Digital Decade", adopted on 15 September 2021.

### **ACTIVITIES OF THE HUNGARIAN MEDICAL CHAMBER**



The new board of the Hungarian Medical Chamber was elected in 2019. The roots of this change go back to a Facebook group called 1001 doctors against gratuities, followed by a new formation previously named "Redesign". The main aim of this group included increasing the appreciation and the quality of life of Hungarian medical doctors by achieving an increase in their salary and forbidding gratuities given by patients.

At the beginning of 2020, we saw our mission as striving for a better existential status of Hungarian medical doctors. After only a few months of work, COVID-19 changed everyone's life. Because of the closures we had to hold our meetings online and soon, in the middle of the pandemic, the board of the Chamber faced a big challenge in the form of the Law on the Health Care Service. This included not only a better pay scale for medical doctors, but also many restrictions on their work. Some of these restrictions were welcome, such as banning gratuities from patients, which distorted the quality of medical care. Other restrictions still need a lot of correction and we are still negotiating with the government in these cases. These areas include, e.g., the regulation of the connection between the private and public sectors and the correct renumeration and compensation of duty hours. According to a survey we carried out in the summer, more than three-quarters of medical doctors said their financial status had improved. However, doctors still cannot be fully satisfied with their situation.

The COVID-19 pandemic shocked not only the population, but also healthcare workers. Colleagues swiftly prepared to treat patients and at the same time to protect themselves from infection. In this hurry we faced many hurdles, such as a shortness of protective equipment. The Hungarian Medical Chamber supplied the government, not only with data about the difficulties of medical doctors, but also tried to increase our colleagues' protection via information augmenting the effectiveness of healthcare. In addition, through our communications campaign, we increased public awareness of the importance of wearing face masks and getting the vaccination.

Owing to the pandemic, we could not make big progress with our plans. However, in these two years we have achieved some successes in becoming more well known in Hungarian society. The Chamber grew into a notable actor in health politics, our societal respect increased and we have a good connection with the media. In addition, the internal organizational culture changed a lot as we made our functioning more transparent - all our activities, correspondence and commitments are publicised on our website and we also try to communicate more actively with our members. More and more divisions of medical doctors are involved in our lobby-ing work, lending their voices and strengthening our professional efforts.

We are at the start of our journey and must do a lot in the upcoming two years to facilitate the development of upto-date healthcare, with sustainable amelioration and fair access for patients. In order to achieve this, we must regain previously lost areas of responsibility and gain new ones (e.g., running the professional committees) so as to be able to influence progress and changes in health care. We must also restructure our chamber with more supporting expert committees and strengthen our connections to other health care societies. We and our members need more legal support, not only in questions of employment and entrepreneurial law, but also in policy questions. We must accompany and oversee professional development, not only of our youngest members, the residents, but also of specialists. In order to fulfil our plans we will need a new and well-established online Chamber service system.

Ildiko Toth, MD , Secretary, Hungarian Medical Chamber

# PROTEST ACTION OF HEALTHCARE PROFESSIONALS IN POLAND



On Saturday, 11 September 2021 a massive, nationwide protest action of Polish healthcare professionals began in Warsaw. 40,000 people representing 600,000 healthcare professionals (doctors, dentists, nurses, midwives, paramedics, physiotherapists, medical caregivers as well as non-medical workers) gathered in Warsaw and marched through its main streets. The day ended with the creation of a "White Town 2.0" near the Prime Minister's Chancellery – following the example of the "White Town" established by protesting healthcare workers in front of the Prime Minister's Chancellery in 2007.

Every day a press conference on various medical topics was held in the White Town. Over the following days, topics regarding Nursing, Child Psychiatry, Surgery and Orthopedics, Internal

Medicine and Family Medicine, Oncology, Prophylaxis of Cancer, Emergency Medicine, Physiotherapy, Laboratory Diagnostics and Electroradiology were raised and presented to the public within the context of the demands of the protesters.

In the meantime, there was also a one-day campaign, "LET BLOOD BE SPILLED!" in which medics took a day off work to donate blood to blood banks.

The protest action of medics and non-medical professions has 8 demands:

- A faster than planned increase in expenditure on the health care system;
- An increase in the salaries of health care professionals to the OECD and EU average levels compared to the national average;
- An increase in the number of employees in the health care system to the average levels in OECD and EU countries (including additional administrative and support staff) and the introduction of employment standards depending on the number of patients;
- A real increase in the valuation of medical services, ambulance services and improving the availability of services to patients;
- An improvement in the quality of medical services improving the quality of medical, nursing, physiotherapy, rehabilitation and pharmaceutical care and increasing access to modern forms of laboratory and imaging diagnostics;
- The adoption of laws on laboratory medicine, the paramedic profession and other medical professions;
- The introduction of health leave after 15 years of professional work;
- Granting medical professionals the status of a public official.

The Protest Committee is awaiting the Prime Minister's personal participation in negotiation talks, but the government constantly maintains that it is impossible to meet the demands presented by medics and that the Prime Minister will not meet the protesters personally until these are made more realistic.

On Saturday, 18 September, the eighth day of the protest, an elderly man committed suicide in the White Town. This took place at the end of a press conference. In the face of this tragedy right in front of the Prime Minister's Chancellery, it was decided to change the activity of the White Town to 'Quiet on-call' for many days.

Meanwhile, a new Deputy Minister of Health has been appointed with the main task of maintaining contact with the protesters. However, after a couple of meetings the protesters are still disappointed – they have not received any data or actual calculations and the proposal for an agreement presented by the Ministry did not contain any details or specific deadlines, which does not serve as a basis for discussing the subject of improving health protection in Poland. The protest is still ongoing and no agreement has been reached.

Dr Michał Matuszewski, member of the board of the Warsaw Regional Chamber of Physicians and Dentists

Mr Marek Szewczyński, attorney-at-law at the Polish Supreme Chamber of Physicians and Dentists

# ACTIVITIES OF THE ROYAL DUTCH MEDICAL ASSOCIA-TION IN AN EVENTFUL YEAR



Looking back at the projects of the Royal Dutch Medicine Association (KNMG) during the past year, most attention was still focused on the COVID-19 pandemic.

During the pandemic we tried to support physicians in many different ways. This year's annual (online) KNMG conference was all about coping: dealing with the COVID-19 crisis. Doctors and administrators talked about their experiences and approach to the crisis. What did this crisis do to them as a person, as a doctor and administrator and

how did they keep control? Furthermore, we hosted a webinar focused on vaccination against COVID-19. Various experts addressed medical questions about vaccines, the vaccination strategy and implementation, and practical guidelines. Over 9 000 physicians and medical students took part in this Webinar.

In our role as the representative body of physicians, our districts<sup>1</sup>, in association with Optimal Care- Brave Doctors (Optimale zorg- Dappere Dokters), composed the document: 'being a doctor in times of corona'. It brings together the voices of more than 1,400 doctors from across the country. The crisis made cooperation very important and many things became fluid under the pressure. In the working conferences for 'Doctors in times of corona' they answered the question: what can we as doctors learn from this crisis? The participating physicians were employed in hospitals, general practices, social medicine, geriatric care and mental health care and were all involved in day-to-day patient care. The results of all these work sessions were summarised together with representatives from the districts and translated into concrete action points and recommendations for other physicians, but al-so for politicians in parliament.

Not only were we concerned with the pandemic. Other topics relevant to the work of physicians also deserve the attention of the KNMG, such as domestic violence and child abuse. For this reason, and on the basis of our social commitment, the KNMG wants to encourage doctors to actively contribute towards fighting child abuse and domestic violence. The obligation to report in order to achieve a more effective approach to child abuse and domestic violence was discussed. We find a statutory reporting obligation undesirable as this could lead to defensive reporting and an overload of reports. As a result, the children who really need help would not be identified quickly enough. It could also mean that patients with problems would put off visiting a doctor fearing that a report would follow. Moving away from a so-called obligation to report, we advocate handing physicians a guideline on how to act when there is a suspicion of abuse.

The KNMG has also started a project to tackle the current punitive effect of disciplinary measures, which points towards a more preventive function: 'Disciplinary measures should be used to learn from, giving them a more preventive purpose and leading to an improvement in quality. Many doctors experience a disciplinary complaint as incriminating, even if a complaint is declared unfounded. The emotional burden on themselves, their family and their colleagues is huge. Learning is not so easy when there is punishment hanging over your head.'

Willemijn Put, Junior policy advisor at KNMG

1 Districts are meeting places for doctors at regional and local level and are important for us to collect input on policy themes and what is going on among doctors regionally.

# HEALTHYLIFESTYLE4ALL: THE NEW INITATIVE OF THE EUROPEAN COMMISSION TO PROMOTE HEALTHY LIFESTYLES FOR ALL

Commissioner Mariya Gabriel officially launched the <u>HealthyLifestyle4All</u> initiative on 23 September 2021, in Bled, Slovenia, in the presence of major European and international sports organisations and national sports authorities.



European Commission

HealthyLifestyle4All is a two-year initiative that aims to link sport and active lifestyles with health, food and across various other policies. It showcases the European Commission's commitment to promoting healthy lifestyles for all, across generations and across society, noting that everyone can benefit from activities that improve health and wellbeing.

The campaign has three pillars:

- 1. increased awareness of a healthy lifestyle across all generations;
- 2. **easier access** to sport, physical activity and healthy diets, with special focus on inclusion to ensure the involvement of disadvantaged groups;
- 3. teaming up for a **holistic approach** to food, health, wellbeing and sport.

In order to promote a broad outreach, uptake and ownership of healthy lifestyles across society, the European Commission invites sports movements at national, European and international level to participate, as well as national and local authorities and civil society organisations in EU Member States, Erasmus+ countries, Eastern Partnership and Western Balkans countries.

Commissioner Gabriel invited stakeholders to submit their own commitments in the form of pledges on the online <u>Pledge Board</u>, which will be available for the entire duration of the initiative. In the presence of high-level representatives from EU institutions, sports ministries and the sports movement, the launch of HealthyLifestyle4All was the perfect occasion to present and sign a first set of pledges.

The aim of a pledge is to showcase a concrete contribution to the campaign. It should create added value within one of the aforementioned three pillars, include a call for new activities or policy initiatives, or reinvigorate existing initiatives or policies that promote healthy lifestyles in society. It can either target society at large, or focus on a specific target group in a country or countries, and should be launched and implemented – entirely or in part – during the lifespan of the initiative (2021-2023).

The Commission itself has pledged to:

- establish a "#BeActive Across Generations" Award;
- increase funds for projects supporting a healthy lifestyle;
- promote healthy lifestyles in schools;
- support volunteers in a healthy lifestyle; raise awareness on how a healthy lifestyle can help prevent cancer;
- promote responsible food business and marketing practices and healthy diets for all;
- review its EU School fruit, vegetables and milk scheme in 2023; and
- support evidence-based policy to promote a healthy lifestyle.

Now it is your turn to join Member States, international organisations and sports federations in embracing a more active and healthier society. What will you pledge?



<u>Floor van Houdt</u>, Head of Unit for Sport European Commission - Directorate General for Education, Youth, Sport and Culture

# THE OPPORTUNITY FOR CLEAN AIR FOR ALL IS NOW, WITH HEALTH PROFESSIONALS AS FRONTLINE CLEAN AIR ADVOCATES

The coming months will be crucial for Europe's policy -makers to show they are serious about protecting our health from air pollution, the top environmental threat to health.

Following new WHO recommendations, health groups urge EU and national decision-makers to fully take into account the large body of new evidence showing the health impacts of air pollution in the upcoming update of EU clean air standards.

Air pollution is the largest environmental threat to health in the European region and globally, leading to 400,000 premature deaths and hundreds of billions of euros in



health costs in the EU each year. It is a major public health problem, but one that is largely preventable.

The EU's Ambient Air Quality Standards have helped to tackle persistent poor air quality, prompting national governments and, city decision-makers especially, to introduce measures to lower pollution levels or risk being taken to court. However, the levels allowed under these EU rules are too high; much higher for key pollutants than even previous WHO recommendations consider is best for human health. This mismatch between evidence-based recommendations by WHO and the political compromise that are the EU standards can and needs to be rectified in the coming months.

The process of updating the EU air standards will provide many opportunities for health experts and advocates to have their say and bring in their expertise. Being vocal now will be instrumental in achieving adequate, science-based, binding air pollution limits for protecting health for years and decades to come.

Aligning EU standards with the WHO recommendations has become more important than ever: in its newest update, in September 2021, the World Health Organization (WHO) published much awaited new evidencebased <u>Global Air Quality guidelines</u>, the first update since 2005. They show that air pollution is more harmful to human health than previously thought - even at much lower levels than previously known.

After a systematic review of the accumulated evidence, the WHO recommends lower values for several pollutants, most notably for particulate matter PM2.5, which causes the greatest health burden, for which a new annual concentration of 5  $\mu$ g/m<sup>3</sup> is now recommended (currently the EU's annual standard is 25 $\mu$ g/m<sup>3</sup>); for nitrogen dioxide (NO2), which has come under intense scrutiny in discussions on road transport and inner-city driving bans, a new annual concentration of 10  $\mu$ g/m<sup>3</sup> is now recommended (previously 40  $\mu$ g/m<sup>3</sup>).

With the new science-based recommendations now available, <u>health groups have urged the European Union and</u> <u>national decision-makers</u> to protect the health of hundreds of millions by stepping up efforts for clean air for health, first and foremost by fully aligning EU air quality standards with the science-based guidelines and other new studies – a step that <u>thousands of citizens have been calling for in a petition</u>.

#### Continued health engagement is crucial

The legislative proposal for the revision of the EU's ambient air quality directive is scheduled for the 3rd quarter of 2022. It will be based on an impact assessment and stakeholder consultations.

As a first step in seeking input, the European Commission has launched a <u>public consultation</u>, which is open until 16 December 2021.

This is a not to be missed opportunity for organisations and individuals to voice support for stricter clean air standards. HEAL will take part in this process on the basis of our <u>10 demands for the EU's Clean Air for Health Transition 2021-2030</u>.

Sophie Perroud, EU Policy Coordinator, Health and Environment Alliance (HEAL)

# E-EVIDENCE REGULATION: WHY IT MATTERS FOR MEDICAL CONFIDENTIALITY?

Electronic data has become a defining component of criminal investigations. Emails, data stored "in the cloud", private messages - investigators increasingly seek such data, often held by private companies, as evidence for their criminal cases. This can also encompass health data.

Under current legal rules, when such data is stored abroad, national law enforcement authorities need to rely on socalled "mutual legal assistance treaties" or other types of international instruments for data exchange. These processes involve a dialogue between two competent judicial authorities, which are entrusted to ensure the legality of the data transfer and the protection of fundamental rights.

However, the European Union (EU) Member States and the European Commission consider the current processes too burdensome, slow and inefficient. To remedy this problem, the Commission in 2018 proposed a new law enforcement data-gathering instrument, called the Regulation on European Production and Preservation Orders for electronic evidence in criminal matters (also known as the "e-Evidence Regulation").

This new legislative framework would allow investigative authorities to directly request data from private companies established in other Member States. Law enforcement authorities would simply need to send a request to the company, without any involvement of another competent authority, as is usually the case in cross-border cooperation frameworks. High financial sanctions are foreseen to incentivise companies to automatically comply with orders received without asking further questions.

Digital rights advocates, lawyers, journalists and media organisations have repeatedly pointed out the loopholes and dangers of this proposal for people's rights, including its impacts on the right to a fair trial, freedom of expression and press freedoms, as well as the right to privacy. Police accessing journalists' emails, lawyers' correspondence with their clients or getting hold of someone's data without concrete suspicion of serious criminality is not without consequences for the quality of our democratic societies.

These new cross-border police powers are accompanied by barely adequate safeguards. There is a crucial lack of systematic independent judicial oversight and the secrecy granted to pretrial orders prevents the individuals affected from exercising their defence rights. It is important to stress that this intrusive instrument, ripe for abuse, will also land in the hands of certain EU governments, which, over the past decade, have weakened the independence of their judicial systems, shown their defiance of European values and illegally spied on political dissidents.

Access to health data by foreign authorities in the context of a criminal investigation – be it intentional or not – needs be carefully regulated as it also impacts doctors' legal and ethical duties.

Medical confidentiality is key to the protection of patients' rights. Health data is considered private and sensitive information and, as such, needs to be adequately protected by medical professionals. However, with the digitisation of health records and the increasing use of telemedicine, doctors and healthcare providers rely more and more on private entities for the storage and processing of electronic health data. If such data is accessed for any purpose other than providing healthcare and without the patient's consent, there must be thorough checks and strong safeguards. Something the e-Evidence Regulation is currently failing to provide.

In October 2021, CPME <u>partnered</u> with European Digital Rights (<u>EDRi</u>) and twelve other organisations to showcase in a series of scenarios how the e-Evidence Regulation would undermine funda-

mental rights, including medical confidentiality and patient rights. As the legislative proposal is currently being negotiated by the Council of the EU and the European Parliament, the scenarios and related recommendations give EU legislators concrete ideas of safeguards in order to mitigate these harms.

Doctors and patients need assurances that sensitive health data will not be illegally accessed. As the e-Evidence Regulation passes through the next legislative steps, we will continue to ensure that privacy and fundamental rights are put first.



Chloé Berthélémy, Policy Adviser, European Digital Rights (EDRi)

# THE COVID-19 PANDEMIC AND JUNIOR DOCTORS: MOVING TOWARDS A POST-CRISIS PERIOD

Throughout history medical doctors have been continuously adapting to the evolving health and social issues faced by society, as well as to new scientific knowledge. The COVID-19 pandemic, a once-in-a-hundred years health crisis, has had a tremendous impact on healthcare professionals across the globe as they have faced a rapidly changing health landscape.

Junior Doctors have been on the frontline of the fight against the pandemic. On 22 March 2020, the European Junior Doctors Association (EJD) published <u>a statement on the COVID-19 pandemic</u>, calling upon the European Commission, National Governments and authorities to protect Junior Doctors from unsafe working con-



ditions and to provide doctors and healthcare workers with the necessary training, equipment and medications needed to ensure the best possible treatment of patients.

During the first wave of the pandemic, Junior Doctors were amongst the first to be facing the new pathogen, but were often excluded from the proper provision of safe and adequate PPE<sup>1</sup>. In a survey conducted by EJD in April to May 2020, 13 delegations responded that the provision of PPE in their institution or nation was insufficient. Moreover, of the 15 delegations surveyed, less than half reported that PPE provision improved over the first two months of the pandemic. While it was already the case that Junior Doctors faced substandard working conditions, the pandemic greatly exacerbated the situation. Breaches of the European Working Time Directive were reported by over half of delegations, with several stating that the COVID-19 pandemic had negatively impacted their working hours and ability to take breaks. Junior Doctors were asked to maintain a constant state of readiness to come into work if needed.

COVID-19 has exacerbated the sub-standard working conditions experienced by junior doctors. Alongside this they have experienced the psychological consequences of witnessing a large volume of deaths from COVID-19 and the moral injury associated with the delivery of sub-optimal care. Junior Doctors ought to be able to easily access and follow programmes to recognise and manage work related stress and burnout induced by these circumstances. Regrettably, only seven delegations reported access to such programs, whereas over half of the delegations reported that there were no services available for healthcare staff.

Uniquely to Junior Doctors, Post Graduate Training (PGT) and career progression has also been significantly affected by the pandemic. Due to the cessation of elective procedures, many Junior Doctors are facing the prospect of not meeting caseload requirements and not obtaining adequate experience prior to the completion of training<sup>2</sup>. The redeployment of trainees to ICU/COVID-19 wards<sup>3</sup> has become a practice to mitigate staff shortages during medical surges, and has resulted in a delay to, or reduction in, training for many junior doctors. Many training programs were paused or extended with a clear impact on future work force planning and specialist provision.

In light of these findings, EJD adopted a statement at their November General Assembly regarding the <u>impact of</u> <u>COVID-19 on European Junior Doctors</u>. Although the vaccination coverage across Europe is increasing daily, new COVID-19 variants continue to challenge European health infrastructure and the possibility of future significant waves of COVID-19 remains. COVID-19 has emphasised the fragility of already struggling health systems, the legacy of poor work force planning and the impact of political and economic agendas on healthcare across Europe. EJD urgently calls upon the EU and national governments to properly manage the consequences of the pandemic on healthcare professionals, and to address the historic and ongoing challenges faced by healthcare systems across Europe which have been highlighted and exacerbated by the Covid-19 pandemic.

Mathias Körner, President, European Junior Doctors Association

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<sup>&</sup>lt;sup>1</sup> Pawlak, K. ,Kral, J. ,Khan, R. ,et al. (2020) Impact of COVID-19 on endoscopy trainees: an international survey. Gastrointestinal Endoscopy 92(4):925-935

<sup>&</sup>lt;sup>2</sup> Sneyd, J.,Mathoulin, S. ,O'Sullivan, E. ,et al. (2020) Impact of the COVID-19 pandemic on anaesthesia trainees and their training. British Journal of Anaesthesia 125(5):450-45

<sup>&</sup>lt;sup>3</sup> Blum, P. , Putzer, D. ,Liebensteiner, M.C. ,& Dammerer, D.(2021). Impact of the Covid-19 pandemic on orthopaedic and trauma surgery-A systematic review of the current literature. In Vivo, 35(3),1337–1343

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