



## This issue

Message from the CPME President	<u>2</u>
<b>FEATURE</b>	
EMA and doctors: improving trust as a unified voice throughout the pandemic	<u>3-4</u>
<b>LATEST NEWS</b>	
European Medical Organisations on violence against healthcare professionals	<u>4</u>
Changing EU law and policy to restore balance in the pharmaceutical sector	<u>5</u>
Is the Future Bright for Telemedicine? European Doctors Talk Digital	<u>6-7</u>
Towards the acceptance of a European Health Data Space	<u>7-8</u>
New IMMUNION project to improve European healthcare professionals' cooperation on vaccination	<u>9</u>
<b>NEWS FROM CPME MEMBERS</b>	
Attacks against healthcare professionals must be prevented and condemned	<u>10-11</u>
<b>GUEST ARTICLES</b>	
COVID-19 in Spain: 2021 perspective with the vaccination plan	<u>12</u>
COVID-19 vaccines: an update from the American Medical Association	<u>13</u>
The pandemic within the pandemic: misinformation and myths surrounding COVID-19	<u>14-15</u>
The role of community pharmacists in COVID-19 – Lessons learned from the pandemic	<u>16</u>

## SAVE THE DATE! - CPME Meetings 2021– 2022

26-27 November 2021  
Oslo (Norway)

25-26 March 2022  
Venue tbc

28-29 October 2022  
Venue tbc

# MESSAGE FROM THE CPME PRESIDENT

*Dear Colleagues and friends,*

Welcome to the 35th edition of the CPME Newsletter.

The COVID-19 pandemic has changed our lives. Only few countries around the world were prepared to face such a public health emergency. Today, the European medical community continues to be on the front line while facing different variants of the virus. There are more data and answers available. Contact tracing, a better understanding of the virus and the vaccination strategy help containing the spread of COVID-19.

However, from this public health emergency we must learn how to face future pandemics. Relying on solidarity and ad-hoc decisions did not work. We must equip the EU level with better competences and enforceable mechanisms. For this reason, we, the European doctors, recommend reviewing legislation and policies on pandemic preparedness to strengthen the capacities and the cooperation mechanisms. [We are convinced that the Commission "European Health Union" proposal on strengthening the ECDC, the EMA and the cooperation on serious cross-border health threats move into the right direction.](#) For example, the **European Medicines Agency (EMA) draft proposal** will expand the mandate to include the monitoring of medical devices in crises times, which CPME very much welcomes. On the draft proposal on strengthening the mandate of the **European Centre for Disease Prevention and Control (ECDC)** [we welcome in particular the Health Security Committee and the recognition for the need for preventive action.](#) European doctors welcome as well the proposal to collect comparable data on resources and establish benchmarks for minimum capacities.

CPME continues to follow the debate and strongly believes that the outcome must strengthen the EU's and Member States' capacity to prevent, prepare for and manage future pandemics better.

We invite you to read about the COVID-19 experience from Spain and Lithuania, but also from the United States of America. Also, we feature an article by EMA highlighting the importance of a trustful relation with the medical community during the COVID-19 pandemic. Finally, read about the COVID-19 lessons learned from the Pharmaceutical Group of the European Union (PGEU) and the EMSA-CPME joint campaign to combat false myths linked to the COVID-19 vaccines.

We hope you enjoy reading this edition.

*Prof. Dr Frank Ulrich Montgomery*  
*CPME President*






EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## EMA AND DOCTORS: IMPROVING TRUST AS A UNIFIED VOICE THROUGHOUT THE PANDEMIC

The roles of the European Medicines Agency (EMA) and that of the Standing Committee of European Doctors (CPME) represent two sides of the same coin. The work of the EMA constitutes the first step to medicines following a sound and safe scientific evaluation process. CPME and its doctors work with patients on healthcare's front line. This is especially true in the current pandemic.

COVID-19 is the biggest threat to public health of this generation, and European citizens have turned towards the authorities they can rely on amidst the uncertainty. EMA has attracted much public interest over its role in the approval and monitoring of vaccines, and doctors have been the first port of call for sick or concerned citizens.

Clearly, while the work associated with these responsibilities has dramatically increased during the pandemic, it has also represented a unique opportunity to raise awareness of our work and to reinforce the trust placed in our hands like never before. To make sure that these responsibilities are aligned, that this trust is well placed, actors like EMA and healthcare professionals' organisations need to work together, improving collaboration and supporting each other's roles.



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EMA has been interacting with European doctors and their representative organisations in various areas since it was founded in 1995. As prescribers and handlers of the medicines that the Agency evaluates, doctors have key insights to offer and EMA is committed to strengthening this working relationship.

Doctors provide independent expertise acquired in their day-to-day clinical practice. They contribute their real-world experience to the development, approval and monitoring of medicines. At EMA, doctors are members of EMA's Committees and Management Board. In the context of COVID-19, they contribute to a more efficient, targeted communication on vaccines and therapeutics, ensuring that reliable information reaches the patients and citizens of Europe in order to promote safe and optimal use of these medicines.

COVID-19 has presented three major challenges: the need to speed up development and approval processes, for example through the [rolling reviews](#) of available data as medicines are developed, the need to communicate fast about newly developing scientific evidence and the need to contextualise and manage a large amount of uncertainty. EMA is doing so through its own channels, but these messages also need to come through doctors. They are the ones who receive individuals' questions, speak to patients daily, address their concerns and reassure them. This became very clear when the cases of thrombosis with thrombocytopenia linked to the AstraZeneca vaccine hit the news.

An important tool in EMA's arsenal is direct healthcare professional communications (DHPCs). These are drafted specifically for doctors and other healthcare professionals to transmit information about critical and emerging safety issues so that they make the right decisions for their patients. DHPCs provide up-to-date, sound information about changes in the way medicines are used. In the case of the AstraZeneca vaccine, the DHPC informed doctors of the possibility of this side effect and of the signs and symptoms to look out for. DHPCs are also a tool used to remind doctors of the importance of reporting side effects, which is crucial in the development of new knowledge.

As we enter summer, vaccination efforts continue throughout Europe. This is thanks to all health actors, from regulators, to the individuals involved in the vaccination campaigns: doctors, but also nurses, pharmacists, paramedics

and volunteers. A harmonised public voice from healthcare professionals and regulating authorities has been key to ensuring vaccine uptake and will continue to be. EMA believes in investing in a clear line of communication between regulators and healthcare professionals. Now that the eyes of European citizens are directed at us we must continue to act together and reinforce the confidence they have entrusted us with.

Useful links:

[Direct healthcare professional communications | European Medicines Agency \(europa.eu\)](#)

[COVID-19: latest updates | European Medicines Agency \(europa.eu\)](#)

[Healthcare professionals | European Medicines Agency \(europa.eu\)](#)

[Resources for healthcare professionals | European Medicines Agency \(europa.eu\)](#)

*Giulia Gabrielli and Ivana Silva, Public and Stakeholders Engagement Department, European Medicines Agency*

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## EUROPEAN MEDICAL ORGANISATIONS ON VIOLENCE AGAINST HEALTHCARE PROFESSIONALS

In 2021 the World Health Organisation celebrates the International Year of Health and Care Workers. Despite this, European Medical Organisations face an increase in all types of acts of physical, emotional, and psychological violence against healthcare professionals. This is confirmed in the alarming finding of the FEMS survey about burnout of physicians in Europe. European Medical Organisations reaffirm that they stand in complete solidarity with their colleagues who are in the front line of the fight against the COVID-19 pandemic.

European Medical Organisations strongly urge governments to reconsider how healthcare systems value the well-being of healthcare professionals in their daily practice together along with the wellbeing of the patients they serve every day and the community of employees who work with them. Medicine should be, and must remain, a safe place to work.

The ongoing pandemic has reaffirmed the central role of physicians in ensuring the stability and wellbeing of our societies. On the 12th of March of this year, European Medical Organisations marked the second European Awareness Day on Violence against Doctors and other Healthcare Professionals and committed themselves to acknowledging and addressing those factors contributing to violence against doctors including exhaustion and burnout.

We call on European governments and health authorities, to provide all healthcare staff with a safe working environment and adequate mechanisms to prevent any type of violence so as to decrease the risk of exhaustion and burnout for all healthcare professionals, and to deploy all necessary means to protect the physical and psychological integrity of our colleagues during this pandemic and beyond.

These healthcare professionals, whom we applaud, deserve admiration, respect, appreciation, and protection. European Medical Organisations also pay tribute to all healthcare professionals who sadly lost their lives in the fight against the COVID-19 pandemic.

## CHANGING EU LAW AND POLICY TO RESTORE BALANCE IN THE PHARMACEUTICAL SECTOR

The European Commission is undertaking wide-ranging initiatives to review a number of aspects of EU legislation and policy to tackle the problems facing the current pharmaceutical system. They span a broad range of measures, from strengthening the resilience of pharmaceutical supply chains to adapting regulatory systems and improving health emergency preparedness and biomedical research and development.

These objectives are envisioned in the ambitious, long-term [Pharmaceutical Strategy for Europe](#), published late last year, which seeks to make the European pharmaceutical system “patient-centred, future-proof and crisis-resistant”. The strategy is a key pillar of the Commission’s vision to build a stronger European Health Union (see Newsletter no. 34).

European doctors support the Commission’s plan and agree with the proposed course of action towards ensuring patients’ access to affordable medicines. They [argue that the strategy can lead to restoring balance in the pharmaceutical sector](#), proposing measures to achieve the outlined objectives. CPME emphasizes the role of healthcare professional organisations in implementing reforms in the public interest and confirms its readiness to contribute to this process.

As part of the strategy’s implementation, the Commission is evaluating the current [general pharmaceutical legislation](#) with a view to adapting Directive 2001/83/EC and Regulation (EC) No 726/2004 based on the experience gained over recent years and reflecting technological developments.

In particular, the evaluation will focus on unmet medical needs, inequalities in access to medicines, vulnerabilities in medical supply chains, and whether current rules are fit for new, advanced therapies.

CPME [welcomes](#) most of the goals outlined in the Commission’s inception impact assessment, but stresses that it is necessary to [critically review the current accelerated approval procedures](#), which are over-used, rather than examining ways to further accelerate medicinal product authorization.

Later this year, the Commission will also present a legislative proposal for [establishing a Health Emergency Preparedness and Response Authority \(HERA\)](#) that would support the EU’s capacity and readiness to respond to cross-border threats and emergencies. The Authority is intended to strengthen the coordination across the value chain and develop strategic investments for research, development, manufacturing, deployment, distribution and the use of medical countermeasures.

European doctors point out in their [response to the public consultation](#) that through HERA, the EU should take responsibility for investing in and shaping biomedical innovation. They believe that the new Authority offers the opportunity to establish a new public-driven model of R&D that ensures health innovations respond to real public health needs and are equally accessible. For this to happen, the new authority needs to be transparent and publicly governed in order to guarantee that the objective of increasing health security takes precedence over any economic interests. HERA should define a fair distribution of risks and rewards from the outset.

In early 2022, the Commission also plans to propose how to review the [EU legislation on medicines for rare diseases and children](#). Although the Orphan and Paediatric Medicinal Products Regulations have increased the involvement of pharmaceutical companies in the above areas, the current system of pharmaceutical incentives has numerous shortcomings. CPME’s response to the public consultation on this issue will be published later this month.

Meanwhile, the Pharmaceutical Strategy has recently benefited from a significant success as the European Parliament and Council negotiators reached a long-awaited agreement on a Regulation on health technology assessment.



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*Piotr Kolczyński, Legal Advisor*

# IS THE FUTURE BRIGHT FOR TELEMEDICINE? EUROPEAN DOCTORS TALK DIGITAL



On 1 June, CPME organised a panel discussion on the future of telemedicine. The event was hosted by the Portuguese Presidency during the [eHealth Summit](#) (the main event held in the country on innovation and digital transformation in health).

CPME President, Prof. Dr Frank Ulrich Montgomery, opened the event, noting that the COVID-19 pandemic had accelerated the use of telemedicine. Doctors and patients had experienced the benefits and opportunities of telemedicine, but also its risks and limitations. The panel addressed these issues, offering some recommendations for the future.

Main highlights:

**Ms Mervi Kattelus**, Health Policy Adviser at the Finnish Medical Association, gave an overview of the use of telemedicine in Finland, where telemedicine has helped improve access to healthcare in remote areas and follow-up care of patients with chronic diseases. Patients have been empowered to monitor their health using platforms to share health data with a physician who can give professional advice. Mental health services administered through telemedicine have also increased in certain cities. The implementation of telemedicine has, nonetheless, caused certain concerns, namely that some healthcare organisations had set targets, for instance that 40% of practice be performed via telemedicine. Setting such targets could risk patient safety as physicians should have the right to determine whether a face-to-face consultation is more appropriate.

Moreover, in a virtual environment, physicians cannot control who else is in the room, leading to other concerns (e.g. non-identification of cases of domestic violence). There were also doubts as to whether students or junior doctors should provide telemedicine services, as there could be a risk to patient safety if the physician did not yet have enough knowledge and experience to evaluate the patient correctly and there was no appropriate supervision and support by an experienced physician. She recommended that doctors master telemedicine, understand when a telemedicine appointment is appropriate and



use telemedicine when it brings added value to care.

**Prof. Dr Sebastian Kuhn**, CPME rapporteur on digital competencies, trauma and orthopaedic surgeon at the Johannes Gutenberg Universität Mainz and Professor of Digital Medicine at Bielefeld University, provided insights on what academia is doing for telemedicine. A new medical curriculum needs to be envisioned with digital health as a core competence. The digital transformation of medicine offers the opportunity to rethink the medical profession, with new diagnosis and treatment approaches made available. Important innovations include the ability to detect deterioration in a patient's condition when they are recovering at home and a move towards more frequent monitoring of patients' health, which could help doctors schedule consultations based on medical needs rather than using the traditional 12-week time frame. The reluctance to embrace telemedicine is not linked to a single medical speciality, but rather to doctors' attitude and openness to change. He recommended that doctors rethink patient care with telemedicine playing a role in the interaction between inpatient and outpatient care, as well as in rehabilitation. Empowering doctors to use technology through education is also key.

**Dr Ray Walley**, CPME Vice President and full-time General Practitioner (GP) based in Dublin, spoke of the acceleration of the use of telemedicine across Ireland due to COVID-19. Dr Walley agreed that telemedicine is helpful in the monitoring of chronic conditions, as well as in emergencies where distance to health care facilities is an issue. He cautioned that telemedicine is not an adequate replacement for face-to-face consultations. There are concerns surrounding the duplication of care, quality of care, patient confidentiality and security. Most doctors are now re-

verting back to in-person consultations. The Irish health service computer systems were hit by a cyber-attack, which led to delays and cancellations of in-person and online appointments. Hospitals are highly vulnerable to cyber-attacks and this needs to be considered when implementing a telemedicine system. Telemedicine is also subject to certain access barriers (e.g., for elderly individuals as well as households without internet). He recommended that telemedicine be viewed as a tool and used in limited circumstances, and that national bodies specify which consultations are subject to telemedicine.

Prof. Montgomery concluded by stating that telemedicine has the potential to be a useful tool in several clinical scenarios, but that it is not without risks and is not suitable in all situations. Doctors and patients need to be appropriately trained and understand the technological limitations. Telemedicine requires secure and stable platforms that protect patients' privacy and confidentiality. It should not be driven by commercial interests and governments should only support telemedicine services that improve patient safety, quality of care and efficiency. Telemedicine services need to be appropriately reimbursed as part of the health services catalogue. Finally, when using telemedicine, doctors should follow the same fundamental ethical principles and adhere to the same standards as with face-to-face consultations, as quality of care and patient safety must remain a priority.

The video of the event is available [here](#).

*[Sara Roda](#), EU Senior Policy Advisor*

## TOWARDS THE ACCEPTANCE OF A EUROPEAN HEALTH DATA SPACE



CPME has been selected to participate in the [Joint Action Towards the Acceptance of a European Health Data Space \(TEHDAS\)](#). This Joint Action aims to deliver responses to Member States and the Commission in order to develop and promote health data sharing among public authorities, between private entities and public authorities and among private entities themselves. The access to, and re-use of, certain categories of personal data (health data) for purposes other than those for which they were initially collected (for so-called secondary purposes) is driving the new policy and regulatory trend at EU and national level. TEHDAS is a 30 month project that will

allow detailed reflection on the modes of governance for the use of secondary health data (Work Package 5) as well as on the availability of comparable high quality health data for research and innovation (Work Package 6). Furthermore, it addresses options for a shared European data infrastructure (Work Package 7), on citizen perception of health data and data-sharing practices, as well as a compliant data altruism concept<sup>1</sup> (Work Package 8), and on needs and expectations of stakeholders for economic sustainability of the sharing model (Work Package 4). The results will form the legislative framework for the European Health Data Space (EHDS).

CPME was selected to be part of Work Packages (WP) 4 Policy forum, WP5 Permanent Advisory Group and WP8 Permanent Advisory Group, and hopes to contribute positively to the discussion, providing expertise in relation to professional practice, ethics, medical confidentiality, privacy and personal data protection and interoperability. For CPME, the European Health Data Space (EHDS) is welcomed, but certain conditions need to be put in place to make sure that the Space is trustworthy and the legal framework offers robust guarantees on the health data that it will manage<sup>2</sup>. To this end, the opinions of the European Data Protection Board and the European Data Protection Supervisor need to be followed through<sup>3</sup>. The EHDS needs to lead by example, not only in terms of compliance with EU and national data protection laws, but also as the embodiment of state-of-the art privacy preserving techniques.

The WP5 Permanent Advisory Group started its work very nicely in May. The Group was consulted twice to comment on specific deliverables. The first deliverable analysed the specificities of health data in legislation, focusing on consent, public health, research use, data and cybersecurity, semantic interoperability and legal fragmentation, among others. For CPME, the EU system will always need to take into account national health systems' governance, and ensure that it will not diminish or lower the standards for professional secrecy, respect of patients' privacy and dignity, or create legal uncertainty concerning the protection of patients' personal data. The second deliverable examined possible governance mechanisms for health data, mapping current actors at EU level that manage or could manage health data. For CPME, it will need to be made very clear to each user or contributor to the EHDS, who will have access to what, under which circumstances, for which purposes and for how long, including by the entity that will manage and prepare the data for the user or contributor (e.g. data permit authorities scheme). For further information please see [TEHDAS analysis: Health data needs dedicated EU regulation](#).

The WP8 Permanent Advisory Group also kicked off in May with the objective of providing an overview of WP8 deliverables. This WP will prepare recommendations to raise awareness and engage citizens with their health data in the future EHDS, as well as recommendations to foster 'data altruism' practices, looking into good examples and use cases where consent and accessibility help foster individual's confidence to share health data. The Group will work as a discussion forum, lending a critical eye to the deliverables, and also helping to disseminate and communicate those deliverables. CPME intends to convey the perception of the medical profession, looking into the appropriate checks and balances for access and availability of data (e.g., fees, time limits for accessing research, legitimate users, legitimate purposes), ethics (e.g., system independence and proper oversight, common good purpose), privacy and data protection.

*"The Standing Committee of European Doctors (CPME) is keen to support and take part in all of these groups. The outputs will shape the legislative framework expected by the end of the year."*

Sara Roda

Parallel to this initiative, the eHealth Stakeholders Group (eHSG) is also delving into the EHDS. As explained by the Commission, the EHDS is based on four pillars: i) sharing of health data for healthcare, ii) access to health data for research, innovation and policy making, iii) single market for digital health services, and iv) Artificial Intelligence (AI) in health. Five Sub-groups are being formed to identify and deliver concrete actions for each of these areas, which will then be presented at a webinar on 10 September.

[Sara Roda](#), EU Senior Policy Advisor

1) For EDPS and EDPB, the concept of data altruism is not yet clear, in particular the validity of the consent (as the possibility to withdraw consent cannot be waived by the individual since the protection of personal data is a fundamental right enshrined in Article 8 of the Charter of Fundamental Rights of the European Union) and its consequent added value considering that all requirements related to consent would still need to be fulfilled (see section 3.5 of the [Joint Opinion 3/2021](#) on the Proposal for a regulation of the European Parliament and of the Council on European data governance (Data Governance Act)).

2) Please see [CPME Policy on the European Health Data Space – Focus on Health Research and Policy Making](#), March 2021.

3) See [Statement 05/2021 on the Data Governance Act in light of the legislative developments](#), May 2021.



## NEW IMMUNION PROJECT TO IMPROVE EUROPEAN HEALTHCARE PROFESSIONALS' COOPERATION ON VACCINATION



CPME is partnering in a new IMMUNION project, which was kicked off in April. Its aim is to strengthen the collaboration between healthcare professionals and other stakeholders to communicate evidence-based information about vaccination and increase vaccine confidence and uptake.

Practically, the IMMUNION (“Improving IMMunisation cooperation in the European UNION”) project will focus on strengthening the Coalition for Vaccination, which was convened by the European Commission in 2019 and is co-chaired by CPME together with the European Federation of Nurses Associations (EFN) and the Pharmaceutical Group of the European Union (PGEU). This Coalition brings together European associations of healthcare professionals and relevant student associations in the field and aims to support delivering accurate information to the public, combating myths around vaccines and vaccination, and exchanging best practices on vaccination. One of the IMMUNION project’s tasks is to develop a website for the Coalition, which would also serve as a hub for vaccination training materials for all healthcare professionals. The project also aims to develop the internal collaboration of the Coalition members.

The 2-year project is funded by the European Union Health Programme and led by EuroHealthNet. It brings together the co-chairs of the Coalition for Vaccination as well as other partners across the EU such as four national public health institutes and centres from Italy, Romania, Latvia and Greece, media and communications partners, one think tank, and the University of Antwerp. In addition, the project gets scientific advice from the other Coalition members and organisations, such as WHO Europe and the UCL Institute of Health Equity.

Building on learnings from vaccination efforts at national, regional, and global level, the IMMUNION project will add value to existing EU and national initiatives by increasing stakeholder collaboration to address issues of access to accurate information about vaccination. This will primarily be achieved through strategies focused on communication and training targeted at healthcare professionals and the public. The project will also develop tools and resources to increase vaccine coverage, in particular amongst underserved populations.

Besides developing the Coalition for Vaccination website with a training hub, the project will deliver workshops for healthcare professionals, workshops to train trainers, and communication toolboxes. In addition, it will develop a ‘find an expert’ page which will help journalists, healthcare professionals and the general public to find vaccination experts across Europe to provide quotes and other information about vaccination.

Ideally, the IMMUNION project will increase the visibility of the Coalition for Vaccination but also its engagement with wider networks working in vaccination. The project will focus on streamlining and improving the Coalition’s communication and joint activities. In turn, members of the Coalition for Vaccination will help to achieve IMMUNION project objectives, serving as critical stakeholders and partners by engaging healthcare professionals from across Europe in project activities and disseminating project outputs.

CPME is leading one of the project’s work packages with EFN and PGEU focusing on strengthening the Coalition. As one of its first tasks, the work package is currently conducting a survey on vaccination training in order to develop an online platform for healthcare professionals gathering together useful information and educational materials on vaccination.

*Markus Kujawa, EU Policy Advisor*

## ATTACKS AGAINST HEALTHCARE PROFESSIONALS MUST BE PREVENTED AND CONDEMNED



Violence against health professionals is a prominent, under-reported global occupational hazard<sup>1</sup>. It constitutes a risk, not only to the dignity, but also to the health of professionals. The COVID-19 pandemic has exacerbated violence against healthcare professionals as violence often arises during health emergencies<sup>2</sup>. Although aggression is most often discussed as coming from patients and their relatives, healthcare professionals can experience such acts from their peers and supervisors as well<sup>3,4</sup>. Aggression against healthcare professionals can be exhibited in many ways: verbal/written, physical or psychological violence, and take different forms: harassment, bullying, insults, assault, threats etc<sup>5</sup>. The COVID-19 crisis has, of course, put extra pressure and strain on healthcare staff. Medical personnel are risking their lives daily by caring for COVID-19 patients

and as a result many of them have been infected or even died. Certain healthcare settings can be more prone to workplace aggression than others. Research has shown that workplace violence is most likely to occur in psychiatric departments, emergency services and primary healthcare settings, which may in part be due to the types of patients treated in these settings. Patients with untreated mental disorders or substance abuse, as well as older adults who are often dealing with dementia, have commonly been associated with aggressive and unpredictable behaviour and low levels of self-control. The attacks by patients and their families currently being reported often originate from a healthcare professional's attempt to implement essential COVID-19 prevention and control measures – such as not allowing the family to visit patients in hospital.

On 12<sup>th</sup> March 2021, the Lithuanian Medical Association marked the European day to Fight Violence against Doctors and Health Professionals. All physicians were invited to take part in a research survey regarding violence against doctors in order to identify the frequency and severity of episodes of aggression against them and to estimate the 12-month prevalence of violence during the COVID-19 pandemic.

This study demonstrated that 59% of healthcare professionals have experienced workplace aggression from patients or visitors over the previous 12 months, with 81% of physicians faced with inappropriate or arrogant behaviour from patients. The most prevalent type of aggression was psychological (77%); 4% of health professionals reported physical violence (aggressive acts occurred during assistance and patient care during the pandemic period). Typically, the highest rates of physical aggression were found in emergency departments. Professionals reported that the major risk factors for aggression from patients, in their opinion, were in most cases due to long waiting times, shortages of medical staff and unregulated, huge workloads and a discrepancy between patients' expectations and the services offered. 79% of professionals didn't know what to do when they recognized an episode of aggression, and confirmed that they hadn't taken part in any training courses or workshops concerning the management of situations of aggression.

Another important and more unexpected result was that 78% of doctors had faced aggression from their peers or supervisors in the previous 12 months. 54% had experienced bullying from their Heads of Units in the form of insults or harassment. 75% of professionals didn't know how or where to report the incident or what to do. Half of them kept the incidents to themselves.

Workplace aggression can have significant adverse effects on professionals' health<sup>6</sup>. Workplace violence is one of the possible causes of burnout in the health sector. Research has shown that physicians who experience aggression at work have a worse physical (headaches, sleep issues), psychological (depression, anxiety, burnout, distress, self-esteem issues) and emotional state (often anger, sadness, fear, guilt)<sup>7</sup>. Our study showed that huge

workloads and acts of aggression by patients had the highest impact on health status and caused the most stress among doctors.

The findings suggest the necessity of implementing adequate national prevention strategies to address violence against health professionals<sup>8</sup>. In Lithuania, an integrated violence prevention action plan has been prepared by the Ministry of Health together with NGOs, professional organisations and academic institutions in order to improve the psychological climate in the healthcare system on an individual, institutional and national level. Seven strategic directions were identified:

1. A “Zero tolerance” policy on violence in health care institutions. The reporting of incidents through the “line of trust” followed by an analysis of the root cause of violence.
2. The creation of support networks within the medical community to improve education and sensitivity amongst colleagues to enable them to emotionally support each other.
3. The concept of a Healthful Work Environment - a positive work culture must be created where all those involved (professionals and patients) communicate with respect, with a focus on positive work recognition and conflict resolution.
4. An assessment and elimination of risk factors for violent behaviour. Legal protection measures concerning violent acts are necessary.
5. The improvement of working conditions, which impact the psychological well-being of healthcare professionals. Constructive discussions with the media on how to ethically inform society about adverse events and medical errors.
6. The promotion of supervisors in healthcare institutions to take care of the physical and emotional well-being of their employees.
7. Training courses for medical students in universities to improve awareness, attitudes, and self-confidence with regard to violent acts. Government agencies should also be the main stakeholders and work alongside other parties to reduce incidents of violence.

The Lithuanian Medical Association has already started education and training courses to provide doctors with the knowledge and skills needed to prevent aggression and to teach them how to recognize aggression and apply different techniques during an aggressive event.

*[Dr Daiva Brogienė](#)*

*Member of the Council of the Lithuanian Medical Association*

*CPME Vice President*

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# COVID-19 IN SPAIN: 2021 PERSPECTIVE WITH THE VACCINATION PLAN

OMC

ORGANIZACIÓN  
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Last December, the Spanish National Health System Inter-territorial Council drafted a Vaccination Strategy that required enormous flexibility and management capacity. The initial slowdown in supply and the idea of not being able to “save the summer” had a negative effect on the collective morale, while controlling

the third wave also took its toll by inundating hospitals and ICUs in many Autonomous Communities.

By May 2021, the Vaccination Strategy in Spain had been updated on seven occasions. The challenge was to combine the progressive availability of vaccines with the establishment of priorities.

By May, 17.2 million Pfizer vaccines, 5 million AstraZeneca vaccines, 2.1 million Moderna vaccines and 0.3 million Janssen vaccines had been administered in Spain. A total of 8 million Spaniards have now received two doses (17.1% of the population) and 16.7 million have received at least one dose (35.2%).

The strategy has experienced complications due to problems of availability, in addition to delays or failure to honour production commitments which, in the case of the AstraZeneca vaccine, has led to litigation between the European Commission and the laboratory. Between March and April 2021 the pharmacovigilance system raised the alarm in relation to thromboembolic events in connection with the AZ and Janssen vaccines (particularly among people under 60). In Spain, the Vaxzevria vaccination programme was suspended between 16 and 23 March. On 24 March it

was resumed, increasing the age of those eligible to receive this vaccine to 65 years. From 8 April, following the assessment report drafted by the European Medicines Agency (EMA), the use of this vaccine was confined to people over 60 years of age.

Since the end of April and in May, the vaccine supply and administration rate has rapidly increased, making it feasible to achieve the Government's goal of having 70% of the population immunised before the end of the summer.

The defining of priorities in administering the vaccine has been based on 10 groups, with 9 additional subgroups, taking into consideration criteria related to severity of the disease, the capacity to become infected and workers performing essential jobs.

Managing a vaccination programme with so many age groups and criteria has proved to be extremely complicated, with public debate about adverse reactions, the age of the persons receiving the vaccine and priority groups giving rise to much distrust, which has increased with the doubts and difficulties in explaining the changes in strategy. At all events, the fact that the vaccination

process is now progressing at a very fast rate is now resolving many of the problems related to priority.

The idea of reducing the use of Vaxzevria due to the adverse effects detected has taken precedence, despite their low frequency (up to 25 April, out of a vaccinated population of 5 million, 11 cases of thromboembolic events have been detected in Spain, causing three deaths). This has led the central health authorities to recommend the administering of an mRNA vaccine (Pfizer or Moderna) as the second dose, but this has not been included in the summary of product characteristics due to not having been tested in clinical trials. Instituto de Salud Carlos III has conducted a rapid study on reactogenicity and immunogenicity in administering a second dose of Pfizer, with positive results. For this reason, the use of guidelines is being considered, while accepting that people can voluntarily ask to receive Vaxzevria as the second dose by signing a consent form.

The number of people who refuse to be vaccinated is very small, but in the case of AstraZeneca, following the news about the adverse effects, a considerable number of people have asked to change to another vaccine in some Autonomous Communities.



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*Dr Tomás Cobo Castro*

*President of the Spanish General Medical Council*

## COVID-19 VACCINES: AN UPDATE FROM THE AMERICAN MEDICAL ASSOCIATION



GUEST ARTICLE

The United States of America (USA) had more cases and deaths from COVID-19 than any other country in the world. As of this writing, [33 million cases have been recorded, and 587,000 people have died](#). At the same time, 48 percent of the population has now had at least one vaccine dose and 38 percent are [fully vaccinated against COVID-19](#).

In May 2020, the public-private collaboration [Operation Warp Speed](#) was begun to accelerate development, production and distribution of a safe and effective COVID-19 vaccine. The science behind the breakthrough had a head start. Researchers had already made progress developing vaccines for other types of coronaviruses: they applied lessons learned after the 2003 [SARS epidemic and the 2012 MERS outbreak](#). The allocation of billions of dollars [helped speed the clinical trial process](#) and allowed steps in the process to occur simultaneously rather than consecutively, such as starting manufacturing of the vaccine at industrial scale well before the demonstration of vaccine efficacy and safety.

By December 11, 2020, the U.S. Food and Drug Administration (FDA) had issued an Emergency Use Authorization (EUA) for the use of the Pfizer-BioNTech COVID-19 Vaccine. Under an EUA, the FDA permits a product to be made available for the duration of an emergency

based on the best available evidence, without the full body of evidence utilized in the standard [FDA approval or clearance process](#). The FDA [issued an EUA](#) for the use of the Moderna vaccine later in December, and another was issued in February for the Johnson and Johnson/Janssen vaccine. [The same month, the USA reached the sad milestone of 500,000 dead from COVID-19](#).

First to receive the approved vaccines were front line health care and service workers and the elderly in congregate care settings. As production targets were reached, access was extended to those at higher risk of infection and those over age 65. [All adults age 16 and older](#) in the US became eligible for the vaccine on April 19. On May 15, the Centers for Disease Control and Prevention (CDC) announced that children [older than 12 years can be vaccinated](#) with the Pfizer-BioNTech vaccine. The CDC now recommends [vaccinations in pregnancy](#).

Vaccines are available at no cost to all eligible people living in the USA, [regardless of immigration or health insurance status](#). Supply now exceeds demand and the current vaccination rate in the USA is a rolling seven day average of [1.5 million doses a day](#).

While vaccination rates and supplies in the USA are encouraging, the impact of Covid-19 continues to be felt unequally. Long-standing systemic health and social inequities have put many people from racial and ethnic minorities at higher risk of contracting COVID-19. People who are Black or African American, Hispanic or Latino, American Indian or Alaska Native, and Asian are also [more likely to be hospitalized and to die from COVID-19](#).

Federated state and local responses to mask mandates, public openings and other safety protocols created and continue to present a challenge for Covid-19 infection rates across states. While vaccines are generally now readily available throughout most of the USA, [vaccination rates are slowing](#). Vaccination hesitancy and lack of easy access to vaccines due to transportation, work hours and other factors are the most significant roadblocks to increasing vaccination rates. Vaccination rates for minority populations continue to lag behind the white population. Increasingly, the vaccination campaign in the USA has embraced one-to-one outreach efforts, often with the physician shouldering the effort of educating hesitant patients.

[Susan R. Bailey, MD](#)

*President*

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## THE PANDEMIC WITHIN THE PANDEMIC: MISINFORMATION AND MYTHS SURROUNDING COVID-19

Mis- and disinformation have steadily accompanied the past 18 months of the ongoing COVID-19 pandemic, dividing public opinion worldwide. This “pandemic within the pandemic”, more commonly referred to as an “infodemic”, is a phenomenon that has accompanied multiple public health emergencies in the past. The term Infodemic has been defined as “an overabundance of information, both online and offline [including] deliberate attempts to disseminate wrong information to undermine the public health response and advance alternative agendas of groups or individuals.”<sup>1</sup>



At the beginning of the pandemic, media coverage quickly centred around the disease. Confusion spread widely, giving way to misinformation with COVID-19 related myths spreading via social media channels and direct messaging groups. Research conducted by a team from Stanford University found that the spread of misinformation via social media is similar to that of a virus itself.<sup>2</sup>

Rumours based on misinformation and associated fear surrounding COVID-19 have led to the alienation of societal groups, as well as physical attacks and an overall increase in anti-Asian hate crimes and Xenophobia, amongst others. Conspiracy theories surrounding the origin of the virus, as well as rumours regarding vaccinations, have been continuously on the rise.

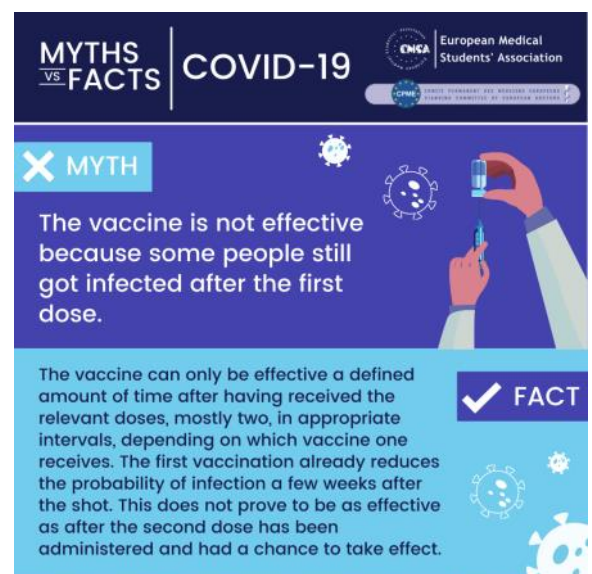
Governments, as well as national and international organisations, have implemented various methods aimed at quickly counteracting the spread of this misinformation, for example

podcasting channels, and have invited experts to address the public on the matter. The continued spread of myths via online social media and direct messaging providers has created a large degree of polarisation on the subject and led to “sides” being taken. The social unrest generated by these divisions has culminated in protests, at times violent.

The management of the spread of these rumours quickly became vital as misinformation in precarious public health emergency situations, such as the current pandemic, has been shown to lead to an increased number of lives lost.

Individuals claiming that masks do not work or suggesting that the intravenous administration of disinfectants may prevent COVID-19 have led to a number of preventable deaths. A survey conducted by the CDC amongst 502 adults in the United States found that 39% of participants were continuing with dangerous practices, including washing food with bleach or intentionally ingesting disinfectant to prevent a possible COVID-19 infection.<sup>3</sup>

With the development of and increasing rates of vaccination, myths surrounding the validity of data related to the efficacy of the vaccines started to spread, as well as theories surrounding the alleged injection of a microchip during vaccination, the vaccinated arm supposedly being magnetic afterwards, or the vaccine allegedly leading to mass sterilization.



Individual health care professionals publicly speaking out against the vaccines or the COVID-19 measures in place, underlining the apparent “validity” of misinformation, threaten to counteract the efforts made by organisations to halt

the spread of mis- and disinformation. Medical students, soon to be medical professionals, should also be aware of the consequences of spreading these myths.

Multiple organisations, including WHO and the UN, have started social media campaigns to address the myths surrounding COVID-19.

CPME, in collaboration with the European Medical Students' Association (EMSA), has launched a similar endeavour to fact check widely circulating COVID-19 related myths, thus far focusing on the use of masks and the efficacy and production of vaccines. The campaign has been successful in providing factual knowledge via social media channels, with positive feedback from local EMSA structures. The posts are available on CPME's twitter (@CPME\_Europa) and Facebook accounts, as well as on EMSA's instagram (emsa.europe), twitter (@emsa\_europe) and facebook channels.

Health care professionals have a continued responsibility to speak up when lives are in danger, especially in the midst of the current pandemic with the spread of misinformation engendering the preventable loss of human lives.

*Alexandra Archodoulakis*

*EMSA Vice President of External Affairs*

*EMSA intern to CPME*

- 1) Managing the COVID-19 infodemic: Promoting healthy behaviours and investigating the harm of misinformation and disinformation. Joint Statement by WHO, UN, UNICEF, UNDP, UNESCO, UNAIDS, ITU, UN Global Pulse and IFRC, 23 September 2020, last accessed 29.06.2021 <https://www.who.int/news/item/23-09-2020-managing-the-covid-19-infodemic-promoting-healthy-behaviours-and-mitigating-the-harm-from-misinformation-and-disinformation> .
- 2) Andrews, E. L. (2019, October 22). How fake news spreads like a real virus. Retrieved June 12, 2020, from <https://engineering.stanford.edu/magazine/article/how-fake-news-spreads-real-virus>
- 3) Gharpure R, Hunter CM, Schnall AH, et al. Knowledge and Practices Regarding Safe Household Cleaning and Disinfection for COVID-19 Prevention – United States, May 2020. MMWR Morb Mortal Wkly Rep 2020;69:705-709. DOI: <http://dx.doi.org/10.15585/mmwr.mm6923e2>

**Myth** X The COVID-19 vaccines were developed too fast, they cannot be trusted.

**Fact** ✓ The European Medicines Agency (EMA) is the European entity ensuring the quality, safety and efficacy of medicines and vaccines. Although the process was faster than with vaccines of the past, each and every standard that applies to vaccine production in the EU was upheld. No steps or trial phases are being left out, no corners were cut. The quality of the vaccines is thus not compromised by the rapid process.

MYTHS VS FACTS COVID-19 EMSA European Medical Students' Association

**MYTH** X Spikes in COVID-19 cases are because of increased testing.

**FACT** ✓ Not the increased number of tests but the increased rate of positive test results are worrisome. An increase in the rate of positive COVID-19 test results indicates an increase in the number of infections in the population. Widespread testing is of great help in identifying hotspots and isolating them. Without such testing strategies, more people would get infected, as the virus could spread more uncontrollably.

MYTHS VS FACTS COVID-19 EMSA European Medical Students' Association



## THE ROLE OF COMMUNITY PHARMACISTS IN COVID-19 – LESSONS LEARNED FROM THE PANDEMIC

COVID-19 has been devastating for public health. Many people have lost their lives and health care systems in Europe and worldwide have been struggling to treat both COVID-19 patients and patients with other health conditions. But even worse than the pandemic itself would be not learning from it and not using it as an opportunity to improve preparedness and response to future challenges.

The main lesson learned for the health care sector is that we must change the way health care is provided and move from hospital centered care to patient centered care, treating patients as close to their home as possible. This means investing more in primary care.

Academics, policy makers and international institutions such as [OECD](#) have repeatedly stressed that investing in primary care pays off: a large body of evidence clearly indicates that it reduces hospitalization rates and prevents unnecessary visits to emergency rooms. It ultimately saves lives and money. Now the time has come. With all countries around the world still battling COVID-19, we cannot afford to continue putting disease prevention and health promotion on hold, especially when facing the challenge of rapidly ageing societies. European community pharmacists are committed to taking up the challenge. They remain in the front-line against COVID-19 providing their communities with timely access to treatments, reliable information and, in some countries, also rapid COVID-19 tests and vaccines. But they are also ready to use their knowledge and expertise to provide more efficient and more effective care to patients. We should use this opportunity to make health systems stronger, more resilient,

and more responsive to patients' needs. We should define new models of care delivery which involve multi-professional teams working seamlessly together, with the support of integrated digital technology, to ensure continuity of care - especially for patients with chronic conditions – to guarantee an optimal allocation of resources within the sector and to improve health outcomes.



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As recommended by the OECD ([here](#) and [here](#)) and [WHO Europe](#), at the onset of the crisis many European countries introduced changes in legislation to expand the role of pharmacists and relieve pressure on the rest of the healthcare system. This was done by enabling pharmacists to renew repeat prescriptions for chronic medications and implementing the electronic transfer of prescriptions to pharmacies where this was not yet in

place. In several countries this also included the extension of pharmacists' scope to provide alternative solutions for medicine shortages. In countries such as France, Portugal, and Spain, community pharmacies have also been granted extended powers to dispense certain medicines, which were previously only accessible via hospitals. In some countries pharmacies also implemented special programs to help victims of domestic violence, which has sadly increased, especially during the lockdowns.

A study conducted by the Institute for Evidence-Based Health (ISBE) of the University of Lisbon has mapped 30 pharmacy interventions on COVID-19 provided throughout Europe. Among the most frequent immediate actions in response to the pandemic are symptom-based referral pathways for suspected cases, increased demand for the home delivery of medicines, pharmacy telephone support to vulnerable patients during isolation and dealing with new vulnerable patients. These are all important patient care interventions in screening, access, and vulnerable patient support.

The wide array of community pharmacy interventions on COVID-19 demonstrates the highly reactive and adaptive character of pharmacies in response to the pandemic. The 400,000 community pharmacists across Europe, through their wide network of 160,000 community pharmacies, are eager to reinforce the delivery of core pharmacy services and to go even further, assuming new responsibilities through advanced pharmaceutical services that have proven to improve people's quality of life and health systems' sustainability.

*[Dr Ilaria Passarani](#)*

*Secretary General*

*Pharmaceutical Group of the European Union*



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For feedback, further information, questions or to express an interest to contribute to future editions, please contact:

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