



**UNION EUROPÉENNE DES MÉDECINS OMNIPRACTICIENS/
MÉDECINS DE FAMILLE – EUROPEAN UNION OF GENERAL
PRACTITIONERS/FAMILY PHYSICIANS**

Dear UEMO Members,

This bulletin is focused on a variety of EU-related health topics including HTA development at EU level, vaccination, e-Health, medicines shortages, antimicrobial resistance and many more.

We hope you enjoy reading this issue!

Yours sincerely,

Aldo LUPO

UEMO President

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EU NEWS

I. PARLIAMENT GIVES GREEN LIGHT ON HTA



UEMO welcomes the MEPs vote on the approval of the report on Health Technology Assessment (HTA) on the 3rd of October, in Strasbourg.

“As healthcare professionals we see clear advantages in clinical HTA: a thorough understanding of the use, safety and clinical effectiveness of a technology is essential to evaluate what will bring true therapeutic added value to a patient.”

The European Parliament voted on the report on HTA, under the leadership of S&D MEP Soledad Cabézon Ruiz, with a majority of MEPs approving the European Commission’s proposal (576 in favour, 56 against) which vows to introduce a joint clinical assessment of health technologies at EU level. The plenary backed an amendment from the European People’s Party that would change the threshold for decisions in the Coordination Group from a two-thirds majority to a qualified majority.

The proposal covers new medicines and certain medical devices, and would provide the basis for permanent EU-level cooperation in four areas: joint clinical assessments; joint scientific consultations;

identification of emerging health technologies; and voluntary cooperation on other aspects of HTA.

All in one, HTA is a research-based tool that focuses specifically on the added therapeutic value of a health technology in comparison with other health technologies. Yet, there are challenges to tackle. Due to the large heterogeneity of the methodologies used across practices and Member States, it is very difficult to obtain a consolidated opinion from a HTA. On the other hand, a number of advantages is unparalleled, such as faster and more efficient drug development, tackling rare diseases and allowing to answer multiple research questions in parallel.

How does the Commission envisage HTA implementation?

Overall, the cooperation would be Member State driven, with the Commission hosting a secretariat to provide administrative, scientific and IT support. Participation in the joint clinical assessments and use of the joint clinical assessment reports at Member State level would become mandatory after six years: following the regulation’s entry into force, the Commission proposes a three-year period for adopting tertiary legislation and another three year (transitional) period to allow Member States to fully adapt to the new system.

Next steps?

We now wish to call upon EU policymakers to initiate trilogue inter-institutional negotiations without delay, in view of reaching a final agreement ahead of the European elections in 2019. In the case of no position adopted before the upcoming elections, next May, a new



parliamentary position may have to be developed and adopted.

Additionally, the reluctance of a number of Member States may come as a hurdle too. Countries like Germany, France, Poland and Czech Republic can block the proposal in the Council of the EU, compromising reached amendments.

II. EU LAUNCHES CONSULTATION ON MEDICINES FOR CHILDREN AND RARE DISEASES



The European Commission has launched a public consultation to evaluate the legislation on medicines for children and rare diseases, commonly for special populations such as children and newborns. The consultation - open until 4 January 2019 - aims to assess the possibility of merging the Paediatric Regulation and the Orphan Drug Regulation. No progress is foreseen before the end of the legislature, however, the Commission is to deliver a report on how to better make the two regulations work together. Despite not being clear yet, there may be a review of one or both legislations in the next term.

More information:

- [EU Orphan Regulation \(141/2000\)](#)
- [EU Paediatric Regulation \(1901/2006\)](#)

- [EU Paediatric Regulation \(1902/2006\) \(amendment\)](#)
- [Commission's ten-year report on implementation of Paediatric Regulation](#)

III. COMMISSION RELEASES REPORT ON THE STATE OF VACCINE CONFIDENCE IN THE EU



UEMO salutes the first results published on the 23th and 24th of October after the adoption of the European Commission's proposal to strengthen the EU cooperation on vaccine preventable diseases. Insufficient vaccination coverage rates have contributed to recent outbreaks of vaccine-preventable diseases in the EU.

Key obstacles to vaccination coverage have been misinformation that has resulted in fears and lack of trust about vaccine safety and side effects. The UEMO fully supports the call for a global solution and a multidimensional action plan both at national level, reinforcing cooperation between Member States and at European level too. The involvement of all key stakeholders is crucial in order to achieve common goals in a more efficient way.

The Expert Panel report "**Vaccination Programmes and Health Systems in the**

European Union” highlights the importance of increasing the vaccination access and availability to healthcare services as well as to promote an active involvement and engagement by healthcare providers.

As for the **“Organization and delivery of vaccination services in the European Union”** study prepared by the European Observatory on Health Systems and Policies (EOHSP), it presents an extensive comparison between the sustained efforts undertaken by the 28 EU Member States in addressing vaccine-preventable diseases. The analysis revealed not only what achievements have been made per country, but also further improvements that could be done to tackle this public health threat.

The UEMO commits itself to participate actively to the Coalition for Vaccination in bringing together European associations of healthcare workers and students’ associations, to commit to delivering accurate information to the public, combating misinformation, myths and exchanging best practices

For more information:

- [State of Vaccine Confidence in the EU](#)
- [Vaccination Programmes and Health Systems in the EU](#)
- [The Organization and delivery of vaccination services in the EU](#)

IV. EUROPEAN ANTIBIOTIC AWARENESS WEEK



On 13 September study published by the Lancet with data from the European Center for Disease Control has reached the conclusion that infections caused by antibiotic-resistant bacteria were responsible for 33.110 deaths in the European Union and European Economic Area in 2015. These estimates are based on data from the European Antimicrobial Resistance Surveillance Network (EARS-Net) data from 2015.

The worst performing countries when it comes to the burden of infections with antibiotic-resistant bacteria are Italy, Greece, Romania, Portugal and Cyprus. The countries scoring higher on this matter are Iceland, Estonia, Norway, Finland and Sweden.

Antimicrobial resistance is a serious threat to public health and preventive action is paramount to tackle this major issue. Moreover, the increasing incidence of infections is yet another hazard for the many impaired healthcare systems across the EU. Moreover, the study assesses that the estimated deaths are a direct consequence of an infection due to bacteria resistant to antibiotics and that the burden of these infections is comparable to that of influenza, tuberculosis and HIV/AIDS combined. It also describes that 75% of the burden of

disease is due to healthcare-associated infections (HAIs) and other healthcare settings. Possible solutions suggested by the study range from reducing infectious-diseases through adequate infection prevention and control measures as well as antibiotic stewardship.

The authors said: “the estimated burden of infections with antibiotic-resistant bacteria in the EU/EEA is substantial compared to that of other infectious diseases, and increased since 2007. Strategies to prevent and control antibiotic-resistant bacteria require coordination at EU/EEA and global level. However, our study showed that the contribution of various antibiotic-resistant bacteria to the overall burden varies greatly between countries, thus highlighting the need for prevention and control strategies tailored to the need of each EU/EEA country”.

Finally, the study reveals that 39% of the burden is caused by infections with bacteria resistant to last-line antibiotics such as *carbapenems* and *colistin*. This represents an increase from 2007 and is alarming because there are no more antibiotics available besides these that seem to start being ineffective.

The results of this study are also used by the **Organisation for Economic Co-operation and Development** to estimate the economic burden of antibiotic resistance.

V. EU CELEBRATES 5 YEARS SINCE THE CROSS-BORDER HEALTHCARE DIRECTIVE WAS TRANSPOSED INTO NATIONAL LAW



On the occasion of celebrating 5 years since the Cross-border Healthcare Directive was transposed into law, the European Commission published “Top 10 Mistakes patients in Cross-border healthcare make before traveling abroad”:

1. Not being informed on their rights to treatment abroad under EU law;
2. Not planning their trip thoroughly;
3. Leaving without prior authorization;
4. Not being informed on the financial implications;
5. Travelling without first contacting the national Contact Point;
6. Travelling without the transfer of medical records;
7. Not taking possible language barriers consideration;
8. Not arranging suitable medical follow-up;
9. Not presenting the required documentation needed to obtain reimbursement;
10. Not being informed on where and how to file a complaint.

More information:

- [Top 10 Mistakes in detail](#)



- [Cross-border healthcare](#)
- [Study on cross-border healthcare](#)

VI. EU HEALTH POLICY PLATFORM ANNUAL MEETING



On 12 November 2018, the EU Health Platform Annual Meeting took place in Brussels, where Commissioner for Health and Food safety delivered a speech addressing the 2018 EU Health Award for NGOs working to prevent tobacco use. The Irish cancer Society initiative, X-HALE was delighted to take the first award home. The event followed with an interactive round table discussing the role of stakeholders in EU health policy. The second part of the event welcomed presentations and discussions about smart healthy age-friendly environments, societal impact of pain and stimulating fresh fruit and vegetable consumption for healthier European consumers. Towards the end of the event, short presentations of the six selected proposals for 2019 thematic networks cycle were featured. The selected proposals were: Deinstitutionalisation and community care (including family-based and home care), improving organ donation and transplantation in the EU, healthcare in cross-border regions, enhancing citizen and patient empowerment and digital

health literacy, improving access to healthcare for vulnerable and underserved groups and finally, improving integrated people-centred healthcare solutions.

VII. EU HEALTH SUMMIT



On 29 November 2018, the EU Health Summit will take place in Brussels. The high-level event represents the efforts of a multi-stakeholder organization, from within and across the health community, to discuss how Europe could further develop and take the lead in areas such as research and innovation, health data and digital health, healthcare organisation and financing as well as health in all policies. The aim of the Summit is to distil recommendations for the next European Commission and European Parliament to bring the necessary changes about.

Earlier this year, around fifty stakeholders that shared a commitment to a positive future for European health gathered to brainstorm about how to keep health an EU priority. Since then, a number of those participating organisations have met regularly to prepare policy recommendations in these four focus areas that will set the scene for the Summit discussions.

More information:

- [Event information and registration](#)

UEMO NEWS

I. Rome General Assembly



On the occasion of the General Assembly, UEMO representatives convened in Rome (October 26-28), where they discussed existing public health concerns. The General Assembly, the last meeting of the Italian presidency, will rotate its presidency to Romania. Tiago Villanueva (Portugal) was also elected as new vice-president. These two changes will be implemented as of the 1st of January 2019.

Regarding policy stances, UEMO adopted a position paper welcoming and supporting the European Commission's strategy on vaccination and its several recommendations to increase the coverage rates in both children and adults. In order to ensure a vigorous handling of this topic, UEMO has decided to establish a Task Force on Vaccination with representatives from Ireland, Romania, Malta and Switzerland.

With Brexit looming in the horizon, the General Assembly dedicated time discussing its consequences for healthcare, with a particular focus on patient safety. How to mitigate possible crisis scenarios such as the lack availability

of medicines, medical care across the Irish border, cross-border care after Brexit, recognition of qualifications, training and research, are some of the major pressing matters that require an urgent solution.

II. Regional Congress in Italy



UEMO, represented by Mary McCarthy, attended a three-day conference (*V Congresso Regionale*) entitled "Health – Comparing Public and Private", at Desenzano, Lake Garda, in Italy, on September 21-23. The programme of the event covered a variety of topics ranging from **data** **privacy**, **healthcare evolution** and **changes** and a **comparison of healthcare systems** in between countries. Yet, as the title of the conference reads, the major block of dialogue was dedicated to debate the arguments in favour and against for both private and public healthcare.

The first day of the conference, September 21, was opened with an afternoon session discussing the new General Data Protection Regulation (GDPR) regulation with presentations from Lavinia Mastroluca, Franco Carnesalli and Genaro Messuti.

The second day was dedicated to discuss questions of public or private domain when it comes to healthcare, with the

introduction of the case study “the privatization of the health system in Lombardi”. From this point on, moderators steered the debate to the question of “What works in Europe?” as a mean of finding solutions, or perhaps trying to find whether different solutions are needed for different countries.

UEMO’s Mary McCarthy has delivered her presentation about the **value of general practitioners**, an important point considering the rise of doctors with symptoms of burnout due to excessive stress. Further on, the debate turned to the **healthcare reforms in the United Kingdom** and the **dangers of privatization**. Moreover, the argument of **bargaining with insurance companies** was also point for discussion as these companies play an important role in the whole structure of each healthcare system in Europe. The last session of the second day was sealed by a **report from an American physician on the healthcare system in the United States**. At the end, a roundtable discussion was created where policy makers replied to the questions from the audience and discussed topics developed by the speakers. Finally, the last day of the conference was dedicated to matters involving **general practitioners’ pensions**.

Overall, the conference was remarkable in the way that it wasn’t just looking at the Italian health system but also looking at other European health systems and what works well or could be adapted. There was a wide variety of speakers and a very interesting discussion after each presentation. The event was featured on Italian TV and generated much interest nationally.

III. UEMO discussed e-Health in Brussels



On the occasion of the 6th e-Health Stakeholder Group Meeting, led by DG CONNECT (Directorate-General Communications Network, Content and Technology) and DG SANTE (Directorate-General for Health and Food Safety), the European Union of General Practitioners (UEMO) seized the opportunity to communicate current challenges and potentials facing e-Health in Europe. The meeting took place on the 12th of October in Brussels, Belgium.

The most pressing concerns regarding e-Health dimension for healthcare practitioners is the **gap between technologists/regulators** – the entities responsible for developing the IT systems and how to implement them – and **healthcare personnel**. In order to tackle this concern, UEMO, represented by Dr Kjartan Olafsson, defends the strengthening of Clinical Informatics as an area of academic research and development of knowledge between technology/informatics and clinical activities. All in one, e-Health must support the relation between healthcare professionals and patients. The most important desired effect is to free up time to personal contact between doctor and patient, but also to contribute to the sustainability of healthcare systems.

The start of a **new Joint Action eHAction** was also covered during the



stakeholder meeting. The members debated upcoming deliverables for the e-Health network and state of play from the Working Group on **electronic health record exchange format** and **common semantic strategies**. Also, a market study on **telemedicine** was discussed.

The e-Health Stakeholder Group Meeting is a temporary group that vows to foster the dialogue amongst the parts in order to create a platform of ideas and best practices. Overall, the e-Health group gives input on the design, implementation and evaluation of eHealth policy activities – in particular on the implementation of the eHealth Action Plan 2012-2020. Additionally, the expert group discuss and give input on the deliverables of the Joint Action supporting the eHealth Network and advise the Commission on eHealth-related activities by preparing reports and opinions and submitting relevant data.

IV. UEMO welcomes Astana Commitment



On 25 October, UEMO welcomed the Astana Commitment which vows to make primary care available and affordable for everyone. United Nations Member States pledged to strengthen their primary healthcare systems as an essential step towards achieving universal health coverage. The Declaration of Astana reaffirms the historic 1978 Declaration of Alma-Ata, the first time world leaders committed to primary health care.

Nowadays, at least half the world's population lacks access to essential health services – including care for noncommunicable and communicable diseases, maternal and child health, mental health, and sexual and reproductive health. “Adoption of the Declaration at this global conference in Astana will set new directions for the development of primary health care as a basis of health care systems,” said Yelzhan Birtanov, Minister of Health of the Republic of Kazakhstan. “The new Declaration reflects obligations of countries, people, communities, health care systems and partners to achieve healthier lives through sustainable primary health care.”

V. UEMO attended medicines shortage workshop at EMA



On 9 November 2018, UEMO attended a workshop regarding the availability of authorised medicines in the EU, at the European Medicines Agency, in London. In fact, availability of medicines is a national, European and global matter that has a significant impact on public health while contributes to health inequalities. Overall, the attendance at the workshop revealed that progress towards an EU wide shortage definition is needed to improve reporting and further develop metrics. For that purpose, it is important that relevant



stakeholders report more information about available alternatives but also that the reporting system is open to all supply chain actors. According to an EMA survey in which 30 out of 31 national agencies responded, almost all authorities publish information on shortages on their website; of those have a dedicated webpage of shortages, such as a catalogue. The majority do not have defined criteria for publication and publish on any shortage that occurs. Also, most authorities update the information as new information becomes available and most of them communicate on revocation or suspension and withdrawals due to commercial reasons. The survey also found that most communication material is prepared by the technical department. A minority involve communications departments in this work. However, a majority of the respondents use organisations' channels (patients, healthcare professionals or learned societies), press releases and professional journals (publications) as tools to send their messages across to their audiences. Overall, the outlook is positive as most EU/EEA authorities are already publishing information on shortages. Current public communication practices can benefit from a better coordination across the network, higher visibility and accessibility of the information by patients and healthcare professionals and a multidisciplinary approach within the agency and more interaction with target audiences.

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