Dear UEMO Members,

This bulletin announces UEMO’s recent reinforced partnership with EMA and it is focused on a variety of EU-related health topics including vaccination, cross-border care, antimicrobial resistance, report from the Digital Assembly, EURIPA’s commitment to stop frailty in the elderly, upcoming events, and many more.

We hope you enjoy reading this issue!

Yours sincerely,

Calin BUMBULUT
UEMO President

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**EU News**

I. Croatia accepts ePrescriptions, joining Finland and Estonia
II. Bulgaria 25th country signing the Joint Procurement Agreement on medication
III. Global Vaccination Summit in Brussels, September 2019
IV. Whole genome sequencing shows promise in fight against AMR
V. EMA Consultation – Guidelines on the quality requirements for drug-device combinations
VI. Portugal to phase out fees for GPs appointments

**UEMO News**

I. UEMO signs official cooperation with EMA and other Primary Care associations
II. Report on the Workshop “Immunization Programs in the EU”, lessons from Cluj
III. EU-JAMRAI 2nd Annual Meeting and Stakeholder Forum in Rome, 16-17 September 2019
V. Report from the Annual Digital Assembly in Bucharest

**Other Medical Organisations**

I. EURIPA published Position Paper on Frailty in the Population in Rural and Remote Areas
As of 14 June 2019, Croatia started accepting Finnish ePrescriptions. The system was pioneered between Finland and Estonia. Now, Finnish citizens travelling to Croatia can retrieve their medicines in Croatian pharmacies thanks to the EU electronic cross-border health services. These exchanges will now be possible as the eHealth Network, comprising e-health agencies in Europe, agreed on 2 April 2019 that Croatia can send and receive ePrescriptions across borders and receive the Patient summaries of citizens coming from other European countries (the sending of patient summaries to other Member States will occur in a second time). This decision was supported by a positive vote of eHealth Member State Expert Group (eHMSEG) on the 11th March.

More information:
- Cross-border healthcare
- Study on cross-border healthcare

On 14 June 2019, Bulgaria became the 25th EU country to sign the Joint Procurement Agreement (JPA) to procure medical countermeasures. Health Minister Kiril Ananiev signed the Agreement for Bulgaria. It will now cover around 455 million people, i.e. around 90% of the population of the European Union.

The outbreak in 2009 of H1N1 pandemic influenza highlighted weaknesses in the access and purchasing power of EU countries to obtain pandemic vaccines and medications. In 2010, the European Council requested the Commission to start the preparation of joint procurement of vaccines in the frame of a future pandemic. Provisions for the joint procurement of medical countermeasures are included in Article 5 of Decision 1082/2013/EU on serious cross-border threats to health. The Joint Procurement Agreement (JPA) was approved by the Commission on 10 April 2014, and as of June 2018 has been signed by 25 EU countries. The JPA:
- Determines the practical arrangements governing the mechanism
• Defines the decision-making process with regard to the choice of the procedures
• Organises the assessment of the tenders and the award of the contract

III. GLOBAL VACCINATION SUMMIT, SEPTEMBER 2019

The European Commission organises, in cooperation with the World Health Organisation, a Global Vaccination Summit on 12 September 2019, in Brussels.

The event takes place under the joint auspices of the European Commission President Jean Claude Juncker and WHO Director General Tedros Adhanom Ghebreyesus. The overall objective is to give high level visibility and political endorsement to the topic of vaccination and issue a statement to endorse and promote the benefits of vaccination as the most successful public health measure that saves millions of lives every year. It will demonstrate EU leadership for global commitment to vaccination, boost political commitment towards eliminating vaccine preventable diseases and engage political leaders and leaders from scientific, medical, industry, philanthropic and civil society.

IV. WHOLE GENOME SEQUENCING SHOWS PROMISE IN FIGHT AGAINST AMR

The use of whole genome sequencing can improve the way antimicrobial resistance (AMR) is monitored in food and animals, EFSA says in a new report published today. Ahead of the revised legislation on AMR monitoring that is due to come into force in 2021, EFSA suggests that these methods could gradually be introduced into Member State monitoring activities.

Using whole genome sequencing, experts can identify resistant genes in bacteria as opposed to current phenotypical methods which test bacteria for resistance to specific antibiotics. This not only has the potential to predict AMR more efficiently but also generates a large amount of data which can be used for other epidemiological studies and analysis.

EFSA’s report also highlights the need to monitor AMR in seafood, about which little is known. This is linked to the recent expansion of aquaculture production and the increase in imported products to the EU.

More information:
• EFSA’s website on the subject
• Full Policy Brief: Averting the AMR Crisis
The European Medicines Agency has released for public consultation a draft guideline on the quality requirements for medical devices in human medicines that include a medical device, known as drug-device combinations. The guideline addresses the new obligations in Regulation (EU) 2017/745 on medical devices, in particular the requirements under Article 117. This article foresees that the marketing authorisation application should include a CE (Conformité Européenne) certificate or declaration of conformity for the device or, in certain cases, an opinion from a notified body (NB) on the conformity of the device. The guideline covers devices that are necessary for the administration, dosing or use of the medicine. It is intended that this guideline will increase transparency and consistency of information in regulatory submissions, reducing work for all stakeholders and ultimately improving patient safety.

EMA intends to finalise the guideline before the regulation fully applies on 26 May 2020. Stakeholders are invited to send their comments by 31 August 2019 to QWP@ema.europa.eu using this template.

Portuguese patients were expected to no longer pay fees when visiting a GP in the National Health Service, as it happened until now - 4,5 euros per consultation - as well as for diagnostic tests and physiotherapy requested by GPs by 2020. However, due to political setbacks, the fees are set to be phased out rather than eliminated at once, and they will not be in force before 2020, according to the Health Minister Marta Temido.

The community of GPs in Portugal is worried as a situation of “no fees” may cause increased pressure on already overstretched services. However, fees will continue to apply in Emergency Departments of hospitals. On the 2nd and 3rd of July, Portuguese doctors will join a strike – called by two different syndicates – which will render the country working at minimum services.

Recently, the European Commission denounced the low level of investment in health, in Portugal, on its “Joint Report on Health Care and Long-Term Care Systems and Fiscal Sustainability”.
I. UEMO SIGNS OFFICIAL COOPERATION WITH EMA

On 6 June 2019, UEMO is pleased to announce a joint collaboration with the European Medicines Agency (EMA), the European Forum for Primary Care (EFPC) and Wonca Europe in order to improve the access and quality of primary care in the European Union. The agreement was signed at EMA, on its new headquarters in Amsterdam. The aim of this reinforced cooperation will pave the way to:

- help EMA gain a better understanding of how medicines are being used in real life and the potential impact of specific regulatory actions on patient care;
- facilitate the incorporation of views and input from GPs/family physicians into EMA’s activities recognising the pivotal role that they play on the front line of health and patient care;
- raise awareness among GPs of the role and activities of the EU medicines regulatory network.

Overall, our new collaboration with EMA, EFPC and Wonca Europe will work on spreading awareness about the importance and the role of GPs and family physicians. A detailed plan for the upcoming 2020 year was also agreed as well as a way of working together and developing communication activities and identifying opportunities for collaboration in regulatory science training. Finally, the European Medicines Agency will also improve its interaction with GPs.

More information:

- Council Recommendation on Vaccination
- Commission Communication on Strengthened Cooperation against Vaccine-preventable diseases

II. REPORT ON THE WORKSHOP: “IMMUNIZATION PROGRAMS IN THE EU”

Representatives from all EU Member States, the EC (DG Sante), WHO Europe, UNICEF, ECDC, the Romanian Ministry of Health, the National Public Health Institute and from professional organizations were present, being one of the actions organized by Romania during the Presidency of the Council of the European Union.

During the breaks we had contacts and discussions with various representatives of the mentioned organizations, the activities of family doctors being well known due to the national and international activity of Dr. Dumitra. The subject of the vaccination strategy and the
The concept of vaccination hesitation are new topics addressed lately by UEMO.

Day 1, 9th May, informal discussions on the subject: Common approaches in public health policies related to vaccination in the EU and candidate countries: common obstacles to ensuring optimal vaccination coverage, joint procurement of vaccines, common "core" antigens in NIPs.

Providing vaccines in the EU is one of the central issues.

The hesitation of vaccination seems more intense in Romania, as is the case in Moldova. There are no shortages in supply, the challenge is the call to vaccination. The communication of health personnel with the population needs to be amplified. Quality data on relevant information and population mobilization are strategic objectives. Joint procurement of vaccines is provided by UNICEF. They have problems with direct procurement, Moldova being a small and economically unattractive country. Baltic countries can provide a model for joint procurement of vaccines. Moldova is currently unable to join a joint vaccine procurement project.

More information:

- EMA’s social awareness video
- 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

III. EU-JAMRAI 2ND ANNUAL MEETING AND STAKEHOLDER FORUM, 16-17 SEPTEMBER

The EU-JAMRAI 2nd annual meeting and stakeholders Forum will take place on 16-17 September at the Instituto Superiore di Sanità in Rome, Italy. This event is reserved for EU-JAMRAI partners and the members of the Advisory Committee and the Stakeholder Forum.

IV. SMART/UEMO REPORT: “BENCHMARKING DEPLOYMENT OF EHEALTH AMONG GPs”

UEMO is proud to announce the publication of the 2018 SMART/UEMO report “Benchmarking Deployment of eHealth among GPs”. UEMO was an active contributor gathering data for the report which has come to the conclusion that
eHealth adoption in primary care is on the rise in the EU.

The European Commission seeks to understand and measure the current use of information and communication technology (ICT) and eHealth applications by general practitioners (GPs) in the European Union (EU), as well as changes in uptake over time. Two studies benchmarking the use of eHealth by GPs in Europe had been conducted to date: Dobrev et al. (2008) and Codagnone and Lupiáñez-Villanueva (2013b). RAND Europe, together with Open Evidence and BDI Research, were commissioned by the Directorate-General for Communications Networks, Content and Technology (DG CONNECT) to undertake the third benchmarking study, which aimed to: (1) measure the use of ICT and eHealth applications by GPs in 27 EU member states since 2013, (2) analyse the main drivers of and barriers to eHealth adoption in primary healthcare, and (3) compare how the levels of adoption, drivers and barriers have evolved since 2013 (Codagnone and Lupiáñez-Villanueva 2013a, 2013b).

More information:

- [Executive Summary](#)
- [Final report, raw data and other information](#)

IV. REPORT FROM THE ANNUAL DIGITAL ASSEMBLY IN BUCHAREST

UEMO attended the Digital Assembly 2019, represented by the President Calin Bumbulut. Supported by the European Commission, the event is a forum for stakeholders to take stock of the achievements of the Digital Single Market Strategy, draw lessons and to exchange views on the contours of a future digital policy. The Communication on Digital Transformation of Health and Care in the Digital Single Market identifies three priorities:

I. **Citizens’ secure access to their health data, also across borders** - enabling citizens to access their health data across the EU. The goal is to make it possible for citizens to exercise their right to access their health data across the EU, including, inter alia, the interoperability of Electronic Health Record (EHR) systems.

II. **Personalised medicine** through shared European data infrastructure - allowing researchers and other professionals to pool resources (data, expertise, computing processing and storage capacities)
Researchers and other professionals should pool resources across the EU, for better health prevention, faster and more personalised diagnosis and treatment. In order to achieve this, authorities and other stakeholders share data and infrastructure for prevention and personalised medicine research and treatment.

**Genomic data**

On 10th April 2018, 13 EU countries signed a declaration for delivering cross-border access to their genomic information. They aim to provide access to at least 1 million sequenced genomes in the EU by 2022.

**III. Citizen empowerment with digital tools** for user feedback and person-centred care - using digital tools to empower people to look after their health, stimulate prevention and enable feedback and interaction between users and healthcare providers

**Improved research and treatment**

Access to healthcare data helps researchers to produce more accurate, faster tests on medicines to be launched on the market. The EU-funded AirPROM project for example helped develop a breakthrough pill against asthma, with the use of digital airway models to predict both disease progression and response to treatment. The research and the development of the pill went much faster and more efficient than normal. It is estimated that about 20 years were saved.

Through the use of big data, researchers can help health care professionals and health policy makers to identify, simulate, select and monitor the effectiveness of current and new treatments. Evotion project - on hearing loss.

**European Leadership in the Digital World**

Only 8% of the amount invested in AI is European.

The priority sectors for digitization are health, mobility and energy.

The problem is more complex: if biotechnology is combined with research in AI, Europe is in a better position than if we take in consideration only the invested money; this combination may lead to the emergence of a new personalized drug industry based on DNA decoding.

The effects of digital technology are measured not in billions, but in trillions, in China these figures are already the first, followed by the US and then by Europe.

Technological competence will be the new currency.
EURIPA, the European Rural and Isolated Practitioners Association, published a Position Paper calling for the protection and assistance of the elderly living in rural and remote areas.

EURIPA urges all relevant authorities and policy makers, to take into account the position paper elaborated by EURIPA. For this they urge to:

- Organise the rural primary care unit, to be able to accomplish their goals described above;
- Organise social and public resources to be able to face to frailty;
- Providing needs in terms, human, organisation, devices and financial support to all the local social and health care stakeholders.

Rural populations in Europe are more and more aged, for several reasons:

- The young generations go to urban places to, finish their education, find a job, and start a family.
- The rural activities, farming, cattle farming, forest, fishing and all rural activities require fewer and fewer workers. The specific workers as agricultural technicians, engineers, agricultural devices do not replace manual workers.
- Elderly populations prefer staying at home, in their familiar surroundings with relatives.
- the cost to live is lower than in urban, mainly for houses, and apartments, (whereas the transportation cost and other living costs could be higher) A rented caregiver for those who can afford it, is very often the only way to be helped at home while social prescribing which can be an effective method to receive help from the community.

But frailty is not directly linked with the age, even if frailty increases with it. Rural populations were less demanding, but nowadays with the information channels as radio, TV and more recently social media they are want to be equal with urban populations.