Dear UEMO Members,

This bulletin is focused on a variety of EU-related health topics including the impact of Brexit on healthcare, vaccination, medical devices, HTA, tuberculosis, and many more.

I am also very pleased to report that the UEMO was invited to the first meeting of the Coalition for Vaccination and that our organization will continue to represent Health Care Professionals at the HTA stakeholder group.

We hope you enjoy reading this issue!

Yours sincerely,

Calin BUMBULUT
UEMO President

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**EU News**

I. Commission’s event “Coalition for Vaccination” vows to increase vaccination rates
II. Impact of Brexit on healthcare discussed at the European Parliament
III. European Medicines Agency officially operating from Amsterdam
IV. EU falsified medicines finally in application
V. EU calls to eliminate tuberculosis in Europe

**UEMO News**

I. UEMO reacts to British Medical Journal regarding the regulation of medical devices
II. France has a new President representing General Practitioners at national level
III. Obesity article co-authored by UEMO referenced by WONCA
IV. UEMO attends HTA meeting in Brussels
V. Portuguese GPs call for 30 minutes medical appointments
I. “COALITION FOR VACCINATION” VOWS TO INCREASE VACCINATION RATES

The European Commission organized, on March 4, an event entitled “Coalition for Vaccination” with the aim of curbing misinformation and hesitancy when it comes to vaccination. The EU Action plan vows to:

- Ensure access to vaccines for all.
- Control all vaccines to ensure highest safety standards.
- Share clear, independent and transparent information.
- Conduct more research to develop new vaccines.

UEMO, as part of the Members of the EU Coalition for Vaccination, commits to strengthen efforts towards elimination of vaccine-preventable diseases in collaboration with stakeholders.

Overall, healthcare workers and students, as well as members of civil society and the scientific community, represented by Associations which are Members of the EU Coalition, commit to:

1. Work in collaboration with the national associations to deliver accurate and transparent information to patients, to the student body, and to the general public.
2. Join efforts to increase confidence in vaccines and improve uptake of vaccination by citizens by combatting myths and fake information related to vaccines.
3. Drive by example by vaccinating ourselves and publicly showing our confidence in vaccination.
4. Exchange good practice among countries, regions, settings and professions.
5. Make vaccination the easiest choice.
6. Strengthening the translation of scientific evidence into tangible positive health outcomes for EU citizens.

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
II. IMPACT OF BREXIT ON HEALTHCARE DISCUSSED AT THE EUROPEAN PARLIAMENT

On February 27, the European Parliament hosted an early event – 8h00 until 9h30 – to discuss the impact of Brexit on healthcare services across the European Union.

The event at the European Parliament was hosted by S&D MEPs Julie Ward and Kari Gloanec Maurin – Co-President to the European Parliament Intergroup on Common Goods & Public Services – and is entitled “Brexit: The impact on the EU27’s Healthcare Services”.

Securing continuing cooperation and mutual recognition between the EU and UK regarding the authorisation, conformity assessments, testing and surveillance of medicines and medical technologies should be a priority outcome of the negotiations.

The Political Declaration on the Future Relationship, discussed between the EU and the UK, envisages a relationship that is centred around a free-trade agreement, in which wider health-related issues are largely absent. All forms of Brexit, however, involve negative consequences for the UK’s leadership and governance of health, in both Europe and globally, with questions about the ability of parliament and other stakeholders to scrutinise and oversee government actions.

More information:
- EMA’S Brexit plans ensure Agency focus on medicines evaluation and supervision

III. EMA OFFICIALLY OPERATING FROM AMSTERDAM

Since the 11th of March, the European Medicines Agency (EMA) is operating from Amsterdam. EMA left its London premises on 1 March, and following a transitional week of teleworking, its staff will gradually move throughout this week into the Spark building in Amsterdam Sloterdijk. The Agency has been working hard, in close cooperation with the Dutch authorities, to ensure these temporary premises would be ready to move into before 30 March, when EMA’s seat formally changes from London to Amsterdam. EMA will operate out of the Spark building until its final, tailor-made premises in Amsterdam Zuidas become available.

More information:
- United Kingdom’s withdrawal of the European Union (Brexit)
IV. EU FALSIFIED MEDICINES FINALLY IN APPLICATION

Since the 9th of February, the EU Falsified Medicines Directive entered into force, after 9 years of its adoption.

Falsified medicines are fake medicines that may look real, authorised medicines. These substances are very dangerous as they can contain ingredients which are low quality, in the wrong dosage (too high or low) or not contain any active ingredient at all. The new Directive aims to improve patient safety by, among other things, seizing such fakes before they reach patients potentially causing serious health damages.

How will the medicines be tracked? All prescription (and some over-the-counter) medicines coming onto the market after 9 February will have a 2D barcode and anti-tampering device on the box, which will be checked by dispensers – whether at pharmacies, hospitals or online pharmacies. Authorities will also be able to trace medicines better in case there are safety concerns.

The body governing and coordinating the circuit of the medicine is the European Verification Medicines Organisation (EMVO) and has for mission to secure the European pharmaceutical market.

More information:
- Letter from the Commission and EMA about the upcoming implementation of the Directive
- Falsified Medicines Directive

V. EU CALLS TO ELIMINATE TUBERCULOSIS IN EUROPE

The European Centre for Disease Prevention and Control published a country report titled “Tuberculosis surveillance and monitoring in Europe, 2019” based on data from the year of 2017 (January-December included). This report was released a few days before the “World Tuberculosis Day”, March 24.

Since many patients are still dying from the disease, the report timely underpins facts and figures as a way of raising awareness for the treatment of tuberculosis. In fact, despite being a curable disease, tuberculosis is still a challenging public health issue in the European Union and European Economic Area, with over 55 000 infections reported annually and thousands of fatalities.

In order to tackle this scourge, global leaders renewed their commitment to end tuberculosis by 2030 at a high-level United
Nations meeting in 2018, as envisioned in the Sustainable Development Goals.

More information:

- ECDC report “Tuberculosis surveillance and monitoring in Europe, 2019”

UEMO NEWS

I. UEMO REACTS TO BMJ REGARDING THE REGULATION OF MEDICAL DEVICES

On March 7, UEMO co-signed a response to the British Medical Journal as a reaction to a previous article regarding the regulation of medical devices, together with several healthcare professionals and patients’ organisations.

“The principle of non-maleficence is at the origin of clinical medicine since Hippocrates: first do no harm (primum non nocere). This principle was revisited with the concept of quaternary prevention1 a core value of the Wonca, the World Organization of Family Doctors. This principle can be extended to all Health Care Professionals (HCPs). There is also a socio-political dimension of this principle2: for this reason HCPs are engaged together with Patients’ Associations to improve

European regulations on Health Technologies at the level of European Commission Health Technology Assessment Network3 and at the European Network for Health Technology Assessment (EUnetHTA4). We welcome your editorial and hope it will contribute to improved safety and transparency. In a public health approach, safety necessitates better evidence before the introduction of a device into the market, better follow-up of side effects in a centralised manner, in relation to drug-device combinations, or companion diagnostics, and device entry procedures that would encompass involvement of the European Medicines Agency (EMA). We consider that transparency is important for informed decision making for both patients and doctors. For this reason, diminishing transparency to protect commercial secrets and to avoid scaring the public is an untenable argument.”

More information:

- BMJ article on medical devices’ lack of regulation
- Medical devices and in vitro diagnostic medical devices
II. FRANCE HAS A NEW PRESIDENT REPRESENTING GENERAL PRACTITIONERS

Following the departure of Professor Pierre-Louis Druais, President and co-founder of the Collège de la Médecine Générale to the Haute Autorité de Santé (High Authority of Health,) the Board of Directors convened on March 14 and elected Dr. Paul Frappé as the new President of the “Collège de la médecine générale”.

Pierre Louis Druais made a notorious work ensure France’s prominence within UEMO as he led the French delegates during the last years. The new president Paul Frappé, 39, is part of the new generation of general practitioners with academic background in general practice from the University Paul Lisfranc and he is also qualified as a general practitioner.

In agreement with the board, which has been extended until the end of 2019, Paul Frappé will lead several important topics for the College, such as:

- the recognition of the National Professional Council (NPC) of general medicine, and its financial sustainability;
- digital health, data record structuration in primary care;
- the place of our specialty general practice /family medicine in the legislation regarding health, currently under discussion by MPs;
- the Congress of General Medicine, from 4 to 6 April 2019 in Paris;
- CME/ CPD for general practitioners;
- Pursue work and events in progress with the institutions and professional partners.

Experience, competence and modernity: the election of Dr. Paul Frappé as President ensures a new stage in the development of the College of General Medicine.

III. OBESITY ARTICLE CO-AUTHORED BY UEMO REFERENCED BY WONCA

The article “European Practical and Patient-Centred Guidelines for Adult Obesity Management in Primary Care” co-authored by UEMO’s Vice President Daniel Widmer, on January 2019, was listed by the WONCA Special Interest Group quaternary prevention.

WONCA Special Interest Group on Quaternary Prevention and Overmedicalization was approved by the WONCA Council in October 2016 and membership is open to interested family doctors.

More information:

- Article “European Practical and Patient-Centred Guidelines for Adult Obesity Management in Primary Care”
On March 21, the European Commission organised another HTA meeting – the second of 2019 - this time for Health Care Providers (HCP). The first meeting of 2019, on February 14, was dedicated to Payers. This time, UEMO, represented by Vice-President Daniel Widmer, presented some suggestions to improve HCP involvement. The main goals of these stakeholder meetings seek to support the development of a Patient, Consumer and Healthcare provider involvement process and also develop recommendations for patient engagement within EUnetHTA.

UEMO defends the idea that behind technologies, devices or processes, there is a professional with specific competencies. It is not sufficient to evaluate the single technology. It is necessary to measure the real world use or added value of innovation by professionals if we want to avoid two pitfalls:

- Overmedicalisation or disease mongering
- Neglect of health priorities (equity, mental health, aging, multimorbidity, etc.)

The HCP decided also unanimously to renew Dr Widmer as their official representative.

The Portuguese daily newspaper “Público” announced that General Practitioners are calling for a minimum time of 30 minutes per appointment with each patient. The decision to push for change came from the Ordem dos Médicos (Medical Order) and it was sent to the Health Ministry for further approval.

The initiative, which was the result of an analysis carried out by the specialized schools of the Ordem dos Médicos (Medical Order), intends to create a regulation of consultation times to deal with “the great pressure” that exists in the area of health and the fact that both patients and doctors did not have “many times the time they should have for this first contact,” explains the Head of the Order, Miguel Guimarães. “We need to protect the doctor-patient relationship, the quality of medicine and the rights of patients.” The lack of time to talk to doctors today is one of the reasons that most cause patients to complain.

The president Miguel Guimarães said that the standard times presented in the proposal, which is not yet definitive, are a reference and that “the need for this intervention has to do with the organization of work.” For example, in general and family medicine,
appointments are scheduled every 15 to 20 minutes, and there is also in hospitals more than one patient at the same time, which leads to waiting times.