



**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 new EU rules for tobacco tracking & tracing, vaccination, the European Cancer Information System, Public Health, HTA cooperation and many more.. We hope you enjoy reading this issue!

Yours sincerely,

Aldo LUPO
UEMO President

EU News

- I. EU Commission's draft regulation on transparency and sustainability in risk assessment
- II. Addressing Antimicrobial resistance (AMR)
- III. Commission calls for stronger EU cooperation against preventable diseases
- IV. Healthcare data in Europe: towards a sharing digital system
- V. Austria's next Presidency to the Council of the EU: an opportunity to set concrete health goals?
- VI. The role of alcohol as a risk factor for cardiovascular diseases (CVDs) and road traffic injuries (RTIs)
- VII. Nordic countries join efforts to tackle childhood obesity
- VIII. Health Systems in the EU: Commission publishes report on Primary Care
- IX. Proportionality Directive: follow up

UEMO News

- I. Steering Group's event on Influenza Vaccination
- II. UEMO will discuss the Commission's proposal to strength cooperation against vaccine preventable diseases
- III. UEMO represented at the EMA-PCWP-HCWP joint meeting

EU NEWS

I. EU COMMISSION'S DRAFT REGULATION ON TRANSPARENCY AND SUSTAINABILITY IN RISK ASSESSMENT



On April, 11, 2018, the European Commission published a press release with an accompanying fact sheet explaining the proposal of the Directorate-General for Health and Food Safety (DG SANTE) for a regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain. The draft regulation aims “to boost trust in scientific studies on food safety” and was developed mostly in response to the citizens’ concerns expressed in the citizens’ initiative on glyphosate and also in line with the recently performed fitness check of the general food law of 2002. The Commission intends to improve the transparency in the EU decision-making cycle as well as addressing the need to safeguard European Food Safety Authority (EFSA). The proposed “targeted revision of the General Food Law Regulation coupled

with the revision of eight pieces of sectoral legislation” will “give citizens greater access to information submitted to the EFSA on approvals concerning the agri-food chain, provide the possibility for additional studies to be requested by the Commission and, will involve Member States’ scientists more closely on approval procedures.”

The increase in transparency will be ensured by making sure that citizens have access to all safety related information submitted by industry in the risk assessment process, by creating a common European Register of commissioned studies, and by holding consultations of stakeholders and the public on studies submitted by industry to support product authorization requests. Further, EFSA will be allowed to request additional studies “upon request of the Commission and financed by the EU budget.

The feedback period will be open until June 8, 2018.

Commission initiatives on General Food Law, vaccination and digital healthcare

Commissioner Andriukaitis (Health and Food Safety), has been invited to the ENVI Committee of the Parliament to present the legislative proposal on the transparency and sustainability of the EU risk assessment in the food chain and to provide updates on the situation as regards e-health and vaccines.

Since the adoption of the General Food Law Regulation in 2002, certain studies provided by the industry and, in



particular, where the industry seeks an authorisation (e.g. for pesticides, GMOs, etc.) have made citizens to start questioning the risk assessment. The Commission has committed to come forward with this legislative proposal covering the transparency and independence of these scientific studies. A targeted revision of the General Food Law Regulation and the revision of eight pieces of sectoral legislation are set to give more transparency in the area of GMOs, feed additives, smoke flavourings, food contact materials, food additives, food enzymes and flavourings, plant protection products and novel foods.

Find out more:

- [Fact Sheet](#)
- [More information](#)

II. ADDRESSING ANTIMICROBIAL RESISTANCE (AMR)



Antimicrobial resistance (AMR) has been at the center of the healthcare debate both in Europe and globally for an extended period. Numbers clearly illustrate the urgency of keeping a high level of attention on this topic, both at societal and economic level. According to

the World Health Organisation (WHO), AMR is estimated to be responsible for around 25,000 deaths per year in the European Union, 700,000 at the global level and projected 10 million deaths every year in 2050, compared to, for example, eight million cancer-related deaths. Such stark numbers need also to be coupled with the healthcare and productivity loss estimated costs, which adds up to €1.5 billion annually in the EU alone, with an expected potential impact worryingly close to the financial crisis that hit global economies in 2008.

EU institutions are trying to play a key role, in particular with the European Commission's 2017 EU One Health Action Plan against Antimicrobial Resistance. The Plan is linked to the 'health in all policies – one health' approach that the Commission is supporting. Achieving its objectives revolves around three ambitious pillars: making the EU a best practice region, boosting research, development and innovation and intensifying EU efforts worldwide to shape the global agenda on AMR.

Find out more:

- [EU One Health Action Plan against Antimicrobial Resistance, 2017](#)
- [WHO, What is Antimicrobial Resistance?](#)



III. COMMISSION CALLS FOR STRONGER EU COOPERATION AGAINST PREVENTABLE DISEASES



On April 26, the European Commission issued a set of recommendations about how the EU can strengthen cooperation on preventing multiple diseases.

According to the press release, vaccination saves between 1 and 3 million lives worldwide every year. The Commission's proposal focuses on three main pillars for action: tackling vaccine hesitancy and improving vaccination coverage; sustainable vaccination policies in the EU; and EU coordination and contribution to global health. Also, it sets 20 concrete actions including developing and implementing national and/or regional vaccination plans by 2020 with a target of at least 95% vaccination coverage for measles and the introduction of introducing routine checks of vaccination status and regular opportunities to vaccinate across different stages of life, for example in schools and workplaces.

The Commission has also proposed the creation of a European vaccination information portal by 2019 to provide online objective, transparent and updated evidence on the benefits and safety of vaccines.

The proposal will be discussed by the Council in order to be adopted by the end of 2018. It will be outlined how the Commission, EU countries, and other partners can work together to address common challenges.

Awareness and implementation of vaccination

Vaccination is one of the most powerful and cost-effective public health measures developed in the 20th century. Every year, immunisation programmes prevent 2.7 million people worldwide from contracting measles and protect around two million people from seasonal flu in Europe alone.

Despite their outstanding track record, several EU and neighbouring countries currently face unprecedented outbreaks of vaccine-preventable diseases due to insufficient vaccination coverage rates. This is caused, in part, by misconceptions surrounding vaccination. According to the most recent data collected by the European Centre for Disease Prevention and Control (ECDC), measles cases tripled in the EU between 2016 and 2017; in the past two years, 50 people have died due to measles and two from diphtheria. Commission President Jean-Claude Juncker referred to this situation as "unacceptable" in his 2017 State of the



Union speech. He subsequently pledged to support national efforts and launch a new EU initiative to increase vaccination rates. Seasonal flu vaccination coverage rates also remain significantly below the 75 per cent target for older age groups, and as a result, around 40,000 people in Europe die from complications of seasonal flu every year.

Misconceptions about vaccination are a contributing factor in falling coverage rates. People are no longer sufficiently aware of the vital role vaccination plays in saving lives; their focus is increasingly turning to fear of possible side effects.

On 23–29 April 2018, European Immunization Week (EIW) is celebrated across the World Health Organization European Region to raise awareness of the critical role vaccines play in protecting public health. According to WHO, in 2016, 1 in 15 infants in the Region did not receive their first measles-containing vaccine. Following a record low in 2016, measles has rebounded in Europe, causing over 22 000 cases in 2017 and already over 11 000 cases in January and February 2018. The largest current outbreaks are found in France, Greece, Serbia and Ukraine. Vaccines prevent a number of diseases, such as rotavirus, measles, rubella, poliomyelitis, whooping cough, hepatitis B and human papillomavirus and contribute to realizing national priorities linked to education and economic development, and to achieving the Sustainable Development Goals.

Find out more:

- [WHO Latest data on measles and rubella in the WHO European Region](#)
- [European Commission fact sheet](#)
- [Vaccination overview \(EC\)](#)
- [WHO Statement – European Immunization Week 2018](#)

IV. HEALTHCARE DATA IN EUROPE: TOWARDS A SHARING DIGITAL SYSTEM



On 25 April, the European Commission published a set of measures to increase the availability of data in the EU. Having as ultimate goal the improvement of research and personalised healthcare and the facilitation of services with digital tools, the new Action Plan will focus on:

- Cross-border access to citizens' electronic health records and the possibility of sharing their records across borders
- Facilitating the use of larger data sets through a shared European data infrastructure to prevent diseases, determine personalised medical treatment and better anticipate epidemics



- Providing digital tools that enable citizens to manage their health more actively within integrated care systems.

The proposal, build on the General Data Protection Regulation (GDPR), which enters into application on 25 May 2018, will focus on securing citizens' healthcare data while fostering European co-operation.

The plans will enable the use of larger data sets to allow for more personalised diagnoses and medical treatment, and to better anticipate epidemics, they say; they will also promote appropriate digital tools and enable public authorities to better use health data for research and for health system reforms.

Commissioner for Health and Food Safety Vytenis Andriukaitis recalled: “Our proposals make use of the full potential of digital technologies to improve healthcare and medical research. This will lead to easier access to health data, which will lead to better disease prevention and patient-centred care, rapid responses to pandemic threats, and improved treatments.”

In an accompanying press release, the Commission said that data-driven innovation was a key enabler not only of market growth but for job creation (particularly for SMEs and start-ups) and the development of new technologies.

The initiative complements the framework for the free flow of non-personal data in the EU presented by the Commission in September 2017, which

still needs to be agreed by the European Parliament and Member States.

In addition, on 4 May, 2018, the European Medicines Agency (EMA) together with Heads of Medicines Agencies (HMA) organized a Joint Big Data Task Force workshop in London. The aim was identifying solutions for big data challenges to further make recommendations in this field in November 2018.

Find out more:

- [Fact Sheet](#)
- [Public Consultation on Health and Care in the Digital Single Market](#)
- [Q&A on data](#)
- [Q&A on eHealth](#)
- [EMA – HMA Task Force](#)

**V. AUSTRIA'S NEXT
PRESIDENCY TO THE COUNCIL
OF THE EU: AN OPPORTUNITY
TO SET CONCRETE HEALTH
GOALS?**

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On 1 July 2018, Austria will take over the EU's Presidency for six months and therefore will have the opportunity to lead the European policies in its areas of priority. Austria's goals for its health system relies on promoting health and



quality of life by increasing sustainably the number of healthy years of life and counteracting the rising costs of healthcare. This perspective is likely to be present during its Presidency, as this programme is seen as an important step towards the national implementation of Health 2020 and is in line with the international strategies initiated by the World Health Organisation (WHO), the United Nations (UN) and the OECD Health Ministerial Meeting Statement and the European Commission.

Science|Business will be organising a half-day Open Conference on Friday 25 May 2018 (14h00-17h00) in Vienna, hosted by the Federal Ministry for Education, Science and Research. The goal is to raise public awareness and present the ambitions for patient outcomes-oriented health reforms, and the challenges in interconnecting European countries. A wide range of people including researchers and innovators, practitioners and nurses, patients and other citizens are strongly encouraged to attend.

Some of the decision-makers participating are the Austrian Federal Ministry for Education, Science and Research; and the Austrian Federal Ministry of Social Affairs, Health and Consumer Protection. The General Directorate Health and Food Safety of the European Commission will discuss the challenges to come for Europe's health system reforms.

Find out more:

- [Event registration](#)

**VI. THE ROLE OF ALCOHOL AS A
RISK FACTOR FOR
CARDIOVASCULAR DISEASES
(CVDs) AND ROAD TRAFFIC
INJURIES (RTIs)**



The World Health Organisation (WHO) has identified cardiovascular diseases (CVDs) and road traffic injuries (RTIs) as major public health hazards in Europe. According to its data, CVDs cause more than half of all deaths across the continent, while RTIs are estimated to be accountable for 85 000 deaths in annually. Drink-driving might be responsible for as many as 1 in 5 deaths on the roads and road traffic injuries in particular affect the younger population –leading cause of premature death in young people aged 15–29 years in the Region.

WHO/Europe recently held a training course on the role of alcohol as a risk factor. Participants were 44 policy-makers from the Eurasian Economic Union (EAEU)



and the Commonwealth of Independent States (CIS). A 4-day workshop was dedicated to national practices and joint regional action on prevention of drink-driving.

Participants analysed case studies of national legislation on drink-driving and considered how health, legal and enforcement practices could be enhanced in each particular case. Since alcohol is a risk factor both for NCDs and RTIs the course focused on effective, joint approaches such as promotion of physically active transport, enhancing emergency care services and using marketing strategies to reduce alcohol consumption, an idea inspired by the successes of anti-smoking campaigns. It also included a discussion on the role of the Eurasian Economic Union (EEU) as a regional organization and examples of European Union policies that could be applied in the EEU.

Throughout the course, participants from each country worked together to develop a national roadmap to address NCDs, drink-driving and injury, which they presented at the closure of the meeting. Most of the 9 presentations recognized the importance of enhancing anti-drink-driving legislation, developing emergency care and promoting physically active transport – but also emphasized the need for a systematic intersectoral approach and communication between national and international stakeholders.

WHO Representative to the Russian Federation, Dr Melita Vujnovic, and the Head of the WHO European Office for the

Prevention and Control of Noncommunicable Diseases (NCD Office), Dr João Breda emphasized the progress that European countries have already made and underlined that WHO is committed to supporting countries in their efforts to mitigate alcohol-related risks and to achieve the Sustainable Development Goals (SDGs). In her speech, Dr Vujnovic explained that the training course included, among other things, arguments that would help convince the governments and parliaments of Member States that regulation of alcohol consumption is beneficial both for national economies and for human development. Dr Breda added that without addressing the problems of alcohol consumption and road safety, countries will not be able to achieve the SDGs.

The course was developed by leading experts from I.M. Sechenov First Moscow State Medical University, the University of Stirling (United Kingdom), the University of Toronto (Canada), and other national and international research and public health organizations. The training was organized by WHO/Europe and its NCD Office, located in Moscow and funded by the Government of the Russian Federation. Speakers included experts in the areas of NCDs, road safety, harmful alcohol use, legislation and enforcement, social marketing, emergency trauma care and physically active transport.

Find out more:



- [European country profiles and the Global Status Report on Road Safety \(2015\)](#)
- [European action plan to reduce the harmful use of alcohol 2012–2020](#)
- [Global Plan for the Decade of Action for Road Safety 2011–2020](#)

VII. NORDIC COUNTRIES JOIN EFFORTS TO TACKLE CHILDHOOD OBESITY



Nordic countries have launched a joint initiative to monitor food marketing to children in their countries using fully comparable methods. The aim is to use the monitoring to inform evaluation policy decisions on this topic.

Marketing of foods and beverages is high in saturated fat, trans-fatty acids, free sugars or salt (HFSS). According to WHO, this influences children's knowledge, attitudes and food preferences and is therefore associated with increased risk of overweight and obesity. As a response to these findings, WHO has called for government action to reduce the harmful impact of food marketing on children, encouraging them to establish monitoring

mechanisms to evaluate the impact in terms of reducing children's overall exposure to marketing and in limiting the persuasive content of marketing communications.

The Nordic countries have recently published a joint monitoring protocol in order to evaluate policies and monitor activity over time. Representatives and experts from Denmark, Finland, Iceland, Norway and Sweden created the methodology addressing the growing influence of non-broadcast marketing, such as online marketing via social media platforms, and in-store promotion.

WHO/Europe supported this process and contributed to the development of the methodology. The protocol goes in line with the WHO Set of Recommendations on the Marketing of Foods and Non-Alcoholic Beverages to Children and the objectives of the WHO European Food and Nutrition Action Plan 2015–2020. In addition, WHO/Europe Nutrient Profile Model has been set as one of the available tools to categorise foods marketed to children. The Nutrient Profile Model was developed as a tool together with Member States participating in the WHO European Action Network on Reducing Marketing Pressure on Children.

Find out more:

[Protocol Full publication](#)



VIII. HEALTH SYSTEMS IN THE EU: COMMISSION PUBLISHES REPORT ON PRIMARY CARE



On March 2, the EU Expert Group on Health Systems Performance Assessment (HSPA) published its report "A new drive for primary care in Europe: rethinking the assessment tools and methodologies". This document is aimed at helping policy makers and health practitioners to set objectives and measure progress towards improving primary care services for the benefit of patients.

The report puts into focus three main challenges: 1) the complexity of the performance aspects of primary care; 2) difficulty in integrating assessments into policies; and 3) pitfalls associated with a culture of excellence. To ensure that performance assessment maximises its potential, the report recommends the following seven essential elements for building primary care performance assessment:

- Improve primary care information systems
- Embed performance assessment in policy processes
- Institutionalise performance systems
- Ensure accountability
- Consider patients' experience and values
- Take advantage of adaptability, which performance assessment can support in the moment of change for primary care
- Support a goal-oriented approach through the better use of professional and contextual evidence

Find out more:

- [Protocol Full publication](#)

VIII. PROPORTIONALITY DIRECTIVE: FOLLOW UP



**Council of the
European Union**

On April 20, 2018, the EU's committee of permanent representatives (Coreper) made an agreement between the Council and European Parliament negotiators on the directive that will require EU member states to carry out a proportionality test before establishing new requirements for professions.

Next steps for entry into force will include the endorsement by the Parliament and the Council.

Find out more:



- [Proposal for a directive of the European Parliament and of the Council on a proportionality test before adoption of new regulation of professions](#)
- [Services package proposals](#)
- [Draft directive on a proportionality test before adoption of new regulation of professions](#)

UEMO NEWS

I. STEERING GROUP'S EVENT ON INFLUENZA VACCINATION

On April 24, 2018 at the Renaissance Hotel in Brussels, it took place The Steering Group's event on Influenza Vaccination. The goal was to launch its manifesto, which calls for more action to increase seasonal influenza vaccination coverage rates in Europe. A series of recommendations were outlined to improve seasonal influenza vaccination coverage rates across Europe and reduce the unacknowledged burden of the disease. The steering group is calling for EU and national policymakers, communities and organisations that represent people most impacted by influenza to increase influenza vaccination coverage in three ways:

- Highlighting the burden of influenza and the role of vaccination;
- Increasing awareness of influenza and improving public trust in vaccination; and
- Improving the exchange of good practice and inter-professional collaboration at local and European level.

The manifesto also provides recommendations for implementation of the strategies to improve vaccination coverage rates and calls for the public health community to come together to support this cause.

UEMO was represented by the Brussels office. It was highlighted the role of the *general* practitioner and how important health professionals are when providing the right information. They are at the forefront to promote flu vaccination, and good medical practices in general. Therefore, the position of general practitioners on these questions was seen as crucial.

Find out more:

[Full manifesto](#)

II. UEMO WILL DISCUSS THE COMMISSION'S PROPOSAL TO STRENGTHEN COOPERATION AGAINST VACCINE PREVENTABLE DISEASES

The European Commissioner for Health and Food Safety, Vytenis Andriukaitis, presented on the 26th of April the Commission's proposal to strengthen the EU cooperation on vaccine-preventable diseases.

According to the Commission vaccination coverage fails due to:

- Vaccine hesitancy and waning confidence, including misconceptions about vaccination, distrust of science and fear of possible side effects
- Variations of vaccination policies and programmes between countries, often due to social, economic, or historical factors, as well as to the way healthcare



systems are organized across the EU countries

- Vaccine shortages due to supply and demand issues
- Challenges related to research and development of vaccines

The Commission's proposal calls for joint action to increase vaccination coverage and to ensure that everybody in the European Union has access to vaccination.

The main goals are:

- Develop and implement national and/or regional vaccination plans by 2020, including a target of at least 95% vaccination coverage for measles;
- Introduce routine checks of vaccination status and regular opportunities to vaccinate across different stages of life, for example in schools and workplaces;
- Present options for a common vaccination card that can be shared electronically across borders;
- Establishing a European vaccination information portal by 2019 to provide online objective, transparent and updated evidence on the benefits and safety of vaccines;
- Mitigating the risks of shortages by developing a virtual repository EU data warehouse with information on vaccine stocks and needs to facilitate voluntary exchange of information on available supplies and shortages of essential vaccines;
- Establishing a European Information Sharing System to gather knowledge and develop guidelines for a core EU

vaccination schedule by 2020 with doses and ages that EU Member States agree as being common to all countries;

- Strengthening partnerships and collaboration on vaccination with international partners.

For the drafting of this proposal, the Commission consulted stakeholders and citizens, and organised a series of meetings with professional healthcare organisations, health NGOs, student organisations and the industry. The proposal will be discussed by the Council and is expected to be adopted before the end of 2018, with an immediate entry into force, with a progress report every three years afterwards.

Find out more:

[Full proposal](#)

II. UEMO REPRESENTED AT THE EMA-PCWP-HCWP JOINT MEETING

On April 17-18, it took place a joint meeting between the European Medicines Agency (London, UK), Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP).

The first day of the event was aimed at discussing digital media and health topic, including recent learnings and trends around health, social media, real-world evidence and electronic product information.

In addition, UEMO was represented by Mary McCarthy (Shrewsbury and Telford Hospital NHS Trust -SaTH) on the second day. PCWP/HCPWP members had a



chance to hear the latest on EMA relocation, clinical data publication policy and implementation of Clinical Trial Regulation.

The main conclusions were as follow:

- Update on public meetings from which the UK had many requests for representation. EMA would wish to increase participation also from other member states
- Implementation of Clinical Trial Regulation – update on EU-CT portal and database on both negative and positive results
- Findings of the EMA survey on awareness of the ‘additional monitoring’ concept and next steps: Few adverse drug reactions being reported but data is often confused
- Relaunch of EMA corporate website this summer with a more modern and user-friendly structure
- EMA-HMA collaboration on shortages and availability of medicines: Need for action at the European level

Next steps will include a Public Meeting on June 13th; a Civic Society meeting on July 17th; a PCWP Stakeholders Meeting on September 24th; a workshop on shortages on November 8th/9th; an annual Training Day- all eligible organisations on November 20th; and an electronic PI Workshop on November 28th/29th.

Find out more:

[Patients' and Consumers' Working Party](#)
[Healthcare Professionals' Working Party](#)

UEMO

European Union of General Practitioners/Family Physicians

Piazza Cola di Rienzo 80/a
IT – 00192 Roma – Italy

 secretariat@uemo.eu

HEAD OFFICE

Rue des Deux Eglises 37-39
1000 Brussels - Belgium

