



UEMO

UNION EUROPÉENNE DES MÉDECINS OMNIPRATICIENS/MÉDECINS DE FAMILLE
EUROPEAN UNION OF GENERAL PRACTITIONERS/FAMILY PHYSICIANS

UEMO BULLETIN N°6 – 2016

Dear UEMO Members,

This month a key focus for healthcare developments across the EU has been on pharmaceutical issues. EU health ministers gathered in a meeting in Brussels and made a commitment to improve access to medicines and pricing of medicines. The EMA has been furthering this cause through its new PRIME scheme, which focuses on the development of medicines that target a currently unmet medical need. According to the first results of the scheme, it is doing really rather well, which is a pleasure to see.

This month has also been interesting for UEMO. At the beginning of the month, there was the very fruitful and engaging UEMO General Assembly. Towards the end of the month, UEMO attended a Dutch EU Presidency organised event in Amsterdam. The main focus there was on professional qualifications and the free movement of professionals in the EU.

Read more about this event and many other news in this edition of the UEMO Bulletin.

Yours sincerely,

Aldo L'UPO

EU NEWS

- ❖ State of Health in the EU Initiative 2016 - 2017
- ❖ European Drug Report 2016 Published
- ❖ EU Member States to Improve Access to Medicines and Address Pricing Issues
- ❖ Opinions and Memorandum from EC Expert Panel
- ❖ EC Launches Consultation Series on Clinical Trials
- ❖ First Results of the EMA PRIME Scheme
- ❖ Event Report: eHealth Week 2016

UEMO NEWS

- ❖ UEMO at Dutch EU Presidency Event in Amsterdam

OTHER NEWS

- ❖ WHO Assessment Tool for Essential Public Health Operations
- ❖ Macedonia Legalises Medical Marijuana
- ❖ Norway to Introduce Plain Packaging for Tobacco



EU NEWS

STATE OF HEALTH IN THE EU INITIATIVE 2016 - 2017

18TH JUNE 2016

In June, the EU Commissioner for Health and Food Safety, Vytenis Andriukaitis, announced a new healthcare initiative for the years 2016 – 2017, entitled “State of Health in the EU”. The initiative aims to bring together internationally recognised expertise to provide Member States with evidence on health that is relevant to their specific country context and that helps maximise the effectiveness, accessibility and resilience of their health systems.

The initiative will be undertaken throughout a two year period, during which the EU will cooperate with the Organisation for Economic Cooperation and Development (OECD), the European Observatory on Health Systems and Policies, as well as EU Member States on healthcare issues. The aim of the initiative is to boost analytical capability and support Member States in their health care policy decisions.

The initiative will officially start in November 2016, with the publishing of the “Health at a Glance: Europe” report, which assesses the progress made towards effective, accessible and resilient healthcare systems. Then the organisations and entities involved in the initiative will work together to

prepare 28 individual country reports, one for each EU Member State, which will highlight the specific characteristics and health care challenges of each country. The country reports will be published towards the end of 2017. Immediately after, the European Commission will issue a paper to accompany the 28 country profiles, which will examine links between the “Health at a Glance: Europe” report and the 28 individual country profiles.

At the end of the initiative a series of voluntary exchanges have been scheduled in order to support EU Member States in exploiting the results of the initiative. Member States will then be able to request to discuss best practices and other findings from the “State of Health in the EU” initiative.



Find out more:

- ❖ Press release from the European Commission:

<http://bit.ly/z8P1omO>



EUROPEAN DRUG REPORT 2016 PUBLISHED

2ND JUNE 2016

The European Drug Report 2016 presents an overview of the latest trends and developments in the EU drug situation and draws attention to some of the persisting problems. The report includes information on drug use, problems, and markets, as well as drug policies and practices in Europe. The report has been prepared with the involvement of the European Commission, Europol, the European Centre for Disease Prevention and Control, and the European Medicines Agency.



According to the report, Europe continues to face an increasingly more complex drug problem. Stimulants, new psychoactive substances, misused medicines and problematic cannabis use are all challenges that are currently facing Europe. In particular, the use of opioids remains a central issue that needs to be addressed. These drugs have had a significant impact on mortality and morbidity rates in Europe.

The report has found that the most commonly used drug type varies depending on the geographical area. In western and southern European countries, cocaine use is higher, whereas amphetamine use is more prominent in eastern Europe. Cannabis, however, accounts for the largest share in value of Europe's illicit drug market.

An important new challenge for drug policy is how to respond to the internet's role as both a communication medium and an emerging source of drug supply. Attention needs to be paid to both darknet drug markets, as well as surface websites, especially with regard to the supply of counterfeit medicines and new psychoactive substances. The internet, according to the report, also presents opportunities to improve prevention, treatment and harm reduction activities, although this aspect is often overlooked.

Find out more:

- ❖ European Drug Report 2016:
<http://bit.ly/296LWQI>



EU MEMBER STATE TO IMPROVE ACCESS TO MEDICINES AND ADDRESS PRICING ISSUES

22ND JUNE 2016

European health ministers met in Brussels on 16th and 17th June at the Council of the European Union. One of the most important outcomes of the meeting is the document “Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States”. The document includes commitment from EU health ministers to improve access to medicines and address medicine pricing issues.



EU health ministers agree that the economic crisis, the ageing European population, and new health threats, have created strains for EU Member State health systems. Medicine shortages and accessibility problems are major challenges that need to be addressed rapidly. The health ministers expressed concerns that the existing complex system of pricing might not be balanced and may not always work in the interests of patients and their safety.

Under EU law, Member States retain the competence to decide the pricing and

reimbursement processes for medicinal products. The European Commission remains responsible for ensuring the competition of medicinal products on the EU market.

The conclusions agreed among EU health ministers recommend Member States to cooperate between themselves in order to achieve higher affordability and better access to medicines. Synergies between the regulatory bodies, health technology assessment bodies and payers should also be explored to facilitate access to innovative medicines.

EU health ministers have also suggested to organise during each EU Presidency an informal meeting to discuss developments in the pharmaceutical policy. Ministers have invited the European Commission to prepare as soon as possible an overview of the current EU legislative instruments and related incentives that aim to facilitate investment in the development of medicinal products.

Find out more:

- ❖ Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States:
<http://bit.ly/29hAbXy>
- ❖ EurActiv news:
<http://bit.ly/28SXeak>



OPINIONS AND MEMORANDUM FROM EC EXPERT PANEL

15TH JUNE 2016

In June, the European Commission's Expert Panel, which provides non-binding advice to the Commission on issues related to effective ways of investing in healthcare, issued a series of Opinions, as well as the Memorandum on "Reflections on hospital reforms in the EU". The Memorandum looks at some of the current challenges facing hospitals in the EU and the actions that have been taken to remedy them.



The Opinions of the Expert Panel cover different healthcare aspects. The first Opinion presents policy responses to improve access to health services at both EU and national level. It points out that cooperation is vital here and that the EU remains ready to assist and support, but can only do so, if the Member States themselves are willing to take action. The second Opinion looks at how health policy could be reformed to achieve the envisioned objectives. Last but not least, the third Opinion includes best practices

and considers whether or not healthcare services should be commissioned from private providers within the EU. This has already been acknowledged as a policy option by the Commission, but further research is necessary to assess viability.

Find out more:

- ❖ First opinion:
<http://bit.ly/1UhDM8y>
- ❖ Second opinion:
<http://bit.ly/1ZTeDmd>
- ❖ Third opinion:
<http://bit.ly/1rrxF7c>
- ❖ Memorandum "Reflections on hospital reforms in the EU":
<http://bit.ly/1UArOnD>



EC LAUNCHES CONSULTATION SERIES ON CLINICAL TRIALS

4TH JUNE 2016

The European Commission has launched a series of consultations with relevance to the implementation of the Clinical Trials Regulation (EU) No 536/2014. There are four consultations running in parallel from 1st June 2016 to 31st August 2016. All of these consultations are open for participation to any interested citizens and organisations.

Consultation on “Risk proportionate approaches to clinical trials”

Objective: to seek views on the document regarding “Risk proportionate approaches in clinical trials”. The main aim is to gather information on how a risk proportionate approach can be implemented in clinical trials.

Consultation on “Summary of Clinical Trial Results for Laypersons”

Objective: to seek views on the document “Summary of Clinical Trial Results for Laypersons”. The Clinical Trials Regulation requires that sponsors provide a summary of clinical trial results in the EU Portal and Database in a format understandable to laypersons. The main objective of the Summary is to provide recommendations and templates for the production of a summary of clinical trials results for laypersons.

Consultation on “Definition of Investigational Medicinal Products (IMPs) and use of Auxiliary Medicinal Products (AMPs)”

Objective: to seek views on the document “Definition of Investigational Medicinal Products (IMPs) and use of Auxiliary Medicinal Products (AMPs)”, which is the revised version of the document “Guidance on Investigational Medicinal Products (IMPs) and Non-Investigational Medicinal Products (NIMPs)”. The main objective of the revision is to align the document with the Clinical Trials Regulation and with the latest research findings.

Consultation on “Ethical Considerations for Clinical Trials on Medicinal Products Conducted with Minors”

Objective: to seek views on the document “Ethical Considerations for Clinical Trials on Medicinal Products Conducted with Minors”. The main aim is to align the document with the Clinical Trials Regulation and with the latest insights on research with children.

Find out more:

- ❖ European Commission press release: <http://bit.ly/1rRN7mJ>



FIRST RESULTS OF THE EMA PRIME SCHEME

2ND JUNE 2016

The European Medicines Agency's (EMA) PRIME scheme was launched in March 2016. News on progress made under the scheme were published at the beginning of June.

PRIME is a new EMA initiative that aims to foster research on and development of medicines that have the potential to address a currently unmet medical need. Through PRIME, EMA offers early, proactive and enhanced support to medicine developers to optimise the generation of robust data on a medicine's benefits and risks and enable accelerated assessment of medicine applications.

In the first month of the PRIME scheme, from its launch in March until 6th April, EMA received a total of 18 applications. These were assessed by the EMA Scientific Advice Working Party, the Committee for Advanced Therapies, and the Committee for Medicinal Products for Human Use. A decision was made to accept 4 of the applications for PRIME.

Detailed information about the applications is now available on the EMA website. Of the 18 applications, 11 were received from SMEs and 7 from unspecified entities (filed under "other"). Of the 4 accepted applications, 3 were from SMEs and 1 from an unspecified entity. The most applications were received for medicines in the fields of infectious diseases, oncology, and pneumology-allergology (three

applications in each of these fields). Regarding the accepted applications, one has been approved in each of the following fields: oncology, immunology-rheumatology-transplantation, neurology, and haematology-haemostaseology.

Since 6th April, the EMA has received another 14 applications and is currently in the process of assessing them.



Find out more:

- ❖ EMA press release:
<http://bit.ly/22xB8P4>



EVENT REPORT: eHEALTH WEEK 2016

10TH JUNE 2016

eHealth week, taking place annually in different cities across Europe, is considered Europe's leading eHealth event. This year it took place in Amsterdam from 6th to 8th June, under the auspices of the Dutch EU Presidency. The event was attended by more than 2,000 experts in IT and healthcare, delegations from public institutions, professional bodies and patient organisations.

The theme "You – at the heart of transition" showed a clear focus of the event on eHealth users – patients, consumers, doctors, nurses and informal care givers. This marked a shift from previous eHealth weeks, which have mainly focused on IT systems or institutions.

The presentations and speeches during the week revolved around three main topics – empowering people, trust & standards, and social innovation & transition.

Empowering people focused on enabling sick and healthy citizens to play a more active role in managing their own health and addressed issues related to how elderly people can continue to live independently and how eHealth applications can meet user needs more effectively.

The topic "trust and innovation" sought to exchange knowledge on promoting and enhancing trust in health IT systems and

on ways to increase the use of standards in eHealth.

Last but not least, the topic "social innovation and transition" encouraged the implementation, scale and use of eHealth by looking at where, why and how implementation and upscaling have been successfully achieved in the past and how best practices can be replicated.

The eHealth week featured a speech from EU Commissioner for Health and Food Safety. He remarked that "it is now time to make a move from developing and testing to actual implementation of eHealth solutions".

The next eHealth week will be held in Malta from 10th to 12th May 2017.



Find out more:

- ❖ Dutch EU Presidency press release: <http://bit.ly/2973Gej>
- ❖ European Commission press release: <http://bit.ly/290vCm3>



UEMO NEWS

UEMO AT DUTCH EU PRESIDENCY EVENT IN AMSTERDAM

30TH JUNE 2016

On 28th June, the Dutch EU Presidency organised an event in Amsterdam entitled “Professional Qualifications safe in Motion”. UEMO was invited to participate in this event and was represented by UEMO President Dr. Aldo Lupo.

The event was organised in light of the recently revised European Directive on the recognition of professional qualifications (Directive 2013/55/EU), which entered into force in 2016.

The event in Amsterdam examined the possible ways to safeguard patient safety in the EU, where healthcare professionals are free to move from country to country. Participants also debated the ways in which healthcare professionals could be supported to ensure that they deliver high-quality care. Other debated issues included the European Professional Card, new methods for recognising professional qualifications, and new alert mechanisms for Member States to warn each other about health professionals who should not be allowed to practice.

The event proved to be a success, allowing Member State

representatives and health care professionals to exchange experiences and share the lessons learned.



Find out more:

- ❖ Dutch EU Presidency article: <http://bit.ly/29fApBA>
- ❖ Directive 2013/55/EU: <http://bit.ly/295ahrZ>



OTHER NEWS

WHO ASSESSMENT TOOL FOR ESSENTIAL PUBLIC HEALTH OPERATIONS

20TH JUNE 2015

The World Health Organisation (WHO) has updated its paper-based self-assessment tool for the evaluation of essential public health operations (EPHOs) and created a new web-based tool.

The WHO has identified ten EPHO's that countries can work on together in order to assess and create better public health services. These operations centre around three main areas of service delivery: health protection, disease prevention, and health promotion.

The WHO European Action Plan on Strengthening Public Health Capacities and Services calls for the establishment of a tool that would help assess country performance on EPHOs. In 2014, a self-assessment paper-based tool for EPHOs was developed at the University of Valencia. This self-assessment tool is a comprehensive questionnaire that can be used as a minimum checklist of public health services. It will still remain as a useable method, alongside the new web-based tool.

The self-assessment tool allows WHO Member States to carry out self-assessments of public health services and capacities. The advantage of the web-based tool, in comparison to the paper-based version, is that it allows

simultaneous data entry from multiple users. It also has a reporting module, which presents results in summary tables and charts. Assessment results can be separated by country or by EPHOs.

The self-assessment tool can be used to strengthen dialogue on strengths, weaknesses and gaps in EPHOs and capacity, to generate policy options or recommendations for public health reforms, and to contribute to national public health policies, strategies or programmes, as well as educational or training purposes.

The web-based tool, developed by the WHO European Region in cooperation with the Ministry of Health of the Russian Federation, is available in English and Russian.



Find out more:

- ❖ WHO press release:
<http://bit.ly/295oKg5>
- ❖ WHO 10 EPHOs:
<http://bit.ly/29fWbFa>
- ❖ WHO Resolution on the European Action Plan on Strengthening Public Health Capacities:
<http://bit.ly/295ggZV>



MACEDONIA LEGALISES MEDICAL MARIJUANA

15TH JUNE 2016

Macedonia has adopted new legislation, which legalises certain types of marijuana-derived medicines. The legislation came into force on 13th June 2016.



Specifically, doctors will now be able to prescribe medicines containing less than 0.2% of tetrahydrocannabinol, the psychoactive ingredient in marijuana. Such medicines will also now become available in pharmacies. It is important to note that the marijuana-derived products will only be accessible under doctors' supervision and with a prescription.

Marijuana-derived medicines can help patients that benefit more from plant-based medications and that are battling cancer, multiple sclerosis or epilepsy.

With this rather monumental step, Macedonia has joined 13 other European countries, which have already legalised similar medications. These countries include Austria, France, Germany, Italy, the Netherlands, Spain, and the UK.

Find out more:

- ❖ EurActiv news article:
<http://bit.ly/297gT6S>



NORWAY TO INTRODUCE PLAIN PACKAGING FOR TOBACCO

3RD JUNE 2016

At the beginning of June, the Norwegian Government announced a new bill on plain packaging for tobacco products. The bill will be handed over to the Parliament to debate in June, as a first step in the legislative process.

According to the new legislation, if adopted, tobacco packaging and tobacco products will be standardised. All tobacco packages will have to be of a specified dark-green colour. The fonts used on the packing will have to be the same and no logos or other design elements will be allowed. As for the tobacco products, the colour of the cigarette paper and cigarette tip will be standardised.



The bill in particular targets younger population groups, which, according to the Norwegian Government, are more affected by the appearance and design of tobacco packaging. The Government wishes to restrict this harmful type of marketing, but insists that the provisions for plain packaging will not affect people's rights of choice and their access to buying products. Instead, the bill will aim to deter new generations from smoking and prevent tobacco addiction.

Find out more:

❖ Norwegian Government press release:

<http://bit.ly/29cuWLd>

❖ WHO news article:

<http://bit.ly/29fOL4M>

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