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

UEMO News

EU NEWS

I. AUSTRIA'S PRIORITIES ON HEALTH FOR ITS UPCOMING EU PRESIDENCY

As Austria just took over the Presidency of the Council of the EU on 1st July 2018, 3 priorities have been already mentioned in the official programme.

- The European Commission Proposal for a Council Recommendation on Strengthened Cooperation against Vaccine Preventable Diseases: The Austrian Presidency strives for the adoption of this Recommendation.
- The EU's position for the Framework Convention on Tobacco Control (FCTC): The Austrian Presidency will have as a goal to prepare a common EU position on the issues under negotiation at the conference.
- The Health Technology Assessment (HTA) proposal: Austria will continue the work started by the Bulgarian Presidency, with the aim of preparing a progress report.

II. COMMISSION ESTABLISHES STEERING GROUP ON HEALTH PROMOTION, DISEASE PREVENTION AND MANAGEMENT OF NON-COMMUNICABLE DISEASES

On 17 July 2018, the European Commission adopted the establishment of the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases ("the Steering Group") as a formal expert body. The goal of the Steering Group is to help the Member States reach the Sustainable Development Goals related to health and to reduce premature mortality from non-communicable disease.

The Steering Group will have a broad overview of public health policy and may set up subgroups to work on specific issues for limited time periods. Therefore, existing Commission expert groups set up for particular diseases, for example, those on cancer control and rare diseases, will now be replaced by the Steering Group.

In practice, the Steering Group will provide expert advice to the Commission on developing and implementing activities in the field of health promotion, disease prevention and the management of non-communicable diseases. It will also foster exchanges of relevant experience, policies

and practices between the Member States.

The Steering Group will advise the Commission on the selection of best practices and using them to support their transfer and scaling up at the national and European level using the funds from the EU Health Programme or other EU financial instruments.

The Commission will chair the Steering Group made up of the Member States. It will hold its first formal meeting on 6 November 2018 in Luxembourg.

More information:

- Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases

III. STUDY ON CROSS-BORDER HEALTHCARE: EMPOWERING NCPS TO HELP PATIENTS EXERCISE THEIR RIGHTS

On 20 July 2018, the results of the study ''Enhancing information provision to patients'', funded under the Third EU Health Programme, were published.

The outcome suggests that patients in Europe are still generally unaware of their rights and the possibility to access health services in other EU Member States, as well as of the existence of National Contact Points (NCPs) to help them exercise their rights under the Cross-border Healthcare Directive.

While the study feeds into the upcoming implementation report on the operation of the Cross-border Healthcare Directive due this October, it is expected to enhance the level of information provided and available to patients, empowering NCPs to be fit for purpose.

For more information:

- Cross-border healthcare
- Study on cross-border healthcare

IV. HEALTH COMMITTEE MEPS BACK PLANS TO BOOST JOINT ASSESSMENT OF MEDICINES

On 13 September 2018, MEPs of the Health Committee adopted a new law that aims at boosting cooperation between member states in the field of HTA, by «laying out the procedure for member states to carry out voluntary joint assessments». It is intended to cover aspects such as rules for sharing data, setting up coordination groups, avoiding conflicts of interest among experts, and publishing the results of the joint work.

The new plan is expected to be voted by the full house at the plenary session in Strasbourg on 1-4 October.

V. WORLD HEPATITIS DAY

On 28 July 2018, EU Commissioner for Health and Food Safety, Vytenis Andriukaitis, gave a statement for the World Hepatitis Day. Mr. Andriukaitis underlined the importance of increasing testing that leads to higher detection rates and the efforts of The EU Health Programme:

"The EU Health Programme finances viral hepatitis activities in the area of public health, in particular in targeting the most vulnerable, as well as in placing a strong focus on improving access to testing and care. Examples of EU Health Programme projects include the INTEGRATE Joint Action of 29 partners from public health institutions, hospitals, NGOs and universities across 15 EU countries to integrate early diagnosis and linkage to prevention and care of viral hepatitis, HIV, TB and STIs in EU countries by 2020. The EU has co-funded INTEGRATE by nearly EUR 2 million. Another project, HEPCARE 怡, with EU co-funding of EUR 1 million, aims to support the development of national hepatitis strategies, screening and treatment guidelines, taking into account available treatment options. It will help to bridge primary, secondary care, and outreach in the community to facilitate access to and uptake of testing and treatment services particularly among key risk groups including drug users and homeless."

More information:

- http://www.worldhepatitisday.org/
- Full statement

VI. BREXIT PREPAREDNESS: EMA TO FURTHER TEMPORARILY SCALE BACK AND SUSPEND ACTIVITIES

The European Medicines Agency (EMA) will launch the next phase of its business continuity plan on 1 October 2018 at the latest. This will allow the Agency to safeguard core activities related to the evaluation and supervision of medicines, while it has to intensify its preparations for the physical move to Amsterdam in March 2019 and cope with significant staff loss.

Detailed plans for the implementation of these measures are currently being developed and will be communicated to stakeholders concerned and the public as soon as they are available.

Activities initially impacted by phase 3 include:

- Collaboration at international level, which will be temporarily scaled back to focus primarily on product-related requests, supply-chain integrity and procedures under Article 58; in other areas, such as the harmonisation of global medicine regulation, EMA will only take a reactive role; EMA's engagement in other global public health issues such as antimicrobial resistance or vaccines will be maintained as long as possible, but reviewed on a case-by-case basis;
- Development and revision of guidelines, which will be temporarily limited to those guidelines that address an urgent public/animal health need or are necessary to support and facilitate preparations for Brexit;
- Holding of non-product-related working parties, which will be temporarily reduced as a consequence of the scaling back of guideline development or revision;
- Programmes and projects, where activities in relation to project governance will be reduced in line with the reduction/suspension of projects;
- Organisation and attendance at stakeholder meetings, which will be limited to Brexit-related interactions;
- Clinical data publication, for which the launch of new procedures will be temporarily suspended as of 1 August 2018; data packages submitted for medicines until the end of July 2018 will be processed and finalised.

More information:

- Brexit preparedness: EMA to further temporarily scale back and suspend activities

VII. TOWARDS IMPROVING THE AVAILABILITY OF MEDICINES IN THE EU

On 29 August 2018, the force task set up by European Union (EU) regulators to better address potential problems with medicines' supply and to avoid shortages published its work programme for the coming two years. The priority will be to improve the availability of human and veterinary medicines authorised in the EU for the benefit of patients in the EU.

The task force will develop and coordinate actions for better prevention, identification, management of and communication on issues that can affect the availability of medicines, in order to improve continuity of supply of human and veterinary medicines across Europe.

The task force will organise a multi-stakeholder workshop on 8-9 November 2018 to gather stakeholders, including patients, consumers, healthcare professionals, industry, wholesalers/distributors, parallel distributors, academia and regulators. They are expected to address availability issues and to include their input into the deliverables of the task force.

More information:

- Towards improving the availability of medicines in the EU

VIII. INFORMAL MEETING OF HEALTH MINISTERS

European Council

Federal Minister Beate Hartinger-Klein identified potential for improvement in the structured exchange of information between regulatory authorities responsible for drug approval and other stakeholders in the healthcare system:

"The question of patient benefit is extremely essential in this context. How can we ensure, for example, that very expensive drugs used to treat critically ill

patients do actually provide patient benefit that meets our expectations? It may thus be necessary to extend the essential criteria for the approval of these drugs to enable the provision of reliable information on new drugs. This should, however, affect neither duration nor costs of the authorization process so that rapid supply of innovative products remains guaranteed."

He also addressed the topic of availability of medicines in Europe and the importance of digital health:

"Every single member of a health profession, whether in medicine or in nursing, is better supported by the use of digital health data: if you know more about the patients to be treated, you can offer them a better diagnosis, therapy or care".

The EU member states agreed to work closely with the services of the European Commission within the framework of the eHealth network that is already in place at EU level in order to develop a guideline for targeted Europe-wide promotion and investment programmes in the eHealth sector. The goal is to make the existing infrastructure of thousands of health service providers fit for the future.

More information:

- https://www.eu2018.at/calendar-events/political-events/BMASGK-2018-09-10-informal-health.html

IX. CALL FOR TENDER N° CHAFEA/2018/HEALTH/10 CONCERNING THE EU DIMENSION OF ALCOHOL RELATED HARM – PILOTING BRIEF INTERVENTIONS TO REDUCE THE RISK OF FAS/FASD (FETAL ALCOHOL SYNDROME / FETAL ALCOHOL SPECTRUM DISORDERS)

Project to obtain regular services to support EU Member States actions in the field of the EU dimension of alcohol related harm. This particular service is the second of a series of four, where the first service has been published in 2017 and subsequent services may be published in the years, 2019, 2020.

More information:

- https://etendering.ted.europa.eu/cft/cft-display.html?cftId=3781

UEMO NEWS

I. Stakeholders confirm support for strengthened EU cooperation on HTA

On 7 July 2018, UEMO discussed together with over 300 policy makers, healthcare providers, patient representatives and other experts about the future cooperation on Health Technology Assessment (HTA). The discussions indicated that, HTA should be more structured, sustainable and efficient, better allowing for an optimal use of resources and sharing of expertise across the EU.

Doctors should be present in these discussions so that their mission between patients and medicine industry does not disappear. Dr Daniel Widmer, UEMO Board member, was there to reiterate the importance of the role of the health professionals.

In addition, participants made recommendations on:

• Engaging with patients and clinicians on HTA. Transparent and systematic engagement with stakeholders is needed, both on product-specific reports and on a broader strategic level. The involvement of patients and health professionals in the joint clinical assessment guarantees that the reports consider patient-relevant endpoints. Appropriate resources such as training are needed to enable their contributions.

•Generating evidence that meets the needs of patients and health system decision makers. A higher involvement of stakeholders will generate the relevant evidence that meets the needs of the health system decision-makers (including regulators, HTA and payer bodies) and that is also relevant for patients. The issue of transparency is key for the success and acceptance of the exercise.

•Managing uncertainty in the post-launch phase. Post-launch evidence is a key component of the re-assessment of health technologies. Registries and real world data form an important part of the body of evidence on the effectiveness and efficacy of medical devices. The EU's Digital Single Market offers numerous opportunities for interoperable ICT solutions, common standards, data security and digital competences.

Commissioner **Vytenis Andriukaitis**, said: *"*We now have an opportunity to establish a mechanism that ensures that HTA is used to its maximum potential throughout the EU *"*.

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