UEMO BULLETIN N°05 - SUMMER 2017

Dear UEMO Members,

This bulletin is focused on a variety of EUrelated health topics including the priorities of the Estonian Presidency for public health, Endocrine Disruptors, Cancer diagnosis, Alcohol Labeling, the regulation of professional services and many more...

We hope you enjoy reading this issue!

Yours sincerely,

Aldo L'UPO

UEMO President

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EU NEWS

THE ESTONIAN PRESIDENCY'S PRIORITIES FOR PUBLIC HEALTH



21ST JULY 2017

Estonia took over the presidency of the Council of the European Union for the first time this month, under the strapline 'Unity through balance', and although not one of the Presidency's four main priorities, public health will also be a key area for action during the next six months.

Having already undertaken to continue the digital health focus with announcement of a high-level meeting on October, e-health in the Estonian Presidency has also put tackling alcohol harm and reducing risks associated with antimicrobial resistance at the top of the public health agenda. The main activities in each area are outlined below:

Transforming Health and Care in the Digital Single Market (DSM)

The high-level meeting on e-health will focus on three main topics: building citizen-driven demand in e-health; and the

use of e-health to support the sustainability of health and social services, and to drive innovation and economic development, with the signing of the Tallinn Declaration on a Digital Health Society. Council recommendations will follow at the end of the year. The same themes are also the subject of a recently-launched public consultation by the European Commission - although the need to protect personal data and patient rights has already been highlighted, it will be crucial that as digital health becomes an integral part of national healthcare systems, such concerns are paid more than lip service and that health data security and protection are mainstreamed digital health initiatives. in counterbalance the DSM's strong economic and consumer focus, how to meet the practical health needs of individuals should be at the heart of the Commission's new digital health strategy, as well as measures to improve inclusive access to healthcare by enhancing digital health literacy and expand e-Skills across all parts of society.

Reducing alcohol-related harm

The recent developments and future strategies of EU alcohol policies were discussed at the 21 July Informal Meeting of Health Ministers in Tallinn. During the conference, Jevgeni Ossinovski, the Estonian Minister for Health and Labour, underlined EU national governments' shared goal to reduce alcohol-related harm by 10% by 2020, as set out in the World Health Organisation's (WHO) global action plan. In order to achieve this, the Estonian Presidency will mainly focusing on the cross-border aspects of alcohol policy, providing special attention to alcohol labelling and the need to protect youth from alcohol advertising. Time will tell if the Estonian Presidency's recognition of the need for joint action by national governments to tackle alcohol-related harm will finally result in tangible policy measures in the Council Conclusions to be



proposed at the end of the year – participants at EPHA's 2017 Annual Conference "Make Health Your Business" will have the opportunity to hear directly from Maris Jesse, Deputy Secretary General for Public Health in Estonia on how the Presidency thinks change can be mobilised for better health and wellbeing.

Tackling Antimicrobial Resistance

Keeping up the focus on Antimicrobial Resistance (AMR), the Estonian Presidency will organise a High-level meeting on 23 November, following the UN High-level meeting in September 2016 and the G20 Leaders' Declaration in July this year. Will this be the moment when the urgency of the situation is marked by urgent action? EPHA has already highlighted its concerns regarding the new EU Action Plan, which lacks concrete targets and benchmarks against which progress on reducing AMR can be measured, and welcomes the Presidency's undertaking that indicators at EU and national level will be developed to address this in the plan's implementation.

Find out more:

The Presidency Programme for the Employment, Social Policy, Health and Consumer Affairs is available here.

CRITERIA TO IDENTIFY ENDOCRINE DISRUPTORS IN PESTICIDES



4THJULY

Experts from the 28 EU member states approved on Tuesday (4 July) a proposed list of criteria to identify endocrine disruptors in plant protection products - a presented by the move European Commission as a step towards a broader regulatory system for similar chemicals cosmetics, used in toys and food packaging.

The scientific criteria determining hormone-disrupting chemicals used in pesticides and biocides was adopted by EU member state representatives sitting in the European Commission's Standing Committee on Plants, Animals, Food and Feed.

Vytenis Andriukaitis, the EU Commissioner for Health and Food Safety, described the agreement as "a great success" and called on the European Parliament and the Council, involved in the decision-making process, to ensure its smooth adoption.

The list "will provide a stepping stone for further actions to protect health and the environment by enabling the Commission



to start working on a new strategy to minimise exposure of EU citizens to endocrine disruptors, beyond pesticides and biocides", the Commission said in a statement.

The new strategy will aim to cover for example toys, cosmetics and food packaging, the EU executive added. The decision is meant to bring to an end a protracted controversy surrounding the definition of endocrine disruptors, which has divided EU member states for years.

The European Commission published its proposed set of scientific criteria to identify chemicals with endocrine disrupting properties in June 2016 – three years later than legally required – prompting Sweden to sue the EU executive.

However, three highly respected international scientific societies of endocrinology (Endocrine Society, European Society Endocrinology, of European Society for **Paediatric** Endocrinology) raised the alarm bell about the shortcomings of the proposed criteria, urging member states not to approve them in their current state. Meanwhile, over 465,000 people all across Europe signed a petition calling on member states to reject the EU Commission's proposal.

"Strong EDC criteria would allow Europe to lead the world by example and to initiate urgently needed measures to reduce our unnecessary exposure to toxic substances. The criteria voted today contain a flawed loophole and require such a high level of proof that they will not protect people or wildlife. We call on the European Parliament to reject these criteria" says

Genon K. Jensen, EDC-Free Europe spokesperson.

Find out more:

The letter from the three international scientific societies of endocrinology is available here.

ALMOST A QUARTER OF CANCERS DIAGNOSED IN EUROPE ARE RARE CANCERS



Nearly a quarter of all cancers diagnosed in the European Union (EU) between 2000 and 2007 were classed as rare, according to updated epidemiologic information from the Information Network on Rare Cancers (RARECAREnet).

The findings were based on data from 94 EU cancer registries, which included nearly 2 million diagnoses of 198 different rare cancers, defined by the RARECARE project as those with an annual incidence of less than six cases per 100,000 people.

Among the 12 major families of rare cancers, which each included several individual cancers, hematologic



malignancies, rare cancers of female genital organs and of the digestive tract, and head and neck cancers had the highest overall incidence rates, with group totals ranging from 19 to 28 per 100,000 people per year. Rare skin cancers and noncutaneous melanoma, and embryonal cancers had the lowest incidences, with group totals of 1.22 and 0.34 cases per 100,000, respectively.

Gemma Gatta (Istituto Nazionale dei Tumori, Milan, Italy) and fellow RARECAREnet investigators report in The Lancet Oncology that 24% of all cancers diagnosed in the EU during 2000–2007 were classified as rare.

The overall incidence of rare cancers rose by 0.5% annually over the course of the study, but the researchers note that this was not significantly different from the 0.9% annual increase seen with common cancers during the same period.

They suggest that the increased incidence could be due to improved diagnosis, but also overdiagnosis in the case of thyroid cancer, as well as increased exposure to risk factors such as human papillomavirus.

And although 5-year relative survival among patients with rare cancers increased from 46% overall in 1999–2001 to 49% in 2005–2007, it was still lower than the 63% observed with common cancers.

The largest 5-year relative survival increases were seen for hematologic tumors and sarcomas, including chronic myeloid leukaemia, increasing from 37% to 58%, and soft tissue sarcoma of the viscera, which increased from 35% to 44%. By contrast, cancers categorized as "other

myelodysplastic syndromes" had decreased 5-year relative survival, falling from 34% in 1999–2001 to 30% in 2005–2007.

Gatta and team also used data from hospitals in seven European countries, treating around 220,000 rare cancer cases between 2000 and 2007, to study the extent of hospital centralization for rare cancers.

They found that overall, centralization of treatment was generally low but varied widely among the countries, leaving "ample room" for improvement, which could in turn improve survival, they say.

Indeed, subsequent discussions in national meetings "confirmed the need for improving the centralisation of rare cancer treatment in fewer, more specialised hospitals," Gatta et al write.

They conclude: "Our data offer a starting point to measure the effects of new policies on rare cancers."

Find out more:

You may purchase the full article here.



ALCOHOL LABELING – CAN THE INDUSTRY SELF-REGULATE?



10TH JULY 2017

Earlier this week report from the Alcohol Health Alliance (AHA) found that alcohol producers in the UK are failing to communicate drinking guidelines. Will it be the case at EU level? The industry has 6 months left to propose industry wide alcohol labelling arrangement to the European Commission.

There is a wide consensus that tougher rules are needed on alcohol labelling to make sure alcohol producers inform the public of the health harms linked with their products. Professor Sir Ian Gilmore, chair of the AHA, said: "Self-regulation has failed. Instead of alcohol producers deciding what to include on labels, the government should now require all labels to contain the latest guidelines and information on the health conditions linked with alcohol"

In March 2017, the European Commission published a long overdue report on alcohol labelling required by Regulation (EU) No 1169/2011. Back in 2011, Regulation 1169/2011 on the provision of food information to consumers exempted alcoholic beverages containing more than 1,2% by volume from the obligation to provide information to consumers. Unlike other food products, they do not have to list their ingredients or provide nutritional information.

The European Commissions' report clearly states that objective grounds have not been identified that would justify the absence of information on ingredients and nutritional information on alcoholic beverages or a differentiated treatment for some alcoholic beverages, such as 'alcopops'.

In its report, the Commission notes that alcohol sector is increasingly prepared to provide responses and therefore it is giving the alcohol producers a year to deliver a self-regulatory proposal that would cover the entire sector of alcoholic beverages. The Commission will assess the industry's proposal and if it is unsatisfactory, it will launch Impact Assessment.

The European Commission has indicated how it will assess whether the alcohol industry proposal is satisfactory. It reads:

"The Commission considers that this approach should cover all types of alcoholic beverages in order to avoid any misunderstanding or confusion from the consumers and to allow comparisons between the different types of alcoholic beverages. The sector has one year to make such a proposal and once submitted, the Commission will consider all its aspects and assess to which extent the proposal pursues the general objectives set out above. The Commission will also assess the compatibility of the proposal with EU law. In accordance with its commitments towards Regulation, Better Commission is prepared to discuss such a proposal with all interested parties, including consumer representatives, in the framework of the Advisory Group on the Food Chain and Animal and Health₂."

Find out more:

- ❖ Access the AHA article here.
- * Read the full EC report here.



PUBLIC CONSULTATION ON HEALTH AND CARE IN THE DIGITAL SINGLE MARKET



20TH JULY 2017

On 20th July, The European Commission has launched a public consultation on transformation of health and care in the Digital Single Market. This consultation investigates the need for policy measures that will promote digital innovation for better health and care in Europe and feed into a new Policy Communication to be adopted by the end of 2017. The consultation is open until 12 October 2017.

Citizens, patient organisations, health professionals, public and care researchers. authorities. industries. investors and users of digital health tools are invited to respond consultation by 12 October 2017. The responses from the public consultation will feed into new a policy Communication to be adopted by the end of 2017.

The consultation collects views on:

- Cross-border access to and management of personal health data;
- A joint European exploitation of resources (digital infrastructure, data capacity), to accelerate research and to advance

- prevention, treatment and personalised medicine;
- Measures for widespread uptake of digital innovation, supporting citizen feedback and interaction between patients and healthcare providers.

Purpose of the consultation

The Digital Single Market Mid-term review proposes that the Commission adopts a Communication addressing the need and scope for measures on digital health and care, in line with legislation on the protection of personal data, patient rights and electronic identification, focusing in particular on:

- Citizens' secure access to their electronic health records and the possibility to share these across borders;
- Support data infrastructure to advance research, prevent diseases and personalise health and care in key areas;
- Facilitate feedback and interaction between patients and healthcare providers and empower people to take responsibility for the management of their own health.

Find out more:

- ❖ Find out more <u>here.</u>
- To respond to the consultation, click here.



CHRONIC HEPATITIS B, C AFFECTS 9 MILLION EUROPEANS



25TH JULY 2017

The European Center for Disease Prevention and Control, or ECDC, estimates that approximately 9 million Europeans are impacted by chronic hepatitis B or C.

That breaks down to 4.7 million with chronic hepatitis B and 3.9 million living with chronic hepatitis C infection, and many do not even know they have the infection.

July 28 was World Hepatitis Day and the ECDC called on leaders in Europe to improve testing, prevention interventions and linkage to treatment services to reach the target of eliminating viral hepatitis by 2030.

"Greater efforts are needed to reduce both the suffering and the costs that hepatitis inflicts across Europe," stated Vytenis Andriukaitis, European Commissioner for Health and Food Safety, said in a press release.

Mr Andriukaitis also pointed that: "the Commission is fully committed to helping Member States achieve the Sustainable Development goal of ending HIV/AIDS and tuberculosis and

reducing viral hepatitis by 2030. Together, we will scale up our prevention and testing programs and reach out to the most vulnerable to reduce health inequalities. In order to tackle the underlying causes of the hepatitis epidemic we need to combine health instruments with social instruments and work together across health, social, and education policies."

Countries in the European Union and European Economic Area, or EU/EEA, reported nearly 60,000 newly diagnosed cases of hepatitis B and C, 24,573 cases of hepatitis B and 34,651 cases of hepatitis C.

An ECDC survey found significant variations across EU/EEA countries found the proportion of undiagnosed infections ranged between 45 percent to 85 percent for hepatitis B virus and between 20 percent and 89 percent for hepatitis C.

"There are highly effective drugs available to treat people infected with hepatitis B and C but the main bottleneck we see in Europe is the actual case detection: too many infections with viral hepatitis remain undiagnosed," concluded ECDC Director Andrea Ammon.

Find out more:

The ECDC press release is available here.



EU SCHOOL CHILDREN TO RECEIVE MILK, FRUIT AND VEGETABLES



31ST JULY 2017

The new EU school fruit, vegetables and milk scheme will be in place on 1 August, ready to be implemented across the Union as of the first day of the 2017/2018 school year.

Aimed at promoting healthy eating habits among children, the scheme will include the distribution of fruit, vegetables and milk products, as well as dedicated educational programmes to teach pupils about the importance of good nutrition and to explain how food is produced.

This single scheme merges and optimises the existing projects that last year reached over 20 million children. Although participation is optional, all 28 Member States indicated they will take part in the initiative in the 2017/2018 school year.

Phil Hogan, Commissioner for Agriculture and Rural Development, said: "I am very pleased that the new school scheme will be introduced tomorrow. The scheme provides valuable support to millions of European schoolchildren and thousands of farmers in every Member State. Such support has proven particularly important for farmers in recent years and the increased funding will enhance the value of this support. In addition, the new scheme

meets my priority of simplification through the integration of the former school milk and vegetable schemes. Finally, I am happy to be involved with an initiative with Commissioners Andriukaitis and Navracsics to promote a healthy lifestyle and I am convinced that this scheme has a valuable part to play."

Fresh fruit, vegetables and drinking milk will be given as a priority to school children. Processed products such as soup, fruit compotes, juice, yoghurts and cheese may also be distributed if this choice is approved by the national health authorities. No added sugar, salt and fat are allowed unless the national health authorities permit limited quantities.

Besides deciding on the exact way to put the scheme in place,like the inclusion of thematic educational measures and other agricultural products, Member States have the option to top up the EU aid with national aid for financing the scheme.

This choice of products shall be based on health and environmental considerations, seasonality, variety and availability with priority to EU products. Member States may encourage local or regional purchasing, organic products, short supply chains, environmental benefits, agricultural quality schemes.

Of the €250 million EU funding agreed for 2017–2018 school year, roughly €150 million will be allocated for fruit and vegetables and €100 million for milk.

The new school scheme forms part of Commissioner Hogan's simplification agenda. It allows for greater synergies and efficiencies in the implementation of the new scheme, and complements other measures in the areas of health and education policies.



From 1 August 2017, the two current schemes - the School Fruit and Vegetables Scheme and the School Milk Scheme - will be brought under a single legal framework. The new rules aim at greater efficiency, more focused support and an enhanced educational dimension.

Currently, 24 Member States take part in the old fruit and vegetable scheme and 28 in the old milk scheme. Last year, around 20 million children benefited from the milk scheme and around 11.7 million children from the fruit and vegetables scheme.

On June 16th, the UEMO officially took position against the raise in childhood obesity in Europe.

Find out more:

- For more information, <u>click here.</u>
- The UEMO position paper on childhood obesity is available here.

EMA PREPARES FOR BREXIT



The European Medicines Agency (EMA) has developed and initiated a business continuity plan to deal with the uncertainty and workload implications linked to the United Kingdom's (UK's) withdrawal from the European Union (EU) and the Agency's relocation.

"changes, and addressing challenges such as possible losses in skilled and experienced staff, in a proactive and efficient way requires considerable internal resources," said Noel Wathion, EMA's Deputy Executive Director and head of EMA's Brexit task force. "With the business continuity plan we aim to ensure that the assessment of medicines is not disrupted and that patients in Europe continue to have access to high quality, safe and effective medicines."

The business continuity plan is a tool that will help EMA take the difficult decision to reallocate the available resources as needed to maintain its priority activities over the next years. It categorises and prioritises tasks and activities according to their impact on public health and the Agency's ability to function. The plan sets out three layers of priority. In May, EMA started to scale back activities in the outer layer, socalled category 3 activities, to free up 43 staff by the end of 2017 who are focusing on the preparations for the UK's withdrawal from the EU and EMA's relocation. To achieve this, the Agency decided to temporarily suspend a number of its activities

EMA will provide further updates on the implementation of its business continuity plan as necessary.

Find out more:

More information here.



TOWARDS TOBACCO-FREE GENERATIONS: STOPPING SECOND-HAND SMOKE AND SMOKING INITIATION AMONG CHILDREN



15th August 2017

Several Member States in the WHO European Region are moving towards becoming "tobacco-free", which means having a smoking prevalence of 5% or less. To achieve this, countries must address a number of tobacco-related issues that specifically impact children, and work to protect children from the harmful effects of tobacco.

A new report from WHO/Europe identifies tools and offers novel approaches that can – and should – be used to pave the way towards a tobacco-free Region. A series of web stories highlights some of the report's key findings and recommendations, and shares examples of measures being taken within countries of the Region to fight the harmful effects of tobacco.

Of the nearly 900 million people living in the Region, roughly 252 million (28%) smoke. Of these, half will die prematurely from tobacco-related causes. On average, smokers lose 20 years of productive life as a direct consequence of tobacco use. The issue of tobacco use is, therefore, a major public health concern for the Region.

The impact of tobacco on children and youth is particularly worrying. Secondhand exposure kills over 600 000 nonsmokers globally each year, many of whom are children. Causes of such deaths include asthma, respiratory infections and cancer. Exposure to smoke in utero also increases of complications such miscarriage and babies born with low birth weight and nicotine dependence. Children exposed to second-hand smoke are also more likely to initiate smoking in the future. Despite these facts, the majority of children under the age of 15 in the Region are exposed to second-hand smoke both inside and outside the home.

Smoking initiation is a problem that occurs predominantly among children and adolescents, as the majority of smokers initiate by age 18. According to the 2013/2014 Health Behaviour in School-aged Children survey, 17% of children in the Region try smoking by age 13, and 12% are smoking regularly by age 15.

Children can begin to demonstrate symptoms of nicotine addiction within just days or weeks of first smoking, long before a habit of daily smoking develops. Furthermore, the younger the age of initiation, the more likely children are to develop an addiction. It is estimated that 3 in 4 children who smoke in adolescence go on to become daily, addicted smokers in adulthood, even if their intention is to quit within a few years.

Find out more:

Download the WHO report here.



PROFESSIONAL SERVICES: CONSIDERATION OF DRAFT REPORT



28th August 2017

On 04 September, Members of the committee on Internal Market & Consumer Protection (IMCO) will consider the EC draft report on the need for reform in professional services. The mutual evaluation of regulated professions, carried out in the framework of Article 59 of the Professional Qualifications Directive. showed great disparities between the Member States in how they choose to profession. The EC regulate a Communication professioncontain specific guidance for reforms in a number of selected professions.

The purpose is to make it easier for services providers to deal with administrative formalities, and to help Member States identify excessively burdensome or outdated requirements on professionals operating internally or across borders.

However, the EU does not regulate professions, the regulation of professional services remains a prerogative of the Member States. It is up to each Member State to decide whether there is a need to intervene and impose rules and restrictions for the access to or pursuit of a profession, so long as the principles of non-discrimination and proportionality are respected. To ensure a coherent and

consistent approach, the Commission is proposing to streamline and clarify how Member States should undertake a comprehensive and transparent proportionality test before adopting or amending national rules on professional services.

While healthcare professions are excluded from the obligation to conduct prior proportionality checks, they however remain subject to proportionality in line with Directive 2005/36/EC. The draft report sets an important margin of appreciation within which Member States may regulate professions.

<u> HEMO NEWS</u>

UEMO PARTICIPATES TO EMA'S JOINT MEETING



27th June 2017

On 27-28 June, the EMA organized a joint with representatives from meeting patients', consumers' and healthcare professionals' organisations (PCWP & HCPWP) in their London headquarters. Dr Ms Marie-Christine Tiago Villanueva, Bonnamour and UEMO president Aldo Lupo attended the event on behalf of the UEMO.



On June 27, EUnetHTA speakers joined the meeting to present on their activities and discuss areas of collaboration with patients and healthcare professionals; on June 28 there was a presentation on the European Commission's report on the shortcomings of product information followed by a discussion on the implementation of the report's recommendations. Also during the two-day meeting, participants learned about the HMA/EMA Taskforce availability of authorised medicines and their involvement discuss the Pharmacovigilance additional monitoring impact analysis. Other topics for discussion included a proposal for revision PCWP/HCPWP mandates and rules of procedure, the principles and practical considerations for streamlining the process for re-assessment of eligibility status, and the drafting process for a joint 2018/19 Work Plan.

Find out more:

Download the meeting agenda <u>here.</u>

EUNETHTA FORUM IN AMSTERDAM



On 13-14 September will take place the EUnetHTA Forum in Amsterdam, Netherlands. UEMO will participate and DR Widmer, elected representative of the

HTA Health Care Professionnals, will chair the second panel on stakeholder involvement in EUnetHTA.

The EUnetHTA Assembly and Forum provide a framework for updates and decisions relevant to the Consortium and a platform for networking, regular networkwide scientific discussions and exchange of experience. The Assembly consists of EUnetHTA Consortium Partners (voting and non-voting members). The Forum consists of the EUnetHTA Consortium Partners, Collaborating Stakeholders (as per definition provided in the guide for applicants for the Joint Action) and other organisations concretely involved in the activities of **EUnetHTA** JA₃.

Find out more:

* Register <u>here.</u> (free of charge)

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