



**UEMO**

UNION EUROPÉENNE DES MÉDECINS OMNIPRATICIENS/MÉDECINS DE FAMILLE

EUROPEAN UNION OF GENERAL PRACTITIONERS/FAMILY PHYSICIANS

## UEMO BULLETIN N°10 – 2016

Dear UEMO Members,

The focus topics in the healthcare community this month are: the upcoming Maltese Presidency in the Council of the European Union, tobacco control, UV radiation exposure and avian flu.

UEMO participated in the presentation of the priorities of the Maltese Presidency in the Council of the European Union.

UEMO Senior Policy Advisor met with the Maltese Health Attache of the Permanent Representation of Malta to the EU and discussed issues of common interest as well as the future collaboration of UEMO with the Maltese Presidency.

I hope you enjoy reading about these developments and much more in this issue.

Yours sincerely,

*Aldo L'UPO*

UEMO President

### EU NEWS

- ❖ DG Santé takes action against the spread of the avian flu
- ❖ SCHEER concludes that there is no safe exposure limit for UV radiation from Sunbeds
- ❖ European Commission urges Croatia, Cyprus, Luxembourg, Slovenia, Spain and Sweden to notify on the transposition of the directive on Tobacco Products sold in the EU
- ❖ DG Santé publishes call for applications for membership in the advisory group on the food chain and animal and plant health
- ❖ European Parliament demands Germany to compensate victims in the EU for killer drug

### UEMO NEWS

- ❖ Maltese Health Attaché presents health priorities of the Maltese Presidency
- ❖ UEMO Senior Policy Advisor meets with Maltese Health Attaché
- ❖ National News from Austria

### OTHER NEWS

- ❖ EMA organises workshop on adaptive pathways
- ❖ WHO launches campaign on depression as theme for the World Health Day
- ❖ ECDC provides risk-assessment on multi-



### DG SANTE TAKES ACTION AGAINST THE SPREAD OF AVIAN FLU

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30<sup>TH</sup> NOVEMBER 2016

The Member States have provided their support to a Commission proposal that consolidates the protective measures in relation to outbreaks of highly pathogenic avian influenza (HPAI) of subtype H5N8 in several Member States.

Commissioner **Andriukaitis** has commented that: *"The Commission has reacted promptly to this situation, and though the virus is still predominantly a bird virus without any specific increased affinity for humans, I call on Member States authorities, and the poultry sector, for extreme vigilance over this virus, and in particular the stepping up of biosecurity on poultry farms"*.

The virus, originating to wild migratory birds, has caused, at present, a total of 56 outbreaks of HPAI in poultry farms in Hungary, Germany, Austria, Denmark, Sweden and The Netherlands affecting poultry species (ducks, geese, turkeys, chickens). Moreover, the virus was found in wild birds in 10 Member States (Hungary, Poland, Germany, Croatia, Austria, Denmark, The Netherlands, Sweden, Finland and Romania), as well as in Switzerland.

So far all affected countries took the necessary measures.

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#### Find out more:

- ❖ The press release is available [here](#).



## SCHEER CONCLUDES THAT THERE IS NO SAFE EXPOSURE LIMIT FOR UV RADIATION FROM SUNBEDS

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30TH NOVEMBER 2016

The European Commission and its Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) has published the final Opinion on the biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes.

Ultraviolet Radiation (UVR), including that emitted by sunbeds, is a complete carcinogen, since it can initiate and promote cancer.

Based on the available scientific evidence, the SCHEER concluded that exposure to UVR in the context of sunbed use is:

- strongly associated with skin melanoma and squamous cell carcinoma, especially when first exposure takes place at a younger age;
- moderately associated with basal cell carcinoma and ocular melanoma;
- responsible for a significant proportion of both melanoma and non-melanoma skin cancer cases associated with early onset melanoma.

The SCHEER emphasised that there is no limit for exposure to UVR from sunbeds.

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Furthermore, as the risks outweigh the benefits, there is no need to use sunbeds to induce vitamin D production.

### **Find out more:**

- ❖ The press release is available [here](#).



## THE EUROPEAN COMMISSION URGES CROATIA, CYPRUS, LUXEMBOURG, SLOVENIA, SPAIN, AND SWEDEN TO NOTIFY TRANSPOSITION OF THE DIRECTIVE ON TOBACCO PRODUCTS SOLD IN THE EU

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08<sup>TH</sup> DECEMBER 2016

On 8<sup>th</sup> Decembert, DG Sante asked Croatia, Cyprus, Luxembourg, Slovenia, Spain, and Sweden to notify full transposition of the [Tobacco Products Directive](#) ([Directive 2014/40/EU](#)). This Directive aims to improve the functioning of the internal market for tobacco and related products, while ensuring a high level of health protection for European citizens. The provisions of the Directive should have been transposed into national law by 20 May 2016.

Sweden has already notified the Commission of a partial transposition of the Directive, while there has been no notification of transposition from Croatia, Cyprus, Luxembourg, Slovenia or Spain. The Member States has a period of two months to inform the Commission of the measures that it has taken in order to remedy the situation; otherwise, the Commission may decide to refer these cases to the Court of Justice of the EU.

### **Find out more:**

❖ The press release is available [here](#).

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## DG SANTE PUBLISHES CALL FOR APPLICATIONS FOR MEMBERSHIP IN THE ADVISORY GROUP ON THE FOOD CHAIN AND ANIMAL AND PLANT HEALTH

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15<sup>th</sup> DECEMBER 2016

The Advisory group on the food chain and animal and plant health ('the group') was set up by decision 2004/613/EC of 6 August 2004. [The Advisory group](#) advises the European Commission on food safety policy, and specifically on issues related to food and feed safety, food and feed labelling and presentation, human nutrition in relation to food legislation, animal health and welfare and matters related to plant health.

In addition, the Commission consults the group on any measures which the Commission has to take or propose in these fields.

The Commission is calling for applications in order to revise the membership of the group, following the requirements of the Commission Expert Groups ('the horizontal rules').

Interested organisations operating at European-level are invited to apply by **31 January 2017** at the latest.

### **Find out more:**

The Register of Commission expert group is available [here](#).

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## EUROPEAN PARLIAMENT DEMANDS GERMANY TO COMPENSATE VICTIMS IN THE EU FOR KILLER DRUG

19<sup>TH</sup> DECEMBER 2016



The European Parliament has demanded compensation for the victims of a German pharmaceutical drug thalidomide, that caused thousands of children to be born with deformities and many more to die, 60 years after the scandal first broke.

German company Grünenthal started selling thalidomide in 1957 as an anti-nausea and dizziness remedy for pregnant women.

EU lawmakers demanded that Berlin amend its forthcoming 2017 “Thalidomide law” so that it does not just pay compensation to German victims but also to other EU nationals, as the drug was not just sold over the counter in West Germany. The resolution, which received huge support from Spanish MEPs called on Madrid to review its 2010 legislation and set up a new record of those affected by thalidomide, in order to facilitate claims for compensation. The text also calls on the European Commission to create an EU-wide protocol that will allow

all survivors of thalidomide exposure to receive compensation.

Over the last two years, the victims of the drug’s side-effects have brought their plight to the attention of the Parliament and the institution’s president, Martin Schulz, has even got involved with the case. According to Avite, Spain’s association for people affected by the drug, more than 20,000 newborns worldwide have been affected by thalidomide, 3,000 of those in Spain itself.

The Spanish government officially acknowledged the existence of the affected parties in 2010, when a royal decree approved aid, a measure that MEP and registered doctor Soledad Cabezon (S&D group) has labelled as “insufficient”. She also called the thalidomide scandal “the worst disaster of 21st century medicine”.

In August 2012, the company apologised to those that had been affected and in November 2013 a Madrid court ordered the German outfit to pay out €20,000 for every disability point officially recognised. This ruling was later quashed by two higher Spanish courts.

During, Spanish MEP Esteban González Pons (EPP group) highlighted that thalidomide had been invented by the Nazis and regretted that the victims had to “grow up crying”. He added that “less bureaucracy” was needed to get the families the compensation they deserve.

Cabezón hopes that Germany will fully compensate all victims but warned that it did not relieve the Bundesrepublik of its “responsibility to other countries”.

### Find out more:

- ❖ The press release is available [here](#).





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## SCIENTIFIC COMMITTEE ON HEALTH PUBLISHES OPINION ON ADDITIVES USED IN TOBACCO PRODUCTS

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19<sup>TH</sup> DECEMBER 2016



Tobacco consumption is the largest avoidable health risk in the European Union. It accounts for nearly 700 000 deaths every year. Around 50% of smokers die prematurely (on average 14 years earlier). That is why the European Commission has taken various tobacco control measures.

The European Commission's Scientific Committee on Health, Environmental and Emerging Risks, (SCENIHR) has published an Opinion on the tobacco additives. SCENIHR searched for additives that make products more toxic in unburnt form or after combustion, those resulting in a characterising flavour or encouraging deeper and longer inhalation, increasing the amount of nicotine that gets into the body.

Of particular concern are flavour additives, especially sweeteners, which

give tobacco products a recognisable and distinct taste identity among the large variety of available brands.

The SCENIHR identified 48 chemicals to be placed on the priority list. These compounds were selected because they have or are suspected to have one or more of the following properties:

- toxicity in unburned form (including carcinogenic, mutagenic or toxic for reproduction)
- facilitating inhalation or increasing nicotine uptake, which may contribute to addictiveness;
- characterising flavour, one of the factors potentially contributing to attractiveness;
- formation of any kind of toxic chemicals after combustion;

The full list and details about how and why single compounds were selected for the priority list can be found in the Opinion.

This Opinion is the first one in a series of two on additives used in tobacco products. The second Opinion will address guidelines for the type and criteria for studies that should be requested from manufacturers to assess the relevance of additives.

### Find out more:

- ❖ SCHEER Opinion on additives used in tobacco products (tobacco additivesII) is available [here](#).



### MALTESE HEALTH ATTACHÉ PRESENTS HEALTH PRIORITIES OF UPCOMING MALTESE PRESIDENCY IN THE COUNCIL OF THE

12<sup>TH</sup> DECEMBER 2016



On 12 December 2016, the European Policy Center co-organised with CHES (Coalition for Health, Ethics and Society) a briefing on the Health Priorities of the Maltese Presidency. UEMO policy advisor participated in the Briefing.

Ms. Claire Dheret, Senior Policy analyst at EPC, was the Chairman of the discussion. The speakers included Ms. Paula Franklin, Policy officer at EPC and Mr. Stephen Mifsud, health attaché of the Maltese Permanent Representation to the EU.

**Mr. Mifsud** emphasized that the work of the Maltese Presidency will be a continuation of the work of previous presidencies. The major issues will be categorized under the following clusters:

- Non-communicable diseases

- Access to innovative medicines:
- Cooperation between health systems

He then analyzed the clusters mentioning the main health policies:

1. **Childhood obesity**: It poses a high burden for Member States. It is a priority area for actions. He emphasized the necessity to promote education on healthy lifestyles. The Maltese Presidency will follow a strategic approach on the obesity action plan 2014-2020 by sharing best practices on plans that have succeeded in the past. A supporting tool will be food procurement which is open to consultation. The Maltese Presidency will focus its strategy primarily on the prevention. The Maltese Presidency will organize a technical workshop in Malta 23-24 February.
2. **Cooperation between Health systems**: Mr. Mifsud mentioned that the cooperation between health systems is included in the Directive on patients' rights and cross border healthcare (ERNs, rare diseases, HTA, e-health). He underlined that health systems efficiency and sustainability may be addressed by increasing health system cooperation. Development in medicine and health care necessitate the generation of evidence on new models of health system. He informed the participants that a political discussion will be organized together with WHO health observatory. The Maltese Presidency will also host a technical workshop on 1-2 March in Malta with 4 parallel sessions: collaborative procurement

strategies, structured cooperation, rare diseases and ERNs (European reference networks) as a mechanism promoting structured cooperation.

3. **HIV Prevention:** Mr. Mifsud commented that the burden of HIV infection remains unacceptably high. The Maltese Presidency will focus its work on ending HIV by 2030, following the UN sustainable development goals. There will be a meeting in Malta in March on sharing achievements in good practices.
4. **Data for Health:** Mr. Mifsud mentioned that the Maltese Presidency aims to provide the opportunity to patients to access their own data. Sharing health data across country borders. This data management analysis will improve effectiveness. Regarding funding and governance of reference networks. Currently the network is composed of experts. The idea is to see how the ERN (European reference networks) reaches all the networks. The objective is to expand and build on the ERNs. The Maltese Presidency plans to explore e-health applications, genetic testing and high-cost medical devices. There will be no further policy on vaccines.

The **second session** included the presentation of Childhood Obesity by Ms. Paula Franklin. She commented that Childhood obesity is a huge problem as it is demonstrated in the 'health at a glance' report in collaboration with OECD. The data were retrieved from GPs.

Ms. Franklin commented on the current challenges:

- Increasing production of processed food. They are available easily and they are the cheaper option. It is also a social indicator of inequalities since processed food is accessible to the lower social classes. There are plenty of initiatives.
- The European Commission has produced a [White Paper on A Strategy for Europe on Nutrition, Overweight and Obesity related health issues](#). The aim is to decrease saturated fats and added sugar. There is also a WHO action plan on prevention and control of non-communicable diseases. Ms. Franklin mentioned that it is undeniable that obesity has a negative impact on the individual's life but also on healthcare systems.
- She commented that another issue is the food reformulation: there is a need for decreasing in ingredients such as salt, fats, sugar. The alternative is to add minerals, vitamins etc. There are different DGs working on these issues. eg. audiovisual directive is part of DG CONNECT. There is DG EDUCATION, DG SANTE, DG AGRI, DG RESEARCH.
- Commenting on the 'Health at a Glance report', Ms. Franklin added that childhood obesity has decreased only in two Member States (Denmark and the UK). She concluded that these countries should provide input and exchange best practices with the rest of the Member States in order to adapt policies preventing and combating childhood obesity.





## UEMO SENIOR POLICY ADVISOR MEETS WITH MALTESE HEALTH ATTACHE

20<sup>TH</sup> DECEMBER 2016



On 20 December, the UEMO Senior Policy Advisor, Ms. Marie-Christine Bonnamour had a meeting with the Health Attaché of the Permanent Representation of Malta to the EU, Mr. Stephen Mifsud. The aim of the meeting was to discuss the top health priorities of the upcoming Maltese Presidency in the Council of the EU and emphasise the added value that UEMO can deliver. Mr. Mifsud informed on the main topics (included in previous article) and commented on what the Maltese Presidency would like to achieve. More precisely:

- On **HIV/AIDS** the focus will be on a technical meeting. The aim is to reach the UN goals 2020. There will be an expert discussion followed by an expert declaration.
- On **Childhood Obesity** the European Commission is

organising an Action Plan mid-term review. The Maltese Presidency wishes to look at the results and address the deficiencies. It will produce procurement guidelines in food at schools. There will be collaboration with WHO, JRC and the Member States as well as a consultation with the industry.

- On **E-health** there will be a focus on e-health applications, genetic testing and high-cost medical devices. Ms. Bonnamour, informed Mr. Mifsud that UEMO is a member of the e-health stakeholder group. The team is working on the data on health.
- On **access to medicines** the focus will be on pharmaceutical prices and transparency. There will be a Member- State meeting on this on February. There are initiatives in workforce. The Maltese Presidency wants to allow doctors to have a training programme and a placement in another Member State in order to expose them to more specialized care.
- On **specialised care**, the aim of the Maltese Presidency is to provide the foundations for creating an Erasmus network for the specialisation of doctors. For this purpose, it is necessary to have the support from the Commission so as to include the proposal in the 2020 programme.

Ms. Bonnamour underlined that the UEMO is interested in primary healthcare and prevention policies. She emphasized



that there is potential for cooperation on childhood obesity. She also proposed to invite a Maltese health attaché to present the policies of the Maltese Presidency during the next UEMO general assembly.

## NATIONAL NEWS FROM AUSTRIA

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DECEMBER 2016

### *Fifth day of general practice*

On the 14<sup>th</sup> of December 2016, the Austrian Medical Chamber organised the so-called 5<sup>th</sup> day of general practice (5. Tag der Allgemeinmedizin). This day was mainly dedicated to the strike throughout Austria of the federal representatives of practitioners and specialists in free practice against the implementation of the health care reform package that also has been resolved on the 14<sup>th</sup> of December.

Among others, the package includes agreements according to Article 15a of the Federal Constitutional Act regarding the reorganisation of Primary Care and was therefore main topic of the day of general practice. According to these agreements, Primary Health Centres should function as practice networks, but also at central level in the form of group practices or of PHCs integrated in health institutions such as hospitals.

In this regard, the Austrian Medical Chamber agrees with the basic ideas, but claims more co-determination of the medical profession in the political discourse in general. Furthermore, the

Chamber insists on keeping a close to domicile health care provision with self-employed physicians in single or group practices instead of ambulatory care.

A government bill will probably be presented in the first half of the year 2017.

### *Austrian Day of Vaccination*

On the 14<sup>th</sup> of January 2017, the so-called Day of Vaccination took place in Vienna with the slogan “Healthy Society – is being vaccinated (still) part of it?” The Austrian Day of Vaccination is the biggest pioneering event concerning vaccination for physicians and pharmacists in Austria. Among others, it has been organised by the Akademie der Ärzte and the Austrian Medical Chamber.



## OTHER NEWS

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### EMA HOSTS WORKSHOP ON ADAPTIVE PATHWAYS

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13<sup>TH</sup> DECEMBER 2016

The European Medicines Agency (EMA) hosted a workshop with stakeholders to discuss adaptive pathways, which aim to facilitate access to medicines that address patients' unmet needs. The participants included representatives from patients' and healthcare professionals' organisations, pharmaceutical companies, HTA bodies and payers, national competent authorities (NCAs), the European Ombudsman, the European Commission and staff from EMA.

The adaptive pathways approach is intended only for medicines expected to have a significant clinical impact in patient populations with high unmet needs. This approach includes the participation of all stakeholders from a very early development process to proactively plan the most appropriate ways of obtaining evidence.

In July 2016, EMA published a report on a pilot project exploring the ways that the adaptive pathways concept can be applied in practice and developed guidance for companies considering using the adaptive pathways approach.

EMA's Executive Director, Professor Guido Rasi, opened the workshop, recognized the considerable interest the adaptive pathways concept has generated among key stakeholders and civil society at large.

Professor Rasi said that "EMA will continue to listen and learn from (the stakeholders) to make best use of the

regulatory tools we have in the interest of patients."

The workshop, organised by EMA and the European Commission (EC), answered to certain questions arising from the adaptive pathways pilot, including how best to address patients' needs and expectations; how to generate appropriate data to aid medicines evaluation; and how to ensure that high standards for approval in the EU continue to be met.

The workshop further discussed the role of organisations, such as HTA bodies and payers, which traditionally evaluated medicines post-authorisation in order to make decisions about price and reimbursement.

Dr. Andrzej Rys of the EC's Directorate-General for Health and Food Safety (DG SANTE) emphasised that "we all want to make sure that patients in the EU get access to safe, effective and affordable medicines."

A full report of the workshop is currently being prepared and will be published on EMA's website.

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#### Find out more:

- ❖ EMA press release is available [here](#).



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## WHO LAUNCHES CAMPAIGN AGAINST DEPRESSION AS WORLD HEALTH DAY THEME

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14<sup>TH</sup> DECEMBER 2016



World Health Day, celebrated on 7 April every year to mark the anniversary of the founding of the World Health Organization, provides a unique opportunity to act and get informed on a specific health topic of concern to people all over the world.

The theme of our 2017 World Health Day campaign is depression.

Depression affects people of all ages, from different backgrounds, in all countries. It causes mental anguish and impacts on people's ability to carry out even the simplest everyday tasks, with devastating consequences for relationships with

family and friends and the ability to work. Depression in its worst form can lead to suicide, which is currently the second leading cause of death among 15-29-year olds.

Depression can be prevented and treated. By enhancing the awareness of what depression is and how it can be prevented and treated, we can reduce the stigma associated with the condition, and lead to more people seeking help.

### Find out more:

The WHO campaign essentials are available [here](http://www.who.int/depression/en).



## ECDC PROVIDES RISK-ASSESSMENT ON MULTI-COUNTRY CLUSTER OF TB

22<sup>TH</sup> DECEMBER 2016

On 22 December 2016, the European Centre for Disease Prevention and Control published information regarding the Agency's latest risk assessment report. According to this report, seven cases of multidrug-resistant tuberculosis (MDR TB) in asylum seekers has been detected in Switzerland between February and August 2016. The seven cases of MDR TB were diagnosed among 15–19 year-olds from Somalia, Eritrea and Ethiopia. The asylum seekers had filed for asylum at different points in time between December 2015 and June 2016.

In addition, the same genetic information with the same drug resistance profile was detected in nine additional MDR TB cases in Austria, Germany and Sweden. One of the patients was diagnosed four months after contact with one of the other cases. So far, no other epidemiological link has been identified.

Moreover, as of 19 December, Germany reported six cases with the same genetic clone in asylum seekers from Somalia. Two cases of MDR TB with the same resistance profile were detected in Austria. One of which showed the same drug susceptibility pattern as the cases detected in Switzerland; for the second, drug susceptibility testing is currently ongoing. The same pattern was identified in Sweden in a patient from Somalia.

The available information from Switzerland demonstrates that there is a possible recent transmission. The patients could have been infected either in their

country of origin or while passing through a transit country along their migration route to the country of destination. Since the numbers of transmission and infection are so low, there is a limited risk that this outbreak could spread wider. However, more cases may occur in association with this cluster.

According to ECDC, Tuberculosis in a foreign-born population does not have a significant influence on TB in the native population in the EU/EEA, however there is still a possibility of transmission for both migrants and the native population.

### Find out more:

- ❖ The full risk assessment is available [here](#).



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