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UNION EUROPÉENNE DES MÉDECINS OMNIPRATICIENS/MÉDECINS DE FAMILLE

EUROPEAN UNION OF GENERAL PRACTITIONERS/FAMILY PHYSICIANS

UEMO BULLETIN N°8 – FEBRUARY 2018

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

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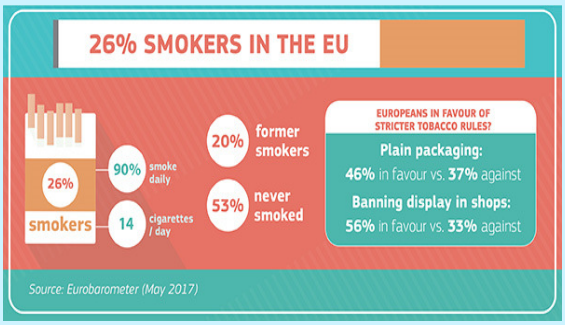
COMMISSION ADOPTS RULES FOR TOBACCO TRACKING & TRACING



Measures that EU countries and economic operators need to enact to put in place the EU-wide tracking and tracing system planned for under the Tobacco Products Directive (2014/40/EU) (articles 15 and 16) have been clarified in secondary legislation adopted by the Commission on December 15th 2017/

Welcoming the adoption of the legal acts, Health Commissioner Vytenis Andriukaitis reminded that "Illicit tobacco trade increases access, including by children and young adults, to cigarettes and other tobacco products, which remain the biggest avoidable cause of premature death in the EU. This fraudulent practice is also responsible for millions of euros in tax revenue losses for EU countries every year."

The Implementing Regulation on technical standards for the establishment and operation of a traceability system for tobacco products lays down rules that will ensure that all unit packets of tobacco products produced in, destined for or placed on the EU market will be marked with a unique identifier and their movements recorded throughout the supply chain (from the manufacturer to the last level before the retail outlet). It obliges each Member State to appoint an entity ('ID issuer') responsible for generating and issuing the unique identifiers, and lays down clear rules to ensure that the traceability system remains fully independent – notably from the tobacco industry, and that functions are carried out impartially.

The Implementing Decision on technical standards for security features applied to tobacco products obliges EU countries to require security features, composed of at least five types of authentication elements (including overt, covert and semi-covert), to be applied to unit packets of tobacco products. One of these elements must be provided by an independent third party provider. Member States must ensure they have the necessary means to ensure the authenticity and integrity of the security features.

Next steps

EU countries and economic operators can now start preparatory work for the two systems of traceability and security features. These should be in place by 20 May 2019 for cigarettes and roll-your-own tobacco and by 24 May 2024, for all other tobacco products (such as cigars, cigarillos and smokeless tobacco products).

Find out more:

- Systems for tobacco traceability and security features
- Revision of the tobacco products directive

NEW EUROPEAN COMISSION INITIATIVE TO IMPROVE VACCINE COVERAGE IN EUROPE

Vaccination is one of the most powerful and cost-effective public health measures developed in the 20th Century and the main tool for primary prevention of disease. Currently, Europe is facing avoidable large measles outbreaks in a number of countries. Even worse, Europe is exporting measles to other parts of the world. In addition, the risk of poliovirus re-introduction or importation to the EU remains a possibility, putting the current EU polio-free status at risk and undermining the global polio eradication initiative.

Seasonal influenza vaccination currently prevents up to 37,000 deaths each year in the EU. Yet, seasonal influenza vaccination coverage rates in the majority of EU countries are significantly below the agreed objective of 75 % for elderly (Council Recommendation on seasonal influenza vaccination, 2009).

Current challenges related to low and declining coverage, supply shortages and vaccine hesitancy require an urgent response. Council conclusions on vaccination as an effective tool in public health call on Member States and the Commission to develop joint actions in order to share best practices on vaccination policies. Furthermore the Council conclusions call on the Commission to identify synergies between vaccination and other EU policies and legislation, in particular as regards crisis management and preparedness.

In May 2017 the Commission organised the workshop "Seeking new partnerships for EU action on vaccination" to explore how cooperation at EU level can increase vaccine coverage, address shortages and strengthen routine immunisation programmes, taking into account possible synergies between vaccination and the use of antibiotics. To this end, a joint action on vaccination, co-funded by the Union´s Health Programme, has started in 2018, focusing on strengthened interaction of immunisation information systems, fostering of vaccine supply management, enhanced prioritisation of vaccine research and development, and tackling vaccine hesitancy.

State of the Union speech on measles prevention

In his State of the Union address last September, European Commission President Juncker stated: “In a Union of equals, there can be no second class citizens. It is unacceptable that in 2017 there are still children dying of diseases that should long have been eradicated in Europe. Children in Romania or Italy must have the same access to measles vaccines as children in other European countries.

No ifs, no buts. This is why we are working with all Member States to support national vaccination efforts. Avoidable deaths must not occur in Europe".

Against this background, DG Santé has prepared a roadmap in December 2017, highlighting the aims and objectives of the initiative. The approach is not to prepare a new legislation but to adopt a Council recommendation which would be aimed at strengthening coordination between Member States, and cooperation with industry and other relevant stakeholders at EU level to reinforce and consolidate vaccination programmes all over Europe, increase vaccination coverage and enhance EU level preparedness in health. To that end, the commission issued a stakeholders consultation on strengthened cooperation against vaccine preventable disease which was completed by the UEMO on February 13th.

On February 2nd 2018, Marie-Christine Bonnamour (UEMO) participated to a DG SANTE meeting on the possible contribution of the GP/Family physicians to the EC's action.

The UEMO developed an answer to the dedicated stakeholders consultation on strengthened cooperation against vaccine preventable diseases.

Find out more:

- EU vaccination policy and tools
- Public consultation on "strengthened cooperation against vaccine preventable diseases"

COMMISSION PROPOSES TO REINFORCE COOPERATION AMONGST MEMBER STATES ON HEALTH TECHNOLOGY ASSESSMENT

On January 31st, the Commission has put forward a proposal to boost cooperation amongst EU Member States for assessing health technology. Greater transparency will empower patients, by ensuring their access to information on the added clinical value of new technology that could potentially benefit them. More assessments could lead to effective, innovative health tools reaching patients faster. For national authorities it means being able to formulate policies for their health systems based on more robust evidence. Furthermore, manufacturers will no longer have to adapt to different national procedures.

Vice-President Katainen said: "Reinforcing Health Technology Assessment co-

operation at EU level boosts innovation and improves competitiveness of the medical industry. The healthcare sector is a crucial part of our economy, it accounts for approximately 10% of the EU's GDP. We are proposing a regulatory framework that will bring benefits to patients all over Europe, whilst encouraging innovation, helping the take-up of high-quality medtech innovations and improving the sustainability of health systems across the EU."

Commissioner for Health and Food Safety, Vytenis Andriukaitis, added: "Today, the Commission has put the wheels in motion for better quality, innovative healthcare for the benefit of patients, especially those with unmet medical needs. I also expect this initiative to result in a more efficient use of resources by Member States through the pooling of resources and exchanges of expertise, thereby avoiding duplications in the assessment of the identical products".

The proposed Regulation on Health Technology Assessment (HTA) covers new medicines and certain new medical devices, providing the basis for permanent and sustainable cooperation at the EU level for joint clinical assessments in these areas. Member States will be able to use common HTA tools, methodologies and procedures across the EU, working together in four main areas:

1) on joint clinical assessments focusing on the most innovative health technologies with the most potential impact for patients;

2) on joint scientific consultations whereby developers can seek advice from HTA authorities;

3) on identification of emerging health technologies to identify promising technologies early; and

4) on continuing voluntary cooperation in other areas.

Individual EU countries will continue to be responsible for assessing non-clinical (e.g. economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

Next steps

The proposal will now be discussed by the European Parliament and the Council of Ministers. It is expected that once it is adopted and enters into force, it will become applicable three years later. Following the date of application, a further three-year period is envisaged to allow for a phase-in approach for Member States to adapt to the new system.

The UEMO is currently preparing a position paper on the proposal.

Find out more:

- Q&A on the proposal

Find out more:

- Related documents

PROPOSAL FOR A REGULATION ON THE DEFINITION, PRESENTATION AND LABELING OF SPIRIT DRINKS

On 24 January, the committee for Environment, Public Health and Food Safety (ENVI) issued a draft report and a draft recommendation on the proposal for a regulation of the European Parliament and of the Council on the definition, presentation and labelling of spirit drinks.

This proposal aligns EU legislation on spirit drinks with the Lisbon Treaty. In addition, it contains minor technical adjustments of such legislation and it replaces the existing procedures for the management of geographical indications in the spirit drinks sector, with new procedures modelled on the more exhaustive and well tested procedures for agricultural products and foodstuffs. 43 compromises have been tabled covering a big range of issuesincluding the protection for geographical indications referred to goods entering the customs territory of the Union without being released for free circulation, the delegation of powers, the definition of the origin of a spirit drink, the procedure applicable for spirits intended for export, traditional practice.

WORLD CANCER DAY AND EUROPEAN CANCER INFORMATION SYSTEM

Given that cancer is still the second leading cause of death in the EU, there is a constant need for a robust, well informed response to it in order to contribute to the prevention, early detection, and adequate treatment. The European Cancer Information System (ECIS) website launched on the occasion of World Cancer Day by the Joint Research Centre (JRC), the European Commission's in-house science and knowledge service, allows experts and practitioners to explore geographical patterns and trends. It gathers data from around 150 European population-based cancer registries covering 25 EU Member States and 7 non-EU European countries providing valuable information on how well national cancer programmes are actually working, and address shortcomings.

Vytenis Andriukaitis, Commissioner for Health and Food Safety, highlighted: "Reliable data is an important aspect of the EU's approach to cancer, along with tackling risk factors such as tobacco, alcohol, pesticides and pollution, screening for diagnosis and treatment, research, and

connecting expertise through the European Reference Networks and joint actions."

"The European Cancer Information System is an excellent example of our support for decision-makers and researchers across the EU and beyond. It allows for the assessment and monitoring of the disease across regions and countries, following trends over time and helping to gather information that could lead to a further decrease of cancer rates." explained Tibor Navracsics, Commissioner for Education, Culture, Youth and Sports, responsible for the Joint Research Centre.

EU has been supporting research to fight cancer since 1985 through its research and innovation programmes. These efforts focus on developing patient-oriented strategies to prevent, cure and help people live with cancer. With funding totalling €2.4 billion since 2007, European cancer research has been leading personalised medicine approaches and efforts to understanding cancer biology as well as better prevention, treatment and care solutions.You can find more information here and here.

Find out more:

- European Cancer Information System
- EU measures against cancer

WHO RAISES AWARENESS ON THE LINK BETWEEN CANCER AND ALCOHOL CONSUMPTION

The WHO European Region has the highest level of alcohol consumption in the world. However, the level of awareness of the link between alcohol consumption and increased risk of cancer remains low. World Cancer Day on 4 February 2018 is an opportunity to reinforce the important message that alcohol use is associated with an increased risk of cancer, and to call for the implementation of effective measures to reduce the overall use of alcohol.

Established link between alcohol and 7 types of cancer

It has been established that drinking alcohol can cause at least 7 types of cancer, those of the:

- bowel (colon and rectum)
- breast
- gullet (oesophagus)
- larynx
- liver
- mouth

- upper throat

The main carcinogenic component of alcohol is ethanol, which is contained in every type of alcoholic drink. Ethanol damages cells in a way that makes them more prone to becoming malignant. It also affects female hormones, stimulating cell proliferation and increasing the risk of breast cancer. When combining alcohol with smoking tobacco, the rate of tissue damage is multiplied and, as a result, the risk of cancer is increased.

Reduced consumption, reduced risks

The dose–effect relationship between alcohol and cancer is clear: the higher the alcohol consumption, the higher the risk of cancer. For example, a woman increases her risk of breast cancer by 50% when drinking 4 glasses of wines per day and by 130% when drinking 8 glasses per day. There is no identified lower threshold, meaning that even small amounts of alcohol increase the risk of cancer.

However, the dose–effect relationship also holds true in reverse: any reduction in alcohol consumption reduces the risk of developing alcohol-linked cancer.

Link often overlooked

A study in the United Kingdom, published by the British Medical Journal in 2016, revealed that, unprompted, only 13% of respondents identified cancer as a potential health outcome of alcohol consumption. Knowledge of the link between alcohol and specific cancers ranged from 18% for breast cancer to 80% for liver cancer, demonstrating a lack of knowledge in the general population. And yet, cancer accounts for 12% of all alcohol-attributable deaths in the Region.

Effective measures and policies needed

Effective measures and policies exist to reduce harms from alcohol and improve population health. The European Action Plan to Reduce the Harmful Use of Alcohol 2012–2020 outlines a range of evidence-based policy options.

Three of the most cost-effective policy areas (the "best-buys") are:

- increasing price via taxation
- restricting access to retail alcohol
- imposing a ban on alcohol advertising.

Another important policy option, relevant in terms of reinforcing the health system response, is the implementation of brief intervention programmes in primary care settings for individuals with hazardous or harmful alcohol consumption. Screening and brief interventions (SBIs), as they are known, for alcohol are an evidence-informed approach to addressing the needs of the many patients presenting in primary care who may benefit from reducing their alcohol consumption. In 2017, the WHO Regional Office for Europe published a training manual for SBIs, designed to equip health-care professionals with adequate skills in supporting patients to change their drinking behaviour.

Find out more:

- European Action Plan to reduce the harmful use of alcohol 2012-2020
- WHO alcohol factsheet

NEW WHO PUBLICATION ADRESSES CHALLENGES FACED BY GOVERNMENTS TO IMPROVE PUBLIC HEALTH

Public Health Panorama, WHO/Europe's public health journal, has dedicated its latest issue to obesity and unhealthy diets in the Region. With unhealthy diets now responsible for 1 in 5 deaths globally, and with the Region at the midway point of implementing the European Food and Nutrition Action Plan 2015–2020, this special issue is a timely source of lessons learned and new research on the subject.

The issue, "Turning the tide on obesity and unhealthy diets", gives a snapshot of the current challenges governments face in making policies for improving public health. It examines the rapid increase in overweight and obesity among children and adolescents, and the need for transforming both service delivery and the scope of practice of health professionals.

The publication also provides concrete and effective solutions that have been implemented in all corners of the Region. It presents lessons learned on topics such as taxation on sugary drinks; clear, consumer-friendly front-of-package labelling; marketing restrictions on the promotion of fatty, salty and sugary foods to children; school food policies; and public procurement.

The value of surveillance, monitoring and evaluation as tools to inform and assess the impact of actions emerges strongly from the wide range of articles.

The overall publication illustrates the enormous progress made in terms of the evidence available and our understanding of effective policies and interventions. It also highlights the need for implementation in the Region, where the latest data show that unhealthy diets are the leading risk factor undermining health and well-being.

In the words of Dr Zsuzsanna Jakab, WHO Regional Director for Europe, the articles "should galvanize us to be more ambitious in our collective efforts to build a healthier Europe".

This is all the more relevant both regionally and globally as, for the first time, the Sustainable Development Goals commit governments to address all forms of malnutrition and prevent avoidable premature mortality from noncommunicable diseases.

Find out more:

- Download the publication here
- European food & nutrition action plan 2015-2020

ENVI COMMITTEE ISSUES NON-BINDING REPORT ON COMMISSION'S EUROPEAN ONE HEALTH ACTION PLAN AGAINST AMR

The EP's ENVI Committee has published its nonbinding own-initiative report on the EC's European One Health Action Plan against Antimicrobial Resistance.

The EP's report, which adds to those critics who say the EC's Action Plan lacks binding measures and clear benchmarks, makes the following recommendations:

- The mandatory routine collection and submission of monitoring data at EU level
- Implementation of measures to prevent doctors and veterinarians who prescribe antibiotics from selling them
- Developing incentives for industry to develop low-cost rapid diagnostic tools, since at present these tests are sometimes more expensive than antibiotics
- Boosting the role and funding of the ECDC (European Centre for Disease Prevention and Control) in the fight against superbugs
- Requiring an environmental risk assessment to be part of marketing authorisations for new antibiotics amid increasing concerns about pharmaceutical runoff

Find out more:

- ENVI committee's report
- One Health Action Plan against AMR

UEMO NEWS

9TH HTA NETWORK MEETING IN BRUSSELS

On Feburary 9th 2018, Daniel Widmer (UEMO) attended the 9th HTA network meeting in Brussels. More specifically, Mr Widmer participated to Topic 5 – Patients-Consumers organisations contribution to the HTA cooperation.

Background

The Multiannual Work Programme of the HTA Network for the period 2016-2020 includes a Discussion Paper on how to "facilitate appropriate involvement of all interested stakeholders in the European collaboration in HTA, notably patients, health professionals, healthcare industry, and payers".

In this context, the Patient and Consumer organisations from the HTA Network Stakeholder Pool developed two papers: "Criteria for the Prioritisation of Technologies for Joint HTA" and "Principles of Patients and Consumers Engagement in HTA". The documents set out key elements which Patient and Consumer organisations consider important for the EU cooperation on HTA, both in the short term (i.e. for the current Joint Action) as well as to feed into the discussion around the post 2020 scenario and to provide input to the implementation of the HTA Network work programme.

The Commission proposal recognises the importance of stakeholder involvement in the future cooperation and this topic will be an important discussion point during the forthcoming negotiations.

Find out more:

- Meeting documents

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