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STANDING COMMITTEE OF EUROPEAN DOCTORS

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This issue

SAVE THE DATE - CPME Meetings 2017 - 2018

24 - 25 November 2017, Brussels

13 - 14 April 2018, Brussels

WELCOME MESSAGE

MESSAGE FROM THE CPME PRESIDENT

Dr Jacques de Haller
CPME President

Dear Colleagues and friends,

Welcome to the 23rd edition of the CPME quarterly newsletter with the latest developments in EU health politics and recent CPME activities.

I am pleased to announce that following the CPME Extraordinary General Assembly held on 27 March 2017, the new 'Statutes of the Standing Committee of European Doctors' are published in the Moniteur Belge (Belgium Official Gazette) and on the CPME website. I would like to take the opportunity to thank all CPME members for their efforts and contributions.

This edition opens with a feature article of Mr Xavier Prats Monné, Director General of the European Commission Directorate-General for Health and Food Safety. The article highlights the EU top priority health policies such as Antimicrobial Resistance (AMR), vaccination, eHealth and Health Technology Assessment (HTA).

With this Newsletter, CPME also welcomes the adoption of the new Regulations on Medical Devices (EU 2017/745) and in vitro diagnostics (EU 2017/746). The new regulation on medical devices will enter into force in three years, and in five years for in vitro diagnostics. In the following pages, you may find updates on the on-going negotiations towards a Directive for proportionality tests for professional regulation.

Furthermore, a special emphasis is placed on the endorsement by CPME of the WMA Declaration of Taipei on ethical considerations regarding health databases and biobanks. The Declaration lays down ethical guidelines for physicians involved in the collection and use of identifiable health data and biological material, building on the WMA Declaration of Helsinki.

This CPME newsletter will give you recent news from three CPME members, featuring articles from the Croatian Medical Chamber, the Cyprus Medical Association and the Slovenian Medical Chamber.

Last but not least, you will find guest articles from the European working group of practitioners and specialists in free practice (EANA), the European Medicines Agency, EUROCARE and United to end Female Genital Mutilation.

I hope you enjoy reading this edition and wish you and your family a sunny, enjoyable summer.

Yours sincerely,

Dr Jacques de Haller, President of CPME

FEATURE

EU HEALTH AGENDA: HIGHLIGHTS FOR HEALTH PROFESSIONALS

If there is one simple truth about health in modern societies, it is this: the quality of a healthcare system can be only as high as the quality of its healthcare professionals. So the best way to start these few comments on the EU health agenda is to pay tribute to Europe's healthcare professionals: the nurses, doctors, midwives who constitute the keystones of care and of the quality of Europe's healthcare systems.

The European Commission, just as the national and regional public health institutions, needs your knowledge and expertise for formulating EU policies in health, as well as your commitment and support to implement them successfully. Let me mention three obvious examples that are also key elements of our health agenda and the focus of our action in the coming months: the fight against antimicrobial resistance, the challenge of increasing vaccination coverage, and the need to reap the benefits of technology in health.

To tackle the growing threat of **Antimicrobial Resistance (AMR)**, before the summer the European Commission will propose a new EU Action Plan. It will be underpinned by a 'One Health' approach that addresses resistance in both humans and animals, and will make clear that everyone is responsible - farmers, veterinarians, pharmacists and, above all when it comes to human medicine, doctors and nurses. The Action Plan will be built on three main pillars: making the EU a best practice region; boosting research; and shaping the global agenda on AMR. An example of practical action will be to launch this year a Joint Action to support collaborative activities and policy development by EU countries to tackle AMR and healthcare-associated infections.

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The prevention of disease and death through **vaccination** is one of the greatest medical achievements of humankind – yet we witness a rising vaccine skepticism and a decline in vaccination coverage in some EU countries. This is a grave concern, and Commissioner Andriukaitis recently reaffirmed Europe's readiness to support countries and improve the response to vaccine-preventable infections. A recent workshop gathering EU institutions and agencies, national authorities, healthcare professionals, patients, industry, civil society, academics and the scientific community, highlighted amongst other points the role of vaccination in reducing antibiotic use and thus contributing to the fight against AMR and the need for a comprehensive, cross-sector approach given the many actors involved. The role for health care workers to better advocate and promote vaccination to enhance people´s trust, is particularly important, as is the need to measure outcomes. The Commission will co-fund a Joint Action with EU countries also on vaccination, starting in 2018, to address the common goal of increasing vaccine coverage rates in Europe

Following on from the mid-term review of the EU Digital Single Market Strategy, the Commission will launch an **eHealth** initiative by the end of 2017 focusing specifically on digital health and care. It will address the need and scope for further measures in this area, in line with legislation on the protection of personal data – a key concern for doctors as well as patients. It will cover, in particular, securing access to and cross-border sharing of electronic health records; supporting data infrastructure to advance research, prevention of diseases and precision medicine; and facilitating feedback and interaction between patients and healthcare providers, to support patient-centred care.

FEATURE

Stakeholders and citizens who responded to the Commission's public consultation on strengthening EU cooperation on **Health Technology Assessment (HTA)** showed overwhelming support, with almost all of them (98%) acknowledging the usefulness of HTA and 87% agreeing that EU cooperation on HTA should continue beyond 2020. Voluntary cooperation on HTA at EU-level has been going on for many years and the Commission intends to put forward a proposal for sustainable cooperation at EU level before the end of the year. This will help avoid duplication in the assessments of the same product or intervention in different Member States, reducing costs and speeding up patient access to innovative healthcare.

I started by saying that Europe's healthcare professionals have an indispensable role to play: in ensuring the cost-effective use of medicines and the improvement of health outcomes through tools such as eHealth; in promoting vaccination; in the prudent use of antibiotics. As our partners and most powerful allies in public health, I really hope Europe, and indeed the European Commission, can count on your continued support.

Xavier Prats Monné, Director General of the European Commission Directorate-General for Health and Food Safety

LATEST NEWS

THE IMPORTANCE OF A 'ONE HEALTH' CULTURE

While the term 'One health' is quite recent, the concept finds its roots in the past centuries. Already in the 19th century, scientists took note of the impact of environmental factors on human health and some similarities in disease processes among animals and humans. However, human and animal healthcare were kept separate until the 20th century. Just in recent years, the scientific world recognised the importance of the 'One health' concept in human, animal and environmental communities.

What is 'One health' approach?

According to the definition of the World Health Organisation, 'One health' recognises the interconnection between the health of humans, animals and ecosystems. Global trade and rapid movements of humans, animals and goods facilitate these interactions, especially as regards infectious diseases. While respecting the autonomy of the different sectors, this interconnection requires extensive co-operation between existing groups and networks, especially between veterinarians and physicians, and a constant participation of environmental and wildlife health practitioners, as well as social scientists.

The aim of this multi-sectoral approach is to improve health and well-being through the prevention of risks and the alleviation of effects of crises that occur in humans, animals and their various environments[1].

For all challenges and health risks caused by greater interactions between humans, animals and the environment, the 'One health' approach is particularly relevant. Examples include zoonoses (diseases that can spread between animals and humans, such as flu and rabies), antimicrobial resistance (when bacteria change after being exposed to antibiotics and become more difficult to treat), as well as modern diseases caused by the current life style. Obesity, cancer, natural or humanmade disasters, food and feed safety crisis are also relevant.

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Prof. Dr Rutger Jan van der Gaag
CPME Vice-President

On 29 June 2017, the Commission renewed its political commitment to tackle antimicrobial resistance (AMR) by publishing a new European 'One health' action plan against AMR. This action plan reiterates the importance of working in collaboration under the 'One health' approach. Sharing best practices, fostering research and innovation as well as cooperating at the global level will be the focal areas of the EU for the coming years.

Prof. van der Gaag, CPME Vice-President and Rapporteur on AMR, said: *"The adoption of this new EU action plan is an important step forward in the fight against antimicrobial resistance. CPME welcomes the emphasis on the 'One health' approach to tackle ongoing global health challenges. Collaboration between health professions is of key importance in changing behaviours and encouraging the prudent use of antibiotics.*

1) http://www.onehealthglobal.net/what-is-one-health/

LATEST NEWS

Interdisciplinary trainings and 'One health' culture

The Federation of Veterinarians of Europe, the International Veterinary Students' Association, the Standing Committee of European Doctors, the European Medical Students Association, the Council of European Dentists and the European Dental Students' Association recognise education as key to raising awareness of the importance of 'One health' and key to encouraging health professionals to co-operate in order to achieve the best possible quality of health.

On the 15 May 2017, the six organisations sent a letter to the deans of medical, dental and veterinary schools across Europe inviting them to work collaboratively under the 'One health' concept to tackle current and future challenges for the three professions and our society. While the 'One health' approach has gained recognition in Europe and worldwide, its application in education needs to be further encouraged and facilitated. For this specific reason, the six organisations call on the deans to stress the importance of creating a 'One health' culture for future health professionals and of encouraging them to collaborate closely starting from their studies and throughout their whole professional lives. Please find the letter here.

For further information, please contact: Miriam D'Ambrosio, Communication and Project Officer

NEGOTIATING THE PROPORTIONALITY DIRECTIVE – HEALTH PROFESSIONS CONTINUE JOINT ACTION

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Since the publication of the Commission proposal for a Proportionality Directive in January 2017, the co-legislators have moved at very different speeds: while the Council completed its negotiations in the adoption of a general approach in May 2017, the European Parliament is still in the early stages of adopting its position. The Council's general approach shows overall support for the initiative, with some amendments to the draft text. Amendments include a clarification on the scope of the Directive, which future changes to professional regulation need not undergo a proportionality test, the degree of independent review the proportionality test must be subjected to, and the extent to which some regulatory requirements serve public interest objectives. The general approach however does not foresee any major changes to the approach proposed by the Commission, in particular it does not grant any sectoral exemptions for professions. By contrast, the first deliberations of the European Parliament have proposed more extensive changes to the draft Directive, including an exemption for health professions as included in the draft Report of the Committee for Internal Market and Consumer Protection (IMCO) and in the draft Opinion of the Committee for Environment, Health and Food Safety (ENVI). CPME, alongside other health stakeholders, in particular the Council of European Dentists (CED) and the Pharmaceutical Group of the European Union (PGEU), has called for such an exemption, highlighting the fundamental difference of conceptual approach to regulation demonstrated by the draft Directive in comparison to the rationale for regulating doctors and other health professions. CPME will continue to follow the negotiations, with first decisions by the European Parliament expected for the autumn.

For further information, please contact: Sarada Das, Deputy Secretary General

LATEST NEWS

EUROPEAN MEDICAL ORGANISATIONS WATCHFUL ON BREXIT

The recent political developments in the United Kingdom have cast new question marks over the Brexit process. Some observers see the new political constellation as an opportunity to review the UK's positions on issues such as continued membership of the single market, which would entail continued free movement of persons, alongside goods, services and capital. In close cooperation with its UK member, the British Medical Association, CPME has continued its joint action with other European Medical Organisations to impress upon negotiators on both the EU and the UK side that health should not become a political bargaining chip in Brexit talks. Instead, doctors call for a quick and clear solution on how free movement and recognition of professional qualifications for doctors will be upheld, how continued cooperation on medical research will be ensured, and how cooperation on public health (e.g. on infectious diseases) for will be safeguarded. The need to maintain the cross-border provision of healthcare on the island of Ireland is also focus of attention. With the first negotiating positions on the EU side indicating that EU citizens living in the UK, as well as UK citizens living in an EU Member State should retain rights i.a. to free movement and the recognition of professional qualifications, the medical community is encouraged that its concerns are being heard. To ensure a positive continuation of this approach, doctors across Europe will closely follow the next steps and contribute to the on-going debate.

For further information, please contact:
Sarada Das, Deputy Secretary General

CPME ENDORSES THE WMA DECLARATION OF TAIPEI ON ETHICAL CONSIDERATIONS REGARDING HEALTH DATABASES AND BIOBANKS

Large amounts of health data are routinely generated within but also increasingly outside healthcare systems. With the ever-increasing digitalization of our society and of healthcare services, the analysis of such 'big data' is expected to improve the quality and effectiveness of diagnostic and therapeutic interventions as well as the efficiency of healthcare systems as a whole. It can also provide information to patients on their current state of health and, therefore, contribute to their empowerment. A common example is the use of mobile health (mHealth) apps in daily life. Finally, it can also significantly foster the understanding of diseases and widen possibilities for diseases prevention[1]. However, research opportunities opened by the use of big data should not hide the ethical challenges surrounding the reuse of personal health data for a purpose which is different from the one for which the person has explicitly provided its consent.

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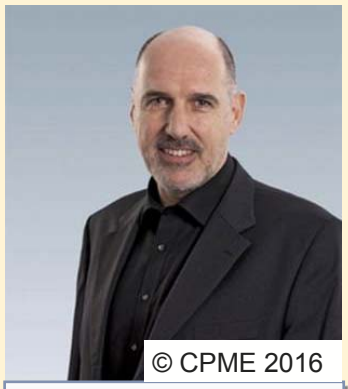
Dr Otmar Kloiber
WMA Secretary General

"Ethical guidelines are needed to ensure that personal health data are used for a meaningful purpose in a manner which is scientifically sound and ethically acceptable. Such guidelines can provide protection for the personal autonomy of the donor of data or specimen, while at the same time, they can foster trust and thus facilitate research" said Dr Otmar Kloiber, Secretary General of the World Medical Association (WMA).

1) https://ec.europa.eu/health/sites/health/files/ehealth/docs/bigdata_report_en.pdf

LATEST NEWS

On 8 April 2017, the Standing Committee of European Doctors (CPME) endorsed the WMA Declaration of Taipei on ethical considerations regarding health databases and biobanks, which was adopted by the General Assembly of the WMA in October 2016. This Declaration lays down ethical guidelines for physicians involved in the collection and use of identifiable health data and biological material, building on the WMA Declaration of Helsinki and on the importance of obtaining informed consent before using personal health data and biologic materials.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Dr Jacques de Haller
CPME President

CPME President, Dr Jacques de Haller, said *"The re-use of health data in the context of medical research is at the centre of EU discussions. If medical research using Big Data has the potential to increase knowledge for the benefit of society, it is equally important to guarantee patients' autonomy and their right to self-determination. The WMA Declaration of Taipei provides ethical guidelines which are needed to guarantee an ethical and transparent re-use of health data."*

CPME considers that this Declaration provides the additional safeguards needed to complement the new EU General Data Protection Regulation (GDPR) that was adopted in April 2016. While the GDPR introduces the notions of 'privacy by design' and 'privacy by default', it was left to the Member States the possibility to provide for appropriate safeguards for the processing of personal data for secondary purposes, including scientific research. In this respect, the Declaration of Taipei provides a transparent governance process in cases where obtaining informed consent is impractical. This governance framework includes the securing of an initial consent given on the basis of limited information and a third party oversight by an ethics committee before any re-use of the personal data (consent plus governance solution).

The Declaration of Taipei on ethical considerations regarding health databases and biobanks is available on the website of the WMA:
https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/

For further information, please contact:
Carole Rouaud, EU Policy Adviser

EMA PUBLISHES A NEW GUIDE FOR HEALTHCARE PROFESSIONALS ON BIOSIMILAR MEDICINES


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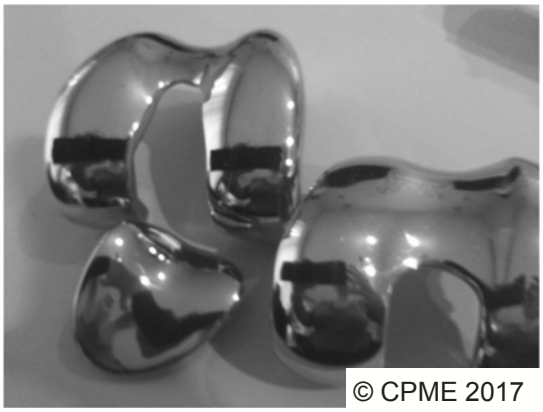
On 5 May 2017, the European Medicines Agency (EMA) officially presented its new information guide for healthcare professionals on biosimilar medicines during the third stakeholder event on biosimilars organised by the Commission. This information guide, developed in collaboration with the European Commission, aims at providing healthcare professionals with reference information on scientific and regulatory aspects related to the use of biosimilars.

This guide was developed in collaboration with scientific experts and organisations representing various healthcare professionals - including doctors, pharmacists and nurses- to ensure that the guide adequately addresses questions relevant to healthcare professionals.

For further information, please contact:
Carole Rouaud, EU Policy Adviser

LATEST NEWS

NEW MEDICAL DEVICE REGULATIONS TO IMPROVE PATIENT SAFETY



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On 5 April 2017, the European Parliament and the Council adopted two new Regulations on general medical devices (EU 2017/745) and in vitro diagnostic medical devices (EU 2017/746). They replace the two Council Directives: 93/42/EEC concerning medical devices and the 90/385/EEC on active implantable medical devices. The new regulation for medical devices will enter into force in three years. The new regulation for in vitro diagnostic medical devices will enter into force in five years.

The new regulations aim to improve patient safety, addressing concerns over the assessment of product safety and performance. CPME adopted its statement on the legislative recast in February 2013. This statement recommends addressing patient safety more specifically and in a more comprehensive manner. Dr Katrín Fjeldsted, CPME Immediate Past President and Rapporteur on Medical Devices, emphasises the necessity to be able to follow up what has now been decided.

The pressure to review the legislation was increased by the breast implants scandal of 2010, in which the French manufacturer Poly Implant Prothèse (PIP) used industrial silicone in the production of breast implants causing harm to women around the globe. In 2012, the European Commission proposed a revision. The long negotiation process between the EU institutions started. In general, the concepts and the requirements of the Council Directives remain part of the new legislation but significant additional requirements have been added.

The scope of the regulation was extended to include certain implantable and other invasive products, medical devices manufactured utilising derivatives of non-viable human tissues or cells, and reprocessed single-use medical devices. The new regulations allocate devices to adapted classes, taking into account the purpose intended by the manufacturer and inherent risks.

Moreover, rules on clinical evaluation and clinical investigation are strengthened, having clear provisions stipulating that clinical investigations shall be subject to scientific and ethical review which should be performed by an ethics committee. Also, the requirements concerning notified bodies and the procedures for classification and conformity assessment have been extensively expanded. Every device will require comprehensive review of technical documentation by the appropriate notified body, which will lead to stricter investigation in relation to the clinical data that is required to ensure patient safety.

The new regulations obligate the manufacturer to monitor their products placed on the market. The post-market surveillance plan must be kept updated. Another important change refers to traceability of medical devices. It will be possible to identify economic operators to whom devices are supplied or from whom devices are purchased. As a safety measure, each device will need to have a Unique Device Identification (UDI) number for traceability purposes all the way to the end-user or patient. This UDI system is to be integrated into Eudamed, a European database on Medical Devices. Its purpose is to strengthen market surveillance and transparency in the field of medical devices, by providing national competent authorities with fast access to information. This information will be available to patients, healthcare professionals and the public.

CPME continues being a member of the Advisory Board of the Joint Action on Market Surveillance of Medical Devices which is coordinated by the Medicines and Healthcare products Regulatory Agency (MHRA).

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Dr Katrín Fjeldsted
CPME Immediate Past President

The project aims to reinforce the market surveillance system for medical devices by improving the coordination of activities by all the EU Member States, and by ensuring adequate communications and cooperation.

Dr Fjeldsted, as a member of the Advisory Board of this joint action, highlights European cooperation and says that it is obvious that there is a lot of knowledge and competence available. Her vision would be to have a comparable European Institution working on medical devices like the European Medicines Agency (EMA) works on medicines, both with pre-market surveillance and post-market surveillance.

For further information, please contact:
Markus Kujawa, EU Policy Adviser

CPME POLICY ON OFF-LABEL USE OF MEDICINES

Under certain circumstances, doctors may have to consider, on the basis of current medical knowledge, the use of a medicinal product outside the terms of its marketing authorisation when it is considered in the best interest of the patient. Such practice is particularly common in certain areas of medicine, such as in paediatrics, where there is a lack of medicinal products which have been adequately tested and authorised for use in children. In this situation, the responsibility falling on the doctor when prescribing a medicinal product off-label is often greater.

The CPME policy on off-label use of medicinal products provides a set of guiding principles to ensure an appropriate use of medicinal products, including appropriate information and monitoring of the patient. The off-label prescribing should be based on firm scientific rationale and sound medical evidence. European doctors also formulate policy recommendations to prevent widespread off-label use without necessary supporting data while addressing legal uncertainty and safety concerns in the cases where the off-label use of a medicine is common and evidence-based.

The CPME policy on off-label use of medicinal products was adopted by the CPME Board on 8 April 2017 and can be found here: CPME 2017/006 FINAL.

For further information, please contact:
Carole Rouaud, EU Policy Adviser

JOIN THE HEALTHCARE IN DANGER COMMUNITY!

In 2011, the International Red Cross and Red Crescent Movement created a network for exchange of all those involved in providing healthcare in situations of violence and conflict. The Healthcare in Danger (HciD) project has successfully created a community within which experiences can be shared, best practices rolled-out and help sought. To sign up, please visit here.

For further information, please contact:
Sarada Das, Deputy Secretary General

DEFENDING FREE MOVEMENT FOR DOCTORS IN SPECIALIST TRAINING

CROATIAN MEDICAL CHAMBER
Serving Croatian Medical Profession

A few days before the second round of local elections in Croatia, which were held on 4 June, four medical doctors wrote to a local political leader on a problem they faced in their specialist medical training in Croatia.

They were asking for help.

Their local hospital wanted them to pay a penalty equivalent to 150.000 euros each because they changed their job after four years of specialist training in the same hospital. Of course, they were not able to pay this sum, and were not likely to earn it in the foreseeable future.

But this case was exemplary for a much bigger problem, which is why the Croatian Medical Chamber (CMC) brought it to the attention of CPME and its members countries at the meetings in Vilnius in April 2017. The CMC held a presentation concerning the deprivation of the rights of young doctors in Croatia in regard to professional mobility within the EU and the free movement on the labour market.

Following the appeal, CPME sent an open letter to the Croatian Minister of Health, Prof. Milan Kujundžić, stating its full support to the CMC in its opposition to any laws which deter or sanction doctors in specialty training from enjoying their right to free movement. The letter also emphasized that this situation does not only infringe personal rights, including those granted by EU citizenship – in particular with regard to choice of occupation and right to remuneration – but also creates an environment which is contrary to European and international health workforce policy objectives such as the WHO Global Strategy on Human Resources for Health.

© Croatian Medical Chamber 2017

© Croatian Medical Chamber 2017

Minister answered that the ministry appreciates the support that CPME is giving to the CMC and to the issue of doctors' right to free movement. However, he also called on CPME to have more understanding for the interests of the Republic Croatia and its citizens in safeguarding the healthcare system and the right of patients' access to treatment. He claimed that the current regulation is fair and that the freedom of movement of doctors is not substantially deterred by the "minimum amount of financial compensation". The safety of patients is preserved since hospitals can retain, for at least some time, the indispensable doctors in whose professional training and development they have invested their resources.

Unfortunately, the response from the Croatian minister is in line with his previous statements but far from the common understandig of the priniciple of free mobility of professionals as one of the cornerstones of EU law. The financial compensation medical doctors who are changing hospitals, changing counties in Croatia or who are going abroad are forced to pay, clearly represents a sanction.

More problematic is the fact that those penalties do not only reflect the expenses of training but also so called 'investments of the hospitals' which consist, to a large extent, of the actual salaries doctors earned.

Nevertheless, the Open letter was successful in raising public awareness. A few days later after its receipt, the president of CMC, Trpimir Goluža, and vice-presidents Krešimir Luetić and Ante-Zvonimir Golem met the Croatian Prime Minister Andrej Plenković.

They proposed the modernisation of the legal framework and the adoption of a more contemporary approach to specialist training. Prime Minister Andrej Plenković expressed his support for the measures taken by the Chamber. They also discussed the Croatian healthcare system in general and problems which Croatian doctors have in their home country. Many doctors are leaving Croatia, a situation which must also be addressed.

The campaign for fairer laws for doctors' training continues, but on other fields.

Andreja Bratić, Journalist
Croatian Medical Chamber

OVERVIEW OF THE HEALTHCARE SYSTEM IN CYPRUS CHALLENGES AND OPPORTUNITIES

Παγκύπριος Ιατρικός Σύλλογος

The accession of Cyprus to the EU created the need for implementing reforms in the healthcare system, particularly in terms of policy, regulation and the provision of services. Major challenges included restraining the rising costs of healthcare, addressing inequalities in the patients' access to healthcare services and improving the quality and financing of the healthcare system. Reforms in these areas will help to maintain the progress achieved in controlling communicable diseases and reducing the incidence of chronic diseases.

It has to be noted that prior to the country's EU accession, the parliament approved a law that called for a new health system based on the principles of solidarity, justice and universality. The General Health Insurance System (GHIS) was designed to provide universal coverage within a comprehensive healthcare system. However, the starting date of the GHIS has been repeatedly postponed due to four main reasons:

1. government concerns over costs,
2. the negative impact of the financial crisis on fiscal revenues,
3. the time-consuming tender procedures associated with the introduction of the new system and
4. the lack of a consensus among the stakeholders involved.

Currently, the healthcare system in Cyprus is comprised of separate public and private systems of comparable size. Cyprus's overall expenditure on health care account' for only 7% of its GDP in 2014, which is a considerably lower percentage than the EU average. The public healthcare system, which is financed by the state budget, is highly centralized and tightly controlled by the Ministry of Health. Entitlement to free health services is based on citizenship and income level and, as a result, around 83% of the population has free access to health care.

The public sector mainly provides outpatient and hospital care services, and offers some specialist services that are otherwise not available from the private sector.

All healthcare professionals working in the public sector have civil servant status and are remunerated on a salary basis. There are notable deficiencies in the public system, such as long waiting lists for some services, as well as lack of computerization, performance payment incentives, monitoring systems and other tools for the improvement of efficiency and quality. This situation is an outcome of the overcrowding of the public hospitals that was enhanced by the financial crisis that affected the country since 2013.

The private sector is almost completely disconnected from the public health system. Only about one-fifth of the population has coverage through voluntary healthcare insurances. The majority of private expenditure is "out-of-pocket" at the point of service, with a significant share of private sector utilization and expenditure by beneficiaries who have free access to the public system. Private sector physicians provide ambulatory care services and work mostly in solo practices, their own surgery centers or are shareholders in private hospitals and polyclinics; they are mostly compensated on a fee-for-service basis.

Despite similarities in their sizes, there is a disequilibrium between the public and the private sector. The public system suffers from long waiting lists for many services, a situation that has been worsened by the recent financial crisis, while the private sector has an overcapacity of expensive medical technology that is underutilized. There is also an imbalance in nursing supply between the public and private sectors, as well as shortages in both sectors in some fields of care, particularly long-term care, rehabilitation care and palliative care. The public sector's inefficiencies under the current system lead to high "out-of-pocket" payments in the private sector, and often there is duplication of services between the public and private sector. Ultimately, it is the vulnerable and low-income groups who suffer the most from inequalities in financing, access and outcomes.

On the other hand it has to be noted that despite the limited national healthcare allocation of resources comparing to the percentage of gross domestic product (7,4%), the Cyprus healthcare statistics are performing better than the EU average and can be easily compared with large and developed EU member-states. The high qualifications of the physicians who work in the island, as well as Medical Association (CyMA)'s efforts towards the upgrading of the quality of the healthcare services, had a significant impact to the Cypriot Health Sector's good performance. The CyMA is focused on maintaining and enhancing these good results.

"The public sector mainly provides outpatient and hospital care services, and offers some specialist services that are otherwise not available from the private sector. All healthcare professionals working in the public sector have civil servant status and are remunerated on a salary basis."
Mr Christos Xenophontos

One of Cyprus' greatest assets is its human capital. Most of the island's physicians have trained at world renowned medical schools, with doctors with an outstanding reputation for their knowledge, experience and professionalism.

Currently, Cyprus is making an effort to move towards a comprehensive system of universal coverage with better benefits, more effective financing mechanisms, cooperation between the public and private sector, as well as restructuring and computerizing all public hospitals. To this end, a new healthcare insurance system has been designed, although it is uncertain as to when this system will ultimately be implemented.

To enable the success of the new system, a number of steps must be taken. For example, while computerization has begun in two public hospitals, IT should be improved and expanded where there is not a comprehensive health data collection mechanism. The design of adequate payment mechanisms and associated incentives for doctors and hospitals will largely depend on the existence of quality data.

For the CyMA the reform of the public healthcare sector, along with the decentralisation of health services with the participation, on equal terms, of the private sector and the appropriate reimbursement of doctors are key priorities in order to secure the efficiency and effectiveness of the healthcare system.

The Cyprus Medical Association maintains that the overall mission of a national healthcare system is to provide high quality healthcare services to all of our patients; yet the current available budget for the healthcare system proposed could create many deficiencies, as according to our point of view is not sufficient. Thus, we are trying to convince all of the stakeholders involved to work towards the increase of the available budget and to focus on introducing best practices that will secure and elevate the healthcare quality provided to our patients.

Mr Christos Xenophontos, Director
Cyprus Medical Association

DISREGARD OF EU LAW BY THE SLOVENIAN GOVERNMENT HARMS THE PATIENTS SEEKING ACCESS TO PUBLIC HEALTHCARE.

Public healthcare services in Slovenia are compatible with the Health Services Act operated by the public Health Care Centres, i.e. *undertakings*, solely owned and managed by the state or the local communities, and private providers on the basis of a concession awarded by the State. Both public and private healthcare providers receive equal payment from the Slovenian Sickness Fund (Health Insurance Institute of Slovenia) to operate the public healthcare services.

They undoubtedly produce services of general economic interest, as defined by the EU law. Their operation and funding should be compliant with the EU Internal Market rules as defined in the Treaty on the Functioning of the European Union and other EU regulations, in particular the rules prohibiting restriction of competition and granting of unlawful state aid.

The Medical Chamber of Slovenia is convinced that the Republic of Slovenia has breached EU state aid laws as it is, through its system of financing of public healthcare institutions, and what is more, the breach has a detrimental effect on the patient seeking treatment in due time. In simple terms, in exchange for providing the same scope of healthcare activity as concessionaires, the publicly owned healthcare institutions receive greater payment from the state. In addition to the lawful payments from the sickness fund, the public institutions receive additional ad hoc funds from the state or municipal budgets. Since public institutions do not perform any additional public services in exchange of these funds, these extra funds clearly put them in competitive advantage against the private operators offering the same services and thus constitute unlawful state aid. Such distortion of competition between providers of healthcare services results in patients ultimately receiving fewer healthcare services than they could have given the same scope of public funding. The issue is also far from purely academic as excessively long waiting periods for patients, due to lack of capacity, have long been a pressing issue in Slovenian healthcare system.

For this reason, in June 2016, the Medical Chamber of Slovenia filed a complaint with the European Commission against the Republic of Slovenia for granting unlawful state aid to public healthcare institutions. The case is still under examination by the European Commission and we expect that the complaint will be resolved to the benefit of the patients requiring public healthcare services.

Despite the issues raised by the Medical Chamber of Slovenia, the current reform of the Slovenian Health Services Act does nothing to bring the organisation of public healthcare services in line with the EU law. On the contrary, the Government's proposal provides for even more preferential treatment of the inefficient publicly-owned health institutions. The reform also completely disregards the warnings of the Medical Chamber of Slovenia that such organisation of healthcare services is not only contrary to EU law, but is also detrimental for the patients requiring prompt access to public healthcare.

Therefore, the Medical Chamber of Slovenia turns to the Standing Committee of European Doctors to inform the European public about the worrying disregard of European law in the healthcare sector by the Slovenian Government and to prompt the European Commission to expedite the handling of the complaint made by the Medical Chamber of Slovenia.

The complaint with the European Commission against the Republic of Slovenia for granting unlawful state aid to public healthcare institutions and the translation of the legal opinion on the draft Health Services Act given by Prof. Rajko Pirnat, PhD, respectable professor in the field of public services at the Faculty of Law in Ljubljana, can be found here.

Zdenka Čebašek – Travnik, M.D., PhD, President of the Medical Chamber of Slovenia

GUEEST ARTICLE

IN THE INTEREST OF PUBLIC HEALTH

Writing about the European Medicines Agency (EMA) and its relationship with healthcare professionals is easy and complex at the same time.

Healthcare professionals are of course part of the scientific committees, working parties and expert groups that constitute the engine of the EU regulatory decision-making for medicines. Depending on their roles and responsibilities within the EMA evaluation bodies, we find a number of colleagues that are either practitioners interacting with patients and/or their carers on a regular basis; or have at some point in their careers been active providers of health care within their national systems. It is worth noting that those at the helm of the organisation, be it the members of the Agency's management board or the executive director, also have a medical or pharmaceutical background; as do the vast majority of EMA staff. So far so easy - but once we start looking deeper into the 'how's and 'when's of bringing real world clinical practice into EU-wide benefit-risk assessments, layers of complexity emerge.

Regulatory decision-making within the European medicines regulatory network is based on the assessment by the EMA scientific committees of all the available scientific evidence generated during the development of a medicine and during its subsequent use in real life after its authorisation. These include academic studies and public authority studies (including by regulators); use of data-sources on real-life use of medicines; clinical guidelines; reports in EudraVigilance and in the scientific literature. The evidence supporting the authorisation of a new medicine or any changes to already marketed medicines then needs to be put into the context of real-world conditions of clinical practice and provision of healthcare.

Many will certainly agree that decisions have to be supported by evidence as much as they need to be feasible and proportionate. There is a need therefore to incorporate clinical expertise and practical experience, address patient needs in real life (including values and preferences) and consider implementation in local healthcare contexts.

So how do we do this? When do we involve clinicians in their individual capacity and when do we involve organisations at large? And how do we do it in a sustainable, consistent and transparent manner? When should this happen, under what conditions? How often, how many?

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The EMA has in place a framework of interaction with healthcare professionals[1] and their representative organisations, which helps to respond to some of these questions.

The main goals of the framework are to support the Agency in order to access the best possible independent expertise in any matter related to medicines; contribute to a more efficient and targeted communications; and to enhance healthcare professional organisations' understanding of the role of the European medicines Regulatory Network.

In this spirit, the framework aims to support and reinforce knowledge that exists in this Network with additional valuable input from day-today clinical practice while enhancing communication and outreach to those impacted by EU decisions. It recognises healthcare professional organisations' including learned societies as key facilitators to channel inputs from and outputs to the wider community of healthcare professionals.

1) http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/12/WC500218303.pdf

In line with the EMA framework for interaction with healthcare professionals, when healthcare professionals are involved in EMA activities on product-specific issues, they usually do so as individual experts. The Agency asks relevant healthcare professional organisations to identify experts who can provide their valued input, on the basis of their individual clinical experience, and subject to the assessment of declared interests and signed confidentiality agreement.

Involvement can also occur in the form of written consultations such as those carried out to gain a better understanding of whether specific elements of the product information and package design (e.g. labelling; expression of strength; posology recommendations; instructions for use; colour differentiation strategy) are sufficiently clear. Furthermore there is a focus on whether additional risk minimisations measures (e.g. key messages to include in educational materials) can reduce potential risk of medication errors in the context of clinical practice reality and facilitate the appropriate and safe use of the medicinal product under assessment.

It is also possible for a scientific committee, working party or drafting group to request additional input from relevant organisations on general matters (not product-specific consultations). The purpose of such consultations is to gather valuable input on certain aspects of clinical practice and standards of care that can support the scientific bodies on its further discussions related with on-going evaluations or guideline development.

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In addition, the EMA Working Party with Healthcare Professionals Organisations (HCPWP), established in June 2013, plays a key role in the Agency's interaction with healthcare professionals' organisations, it is the platform where they can exchange information and talk about issues of common interest, within the remit of the Agency's responsibilities. The working party helps provide recommendations to the EMA and its scientific committees on all aspects related to medicines. The members of the HCPWP represent the eligible organisations but there are also representatives from the scientific committees and additionally observers from the EMA Management Board and the European Commission. The working party meets 3 times a year, they have plenary meetings as well as joint meetings with the Patients and Consumers working party.

CPME has been part of the list of eligible organisations since 2012 and became a member of the EMA Healthcare Professionals Working Party (HCPWP) in 2013.

The HCPWP has been working with a number of ad hoc working groups to brainstorm on specific topics of mutual interest to the European Medicines Agency (EMA) and the working party (referred to as 'topic groups'). These have focused on the following topics: Social media; Risk minimisation measures and assessment of their effectiveness; information on medicines; Academia, learned societies and healthcare professional organisations; and more recently, biosimilars.

The Agency sees organisations such as CPME as relevant intermediaries able to facilitate relations with the wider community of healthcare professionals across the EU (i.e. individual members and/or national associations). We hope to continue to have CPME on board, to pursue the opportunities and guide us in the face of challenges future may bring, in the interest of Public health.

Ivana Silva

Healthcare Professionals and Academia relations Public Engagement Department Stakeholders and Communication Division European Medicines Agency | www.ema.europa.eu

GUEST ARTICLE

WHAT IS REALLY IN YOUR DRINK?

When a consumer drinks an alcoholic beverage in Europe, it is highly unlikely that he or she knows exactly what they are drinking, unless they go through the effort of searching online.

Recently the European Commission (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.

By 13 December 2014, the Commission was required to produce a report concerning the application of Reg 1169/2011 and address whether alcoholic beverages should in the future be covered. In March 2017, the Commission finally delivered the report, which 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'. The report's conclusions appear to be driven by a political decision. 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.

> *"Most of the stakeholders including alcohol producers welcomed the Commissions' report and acknowledged the need to provide information to consumers."*
> *Aleksandra Kaczmarek*

Most of the stakeholders including alcohol producers welcomed the Commissions' report and acknowledged the need to provide information to consumers. Over the last few years, alcohol producers position on the matter of labelling has evolved. Significant differences lie in the method to be used, with the spirits and wine producers preferring to provide information online. The European brewer's association (Brewers of Europe) launched in 2015 a pledge, where their members committed to provide nutrition information on beers. The spirit sector, favours the responsible drinking messages and online provisions for calories and full nutrition information. Only some spirit producers are committed to provide information on-label. The wine sector is also only willing to provide information online on a common website and information on calories per serve and per category of wine.

In 2015 Eurocare conducted a consumer survey which found that only 25 percent of respondents searched for information online, regarding ingredients or additives in their alcoholic beverages. Around 50 percent of respondents indicated they would like to have more information about ingredient listings, with 43 percent asking for calorie content and 38 percent for nutritional value. Overall labelling information currently provided to consumers is simply not sufficient.

The burden of finding nutritional values and ingredient listings should not be placed on the consumers. By asking them to go online and find out for themselves. Labels remain the best option to inform consumers, at the point of sale, about nutritional value and ingredients.

We, as the European Alcohol Policy Alliance (Eurocare) welcome the publication of the report as it clearly recognises the need for better alcohol labelling. Disappointingly, the conclusions only ask for a self-regulatory proposal from the industry. Self-regulation is not a suitable regulatory mechanism. Member States in the European Council should follow up and empower the European Commission to take regulatory actions.

Listing ingredients contained in a beverage alerts the consumers to the presence of any potentially harmful or problematic substances. Providing nutritional information such as energy content allows consumers to monitor their diets better, and makes it easier for them to keep a healthy lifestyle.

To date, European legislation has failed to allow consumers to make an informed choice about the alcoholic products they purchase. We hope that the publication of the report will be the first step to align alcohol with other food products.

Aleksandra Kaczmarek Senior Policy Officer
Eurocare (The European Alcohol Policy Alliance)

GUEST ARTICLE

EANA, OUTCOMES FROM THE MEETING IN PARIS

The European working group of practitioners and specialists in free practice (EANA) met in Basel on 16 and 17 June to discuss e-health – a topical issue requiring harmonisation between the different European countries.

Five proposals were unanimously adopted at the end of the discussions:

1) The crossborder interoperability of the system is necessary to obtain significant data with regard health research and policy.

2) Security and confidence of all users must be ensured in particular through interdisciplinarity, interprofessionalism and transversality.

3) The confidence of health professionals requires the creation of a practical and transparent economic model.

4) The evaluation of e-health and mHealth devices is essential to ensure patient safety and quality of care.

5) The training of doctors and the support of patients to e-health must allow the active collaboration of all actors.

In addition, support was given to the CPME in its actions towards the exclusion of health professions from the Proportionality Directive. CPME's statement will therefore be taken over by the EANA communication bodies.

Finally, an important session was dedicated to the rights of doctors in Europe: respect, safety and working time, were considered from the point of view of European law – which marks the beginning of an exercise, respecting the common values to all citizens of Europe.

EANA will meet in the fall again to discuss another key issue for the indpendent exercise of the profession: medical demographics and the recognition of diplomas.

Dr Philippe Boutin, *President of EANA*

GUEEST ARTICLE

FREE ONLINE COURSE ON FEMALE GENITAL MUTILATION FOR DOCTORS

The United to End FGM knowledge platform is a free online training tool for professionals dealing with those affected by female genital mutilation and is available in 9 European languages.

Research has shown that doctors in Europe are often unprepared to face situations relating to FGM. In response to this, The European Knowledge Platform for Professionals dealing with Female Genital Mutilation (FGM) was launched earlier this year. UEFGM is a transnational project funded by the European Union and implemented by a consortium of 12 partners and 4 associate partners across the EU.

An estimated 200 million girls and women in 30 countries are currently living with FGM, with a further 8,000 girls at risk every day—some 3 million girls a year (UNICEF, 2016). According to research by the European Parliament, an estimated 500,000 women and girls in the European Union (EU) have been subjected to FGM (EU, 2016). Around 20,000 women and girls from FGM-risk countries of origin seek asylum in the EU each year—20% of all female applicants in 2011. Around 8,800 of these—mostly from Somalia, Eritrea or Guinea—are affected by FGM. However, in Europe, there is still lack of accurate data and limited research regarding the prevalence of FGM.

UEFGM is an EU-wide multilingual information and educational resource centre, providing easily accessible and culturally appropriate information and support to professionals from diverse backgrounds across the EU, to effectively deliver victim support, raise awareness of FGM, and protect women and girls living with or at risk of FGM.

The UEFGM e-learning tool aims to raise awareness of and improve knowledge about FGM amongst health professionals and asylum officers working in Europe, including midwives, gynaecologists, paediatricians, nurses, health visitors, medical and nursing students, judges, asylum case and reviewing authority officers, asylum support-centre staff, police, child protection officers, social workers and related NGOs.

UEFGM offers professionals working in the medical and health field a four part module course on:

1) An Introduction to Female Genital Mutilation (FGM),
2) FGM: Understanding Gender and Social Dynamics
3) The Consequences of FGM on Health and their Management
4) Ethics, communication and counselling in the Health Context.

To learn more and sign up for your free UEFGM online course, visit the UEFGM website today.

Lisa O ' Leary, Communications Officer
End FGM European Network

CPME NEWS

On 20-22 April 2017, CPME President Dr Jacques de Haller attended the 206th World Medical Association Council session in Livingstone (Zambia). More info available here.

On 27-28 April 2017, CPME President Dr Jacques de Haller attended the UEMS Council Meeting in Tel Aviv (Israel). More info available here.

On 4 May 2017, CPME Vice-President Dr Bernard Maillet participated in the AEMH Conference on eHealth in Luxembourg. Please find more information here.

On 11-13 May 2017, CPME Vice-President Dr Bernard Maillet participated in the FEMS spring conference and General Assembly in Rotterdam (Netherlands). Info available here.

On 23-26 May 2017, CPME President Dr Jacques de Haller and Secretary General Annabel Seebohm attended the 120th German Medical Assembly in Freiburg (Germany). Info available here.

On 22-23 May 2017, CPME Immediate Past President Dr Katrín Fjeldsted attended the European Commission Workshop on system solutions of monitoring and implementing measures for sentinel events in Ljubljana (Slovenia).

On 30-31 May 2017, CPME Vice-President Prof. Dr Rutger Jan van der Gaag participated in the EFSA Stakeholder Forum in Parma (Italy). Info and agenda available here.

On 16 June 2017, CPME President Dr Jacques de Haller participated in the EANA meetings in Basel (Switzerland). Info on outcomes available here.

On 25-29 June 2017, CPME Immediate Past President Dr Katrín Fjeldsted attended the BMA Annual Representative Meeting in Bournemouth (UK). All info available here.

On 27 June 2017, CPME Vice-President Prof. Dr Rutger Jan van der Gaag participated in the antimicrobial resistance (AMR) event on "Preserving the old, creating the new: How to avoid the Antimicrobial Resistance doomsday scenario" at the European Parliament in Brussels.

On 29 June 2017, CPME Vice-President Dr Bernard Maillet participated in the AIM European Affairs Committee on Big Data in healthcare. Please find more information here.

On 29-30 June 2017, CPME President Dr Jacques de Haller and CPME Secretary General Annabel Seebohm attended the EFMA Annual meeting in Tel Aviv (Israel). Info available here.

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OPPORTUNITIES TO ENHANCE DIRECT ACCESS TO HEALTH POLICY DEBATES IN THE EU

- EU Transparency Register: To enhance visibility and accountability in the interaction between interest groups and policy-makers, the EU institutions host a joint Transparency Register. Being registered is a requirement for certain activities or allows enhanced access e.g. in the context of consultations and other EU initiative, e.g. the EU Health Policy Platform (see below). CPME is in the register, CPME members are welcome to join too. More information can be found here.
- EU Health Policy Platform: In 2016, the European Commission launched the European Health Policy Platform (EUHPP) as an online forum for the European health community to exchange information, discuss policy and develop joint statements. CPME was leader of one of the first collaborations on the new platform which resulted in the adoption of the Call for Action on Patient Safety co-signed by 20 organisations including CPME. This year's thematic networks will focus on migration & health, employment of people with chronic diseases, medical training and professional development for patient safety, and antimicrobial resistance (AMR). Any health stakeholder with Transparency Register credentials (see above) can sign-up to the platform and provide input to the discussions. In addition, all users have access to and use of a forum to post information on events, publications and other news. For more information please visit the EUHPP homepage.

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EU INSTITUTIONAL NEWS

May 2017	In May 2017, The European Parliament granted a mandate to the Committee on Culture and Education (CULT) to start negotiations with the Council of the EU which also reached a general approach on the proposal for a revised Audiovisual Media Services Directive (AVMSD). The next step is a trilogue between the institutions which is expected to start with a view to adopting the directive as soon as possible. CPME recently co-signed an open letter to the Health Ministers identifying improvements to better achieve the objective to minimise children's exposure to high fat, salt or sugar food and alcohol marketing.
16 June 2017	On 16 June 2017, the Council of the EU's Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) adopted the Council conclusions to contribute towards halting the rise in Childhood Overweight and Obesity. The Council calls for tackling childhood obesity by addressing both the lack of physical activity and unhealthy diets. Member states are invited to promote physical activity in schools and "leisure clubs". It is also notable that the Conclusions call members to reduce the advertisement and sponsorship of sugary and fatty foods which are targeted at children and adolescents. Please find the Conclusions here.
29 June 2017	The European Parliament's Rapporteur MEP Andreas Schwab has proposed to exclude health professions from the Proportionality Directive in his draft report. A debate in the European Parliament's ENVI committee on 29 June, shows some support for an exclusion; as you are aware the ENVI Rapporteur MEP Françoise Grossetête has called for the same in her draft Opinion. The draft report is available at here
1 July 2017	On 1 July 2017, Estonia took over the rotating six-month presidency of the Council of the European Union from Malta. More information on the presidency's priorities can be found here.

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