



## This issue

Message from the CPME President 2

### FEATURE

Commission proposes central role for health in new EU budget 3

### SPOTLIGHT

Regulation on Health Technology Assessment (HTA): MEPs outline what's next 4 - 5 - 6 - 7

### LATEST NEWS

Publication of the communication on digital health 8

CPME extends its nutrition policies to trans fats 9

Experts wanted! The SEPEN joint tender launches recruitment 10

Standardisation 10

### NEWS FROM CPME MEMBERS

BMA urges clarity for health profession in wake of Brexit 11

Irish Medical Organisation: Brexit and Collaboration in Healthcare 12

Ukrainian physicians on the way to self-government 13 - 14

Medical Women's International Association (MWIA): a global network of medical women 14 - 15

Austrian smoking ban abandoned: A brief overview of developments and prospects 16 - 17

### GUEST ARTICLES

Smoke Free Partnership on illicit tobacco trade. A global problem with a global solution 18 - 19

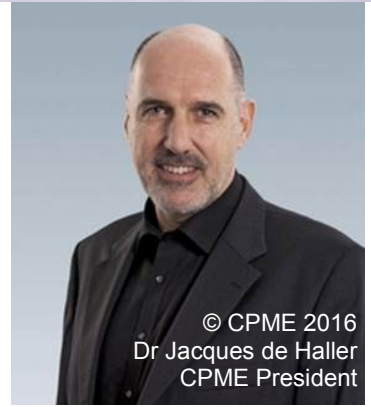
Updates from the European Junior Doctors 19 - 20

Alliance for Safe Online Pharmacy in the EU: The rising tide of falsified medicines 20 - 21

### EVENTS - UPDATES

Institutional events 22

# MESSAGE FROM THE CPME PRESIDENT



*Dear Colleagues and friends,*

Welcome to the 26th edition of the CPME Newsletter. The following pages contain the latest developments in health politics at EU level and recent CPME activities.

This edition opens with a feature article by the Commissioner for Health and Food Safety, Dr Vytenis Andriukaitis. The article highlights the importance of confirming the central role of health in the next EU budget.

On 2nd May 2018, the European Commission issued a proposal for the next long-term EU budget, the Multiannual Financial Framework (MFF). The current proposal does not foresee any specific financing tool for all EU initiatives in the health sector, but allocates health to the European Social Fund. Although we welcome this recognition of health in the EU agenda, we fear that with this approach health policy will be diluted and governed by bodies other than a Directorate for Health, for instance it might end up in the hands of those who think more about commercial interests. We therefore urge the European Commission to clarify the policy governance and to maintain a dedicated Directorate for Health with full responsibility for the implementation of EU health policies.

Also, a special emphasis is placed in this Newsletter on the European Commission proposal for a Regulation on Health Technology Assessment (HTA). We consider that HTA cooperation at EU level has the potential to enhance evidence-based decisions on new drugs and medical technologies. However, we also believe that to achieve this objective we need to guarantee the application of the highest scientific and clinical standards, together with stringent rules on independence and transparency. In this regard, we invite you to read the interviews with MEPs Dr Cabezón Ruiz, Ms Grossetête and Dr Liese.

Furthermore, five CPME members and other stakeholders in the health sector report on their current policies, developments and priorities.

Finally, please note that the General Data Protection Regulation (GDPR) came into force on the 25th May 2018. At CPME, measures and procedures have been updated respectively. We invite you to read our revised [privacy policy](#).

I hope you enjoy reading this edition.

Best regards,

Dr Jacques de Haller, President of CPME

A handwritten signature in black ink, appearing to be 'J. de Haller', written in a cursive style.

# COMMISSION PROPOSES CENTRAL ROLE FOR HEALTH IN NEW EU BUDGET



What price can one put on people's health? If you ask me, I would say that no price is too high as health is a **right** of all EU citizens. Indeed, we all have the right to healthcare, including preventative healthcare, regardless of our financial means, gender or nationality. The universality of health is fundamental in a Europe of values. Health is also a socio-economic issue: healthy people are more productive and hence healthcare systems are less costly. Moreover, greater health equality improves social cohesion, which benefits us all.

The health budget for the next financial period 2021-2027 is therefore an important element of the **investing in people, cohesion and values** heading in the Commission's proposal for the next Multiannual Financial Framework adopted on 2 May. Indeed, as part of the **European Social Fund + programme**, investment in health will be a significant component of the

Commission's social agenda. It will provide a dynamic link to policy coordination (European Semester), which aims to increase EU added-value by better targeting EU funding towards priority needs.

More specifically, the future health budget aims, among other things, to enable targeted actions with proven benefits for EU citizens to prevent and respond to health crises, reduce vaccine-preventable diseases, ensure the safety of medicines and support people with rare diseases through the European Reference Networks. We will also continue to devote resources to prevention and screening to reduce chronic diseases and help EU countries to ensure the resilience, accessibility, efficiency and sustainability of their health systems.

Health is one of the key areas for research and innovation and will therefore have a prominent role in the new **Horizon Europe** programme as well as the **Digital Europe** programme. This will allow us to capitalise on opportunities to advance technology, develop new treatments and help patients in the EU and beyond. Actions will support a pan-EU digital health infrastructure to improve the efficiency of care, including cross-border healthcare, and will help patients manage their own care. It will also give us the opportunity to make better use of EU-wide evidence and expertise, triggering research that could help us detect disease outbreaks, accelerate diagnosis, develop better treatments and much more. Other tools such as the **InvestEU** and the **European Regional Development** funds can boost health through investment in a skilled health workforce and infrastructure such as hospitals.

A prerequisite for good health is safe food. In the 2021-2027 budget food safety, animal health, plant health and animal welfare will be core principles of the **Single Market Programme**, which will also focus on making the food chain more responsible, with actions to fight food fraud and reduce food waste. Moreover, one of the objectives of the new **Common Agricultural Policy** (CAP) will be nutrition, giving us new opportunities to improve citizens' health. Other key aims of the new CAP include ensuring safe food production, animal welfare, reducing food waste, and promoting the sustainable use of pesticides and antibiotics.

In adopting our proposal for the next financial period, the Commission has put forward a new and modern budgetary framework that aims to focus on EU actions with the highest added value and on those that can best support our citizens. I am delighted that health and safe food take an important role in the EU budget for 2021 to 2027, and I count on our partners in health to help us ensure that we get the biggest possible return on investment.

[Vytenis Andriukaitis](#)

*European Commissioner for Health & Food Safety*

# HTA AT THE EDGE. CPME ASKS FOR THE HIGHEST SCIENTIFIC AND CLINICAL STANDARDS AND STRICT RULES ON INDEPENDENCE AND TRANSPARENCY

At a time when the healthcare sector faces significant budgetary constraints, the role of Health Technology Assessment (HTA) has become increasingly important to inform decision-makers at national level on the added value of health technologies (incl. medicines and medical devices). This multidisciplinary process encompasses the evaluation of clinical aspects but also economic, social and ethical dimensions related to the use of a health technology.

The voluntary cooperation on HTA at EU level will come to an end in 2020 with the completion of the third joint action on HTA ([EUnetHTA](#)). After this date, the European Commission is intending to establish a sustainable structure for HTA cooperation at EU level. This sustainable framework, which is

presented in the [Commission proposal for a regulation on HTA](#), aims at overcoming one of the main shortcomings of the voluntary approach, which is the low uptake of the joint work of EUnetHTA at national level.

The cornerstone of the Commission's proposal is the joint clinical assessments for new medicines authorised at EU level, as well as certain new class IIb and III medical devices. While it will become mandatory for Member States to participate and adopt the results of the joint clinical assessments, EU countries will also be able to cooperate on non-clinical aspects on a voluntary basis. Another aspect of the proposed regulation is the possibility for developers to seek advice from HTA authorities on scientific evidence to be collected during the development phase of a health technology. Finally, Member States will work jointly on the identification of emerging health technologies in order to identify innovative technologies at an early stage.

Having been involved in EUnetHTA activities from the start, CPME welcomes the intention of the Commission to further structure this cooperation (see [CPME statement](#)). Doctors could benefit from greater access to reliable, timely and objective information on medical technologies to take better informed decisions with their patients on the best treatment. In order to have a robust framework, European doctors emphasise that the methodology, timelines and evidence requirements for the joint clinical assessments need to be agreed upfront so as to guarantee the highest scientific standards but also compatibility with national decision-making processes. In addition, CPME considers it of utmost importance to ensure a meaningful involvement of healthcare professionals (via the stakeholder network but also the coordination group itself), as well as the highest level of independence and transparency in the context of the joint work to foster trust in the system. Transparency must encompass not only the results of the joint work but also the methodologies and processes in place under each pillar. The CPME statement on the European Commission proposal for a Regulation on Health Technology Assessment (HTA) was adopted by the CPME Board on 14 April 2018 and can be found here: [CPME 2018/008 FINAL](#).

The coming months will be crucial for the HTA legislative proposal, and therefore the future of EU cooperation on HTA. While the European Parliament plans to adopt its [position](#) in autumn 2018, Member States will need to show progress in defining a common line in the EU Council before the renewal of the European Parliament and the new Commission takes office. A crucial moment will be the discussion between Health Ministers during the [EPSCO meeting](#) in June 2018 under the Bulgarian Presidency. This will give further orientation regarding the position of Member States towards the Commission's proposal and their readiness to further discuss the text in the coming months.

*"HTA cooperation at EU level has the potential to enhance evidence-based decisions on new drugs and medical technologies. To reach that objective, we need to guarantee the application of the highest scientific and clinical standards together with stringent rules on independence and transparency."*

*Dr Jacques de Haller, CPME President.*

*Carole Rouaud, EU Senior Policy Adviser*

# MEPS OUTLINE WHAT'S NEXT

⇒ **On 31 January 2018 the Commission adopted its legislative proposal on Health Technology Assessment (HTA). Which benefits do you see in the creation of a sustainable framework for cooperation on HTA? What are the limits?**

**MEP Soledad Cabezón Ruiz:** *The European Commission's proposal is opportune and contributes to "make more Europe". In 1995 the EMA was created to centralise the authorisation process based on efficacy and security criteria, but introducing new medicines into the market without proving real effectiveness related to added therapeutic value is ethically questionable. The Member States carry out an evaluation framed in the pricing process, but harmonizing criteria and methodology is essential to increase clinical value, patient safety, and cases of guaranteed-access medicines, as well as to stimulate quality research and innovation. On the other hand, progress in medicine, new medications, advanced therapies and technology need sufficient clinical evidence to support decisions on their benefits. That is why it is necessary to build on the voluntary EUnetHTA in order to achieve stable, regulated cooperation with long-term funding. In short, this initiative contributes to making the right to health a reality, while supporting the sustainability of national health systems and improving the predictability and competitiveness of the European pharmaceutical industry.*

**MEP Françoise Grossetête:** *I think that such cooperation could clearly create a level-playing field across Europe in terms of evaluation of the clinical benefit of new health technologies. In doing so, it should also accelerate patients' access to new therapies and allow national health systems to focus on products and methods bringing real added value. However, we should be aware that it will take time and that it will not magically solve all the problems of access to medicines.*

**MEP Peter Liese:** *I see two main advantages. First, when clinical assessment is done in a coordinated way, national authorities as well as companies can save a lot of resources because they don't do the same work 27 times, but only once. Even more important for me personally is the early dialogue between the EMA and the HTA authorities. With this early dialogue 'me too' medicines, which means more of the same without any added value for patients, can be avoided and investment will be focussed much more on medicines with real added value. The proposal should not and will not lead to a complete harmonisation of the market because the question as to whether a drug is reimbursed should and will be decided at the level of the Member States.*

⇒ **Some Member States already expressed reluctance, even opposition, towards the proposed Regulation. What could convince them to take this proposal into consideration?**

**MEP Soledad Cabezón Ruiz:** *The EC supports the proposal on the necessity to im-*



MEP Soledad Cabezón Ruiz

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MEP Françoise Grossetête

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MEP Peter Liese

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## Health Technology Assessment (HTA)

prove the internal market and the industry's predictability. However, the benefits for the industry in the harmonisation are far from the expected savings for the MS in reducing the workload of evaluators and thus contributing to the sustainability of national health systems. The market distortion alleged by the Commission should be contextualised within the market-driven European medicines system that fails to require added therapeutic value of medical products at the European level. Moreover, many of these medical products aren't available in all MS because economic criteria determine their marketing.

In addition to avoiding assessment duplication, and thus improving the internal market, the proposal also increases the quality of medicines, which is also the aspiration of the Commission. Above all, European citizens are concerned about the functioning of the EU medicines system, including the high prices of new medicines, the absence of real innovation behind new marketing authorisations, and the lack of research in areas less economically interesting for the industry. Beyond the industry's predictability, the proposal will tackle these concerns provided that the principles of independency, transparency, objectivity and external evaluation are abided by. This Regulation will also improve patients' access to health technologies, the sustainability of health systems and the efficiency of research.

**MEP Françoise Grossetête:** *I think the proposal could show more flexibility towards Member States and its governance structure should be made more collegial. Member States and national HTA agencies need to be reassured as to the final quality of the evaluations. A number of points, for example on the methodology used, also need to be clarified to make sure we are all on the same page. I believe the mandatory elements (participation and uptake) should not be called into question, but maybe the phase-in approach could take more time.*

**MEP Peter Liese:** *We should present the arguments again and again, especially that Member States will save money and resources when the HTA is done properly at EU level. At the same time, everybody should stop talking about full harmonisation because this rightly creates opposition within the Member States.*



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⇒ **The proposal foresees joint clinical assessments as the cornerstone of the future EU cooperation on HTA. What should be the core elements of the clinical assessment procedure?**

**MEP Soledad Cabezón Ruiz:** *The HTA comprises clinical, social, ethical and economic aspects, which are considered within a national decision-making process on pricing and reimbursement. The harmonisation of the economic aspects is difficult due to the fact that the prices of medicines are determined by the market. Nowadays, however, there is a general consensus around the need for new pricing systems and funding for innovation, among other questions. On the other hand, even if the clinical value of health technologies can be determined at the European level, there are national circumstances that must be considered at the MS level. Even bearing in mind national specificities, the harmonisation of criteria and methodology in the clinical sector, together with trust-based collaboration and experience sharing, can result in valuable research and innovation.*

**MEP Françoise Grossetête:** *That is the whole point of the debates we are going to have! It is therefore difficult to answer the question in just a few lines. However, I think that trial and safety data, as well as indirect comparisons, are key. What matters in the end is that we have rigorous standards in place and evaluations of equal quality, no matter which Member State(s) hold the rapporteurship.*

**MEP Peter Liese:** *The quality of the joint clinical assessment is crucial. Like CPME I see a weakness in the Commission proposal. It is not clearly described how the clinical assessment will work. We need to do everything so that the quality of the assessment is not lower than in the best Member States.*

## Health Technology Assessment (HTA)

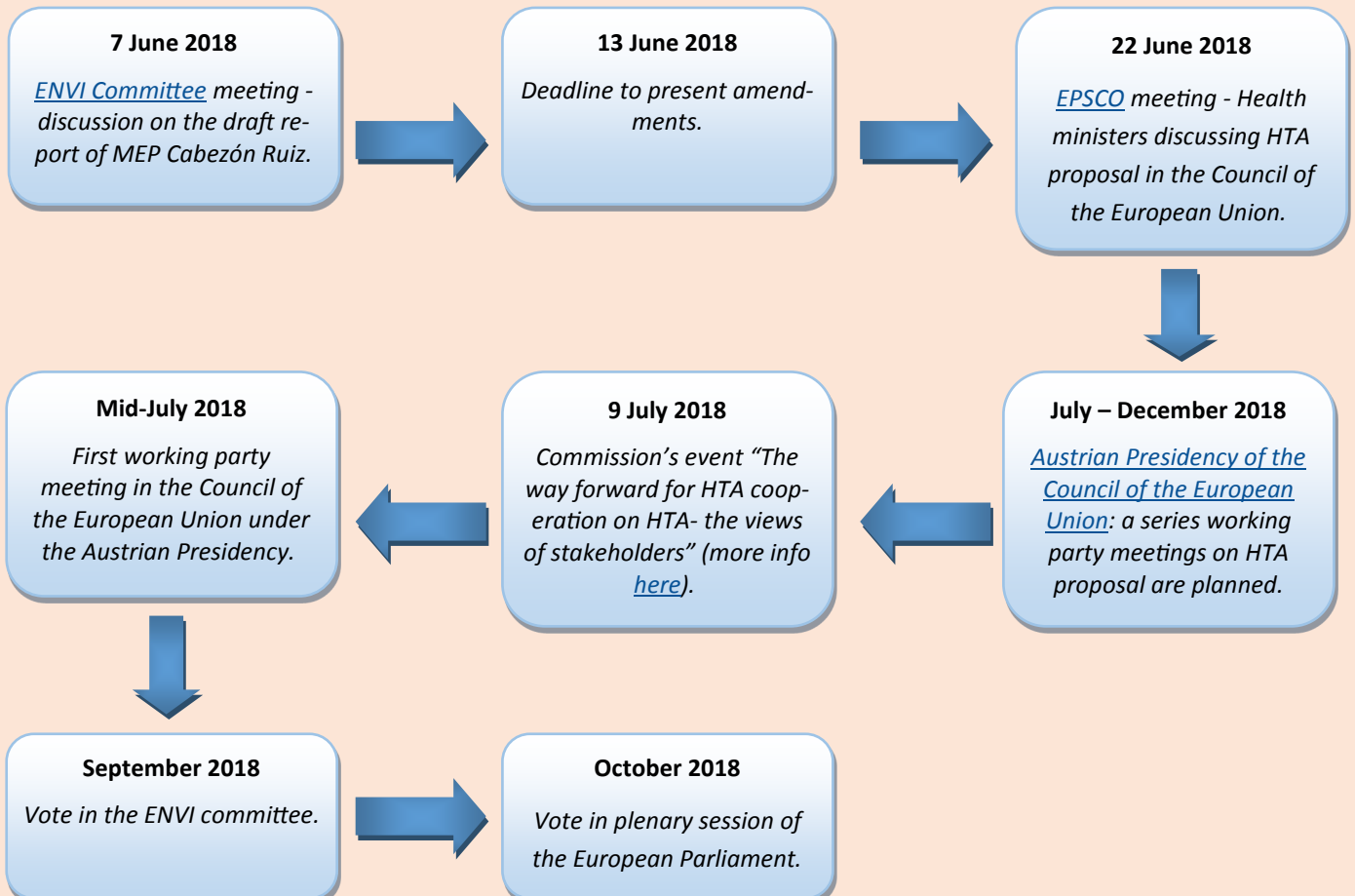
⇒ According to the proposed Regulation, the Commission will provide financial and administrative support to the future EU framework. What is your position towards this approach?

**MEP Soledad Cabezón Ruiz:** *The basis of a quality system is formed by the principles of independency, objectivity, transparency and repeatability, as well as a trust based relationship among stakeholders. For this reason, the financial independence of the technology developers' assessment is essential. The HTA system needs stable public funding, which makes its inclusion in the Multiannual Financial Framework the advisable option, rather than depending on industry fees (which could be compatible with other complementary initiatives, such as funding areas insufficiently covered by research or an innovative treatments acquisition fund).*

**MEP Françoise Grossetête:** *In a first phase, I think this is a good idea... provided that enough funding and capacities are provided to the future framework! The key is efficiency. If the new framework takes more time or is less efficient than national evaluations, confidence will be lost. It is therefore crucial that the Commission commits enough resources to the EU HTA system. Once more, unfortunately, money will matter.*

**MEP Peter Liese:** *I think it's a good proposal that the Commission provides a secretariat for the common HTA. We don't need a new agency, but a permanent structure. We have been carrying out pilot projects for almost 20 years; it's now time to put a stable framework in place. It is still to be discussed whether it is appropriate that the COM has the last word.*

## HTA STEP BY STEP



# PUBLICATION OF THE COMMUNICATION ON DIGITAL HEALTH



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On 25 April 2018, the Commission released its [communication](#) on enabling the digital transformation of health and care in the Digital Single Market (DSM). This publication coincides with the presentation of [several initiatives](#) by the Commission as part of its 3<sup>rd</sup> data package. This communication on eHealth aims at: 1) ensuring patients' access to their health data (incl. e-prescriptions, patient summary and electronic health record), 2) fostering the sharing of health data for research purposes (in particular for rare diseases, medicine development and anticipating epidemics) and 3) promoting the use of digital tools/services for patient empowerment and patient-centric care.

Among other things, the Commission plans to develop technical specifications for a European electronic health record exchange format, as well as a mechanism for voluntary coordination of national authorities for the secure access and cross-border exchange of genomic and other health datasets. In this respect, 13 countries already signed a [declaration of cooperation on genomic databanks](#) for enhancing cross-border access to national and regional banks of genetic data and other data relevant for health. The setting up of such a voluntary coordination mechanism will be the first step in the implementation of the Commission's communication. Since health and genetic data are particularly sensitive data, it will be critical for the Commission to ensure the highest possible level of data privacy and confidentiality within this coordination framework in line with the General Data Protection Regulation (GDPR) and national safeguards on the further processing of personal data for secondary purposes, incl. research purposes. CPME considers it essential to support medical research in order to strengthen the European knowledge base, while respecting ethical standards and the highest level of protection for patients participating in research.

On 8 April 2017, CPME endorsed the [WMA Declaration of Taipei on ethical considerations regarding health databases and biobanks](#), which was adopted by the General Assembly of the World Medical Association (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 biological materials.

*Carole Rouaud, EU Senior Policy Adviser*





# CPME EXTENDS ITS NUTRITION POLICIES TO TRANS FATS



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In April 2018, the CPME Board adopted a new policy on trans fats. It is a follow-up to another nutrition policy CPME adopted last year on obesity. The new policy encourages the European Union to take actions to limit intakes of trans fats whose consumption increases the risk of coronary heart disease, which among other cardiovascular diseases, is the leading cause of death in Europe at the moment.

The European Commission is currently carrying out an impact assessment on a possible EU-based initiative to limit intakes of industrial trans fats. CPME calls on the Commission to propose a legislative limit for the amount of industrially produced trans fats contained in foods of

2 g per 100 g of fat, and to introduce mandatory labelling of the trans fats content of foods in the nutrition declaration on food labels.

At the moment, the average daily intake of trans fats in Europe is below the 1% maximum consumption level recommended by WHO, but certain population groups, such as students, young adults and lower income population groups, are at risk of having higher trans fat intakes. Moreover, there are differences in the foods produced in different European countries. In particular, in eastern and southeastern countries the intake of industrial trans fats is very high. Eight CPME member countries have already taken measures at national level to limit industrially produced trans fats in foodstuffs.

*“A legislative limit would protect the health of all EU citizens regardless of their health literacy, financial resources or access to food products. Doctors should receive the necessary nutrition education including information about the health effects of trans fats during their medical training, so that they can contribute to improving and maintaining healthy lives”,* argues Dr Patrick O’Sullivan, the new Chair of the CPME Working Group on Diet, Nutrition and Physical Activity.

Therefore, the new CPME policy highlights that adequate skills training to provide this information for patients should be included in undergraduate and postgraduate medical education. This is how doctors and other healthcare workers could be better aware of the negative health effects of trans fats on their patients and promote healthy lifestyles with healthy diets and adequate exercise. Also the CPME policy on obesity calls on doctors to promote healthy lifestyles.

The EU has realised that health promotion and non-communicable disease prevention can lead to more effective and efficient health systems. However, at the moment, only 3% of European health budgets are spent on prevention. At the same time, non-communicable diseases account for up to 80% of all healthcare costs. This number could be reduced by taking actions in the areas of promotion and prevention, including addressing health inequalities, nutrition, physical activity, reduction of tobacco use and alcohol-related harm. CPME has frequently underlined the need for coherent policies across sectors and called for stricter controls in legislation, aiming for example at restricting advertising for unhealthy foods and drinks.

In the future, the CPME Working Group on Diet, Nutrition and Physical Activity will also focus on alcohol and tobacco. Its next goal is to end the exemption for alcoholic beverages from the mandatory list of ingredients and the nutrition declaration. At the moment, the alcohol industry gets a special treatment in the EU food information regulation and is not obliged to list this information on the label. CPME, together with other European medical organisations, as well as health and consumer NGOs, is urging the Commission to simply align the whole alcohol sector with the regulation.

*Markus Kujawa, EU Policy Adviser*

## EXPERTS WANTED! THE SEPEN JOINT TENDER LAUNCHES RECRUITMENT



SUPPORT FOR THE HEALTH  
WORKFORCE PLANNING AND  
FORECASTING EXPERT NETWORK

Following its kick-off in September 2017, the joint tender 'Support for the health workforce planning and forecasting expert network' (SEPEN) has finally launched the recruitment for the expert network. The objective is now to build a dynamic community of experts across Europe and provide an ever-growing platform for interactive knowledge transfer. Registration is possible via the [SEPEN website](#) –

the invitation and registration/consent form is available [here](#).

The expert network will also be a vital influence on the joint tender's other activities, in particular the series of technical workshops, the mapping study and the national exchange of expertise. All activities are already underway. In February 2018 the first SEPEN technical workshop brought together experts across Europe to discuss 'Planning for health professions: how to act on skills needs.' The two-day discussion brought insight into the process of integrating skills needs into health workforce planning. The report is available [here](#) and a summary video if available [here](#). The next workshop will be dedicated to data and is scheduled to take place in the autumn of 2018. At the same time, knowledge brokers have been contributing to the mapping of national health workforce practices and policies. Research is on-going and shall produce an in-depth analysis as well as focussed presentations of the situation across Europe. Lastly, there are also preparations for the first of the national exchange of expertise activities. This format will allow Member States to request tailored technical advice by peers and other experts on the development of their health workforce planning and forecasting processes. More detailed information [here](#). The coming months will therefore offer many exciting opportunities to become engaged in SEPEN - we look forward to welcoming you!

*[Sarada Das](#), Deputy Secretary General*

## REALITY CHECK FOR STANDARDISATION OF HEALTHCARE SERVICES – CEN FOCUS GROUP DISBANDED

The European Committee for Standardization (CEN) has decided to disband its Healthcare Services Focus Group. Instead, future initiatives on healthcare services are dealt within the general CEN framework. In its decision, CEN acknowledges that there are concerns among European level stakeholder organisations as regards standardisation of healthcare services. It also refers to the fact that the European Commission does not consider healthcare services to be a priority for standardisation. CEN's decision to disband the Healthcare Services Focus Group can be considered a great lobbying success. However, CPME will continue to be alert.

CEN's acknowledgment of this opposition to the standardisation of healthcare services follows a long-standing dispute. CPME has continuously voiced its [concerns](#) about the involvement of standardisation bodies in this area, engaging in extensive outreach at EU and national level to raise awareness. CPME's opposition to CEN's activities is shared by the other [European Medical Organisations](#) as well as other [health stakeholders](#) including the International Association of Mutual Benefit Societies (AIM), the Council of European Dentists (CED), the European Federation of Public Service Unions (EPSU), the European Social Insurance Platform (ESIP), and the European Hospital and Healthcare Federation (HOPE). CPME participated in the CEN Healthcare Services Focus Group in 2016 and 2017 with the objective of moving the debate forward in a constructive manner towards a sustainable outcome. This process however failed to find common ground between those in favour of standardisation and those against. At the same time, the EU institutions, in particular the Council, have become increasingly vocal. Many Member States oppose the CEN activities on healthcare services.

*[Sarada Das](#), Deputy Secretary General*

# BMA URGES CLARITY FOR HEALTH PROFESSION IN WAKE OF BREXIT



The British Medical Association (BMA) is today calling for urgent clarity around the future of doctors currently working in the UK who may otherwise move to work outside the European Union because of Brexit.

Speaking at an event at the European Parliament today (23 May), Dr Kitty Mohan, BMA council member and President of

the European Junior Doctor Association, will warn that freedom of movement for doctors, which is currently facilitated by Directive 2005/36/EC, has been essential for doctors to be able to provide high quality medical care across the continent. It is vital any new immigration model is flexible enough to allow for the movement of doctors.

A recent BMA survey of EEA (European Economic Area) doctors working in the UK found that almost half are considering leaving following the EU referendum result, with almost one in five having already made solid plans to relocate elsewhere.

Dr Mohan will also raise the need for maintaining a mutual system of recognising professional qualifications after Brexit. There are estimated to be around 750 EU medical students in U.K. schools who are facing uncertain futures about their ability to practice in their home countries when they qualify after March 2019. The BMA will call for urgent assurances on the status of these students both within the UK and in their home countries.

The event, hosted by the BMA and Wajid Khan MEP, will also explore other health challenges posed by Brexit, including how Brexit affects the European medical profession and medical research, and what healthcare collaboration could look like in a post-Brexit Ireland.

Dr Kitty Mohan, BMA council member, said:

“The challenges posed to our health services by Brexit are considerable and though there has been some progress, there is still much uncertainty around what the immigration implications will be for doctors once the UK has left the European Union.

“Today we are calling on negotiators on both sides of the table to urgently address these issues to provide certainty for doctors, health services and patients across Europe.

“It is vital that any future immigration system is flexible enough to ensure that our health services can recruit and retain doctors and researchers, and that the professional qualifications of medical staff continue to be recognised in the UK and in the EU.

“The future of Europe’s healthcare is dependent upon the continued professional migration of doctors and finding a solution to this should be a priority during negotiations. While Brexit will fundamentally alter both the UK and the EU, it absolutely must not threaten patient safety.”

Dr Jacques de Haller, President of the CPME, said:

“We want to make it clear to negotiators on all sides that Brexit cannot be permitted to threaten the European medical profession nor the patients it serves. European doctors will continue to advocate for a solution which safeguards quality of care and a continued knowledge transfer in the profession throughout Europe.”

*[British Medical Association](#)*

Note to editors available [here](#).

# IRISH MEDICAL ORGANISATION: BREXIT AND COLLABORATION IN HEALTHCARE



Depending on how hard or soft the future border between the UK and Ireland turns out to be, the United Kingdom's withdrawal from the European Union will pose a number of challenges to healthcare in Ireland, including cross border collaboration, the mutual recognition of qualifications and access to medicines.

One of the biggest challenges posed by the UK's withdrawal from the EU will be ensuring ongoing and future collaboration in the field of healthcare. Of necessity, cross-border cooperation exists in the area of public health, particularly in the area of health protection, but Membership of the European Union has facilitated cooperation on the island of Ireland in the delivery of healthcare services.

The Cooperation and Working Together (CAWT) partnership between health and social care services in Ireland and Northern Ireland have facilitated a number of successful collaborative projects in healthcare in the border regions managing funding from the EU INTERREG Programme and the Special EU Programmes Body. Many of these have resulted in longer-term service level agreements, including agreements for the provision of GP out-of-hours services, shared dermatology clinics, ENT services and renal services in the border areas.

Other cross-border service level agreements exist as a result of collaboration and capital investment from both sides of the border, including radiation oncology services and emergency cardiology Services at Altnagelvin Hospital, Derry as well as the provision of all-island paediatric cardiac surgery services for children with congenital heart disease at Our Lady's Children's Hospital Crumlin, Dublin.

Whatever final agreement is made on Brexit, it is essential to ensure that seed-funding for cross-border projects continues into the future and current and future collaborative agreements are watertight. For each collaborative arrangement, all possible future scenarios should be developed to assess potential risks and barriers to patient care that may develop and to ensure that pathways for accessing services, treatment, and follow-on care are seamless.

A second challenge will be assuring the on-going recognition of qualifications while at the same time assuring that we don't lose more of our medical workforce to the UK. There is a long history of collaboration between the medical training bodies in Ireland and the UK. Currently, 742 doctors registered with the Medical Council in Ireland received their primary medical degree in the UK. Many Irish graduates complete their post graduate training and/or spend a period of time in the UK before returning to Ireland.

Ireland's public health system is undergoing a recruitment and retention crisis. One in eight consultant posts remain unfilled and many of our newly qualified specialists are emigrating to other English speaking countries with better working conditions and career opportunities. Since 2008 the number of doctors moving from Ireland to the UK to practice has more than doubled from 108 to 246. In the UK, the NHS has a high dependency on EU workers, including 3,196 doctors registered with the GMC who received their medical degree in Ireland. While it is possible that a bi-lateral agreement will be put in place between Ireland and the UK for the recognition of medical qualifications, Ireland will need to become more competitive in attracting and retaining medical professionals.

A third challenge will be access to medicines where up to 70% of medicines in Ireland are imported through the UK or share the market with the UK. Regulatory requirements, such as market and batch authorisations, in both jurisdictions will likely increase the cost of medicines to Irish patients and may deter manufacturers from supplying the Irish market if they consider it too small. Pragmatic solutions such as joint packaging arrangements will be required to lessen the impact.

*"It is essential to ensure that seed-funding for cross-border projects continues into the future and current and future collaborative agreements are watertight."*

*Irish Medical Organisation*

[Vanessa Hetherington](#)

*Assistant Director, Policy and International Affairs of the Irish Medical Organisation*

# UKRAINIAN PHYSICIANS ON THE WAY TO SELF-GOVERNMENT



Professional self-governance of the medical professions is of great importance to the successful modernization of national health care in Ukraine. Unfortunately, the need for medical self-government has not yet become a priority for most physicians. A lack of clear concepts and unreasonable fears are typical for professional medical associations. Therefore, the Ukrainian Medical Association (hereafter UMA) remains the main promoter of this issue. The UMA has initiated several draft laws on medical self-government in Ukraine (VKarpuk, 2008, R. Ilyk, 2014). In the course of early elections to the Verkhovna Rada (2014), most political forces supported the introduction of medical self-government in Ukraine. After the election of the new Verkhovna Rada, this was recorded in the coalition agreement in the declarations of the President and the Government. On 1 July 2015, UMA organized thematic committee hearings on ways to introduce medical self-government in Ukraine. The UMA Board invited foreign speakers to this event, including Otmar Kloiber, Secretary General of the World

Medical Association, Maciej Gamankiyevich, President of the Polish Medical Chamber.

In September 2015, the Ukrainian Medical Assembly held in Odessa supported the initiative of UMA to unite the main public organisations of doctors through the creation of a civil platform for the introduction of medical self-government. On 23 November 2015 the National Medical Council of Ukraine (NMCU) was founded, which includes more than 40 national-level medical organisations. During 2016-2017, several thematic meetings of the Council were held, with the participation of deputies of Verhovna Rada, Olga Bohomolets and Oleg Musii.

Unfortunately, the differences in the perceptions of what Ukrainian medical self-government should look like could not be fully overcome. At the heart of these differences is that in most countries of the world dentists are a separate profession, and accordingly they have their own self-government. In post-Soviet countries dentists are physicians. For doctors of dentistry there are two questions: whether they have the right to self-government, and if they have one, is it expedient to implement it. Or is it better to be included in the general medical self-governing organization?

Another issue is a certain amount of confrontation between general practitioners and specialist doctors, which is not unique. The specificity of Ukraine is that general practice is a young medical specialty that still needs to be established in the general health system and seeks to ensure its rights in the medical association are securely protected.

Unfortunately, these important needs have not been sufficiently taken into account in the draft law 5617 (O. Musiy), which is based on the model of a self-governing organization traditional for European countries. Indeed, the pendulum swung to the other side and in the bill 5617-1 (O. Bogomolets), a completely different, unprecedented construction was proposed: an umbrella organization for three separate self-governing medical chambers (specialist doctors, dental doctors and general practitioners practising family medicine), a confederation of three separate self-governing organizations.

In search of a compromise alternative, the Board of UMA decided to set up a special expert group and involve experts from Germany and Poland in it. Thus, a project on international expert support for the introduction of medical self-government in Ukraine was launched.

*"It is extremely important for Ukrainian doctors to further support our European colleagues in promotion and implementation of medical self-government in Ukraine. In the interests of our potency, our future, and the wellbeing of our patients we must preserve our diversity and be united at the same time."*

*Ukrainian Medical Association*

The main task of the project at the initial stage was the expertise of the aforementioned bills. The first working session of the international expert group was devoted to this goal. It took place on 1-2 June 2017 in the National Scientific Medical Library of Ukraine (with the participation of experts from Germany, Poland and Ukraine).

For the comparison of the aforementioned bills, the Polish Law on Medical Chambers (Ustawa ob izbah Lekarskih) (1989) was used. Subject to separate consideration were the questions of the structure and organization of medical self-government, because, in this part fundamental differences were found.

As the result of this work, a consolidated version of the draft law appeared. This edition was considered and approved by the XVII Congress of the UMA (29 September 2017, Kamyanets-Podilskyi), after which it became the subject of consideration at two meetings of NMCU.

In February 2018, following the final agreement of the position, NMCU appealed to deputies of Verhovna Rada with a proposal to submit a consolidated version of the bill. On 6 April 2018, this edition was registered by a group of deputies (No. 8250). Therefore, the main task now is to ensure that this bill is considered by the Verkhovna Rada and becomes a valid law in Ukraine.

In this situation, it is extremely important for Ukrainian doctors that our European colleagues further support us in promotion and implementation of medical self-government in Ukraine. In the interests of our potency, our future, and the wellbeing of our patients we must preserve our diversity and be united at the same time.

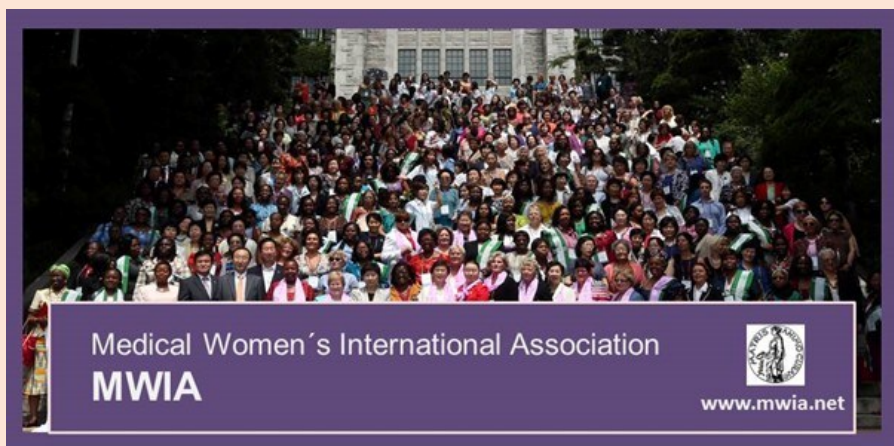
*MD Oleg Musii, UMA President, MP*

*MD Mykola Tyshchuk, UMA board chairman*

*Prof. Irina Mazur, President of Ukrainian Dentists Association*

## MEDICAL WOMEN'S INTERNATIONAL ASSOCIATION (MWIA) –

## A GLOBAL NETWORK OF MEDICAL WOMEN



MWIA recently became an associated organization of CPME at the last General Assembly in Brussels. We are pleased to have the opportunity to introduce MWIA in this newsletter!

MWIA is an association of medical women doctors and students from six continents. Founded in 1919, MWIA is one of the oldest professional international bodies. It is non-sectarian and non-profit making and serves as an international non-governmental organization (NGO). The current president is Prof. Dr. Dr. Bettina Pfleiderer from Germany (2016-2019). The theme of this triennium is "Medical women - ambassadors of change!"

- **MWIA has an important global political voice and influence on issues of interest to medical women** e.g. work-life balance, maternity leave, career progression, fighting discrimination and mentoring of young medical doctors and students. We campaign and stand up for women's rights.

- **MWIA initiates and supports scientific projects as part of multicenter studies and grant proposals** related to refugee health, violence, sex/gender sensitive medicine, health and well-being of physicians locally, nationally and globally.
- **MWIA has developed training modules for physicians** e.g. on gender mainstreaming, violence against women and girls, and adolescent sexuality.
- **MWIA strengthens and raises the profile of medical women. It serves as a platform for medical women and students to foster dialogue and action** on various health issues internationally e.g. female genital mutilation, women's reproductive health, maternal and infant mortality.

#### **MWIA has consultative status** with

- the Economic and Social Council (**ECOSOC**) of the United Nations.
- the Department of Public Information (**DPI**).
- the World Health Organisation (**WHO**).

#### **MWIA is an associate organization** of

- the World Medical Association (**WMA**).
- the Standing Committee of European doctors (**CPME**).

#### **MWIA is a member** of

- the European Women's Lobby (**EWL**).
- the Council for International Organizations of Medical Sciences (**CIOMS**).

#### **MWIA partners** with

- the NGO "**Women in War**" - a gendered think tank on gendering armed conflict.

#### **What do we do?**

- Develop manuals and online teaching materials.
- Conduct surveys within our membership, such as on violence against women, sexual harassment #medtoo as valuable input for national campaigns.
- Advocate for gender sensitive medicine.
- Organise regional and triennial international congresses, workshops on violence and gender sensitive medicine, side events at the Commission on the Status of Women (UN women; in New York).
- Humanitarian project with *Women in War*: The MWIA Southern European Region is working with this NGO on policies regarding the care of refugee women that reach the countries of southern Europe. In addition, we plan to conduct a survey among the medical women involved in the care of migrants in order to identify the main welfare deficiencies which should be addressed.
- Draft statements and press releases.

MWIA looks forward to working together with CPME!

*"We warmly invite you all to the **Centennial Congress of the Medical Women's International Association** in New York from 25 - 28 July 2019.*

*MWIA will be 100 years old!*

*Theme: "**Medical Women: Ambassadors of Change in a Challenging Global World**"*

*More information may be found under: <https://www.amwa-doc>"*

*Prof. Dr. Dr. Bettina Pfeleiderer (MWIA president)*

#### **Social media and communication**

*Email: [secretariat@mwia.net](mailto:secretariat@mwia.net)*

*Website: <http://www.mwia.net>*

*[Twitter](#)*

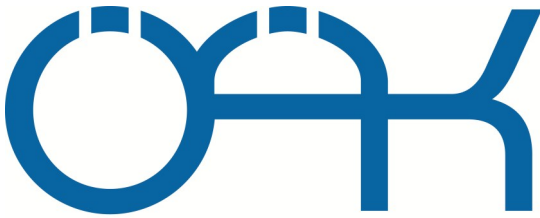
*[Facebook page](#)*

*[Facebook MWIA Group](#)*

*[Facebook page MWIA Young Doctors and Medical Students](#)*

*[Prof. Dr. Dr. Bettina Pfeleiderer](#), (MWIA president)*

# AUSTRIAN SMOKING BAN ABANDONED: A BRIEF OVERVIEW OF DEVELOPMENTS AND PROSPECTS



ÖSTERREICHISCHE  
ÄRZTEKAMMER

In Austria, enjoying a meal or drink in a smoke-free environment is not something to be taken for granted – according to current legislation, smoking in bars and restaurants is allowed in separate smoking rooms, and small pubs may operate as designated smoking establishments. With these liberal regulations, Austria is at the bottom of the league in Europe when it comes to the protection of non-smokers: At present, comprehensive smoke-free laws are in place in 17 EU countries.

## 2015: Austrian parliament votes for general smoking ban in bars and restaurants

Three years ago, however, things seemed to be about to change: According to a parliamentary decision taken by the former SPÖ/ÖVP coalition parties and the Greens in July 2015, a general smoking ban for bars and restaurants was scheduled to enter into force on 1 May 2018. The discussion process leading to this decision was kicked off by the “Don’t Smoke” initiative, a platform founded in 2014 under the auspices of the Austrian Society of Haematology and Medical Oncology (OeGHO).

## 2017: Government U-turn under ÖVP/FPÖ

Early elections in October 2017 resulted in a new political landscape: Since December last year, Austria has been led by a coalition government of the ÖVP and the FPÖ, with Sebastian Kurz (ÖVP) as the republic’s new chancellor.

The FPÖ had already opposed the tightening of the smoking laws in 2015 and could now successfully make the abandonment of the former government’s plans a condition for entering into a coalition with the ÖVP. The plan eventually found its way into the government programme, which stipulates that “in line with entrepreneurial freedom, bars and restaurants continue to be allowed to offer dedicated smoking areas”. In their efforts to lower the general tax burden, the government has also announced that it will not raise taxes on tobacco in the coming years.

*“The petition is not intended to discriminate against smokers or harm restaurant owners, but focuses exclusively on people’s health.”*

*Mag. Helene Wöger*

## 2018: Launch of “Don’t Smoke” petition

Unsurprisingly, the coalition’s plans to drop the ban sparked harsh criticism, not only from the opposition but also from the medical profession. After all, the negative health effects of smoking are clear: According to data from Austrian Cancer Aid, one third of all cancerous diseases in Austria can be attributed to smoking and passive smoking, which corresponds to 13,000 newly diagnosed cases each year.

The Medical Chamber of Vienna, therefore, decided to take action and initiated a public petition together with Austrian Cancer Aid. The petition is named after the 2015 initiative “Don’t Smoke” and calls for the retention of the amendments to the federal law on the protection of non-smokers (Tobacco Act) adopted in 2015. The Austrian Medical Chamber has expressed its full support for the petition, alongside a long list of other notable public and private organisations and individuals. The full list of supporters, as well as further information on the petition, is available at [www.dontsmoke.at](http://www.dontsmoke.at).

It is particularly important for the initiators to emphasise that the petition is not intended to discriminate against smokers or harm restaurant owners, but focuses exclusively on people’s health. “We only want a clear line to be drawn where – from a medical point of view – we have massive health concerns about non-smokers”, says Thomas Szekeres, president of the Medical Chamber of Vienna and the Austrian Medical Chamber.





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### Overwhelming response

The Don't Smoke petition can be signed by all Austrian nationals eligible to vote and is organised in two phases: Between 15 February and 4 April 2018, citizens were able to provide declarations of support. The petition itself will be open for signature from 1 October to 8 October 2018. If a petition is signed by at least 100,000 people, the parliament is obliged to deal with the subject matter in question. After an impressive start, the threshold of 100 000 signatures was reached in only three days, and by the end of the first phase, as many as 591 146 Austrians had declared their support.

### The way forward

Despite this clear sign of opposition from the public to the government's plans and for the protection of non-smokers in Austria, the coalition parties confirmed the cancellation of the smoking ban by parliamentary vote in late March 2018.

For the Medical Chamber, this "unique negative example", as President Szekeres puts it, only serves as additional motivation for the final phase of the Don't Smoke petition in October 2018. All efforts will be made to gather as many additional signatures as possible and send out a strong message to the government. At the very least, the discussion process over the past months seems to have resonated within the catering sector itself: More and more bar and restaurant owners have voluntarily decided to go smoke-free, with a growing number of initiatives at provincial and community level supporting them in protecting the health of customers and employees.

*Mag. Helene Wöger, MA*

*International Department, Austrian Medical Chamber*

*1 Social Democratic Party of Austria / Austrian People's Party*

*2 Freedom Party of Austria*

*3 According to legal requirements, a petition must be supported by one thousandth of the population, i.e. 8.401 citizens, in order to be formally initiated.*

# ILLICIT TOBACCO TRADE: A GLOBAL PROBLEM WITH A GLOBAL SOLUTION



Illicit tobacco trade is a global problem that has very big negative effects on public health. It undermines public health policies by providing products that do not comply with EU rules; products that are cheaper and without health warnings or restrictions on additives and flavours. Cheaper cigarettes lure young people and other new customers, and make it more difficult for smokers to quit. Furthermore, illegal tobacco deepens health inequalities because it makes tobacco

easily available to poor people who are its keenest customers. As a result, illicit trade adds steadily to health care costs, [reduces worker productivity](#) and increases health inequalities. The growing global death toll from tobacco use equals 5.4 million lives per year, projected to rise to 8 million by 2030. In the EU alone, smoking is responsible for the loss of almost 700,000 lives every year. <sup>1 2</sup>

The answer to the above mentioned concerns just might be the WHO FCTC Protocol to Eliminate Illicit Trade of Tobacco Products. The Protocol is the first global legally binding treaty specifically created to tackle the problem of illicit tobacco trade. It sets out measures to secure the supply chain through the creation of a global tracking and tracing system, licensing, due diligence and other record keeping requirements. It also foresees international cooperation through mutual assistance between authorities and increased sanctions. A crucial article in the Protocol is Article 8, which sets out the establishment of a global tracking and tracing regime, consisting of national and regional tracking and tracing systems that are inter-linked and, most importantly, operate without unnecessary interaction with the tobacco industry. In order for the Protocol to be legally binding it needs at least 40 signatories to have approved, accepted, accessed, formally confirmed or ratified it. Currently, 34 Parties in the world have ratified it, as well as the EU as a separate entity. Out of the 34 Parties, 9 are from the EU: Austria, Spain, Portugal France, Latvia, Slovakia, Cyprus, Lithuania and Germany. <sup>3</sup>

Apart from the Protocol, the EU has also been active in trying to address the problem. Under the Tobacco Products Directive (TPD) 2014/40/EU, Article 15, the European Commission (EC) and the Member States adopted standards for establishing an EU tracking and tracing system by means of implementing and delegating acts (under the *Comitology procedure*)<sup>4</sup>. This entails that all tobacco products in the EU market will be tracked and traced. All unit packets of tobacco products manufactured in or imported into the Union must be marked with a special code - a unique identifier (UI) code - and their movements must be recorded throughout the supply chain. The system will be introduced by May 2019 for cigarettes and roll-your-own tobacco products, and by 2024 for all other tobacco products. Furthermore, the adopted EU standards aim to be compliant with the Illicit Trade Protocol and limit the control and involvement of the tobacco industry by putting in place specific safeguard measures when considering the operational aspects of the system.

However, what does tracking and tracing actually entail? It is a process which determines the current and past locations (and other information) of a unique item or property. Tracking and tracing refers to the control and monitoring of tobacco products through the supply chain. It should determine the current, past and future location of all tobacco packaging such as packs, cartons, master cases and pallets, from the manufacturer, importer, exporter



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*“Tracking and tracing is a process which determines the current and past locations (and other information) of a unique item or property. It refers to the control and monitoring of tobacco products through the supply chain.”*

*Kristina Stoyanova*

and trader to the distributor and retailer. A tracking and tracing system should also be sufficiently secure to prevent any unauthorised users from having access to confidential information, and specifically any access to information which might disclose investigations and enquiries from enforcement authorities<sup>5</sup>. This being said, both the Protocol and the future EU system for tracking and tracing of tobacco products seem to cover these requirements, increasing the chances of reducing illicit tobacco trade and its negative impacts on the health of citizens on a global scale.

*Kristina Stoyanova,  
Policy Officer at Smoke Free Partnership*

1 [http://global.tobaccofreekids.org/files/pdfs/en/ILL\\_overview\\_en.pdf](http://global.tobaccofreekids.org/files/pdfs/en/ILL_overview_en.pdf)

2 [https://ec.europa.eu/commission/commissioners/2014-2019/georgieva/announcements/fighting-illicit-trade-tobacco-products-requires-joint-global-effort-eu-calls-international-partners\\_en](https://ec.europa.eu/commission/commissioners/2014-2019/georgieva/announcements/fighting-illicit-trade-tobacco-products-requires-joint-global-effort-eu-calls-international-partners_en)

3 [http://www.who.int/fctc/protocol/Protocol\\_summary\\_en.pdf?ua=1](http://www.who.int/fctc/protocol/Protocol_summary_en.pdf?ua=1)

4 [https://ec.europa.eu/info/implementing-and-delegated-acts/comitology\\_en](https://ec.europa.eu/info/implementing-and-delegated-acts/comitology_en)

5 Luk Joossens, Advocacy Officer of the Association of European Cancer Leagues (ECL), International Expert on illicit tobacco trade

## UPDATES FROM THE EUROPEAN JUNIOR DOCTORS



It was in October 2016 at the Conservative Party Conference that the Jeremy Hunt, UK Secretary of State for Health (now Secretary of State for Health and Social Care) announced plans to introduce a mandatory four-year NHS service term for UK medical graduates. Hunt's proposed "military-style restrictions" set out that newly qualified doctors would have to work a minimum four-year period in the NHS or pay back the cost of their medical education, which the UK Government estimated to be £220,000. With a starting salary of £26,614 for doctors in their first year post-qualification, it was unsurprising that the idea was seemingly put on hold amidst the uproar and concerns voiced. Put on hold but not forgotten it would seem as in January 2018 Niall Dickson, the chief executive of the NHS Confederation, the membership body for organisations that commis-

sion and provide NHS services in England, called for a "public debate" on whether sanctions should be used to tie graduate doctors to the health service.

However, a mandatory period of medical service for doctors is not only being discussed in the UK. At the General Assembly of the European Junior Doctors Association (EJD) in October 2017, three delegations present (Slovenia, Croatia and Latvia) described mandatory service measures currently used in their countries. In Slovenia, after completion of residency, doctors are obliged to stay in the region and/or country for the length of their residency (a period of 4 to 6 years). If they do not do this, doctors must pay back the money spent on their education during residency, usually totalling a few thousand euros. Mandatory service also exists in Croatia, where on completion of residency medical residents must remain in the same hospital/institution for the same length of time as their residency programme. If doctors break this contract they are obliged to pay back the money invested during their training, which can range from 2000€ to 70000€. A further five EJD delegations described on-going threats that similar measures may be introduced in their countries. This has also become an important issue in the Polish junior doctor dispute, with the Polish government announcing that junior doctors will receive a monthly salary increase equivalent to 143€, which will double if they commit to working in Poland for a minimum of two years.

Fundamentally, mandatory service fails to acknowledge the reasons why junior doctors, and indeed many other doctors, leave the country in which they have studied and often lived for many years. In 2017 Pinto da Costa *et al*, on behalf of the European Federation of Psychiatric Trainees, published the results of a survey of psychiatric trainees in 33 European countries. The survey explored actual and potential reasons for psychiatric trainees staying in and leaving their country of origin. 303 (13.3%) of the 2281 respondents had already moved countries citing academic reasons as the main motivator for leaving their country of origin.

The reasons for doctors moving from their “home” country are complex. Further work is needed to identify what motivates doctors to move country and what factors cause them to remain in their country of origin. Forcing doctors to stay via mandatory service is clearly not the answer and contrary to the principles of free movement of European doctors as outlined in the Mutual Recognition of Professional Qualifications Directive (2005/36/EC). This topic was explored in some detail at our EJD General Assembly Spring Meeting in Zagreb last month. A pre-meeting conference “Junior Doctors in Croatia – Employment and Free Mobility” also took place in conjunction with the Junior Doctors’ Committee of the Croatian Medical Chamber. This is a priority area for the European Junior Doctors Association and we shall continue to work on this topic through our Working Group on Free Movement as this year progresses.

*Dr Kitty Mohan, EJD President*

## THE RISING TIDE OF FALSIFIED MEDICINES

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There is a rising tide of criminal activity to manufacture and distribute falsified, substandard or fake medicines. The two patient safety organisations that I work for, the [Alliance for Safe Online Pharmacy in the EU](#) and the [European Alliance for Access to Safe Medicines](#), focus on making the internet a safer place to buy medicines.

The exact size of the problem is difficult to determine but there are approximately 40,000 – 50,000 active online medical product sellers worldwide, and 93-96% of them are operating illegally. It is worrying that evidence shows that the issue is growing. However it is clear that consumers/patients are becoming increasingly reliant on, and trusting of, the Internet to buy medicines.

According to the World Health Organisation’s (WHO) recent reports on substandard and falsified medical products <sup>1 2</sup> published in November 2017, calls for a collaborative government backed approach to tackle this public health threat.

A number of non-profit organisations are working to raise public awareness such as [Fight the Fakes](#), [Fondation Chirac](#), [CSIP](#), [ASOP Global](#), [ASOP EU](#), [EAASM](#), [Fakeshare](#), [NABP](#), [FMEDS](#) and [IRACM](#).

It is of utmost importance to encourage healthcare professionals, **as pillars in the public health system, to contribute to combat this problem via their interactions with patients**. There are many approaches that medical associations can adopt to help inform patients about falsified medicines. Key messages can be summarised as follows:

- Do not buy from an website that:
- Doesn’t require a valid prescription for prescription medicines
- Sells medicines that are not approved by the European Medicines Agency and so will not be licensed in the EU

- Doesn't have a physical address and phone number
- Doesn't have a licensed pharmacist who is easily contactable
- Offers 'bulk discounts', 'sample packs', 'new cures' or 'amazing results' so the offers are too good to be true
- Doesn't include the EU Common logo.

If the website has all of the above information then it is likely to be operating legally but the patient should also check with their [national medical agency](#).

There are a number of important initiatives to help protect the public. One which guarantees arriving at a genuine legally operating website are those that are certified and approved by the National Association of Boards of Pharmacy (NABP). This non profit organisation acquired and governs the use of the TOP LEVEL DOMAIN NAME .pharmacy. So once verified NABP will add the entity to the verified websites list and can use the .pharmacy domain name at the end of the website URL, like .com or .biz. At the moment .pharmacy approved websites are largely present in the US but plans to gain a presence in the EU are ongoing.

Similarly, a pan EU initiative using a Common Logo was implemented in July 2015 under the Falsified Medicines Directive to help protect patients from fake medicines. This Directive obliged every Member State to allow the sale of medicines "at a distance" i.e. via the Internet. So how does the logo work? The Common Logo links to the website of the national competent authority listing all legally operating online pharmacies/retailers. National websites are listed with the European Medicines Agency. By simply clicking on the logo which must appear on every page selling a medicine, the visitor will be routed to the national list of registered online sellers of medicines.



It is therefore important to develop an integrated, comprehensive approach and strengthen coordination with all stakeholders to drive awareness and actions across EU countries to restrict this illegal and potentially fatal trade. The medical profession have a pivotal role to play in the education of patients and also the detection of medicines that may have been bought and are in some way not appropriate for the patient.

*[Mike Isles](#), Executive Director, ASOP EU / EAASM*

1 <http://www.who.int/medicines/regulation/ssffc/publications/gsms-report-sf/en/>

2 <http://www.who.int/medicines/regulation/ssffc/publications/se-study-sf/en/>

## EU INSTITUTIONAL NEWS

02 May 2018	On 2 May, the Commission presented its proposal for the Multiannual Financial Framework for the 2021-2027 period (2021-2027 MFF), outlining the structure of the EU budget and the policy priorities of the EU for a period of seven years, together with proposals on own resources financing the EU budget and a proposal to link the EU budget and the rule of law. This proposal does not foresee a specific financing tool for EU initiatives in the field of health, but allocates health to the European Social Fund. On 30 May, the Commission adopted accordingly the legislative proposal for a new European Social Fund Plus (ESF+) Programme. More details on European Social Fund Plus (ESF+) can be found <a href="#">here</a> .
06 June 2018	On 6 June 2018, the European Parliament, the Council and the Commission confirmed the preliminary political agreement on the revised rules that will apply to audiovisual media in the EU. What comes to public health, the revised Audiovisual Media Services Directive (AVMSD) strengthens provisions to protect children from inappropriate audiovisual commercial communications of foods high in fat, salt and sodium, and sugars, by encouraging codes of conduct at EU level. Tobacco advertising remains forbidden in all types of media. For alcohol advertising, the co-legislators agreed to encourage further development of self- or co-regulation to effectively reduce the exposure of minors to such advertisements. This does not prevent Member States from applying stricter rules, such as banning alcohol advertisements. The revised text will be formally adopted in autumn 2018.
14 June 2018	In a plenary vote on Thursday 14 June 2018, the European Parliament has adopted the Proportionality Directive. The last step of the process is now the Council's formal approval, which will take place in the coming weeks. After this the Directive can be published in the Official Journal and enter into force. Please find the text as adopted by the European Parliament <a href="#">here</a> .
21 - 22 June 2018	On 22 June 2018, the EU Ministers for Employment, Social Policy, Health and Consumer Affairs (EPSCO) meet on 21 and 22 June 2018 in Luxembourg to discuss social policy and health topics. In particular, the EPSCO is expected to adopt Council conclusions on healthy nutrition for children and to discuss the HTA dossier. Further details on the meeting and on the agenda can be found <a href="#">here</a> .
01 July 2018	On 1st July 2018 Austria takes over the rotating six-month presidency of the Council of the European Union from Bulgaria. More information on the presidency's priorities can be found <a href="#">here</a> .

### Save the date!

#### SEPEN expert network launch webinar

We would be delighted to welcome you to the launch webinar of the [SEPEN expert network](#)! Please join us on **11 July 2018** at **11.00h CEST** for an introduction to SEPEN, a presentation of the online forum and a lively discussion. To participate and join the expert network, please find further details and the registration form [here](#). More info will follow.

We look forward to meeting you !



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## SAVE THE DATE! CPME MEETINGS 2018

09-10 November 2018  
Geneva (Switzerland)

05 - 06 April 2019  
La Valetta (Malta)



COMITÉ PERMANENT DES MÉDECINS EUROPÉENS  
STANDING COMMITTEE OF EUROPEAN DOCTORS

