



## Message from the CPME President:



Welcome to the 9<sup>th</sup> edition of the CPME Newsletter.

The autumn period is a busy time as public health and other health-related initiatives are continuing to develop and some will finalise before the end of the year.

This edition includes several ongoing legislative activities at EU level, including: the Tobacco Products Directive, Clinical Trials, Data Protection, and Medical Devices.

CPME has actively followed these initiatives and issued statements addressing the concerns of medical doctors with regards to ensuring ethical principles as well as patient safety.

I invite you to read the main messages CPME has to convey on these latest developments and hope to see you at our upcoming General Assembly and Board meeting on 23 November 2013 in Bucharest, Romania.

Yours sincerely,

Dr Katrín Fjeldsted  
CPME President

## TOBACCO PRODUCTS DIRECTIVE—ALL EYES ON THE PLENARY VOTE



In the European Parliament, the progress made on the negotiations towards a new Tobacco Products Directive has been halted by new delays. On 10 July 2013, the European Parliament's Committee on Environment, Public Health and Food Safety (ENVI) adopted its [Report on the draft Directive prepared under the lead of Rapporteur MEP Linda McAvan \(UK, S&D\)](#).

The Report enshrined a number of provisions seen to strengthen the controls on tobacco manufacture, presentation and sale of tobacco and related products. The Report foresees to introduce an exhaustive positive list of additives which are authorised for use in tobacco products by the European Commission, prohibiting all others, in particular additives producing a characterising flavour, including menthol, additives that imply benefits to health, energy or vitality, or colour smoke, to ban cross-border distance sales of tobacco products, to provide that all nicotine-containing products to be given market access only after authorisation, in line with the Medicinal Products Directive 2001/83/EC.

With labelling of tobacco products being among the most contested issues, the Committee did not achieve a majority for standardized ('plain') packaging, but up-held the

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Commission proposal's provision for combined health warnings, i.e. pictures and text, to cover a surface of 75% of the front and back of cigarette and roll-your own tobacco unit packets. The committee also upheld the Commission proposal's ban of so-called 'slim' cigarettes with a diameter of less than 7.5 mm.

This Report was welcomed as a strong position to enter into negotiations with the [Council, which in turn had adopted its general approach in June 2013](#), proposing i.a. to downsize the health warnings to 65% of a packet's size and to drop the proposed ban on so-called 'slim' cigarettes. Both institutions however upheld Article 24 which permits Member States to adopt more stringent measures if it is deemed necessary in the interest of public health.

Having progressed thus through early stages of negotiations, the Directive now faces new obstacles caused by the postponement of the European Parliament's plenary vote which followed an application by several political groups, foremost



the European Peoples' Party (EPP) and the Alliance of Liberals and Democrats for Europe (ALDE).

This intervention is viewed most critically against the background of the tobacco industry's lobbying efforts and the pressure it entails on the timeline for completing negotiations. [CPME](#) is committed to supporting a plenary vote with no further delays and shall be calling for strong and decisive action to safeguard the legislation's objectives.

For further information, please contact:  
[Sarada Das](#).

## MEDICAL DEVICES: ENVI VOTE AHEAD

 On Wednesday, 25 September the Environment, Public Health and Food Safety (ENVI) Committee of the European Parliament will vote to adopt two reports on medical devices and IVD medical devices respectively.

The role of ethics committees with regard to clinical trials is paramount for the medical devices report. Ethical principles of the WMA Declaration of Helsinki need to be reflected in the final position of the European Parliament. Clinical trials for medical devices may not proceed without the approval of the ethics committees.

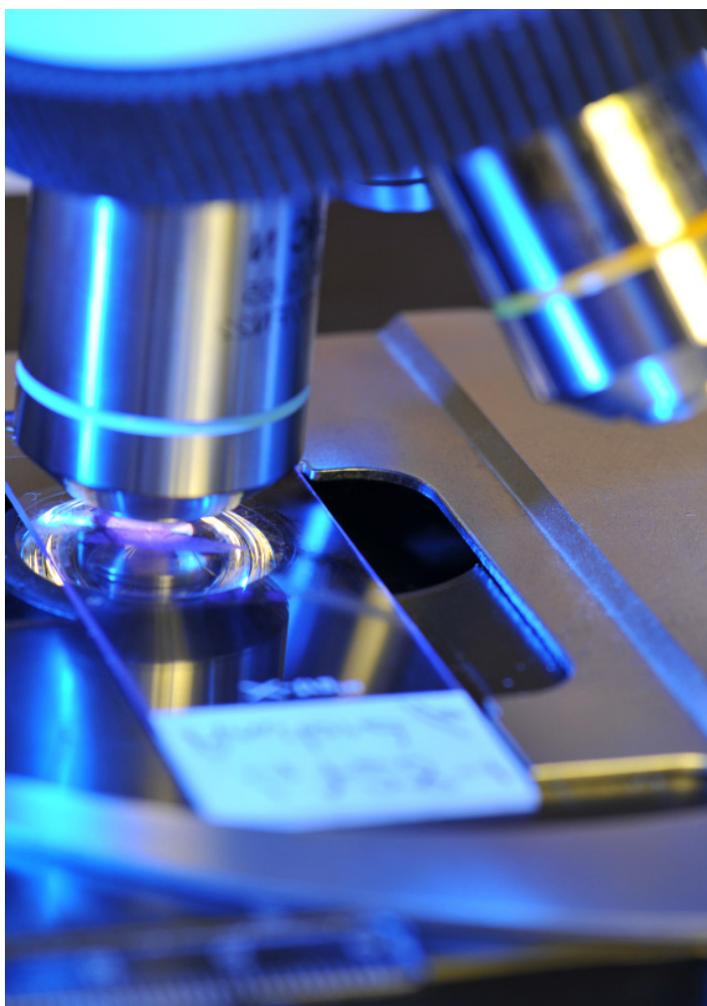
CPME President and Medical devices Rapporteur, Dr Katrín Fjeldsted declared:

*The ENVI vote next Wednesday is decisive with regards to much needed ethical principles for clinical assessment of medical devices. It is our hope that MEPs will reaffirm strong ethical principles, agreeing that a clinical assessment should only start after being granted a positive evaluation by an independent ethics committee. Member States should also follow this direction.*

The second report concerns in vitro diagnostics medical devices. The report introduces rules on the application of genetic testing. Whether these are compatible with existing member state law in this field remains to be seen.

CPME will continue to monitor closely the vote on the two draft reports. Member States should find the ethical ground as a common point of discussion in the future legislation on medical devices.

For further information, please contact:  
[Anamaria Corca](#).



## GENERAL DATA PROTECTION REGULATION: CONSENT IN THE FIELD OF RESEARCH

**N**egotiations on the General Data Protection Regulation are being slowed down and the vote in the Civil Liberties Committee (LIBE) of the European Parliament is to take place this autumn. Recently, CPME drew the attention of European Parliamentarians (open letter accessible [here](#)) towards the dangerous trends which can be observed as regards the definition of consent in the field of research. CPME firmly opposes any new notion or definition of consent in the field of research. A research project can in no way be conducted without the freely given informed consent of the patient, a principle internationally recognised through the [World Medical Association's Declaration of Helsinki, 2008](#). Circumventing this principle is a clear violation of patients' rights to self-determination and jeopardizes all internationally agreed ethical principles applying to medical research on human beings. CPME invites the responsible Parliamentarians to seriously reconsider their approach and refrain from introducing new medical ethical standards in a regulation aimed at protecting citizens' data.

*For further information, please contact:*  
[Constance Colin](#)

## MORE TRANSPARENCY FOR CLINICAL TRIAL DATA

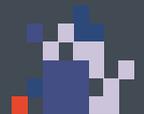
**C**PME warmly welcomes the draft policy of the European Medicines Agency (EMA) on the publication of and access to clinical trial data. In medical research, secrecy and non-disclosure is not the way forward. Fostering full transparency and opening access to trial data is essential to enable substantial advances in treating diseases. Therefore endeavours of the EMA to facilitate greater access to protocols, trials' results and clinical study reports are highly appreciated. At the end of the day this is a matter of public trust: society expects that decisions by the EMA are taken free from any undue influence and that no crucial information is kept away from patients and physicians.

*For further information, please contact:*  
[Constance Colin](#)

## CPME News

◆ CPME President Dr Katrín Fjeldsted and CPME Secretary General Ms Birgit Beger attended the 63rd session of the **WHO Regional Committee for Europe** which took place in Izmir, Turkey from 16 to 19 September 2013. The following topics were identified as of special interest to the CPME: the European Mental Health Action Plan 2014-2020, ethical aspects of medical research, patient safety, healthy ageing, childhood immunisation and eHealth.

◆ From 2 to 4 October 2013, the CPME President Dr Katrín Fjeldsted will attend the 16<sup>th</sup> **European Health Forum (EHF)** meeting in Gastein, Austria. Dr Katrín Fjeldsted will participate in sessions dedicated to patient empowerment and health literacy programmes. During the European Health Forum, CPME Vice-President Dr Jacques de Haller will also deliver a speech dedicated to men's health and main concerns in this area of public health. For further information please see the EHF Gastein agenda [here](#).



### NEXT CPME MEETINGS

SAVE THE DATES!

Bucharest, Romania

**November 2013**

Friday	Saturday
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<b>22</b>	<b>23</b>
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Brussels, Belgium

**April 2014**

Friday	Saturday
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<b>04</b>	<b>05</b>
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## CPME News

◆ On 24 September 2013, CPME Immediate Past President Dr Konstanty Radziwill will represent CPME at the ENVI committee **workshop dedicated to eHealth** hosted in the European Parliament by MEP Pilar Ayuso.

◆ CPME Immediate Past President Dr Konstanty Radziwill will attend the **eHealth Stakeholder Group meeting** from 30 September to 1 October 2013 in Brussels. The meeting's agenda include topics such as telemedicine deployment, eHealth inequalities, mHealth and the review of the Professional Qualifications Directive.

◆ CPME EMA representative, Dr Erzsébet Podmaniczky will be attending the **Health Care Professional Working Party (WP)** meeting at the **EMA** on 25 September 2013. For further details, please see [here](#).

◆ On 27 September, CPME EMA representative Dr Erzsébet Podmaniczky will participate in **the EMA 7<sup>th</sup> stakeholder forum**. The purpose of this meeting is to present an update on the implementation of the pharmacovigilance legislation. Find more information on the previous meetings of the stakeholder forum [here](#).

◆ Dr Wolf-Dieter Ludwig, CPME representative at the management board of the European Medicines Agency and Chairman of the Drug Commission of the German Medical Association, chaired a meeting organised by the EMA dedicated to the conflict of interest. The meeting took place in London on 6 September 2013. Feel free to access more information on the meeting [here](#).

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## THE RIGHTS OF PATIENTS & HEALTH PROFESSIONALS' MOBILITY IN THE EU

### GUEST ARTICLE:



MEP Minodora Cliveti  
S&D, Romania

Nowadays, a wide range of factors influence the quality of health of the population: lifestyle, environment, socio-economic conditions, health services and health related systems.

Over the past years, a constantly underfunded Romanian health system resulted in medical personnel shortages. A study conducted by the Romanian Medical College shows that 14.000 doctors left the country in the last six years because of low wages and difficult working conditions. In this respect, Romania is facing a migration rate of 9%, while the European average is 2.5%.

According to a survey conducted by the Faculty of Medicine in Romania, 64% of students intend to leave the country after graduation. The EU average wage for a resident doctor is 1.300 euros, compared to only 200 euros in Romania. A physician in Romania earns between 500 and 800 euros while the European average is about ten times higher, respectively 7.000-8.000 euros.

Among the factors that push the medical staff to choose to work in other countries, we can mention the level and opportunities of professional development, the respect towards health professionals and opportunities for the whole family – education for the children, etc., all driving people to gain a better life for themselves and their families.

It is well known that the free movement of services provides significant benefits for the EU as a whole, for its individual Member States and for its citizens. In the medical field, patients are those who suffer most from the lack of health professionals, and we have to offer them appropriate, high standard healthcare.

For these reasons, we should ensure adequate medical care for patients in the context of health professionals' mobility and we have to find European solutions to these problems.

### MEP Minodora Cliveti

Member of the ENVI Committee  
S&D, Romania  
European Parliament

## NSA SCANDAL: MEDICAL DATA UNDER THREAT

CPME addressed an [open letter](#) to the heads of European Institutions and the US Ambassador to the EU on the recent NSA scandal. European physicians are deeply concerned that the personal data which telecommunication companies provided to the US State Authorities, would also concern individual health information. The good conduct of medicine is based on the premise that patients' confidentiality shall not be breached. Hence no third party - be it an individual or an institution - should breach the trust relationship established between a physician and his patient, by accessing personal health information. Likewise, CPME is concerned that personal health information trustfully introduced by European citizens in health applications such as Microsoft Health Vault or Google Health, have also been accessed. CPME looks forward to knowing what the US and EU authorities envisage to guarantee the right of each individual to the full protection of his data, especially when health data is concerned.

For further information, please contact:  
[Constance Colin](#)

## JOINT ACTION EUROPEAN HEALTH WORKFORCE PLANNING AND FORECASTING – PARTNERS DISCUSS ‘SUSTAINABILITY’

On 3 and 4 September 2013, partners of Work Package 7 of the [EU Joint Action on Health Workforce Planning and Forecasting](#) met in Sofia to explore action to support the sustainability of activities' outputs. Led by Prof. Todorka Kostadinova of the University of Varna (Bulgaria), the Work Package aims to ensure that the recommendations produced by the Joint Action are disseminated and utilised meaningfully. Objectives are to inform workforce planning and forecasting in all Member States and utilise its results to benefit the quality of healthcare systems. Partners plan to create an expert network to support and facilitate these processes. CPME looks forward to the work ahead.

*For further information, please contact:*  
[Sarada Das](#).

## PATIENT EMPOWERMENT

The CPME, part of a consortium led by the Foundation Avedis Donabedian, won a European tender regarding the patient empowerment in the area of chronic conditions management. The aim of the project, for which the CPME has an overall supporting role for some specific and technical tasks is the creation of a study that will improve the understanding of the concept of patient empowerment (PE) in relation to chronic diseases management. The consortium has 10 months to prepare a study that will contribute to EU knowledge and facilitate the development of patient centred healthcare system policies while also feeding into the reflection on chronic disease management, a joint process currently on the agenda of the Commission and EU Member States.

*For further information, please contact:*  
[Miriam D'Ambrosio](#).

## CPME STEERING A TENDER ON CONTINUOUS PROFESSIONAL DEVELOPMENT

The CPME, as the leader of a consortium composed of [CED](#), [EFN](#), [EMA](#), [EPHA](#) and [PGEU](#), won a European tender, concerning the review and mapping of continuous professional development (CPD) and lifelong learning for health professionals in the EU and the EFTA/EEA countries. The final result of the project aims to explore the existing evidence base of CPD practices and identify emerging trends to provide a more comprehensive European overview. Another important aspect will be the provision of greater transparency and the improvement of mutual understanding of CPD systems and practices in the EU. In the coming weeks representatives of the consortium will go to Luxembourg to the Executive Agency for Health and Consumers to sign the contract and launch activities for the next 10 months of project execution.

*For further information, please contact:*  
[Miriam D'Ambrosio](#).

◆ By visiting the CPME website you can learn more about the on-line campaign run by the organisation **United to End Female Genital Mutilation (FGM)**. Acts defined as FGM are generally condemned by the European medical profession and recognised as illegal by the EU governments. Nevertheless, women who became victims of such crimes still constitute a significant percentage of the EU population (500,000 girls and women living in the European Union are affected or threatened by FGM). You can access more information [here](#).

◆ European Medical Students' Association (**EMSA**) recently released another issue of its magazine for medical students: [EuroMeds](#). This edition has been dedicated to the Active Healthy Ageing policy area on which EMSA has started working this year. Moreover, the 23rd GA of EMSA Europe which took place on 4 - 8 September 2013 elected Olga Roszkowska from Warsaw, Poland as the new EMSA President for the mandate 2013/2014.

◆ From 8 to 12 July 2013, the European Patients' Forum (EPF) held a symposium in Brussels dedicated to the needs of young patients with chronic conditions. The conference was part of a long-standing project called **EMPATHY**. CPME was represented there by the Secretary General Ms Birgit Beger who was invited to speak during a debate on the approach to adolescents with untreatable illnesses. The event was attended by 3 representatives of the European Medical Student's Association (EMSA), remaining in close cooperation with CPME.



## EU Institutional News

9 September	The European Commission released a report on health inequalities in the European Union. For further information, please click <a href="#">here</a> .
26 September	The Action Group of Prevention of Frailty and Functional Decline of the European Innovation Partnership on Active and Healthy Ageing will organise a progress meeting and decide next steps.
8 October	The Tobacco Products Directive will be voted on during the European Parliament plenary session in Strasbourg.
10 - 11 October	A conference on <i>Mental Health: Challenges and Possibilities</i> will be organized under the auspices of the Lithuanian EU Presidency in Vilnius. For further information and the conference programme, click <a href="#">here</a> .
4 November	The Environment, Public Health and Food Safety Committee (ENVI) of the European Parliament will vote on the Initiative Report of MEP Pilar Ayuso on the 'eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century'.
19-20 November	CPME President, Dr Katrín Fjeldsted will be speaking at the annual conference of the Health Forum, "Sustainable Health Systems for Inclusive Growth in Europe", organized under the auspices of the Lithuanian Presidency to the European Union together with the Ministry of Foreign Affairs, Ministry of Health, Ministry of Education and Science and three European non-governmental organisations: the European Public Health Alliance, the European Patients' Forum and the European Federation of Pharmaceutical Industry Associations. For further information and the conference programme, click <a href="#">here</a> .

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## CPME Mission Statement

*The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.*

- *We believe the best possible quality of health and access to healthcare should be a reality for everyone. To achieve this, CPME promotes the highest level of medical training and practice, the safe mobility of physicians and patients, lawful and supportive working conditions for physicians and the provision of evidence-based, ethical and equitable healthcare services. We offer support to those working towards these objectives whenever needed.*

- *We see the patient-doctor relationship as fundamental in achieving these objectives and are committed to ensuring its trust and confidentiality are protected while the relationship evolves with healthcare systems. Patient safety and quality of care are central to our policies.*

- *We strongly advocate a 'health in all policies' approach to encourage cross-sectoral awareness for and action on the determinants of health, to prevent disease and promote good health across society.*

*CPME's policies are shaped through the expertise provided by our membership of national medical associations, representing physicians across all medical specialties all over Europe and creating a dialogue between the national and European dimensions of health and healthcare.*



The CPME Twitter account is open to discuss relevant health policy topics. Please follow us on Twitter: @CPME\_Europa.

### Guest commentary:

CPME values your feedback! Feel free to leave us a message by [clicking here](#).



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