



Message from the CPME President:



Spring is around the corner and I hope it brings everyone positive thoughts and joy! Welcome to the CPME newsletter edition, now on its 7th issue, highlighting latest developments on medical devices, clinical trials, antimicrobial resistance, tobacco, professional qualifications and many other news on upcoming events and public health themes of interest.

This edition informs on the CPME consolidated cooperation with Federation of Veterinarians of Europe and we invite you to read further this edition's article on antimicrobial resistance.

I would also like to extend our thanks to Member of European Parliament, Ms Glenis Willmott, for her constructive and patient-centric work on the Parliament's clinical trials report. We welcome her article in the present edition and hope for a constructive dialogue ahead that will secure patient safety.

Last week, I attended the European Parliament workshop on medical devices, the panels moderated by Member of the European Parliament, Ms Dagmar Roth-Behrendt and was pleased to hear what proved to be a very diverse and rich debate. The CPME Statement on Medical Devices, we hope, will provide insights to the current debate.

Enjoy the CPME news and have a healthy, reviving spring!

Yours sincerely,

Dr Katrín Fjeldsted
CPME President

Medical devices: CPME's voice on the future legal framework

On 21 February 2013, the CPME Executive Committee adopted the [CPME Statement on Medical Devices and in Vitro Medical Devices](#) following a process of consultation within the CPME Working Group on Medical Devices, which is chaired by Dr Katrín Fjeldsted, CPME President. Two weeks ago on Tuesday, 26 February, the CPME President addressed a wide audience of stakeholders at the European Parliament [workshop on medical devices](#) moderated by MEP Dagmar Roth-Behrendt (DE S&D).

Medical devices are essential for high quality medicine. The recent incident of faulty medical devices have shown that, in its current form, the EU MD Regulation needs to address patient safety more comprehensive manner. In particular, if the regulation is to promote innovation, competitiveness, prompt and reasonably priced access to the market for innovative medical devices.

The EU MD Regulation needs a more balanced degree of detail, especially with regard to clinical investigations. The formulation of ethical principles and their analysis by an independent body of ethics experts



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are therefore two pillars of the international [Declaration of Helsinki](#) which, from the perspective of the medical profession, represents an inseparable unit. CPME recommends that for clinical investigations, the ethics committee is to be maintained.

Undoubtedly, physicians are in the position to provide expertise in day-to-day clinical routines and can properly assess any medical questions which arise.

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

Dr Katrín Fjeldsted address during the European Parliament workshop on medical devices, 26 February 2013:
[Please click here, to watch the video](#)

Clinical trials - next phase of negotiations in Parliament

Member of European Parliament Glenis Willmott (S&D, UK), Rapporteur on Clinical trials, published her report on 31 January and kindly agreed to present it in the CPME Newsletter. In its statement adopted on 24 November 2012, CPME highlighted many loopholes in the proposal of the European Commission: absence of ethics committees; short timelines for the approval procedures of a trial; insufficient protection safeguards for the subjects; insufficient recognition of the physicians' role in the conduct of trials and low transparency standards. The report of Glenis Willmott addresses many of the CPME's concerns. In the coming weeks, CPME will closely monitor the developments in Parliament in order to achieve a text that satisfies the best interest of patients all over Europe.

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

Putting patient safety and transparency at the heart of clinical trials

GUEST ARTICLE: MEP *Glenis Willmott*



The current EU Clinical Trials Directive has been widely criticized. Industry say trials are too lengthy, academic sponsors say they are too expensive, those working with rare diseases say it is difficult to work across borders, and there is widespread concern about the transparency of trial results. That is why it is vital we get the new Clinical Trials Regulation right. We have to find a balance between speeding up approval times and guaranteeing patient safety and wellbeing. We have to try and reduce bureaucracy, whilst ensuring that the data produced by

trials is not misleading, biased or withheld. Overall I think the Commission has done a good job with their proposal.



But there were some crucial points missing. The omission of ethics committees from the text has caused a lot of concern. Whilst I understand that the Commission wanting to leave the issue up to Member States, I feel it is important that ethics committees are explicitly mentioned in the legislation. In my draft report I have included a number of amendments about the role of ethics committees in assessing and approving applications for clinical trials. I have also dedicated a lot of the report to measures which should increase transparency and public trust in trial results. I think that requiring sponsors to upload a full clinical study report to a public database will ensure that we see all results, both positive and negative, and allow for better systematic reviews. Increased transparency is in the interests of patient safety, better treatment and good science.

For further information, please visit:
www.gleniswillmott.eu

Glenis Willmott

Rapporteur on Clinical Trials
(European Parliament)

SAVE THE DATE: 09 April 2013:

European Parliamentary evening on Clinical trials, European Parliament, with MEP Dr Peter Liese, MEP Dagmar Roth-Behrendt, CPME President Dr Katrín Fjeldsted, BAEK President Dr Frank Ulrich Montgomery, Dr Andrzej Rys from the European Commission.

CPME and FVE join forces against Antimicrobial Resistance

Antimicrobial Resistance (AMR) is a pressing challenge, crossing borders both between countries and between human and animal health. Effective action must therefore seek coordination at European level and ensure physicians and veterinarians join forces, to facilitate the implementation of mutually beneficial measures and reflect the collective responsibility of all actors involved. In recognition of the need to take action forward with this 'One Health' approach, the Federation of Veterinarians of Europe (FVE) and CPME have committed to strengthening their cooperation in promoting the prudent use of antibiotics and containing AMR. [A Memorandum of Understanding](#), highlighting the guiding principles and main objectives of the cooperation, was endorsed by the Boards of CPME and FVE in 2012.



22 January 2013: Dr Christophe Buhot, FVE President, Ms Birgit Beger, CPME Secretary General, Dr Jan Vaarten, FVE Executive Director CPME—FVE Signing of the Memorandum of Understanding.

On 22 January 2013, representatives of both organizations came together to sign the Memorandum and launch its implementation. The implementation of the Memorandum of Understanding shall be supported by the activities of the CPME Working Group on AMR which took up its activities in 2012 in order to consolidate and advance CPME's [long-standing commitment to combatting AMR](#). The findings and recommendations of an ongoing mapping exercise of guidelines and practices in the use of antibiotics across Europe shall be prepared for discussion at the forthcoming CPME Board meeting in April 2013. The CPME Working Group on Antimicrobial resistance is chaired by Dr Mads Koch Hansen (DK).

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



Healthy ageing: CPME progresses to fulfill its commitment in partnership

Within the [European Innovation Partnership on Active and Healthy Ageing](#), the Action Group on Prevention of Frailty and Functional Decline, AG A3 of the European Commission, progressed towards the implementation of the Action Plan adopted in November 2012. CPME organised a working group meeting with participants from its member organisations, dedicated to the topic in Cyprus, on 21 November 2012. This step was followed by a call on 3 January 2013 for medical and research experts to contribute at EU level and regionally on prevention of frailty and functional decline in the elderly.

Furthermore, on 8 February CPME organised a workshop in Brussels with different partners and regional representatives to raise public and professional awareness on the risk of functional decline and frailty. A discussion was opened on what practical approaches could be assumed in order to address the issue of the ageing society – including possible research perspectives, statistics analysis and doctor-to-patient communication strategies. The issue has been progressing gradually since then.

On 26 February, Dr Jacques van der Vliet, CPME co-chair of the Working Group on Healthy Ageing attended the A3 Action Group meeting on prevention of functional decline and frailty presenting further steps to contribute to the partnership. The European Medical Students Association (EMSA), represented by Ms Olga Rostkowska provided the perspective of medical students, who, as future medical doctors, have taken a position on that topic in a recent [publication](#).

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

CPME News

26 February 2013

CPME President, Dr Katrín Fjeldsted attended the conference "Cross-border healthcare in Europe: Removing the barriers to deliver clarity and quality". She highlighted the related position of European doctors and its development.

For further information please click [here](#).

21 to 22 March 2013

CPME will attend the European Forum of Medical Associations (EFMA) in Riga, Latvia. Dr Katrín Fjeldsted, CPME President will speak during Session 3 on professional autonomy and self-governance.

For further information regarding the provisional program, please click [here](#).

Dublin, Ireland

April 2013

Friday	Saturday
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26	27
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26 April 2013:
CPME—IMO Conference,
Dublin, Ireland.
'Combating Health Inequalities—Putting Ethics Into Practice'
Please see further information on page 6.

Bucharest, Romania

November 2013

Friday	Saturday
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22	23
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**SAVE THE DATE:
09 April 2013**

European Parliamentary evening on Clinical trials, European Parliament, with MEP Dr Peter Liese, MEP Dagmar Roth-Behrendt, CPME President Dr Katrín Fjeldsted, BAEK President Dr Frank Ulrich Montgomery, Dr Andrzej Rys, European

◆
18 April 2013
CPME will attend the European Commission Conference on “[Prevention of Frailty and Functional Decline](#)”.

◆
13—15 May 2013
The annually EU Presidency [eHealth week](#) takes place in the Convention Centre Dublin, Ireland.

Please find the program [here](#).

◆
European Medical Students' Association ([EMSA Europe](#)) has a blog spot with the most recent news: www.bluemist.eu
Information on policy papers, medical ethics newsletter, EMSA Europe official magazine, announcements about internships, news on trainings and annual events. Updated every week, BlueMist is one of the most dynamic platforms for the network of medical students in Europe.

The European Parliament moves forward on the Professional Qualifications Directive



Since the publication of the Commission's proposal for a Directive amending the Professional Qualifications Directive 2005/36/EC in December 2011, the EU institutions have been discussing on how to achieve greater clarity and better mobility. On 23 January 2013, the Committee on Internal Market and Consumers (IMCO), which is leading the European Parliament's work on the dossier, adopted its Report drafted under Rapporteur MEP Bernadette Vergnaud (FR, S&D).

The Report seeks compromises on some of the most contested issues of the draft legislation, i.e. the application of the principle of partial access, the 'tacit authorisation' of qualifications, the introduction of a European Professional Card and the establishment of a European-wide alert mechanism for professionals who have lost their licence to practice. On the regulation of doctors' qualifications, the Report follows the Commission proposal to set the minimum duration for basic medical training at 5 years consisting of 5500 hours.

The CPME however, in its position outlined that in order to ensure patient safety all over Europe, a minimum duration for medical training should comprise 6 years and 5500 hours, whereby exceptions for well proven and established training programmes are possible, please find the CPME position paper [here](#).

The CPME Working Group on Professional Qualifications chaired by Prof Frank Ulrich Montgomery (DE) will continue to monitor the decision-making negotiations and take action forward in the next steps of the process.

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

Tobacco Products Directive - Revision process is underway

On 19 December 2012, the European Commission published its [proposal for a revision of the Tobacco Products Directive 2001/37/EC](#). The publication of the proposal follows a preparatory process of several years which was delayed and diverted significantly by the



influence of powerful commercial interests opposing a stricter regulation of the manufacture, presentation and sale of tobacco and related products. The CPME Working Group on Tobacco Policy, which is chaired by Dr Konstanty Radziwiłł (PL) is currently reviewing the proposal. A discussion on the draft legislation and the negotiations' progress shall take place at the CPME Board meeting in April 2013.

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

EU Institutions News

◆ The Executive Agency for Health and Consumers (EAHC) has published an “*Economic analysis of workplace mental health promotion and mental disorder prevention programs and of their potential contribution of EU health, social and economic policy objectives*”.

Please find the full study [here](#).

◆ The European Union awarded the health journalism prize for the following areas: [mental health](#), [cord blood banking](#), [cancer screening](#) and [tobacco control](#).

For the press release please click [here](#).

◆ The European Commission launched a web-based Rapid Alert system for Tissues and Cells (RATC) to improve patient safety in medical procedures involving human cell and tissue.

For further information please click [here](#).

◆ The European Commission has published its report on the implementation of the Council Recommendation of 30. 11. 2009 on Smoke-free Environments (2009/C 296/02). On the occasion of its launch, Commissioner Tonio Borg noted that while protection has improved there are still disparities between the Member States in the effective enforcement laws.

For the press release please click [here](#), the full report can be retrieved [here](#).

◆ The Health and Environment Alliance (HEAL) has published a report entitled ‘*The Unpaid Health Bill: How coal power plants make us sick*’, explaining in detail the effects of coal power plant emissions on air pollution and the consequent harm caused to health. CPME has long-since highlighted the health impact of air pollution and welcomes the report as an important contribution to making a case for action.

Please find the full report [here](#).



Chain of Trust — an eHealth project

After three years of intensive work, the EU funded project called “Chain of trust” which was led by the European Patient Forum (EPF) successfully terminated its work with a final report. In co-operation with other European Health care organisations, for example like the European Nurses Federation (EFN), the European Pharmacists Group (PGEU), the CPME elaborated recommendations which will be valuable and decisive tools for policy makers in the future when looking for sustainable eHealth implementation at national and European level.

Chain of Trust: Final report available [here](#).

For further information, please contact:

[Constance Colin](#)



InterQuality—share your views on doctors’ remuneration!

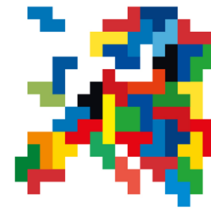
CPME is a partner in the project on ‘*International Research on Financing Quality in Healthcare*’ ([InterQuality](#)). In this context, CPME has cooperated with the project leader, the Medical University of Warsaw, to develop a [survey on doctors’ views on payment systems](#), looking at the medical profession’s opinion on the effect different models of remuneration have on quality and utilisation of as well as access to healthcare. **We invite all doctors to participate in the survey which can be accessed [here](#).**

In advance, many thanks for your valuable input!

For further information, please contact:

[Sarada Das](#).

Patient safety: CPME continues its sustained support



PaSQ
European Union Network for Patient Safety and Quality of Care

The European Union Network for Patient Safety and Quality of Care Joint Action (PASQ JA) sustained by the European Commission and comprises of member states and European health care and patient organizations aims to promote the organization of **Patient Safety and Quality of Care platforms** in all European Member States to improve Patient Safety and Quality of Care through sharing of information, experiences and the implementation of good practices. [www.pasq.eu](#)

CPME’S INVOLVEMENT

CPME participates in the PASQ JA within WP4 on Patient Safety Good Clinical Practices and WP5 on Patient Safety Initiatives Implementation. On 15 January, the consortium met in Berlin to further present progress on each of the work packages.

CPME, through its experts and members, is ready to implement within the project timeline.

We take this opportunity to thank Dr Jesper Poulsen (DK), Prof Dr Gelu Onose (RO), Univ Assist Monica Haras, MD, PhD (RO), Ms Aura Spănu, MD, Postgrad (RO), Dr Borislav Manev (EMSA). We would also like to invite CPME members to contact us as it is still possible to submit answers to some of the project surveys.

Currently, several other safe clinical practices and clinical risk management practices will be identified and collected within WP4. These will be available within the wiki platform of the platform website: [www.pasq.eu](#).

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



COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS



IRISH MEDICAL ORGANISATION
Ceardchumann Dochtúirí na hÉireann

Combatting Health Inequalities Putting Ethics into Practice



26th April 2013 - 9:30h to 12:30h
Dublin



SAVE THE DATE

CPME invites to a multi-stakeholder conference with following panel topics:

- **Improving policies:** tackling health inequalities through European cooperation
- **Learning from good practice:** tackling health inequalities on the ground

Speakers include

- Dr Katrín Fjeldsted, President, CPME
- Dr Paul McKeown, Immediate Past President, IMO
- Dr Erio Ziglio, Head, WHO (tbc)

Click [here](#) to visit the conference program

Join us live on:



[CPME Europa](#)

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 proactive 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.

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Guest commentary:

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



COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
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