COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

CPME Newsletter

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This issue

Message from the CPME President:

Welcome to the 8th edition of the CPME Newsletter. Hosted by the Irish Medical Organisation (IMO), CPME held its Board and General Assembly meetings in Dublin on 26-27 April 2013. On the first morning, a joint IMO – CPME conference addressed health inequalities and welcomed notable guests from WHO Europe, the EU Fundamental Rights Agency, the European Public Health Alliance and EuroHealthNet. In the afternoon, members regrouped in 7 different thematic working groups to discuss health policy of relevance for the EU and physicians. These included: tobacco, eHealth, antimicrobial resistance, healthy ageing, professional qualifications, medical devices and mental health.

The CPME Board adopted several policy statements the following day and I invite you to consult the messages European doctors have to give to EU citizens and and decision-makers alike, in particular with regard to antibiotic resistance, prevention of frailty, management of chronic conditions, childhood immunization, minimum pricing on alcohol and expressions of solidarity towards the situations of healthcare in Greece and Cyprus.

Feel welcome to consult the present edition for further policy developments and news from CPME and EU institutions. Clinical trials, data protection and medical devices are only some of the feature articles of this edition tackling aspects of ethics and patient safety that the European doctors consider key to ensure.

Yours sincerely,

Dr Katrín Fjeldsted
CPME President

Clinical trials Regulation: Improvement still needed!

On 29 May, the European Parliament's Environment and Public Health Committee voted on the Clinical trials regulation and gave mandate to its rapporteur, MEP Glenis Willmott (UK, S&D), to start negotiations with the Council.

Significant progress has been made with the reintroduction of the definition of ethics committees, the reinforcement of safety standards for vulnerable patients and the recognition of the role of doctors in the assessing team.

However, ethics committees are still only seen as a consultation body in the authorisation process, since they are only required to "examine" the trial protocol. The internationally recognised World Medical Association's Declaration of Helsinki clearly stipulates since 1975 that a clinical trial cannot start without the formal prior approval of an independent ethics committee. The approval of a trial protocol by the concerned ethics committee should be made mandatory before the trial starts.

Additionally, derogations to the provision of informed consent have been introduced. In medical research, obtaining the informed consent of a patient is a matter of trust. Denying this central element, first constitutes a threat to patients' safety, second will harm in the long run the credibility of research.

Other concerns relate to the deadlines set for the authorisation process, which are clearly insufficient, especially for academic researchers that do not have the same capacities as large pharmaceutical companies to comply with these deadlines. CPME closely monitors the development of this dossier and calls on the legislator to act first and foremost in the best interest of patients. Further CPME Statements and press releases are available here: PR_WMACPME; CPME 2013/019; CPME 2012/132.

For further information, please contact: Constance Colin

Medical devices: No safety without ethics. Upholding international norms and standards is key.

According to MEP Dagmar Roth Behrendt, (DE, S&D), it is crucial to consider the safety of patients and health professionals in the future regulation on medical devices:

"The Committee on public health of the European Parliament will vote on 10th July on medical devices. In my report, I have stressed that the safety of patients

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and of health professionals is crucial. So, we need to reinforce the approval mechanism for high-risk medical devices and to introduce a system of marketing authorisation, and we must ensure that we have the most robust clinical data on devices that are implanted by surgeons into the body of patients, for instance. For this, we need to strengthen the conditions in which clinical investigations take place. So, we need to involve ethics committee in these trials. I also firmly believe that we need to ensure notified bodies have the necessary "in house" expertise and only subcontract their duties to third party experts in cases where they cannot do otherwise. Finally, I want to clarify the cases where a producer can label its device as single-use and the conditions in which reprocessing of devices occur."

European doctors consider that introducing mandatory approval of the ethics committee for medical devices before the clinical investigation begins is crucial for patient safety. This principle is also subject of long standing internationally recognised standards of protection. Such standards applying to research involving human subjects state clearly that planned research protocols must be submitted to an independent, interdisciplinary ethics committee for consideration, comment, guidance and approval before the study begins (Declaration of Helsinki, Rev. 2008, paragraph 15).
In this respect, the CPME welcomes the legislative amendments of MEP Dagmar Roth–Behrendt (DE, S&D) and believes it to be of utmost importance that these are kept in their present form, unaltered by less lenient requirements.
In amendment 15 of the draft report on Medical devices, MEP Dagmar Roth Behrendt, (DE, S&D) introduces a new recital 48, which foresees the role and mandatory approval of ethics committees before the clinical investigation begins:

A clinical investigation should only start after being granted a positive evaluation by an independent ethics committee. Member States should take the necessary measures to establish Ethics Committees where such committees do not exist.

Amendment 84 further introduces a new article 50a, requiring the authorisation of clinical trials by an independent ethics committee. In the absence of a positive authorisation, clinical investigations may not take place as they are not authorised. Furthermore, amendment 84 defines other aspects connected with the set-up of ethics committees, such as the need for such bodies to be independent and their overall composition. Ethics committees analyse whether the trial has medical justification, whether consent of the test subjects has been obtained and last but not least, whether the investigators or investigation facilities are suitable for the conduct of the trials. Their role is in general to ensure that the rights, safety and well-being of test subjects are protected, which is paramount to be maintained as foreseen by the current legal provisions within the draft report.

Notwithstanding the different ramifications of the proposal for patient safety and innovation, CPME reminds that similar principles apply with medical devices as with clinical trials for medicines. The Standing Committee of European Doctors calls on Members of the European Parliament of the need to maintain the mandatory role of ethics committees and calls for a positive vote of amendments 15, respectively 84 when they cast their vote on 10 July.

The CPME Statements on medical devices are available here: CPME 2012/150, legislative recommendations, EC 2012/026.

For further information, please contact:
Anamaria Corca.

The General Data Protection Regulation to be voted in Parliament

The vote on the general data protection regulation is foreseen to take place end of June in the European Parliament's Civil Liberties Committee; it will shape future negotiations between Council and Parliament.
CPME advocates since the very beginning for health data to be appropriately addressed in this legislation, both to protect patients' data and to not undermine the provision of high quality of care to European citizens. It is thus essential that a distinction is made between primary and secondary use of health data, and to differentiate the consent requirements for both cases. While with the primary use of data it might be difficult to obtain the explicit consent of a patient in addition to his agreement to be treated, for secondary use of identifiable health data, e.g. for insurance or research purposes, the patient should explicitly consent for his data to be processed. This is a broadly recognised principle, contained in the WMA's Declaration of Helsinki. CPME is therefore particularly concerned by some amendments introducing a new notion of broad consent, which will open a "grey zone" and will inevitably lead in practice to legal uncertainties at the detriment of the patients' fundamental rights to control their personal data.
CPME is of the opinion that in healthcare, the notion of consent should remain unchanged; the facilitation of the safe processing of data and patients' rights should be balanced; the bureaucratic complexity should not impede physicians to deliver good quality care to their patients. We call on the legislator to ensure patients the best data protection possible and to protect medical practice in Europe. Further CPME Statements are available here: CPME 2013/026; CPME 2012/064

For further information, please contact:
Constance Colin

Tobacco Products Directive: progress at institutional level

The European Parliament is taking forward its work on the revision of the Tobacco Products Directive 2001/37/EC. Following the publication of the draft Report by Rapporteur MEP Linda McAvan (UK, S&D) in April 2013, the members of the Committee on the Environment, Public Health and Food Safety (ENVI) have tabled approx. 1300 amendments. These propose, i.a., the introduction of standardised packaging for cigarette and roll-your-own tobacco, a ban of point-of-sale display, and the prohibition of cross-border internet sales of products, points also addressed in the CPME position.

CPME welcomes the commitment of many MEPs to work towards conducive provisions for the better protection of health. CPME is also monitoring closely the development of discussions in the Council. As Ireland concludes its successful Presidency, it is hoped that

the forthcoming Lithuanian Presidency of the Council of the EU will be able to advance negotiations, with a view to achieving a sound basis for political agreement by the end of the year. CPME also looks forward to continuing its cooperation with partners in the health community, building on the successful joint initiatives launched in the past months.

For further information, please contact:
Sarada Das.

Final Stage of Revision of Professional Qualifications Directive

On 12 June, the European Parliament and the Council reached a political agreement on the revision of the Professional Qualifications Directive 2005/36/EC. The introduction of a recognition regime through the issuing of a European Professional Card is one of the

major innovations of the revision. For the medical profession, the new Directive will foresee a minimum duration of 5 years consisting of 5500 hours for basic medical training, with the objective of clarifying the existing provision.

CPME had opposed a reduction of the minimum duration of training, therefore an explicit explanation of the clarifying nature of the new provision as guidance for interpretation is welcomed. The Directive shall also establish an alert mechanism for healthcare professionals, through which competent authorities can inform one another if a professional has lost or is restricted in his or her licence to practice. A further novelty is the codification of the principle of partial access. This mechanism is to allow professionals to perform a restricted range of activities of a profession, in cases in which this range of activities constitutes a profession in the home Member State but not in the host Member State. CPME had called for the explicit exemption of the medical profession from the application of partial access in the interest of patient safety, however this was not enshrined in the Directive, but rather left for the Member States to consider in the implementation. CPME will be monitoring closely the final stages of the draft Directive's adoption by the institutions and its transposition into national law.

For further information, please contact:
Sarada Das.

CPME News

♦ The 3rd Global Transparency Reporting Congress took place on 10-11th of April in Brussels during which CPME President, Dr Fjeldsted was an invited speaker. Dr Fjeldsted delivered a presentation on behalf of CPME about 'Physicians and Industry – Transparency for Trust'. For more information about the Congress, please find the programme here .

♦ On 14th of May, the Group of the Progressive Alliance of Socialists & Democrats held a meeting "The rights of the patients and the health professional mobility in the EU" at the European Parliament. The Romanian Chamber of Physicians nominated Dr Cristina Gavrilovici to present the outcomes of a study performed on medical mobility.
For more information on the event, please see here.

NEXT CPME MEETINGS

SAVE THE DATES!

Bucharest, Romania

November 2013	
Friday	Saturday
22	23

Brussels, Belgium

April 2014	
Friday	Saturday
04	05

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CPME News

♦

CPME President, Dr Katrín Fjeldsted is invited as a speaker at the symposium *Leadership in Health Care Organisations* hosted on 12th July 2013 by the University of Graz, in Austria. Dr Fjeldsted will deliver a presentation on the topic of 'Female leadership in health-care'.

♦

Members of the European Association of Senior Hospital Physicians (AEMH) held a Plenary Meeting on the 24-25th May 2013 in Paris, France. The meeting was attended by the CPME President, Dr Katrín Fjeldsted and CPME Secretary General, Ms Birgit Beger. The assembly was preceded by a conference "Role, Practice and Future of the Senior Hospital Physicians" organised on 23rd May 2013 in the same venue.

♦

This year the European Patients Forum (EPF) celebrates its 10th anniversary. A conference was organized with this occasion entitled: '*Towards active patients' involvement in healthcare'*. Discussions were focused on the importance for patients to be pro-active in defining health policy agendas at EU and national level as well as the importance of patients' involvement in the research agenda.

♦

On 7th May 2013 and on 7th June 2013 the British Medical Association (BMA) and the Danish Medical Association (DMA), respectively, visited the premises of the CPME office on Rue Guimard 15, 1040 in Brussels. All representatives of the National Medical Association of CPME are always very welcome within the premises of the Office in Brussels. It has shown, that the exchange about national and European experiences in health policy is always fruitful, full of insights and additionally enjoyable.

Healthy ageing: health literacy and integrated care of frailty

Today Europe is facing an unprecedented demographic trend. The European Union has a total population of more than 500 million, growing nearly two million per year. However, the number of old people is growing rapidly. Eurostat's latest set of population projections show that population ageing is likely to affect all EU Member States over the period from 2011 to 2060.This scenario has led the European Union to study strategies to deal with new needs and new forms of development.

The first step for the European Commission has been to identify active and healthy ageing as a major societal challenge in common with all the European Member States, an area which presents considerable potential for Europe to show leadership in providing innovative responses to this challenge.

In this framework, the European Innovation Partnership on Active and Healthy Ageing plays the main role. The partnership launched in 2010 by the European Commission, aims to improve the general conditions associated with aging, through financing and investment in innovation and improving at European, national and regional levels, co-ordination and coherence between funding for research and innovation.

After 2 years that the European Innovation Partnership on Active and Healthy Ageing has been launched the partnership is delivering its first results. The European Commission has a monitoring and coordination role. According to Ms Maria Iglesia-Gomez, Head of Unit, Innovation for Health and Consumers (DG SANCO), '*the work of the partners of the EIP on Active and Healthy Ageing is providing valuable expertise and evidence on innovative solutions implemented to improve the quality of life of older people. The members of the Action Groups and the European Commission are working to analyse good practices to identify the key elements of successful implementation, transferability and scale up. The practical recommendations and toolkits inspired by the work of the partners provide valuable input to the policy development on integrated care or frailty.'*

Ms Gomez also confirms that *the EIP on AHA will monitor different aspects of the process like the involvement of stakeholders, knowledge transfers and the absorption of innovation by the health systems and the added value for the participating organisations'.*

Within the European Parliament, a report was adopted and published on 1 February by MEP Kartika Tamara Liotard (NL, GUE-NGL). CPME expressed its views with regard to a sustainable and result-oriented continuation of the EIP on AHA (CPME 2013/048).

For instance, there is a need to further emphasize that people should stay active in society as long as possible, either in work, or in a social environment. They must be prevented from getting in an isolated position or become lonely; older people should be entitled to a meaningful place in society. In parallel, calling for such innovations to be user-oriented includes both patients and healthcare professionals, which is ultimately in the interest of patients.

Furthermore, timely and strategic dissemination of the different commitment results as well as evidence based indicators to measure results are more operational but equally important policy tools that so far are being taken into account by the European Commission and next steps have been taken in this regard.

CPME steered this process early on, as part of the High Level Group or Steering Committee that discussed and adopted the Strategic Implementation Plan. This plan is based on three pillars:

1) Prevention, Screening and Early diagnosis;
2) Care and Cure;
3) Active Ageing and Independent living.

CPME dedicated its efforts mainly to prevention of functional decline and frailty. The participation of CPME to the partnership is active and constant. On 7 June 2013, CPME took part in a meeting launched also by the Action Group B3 on "Integrated care", in response to the invitation for commitment. Another important event with the Action Group A3 is scheduled for 4 July which will be the first one aiming to bring together partners representing the "old commitments" and those who responded to the second call in 2013 and thus representing the "new commitments".

Within the A3 group, the *I2FRESCO* initiative was more than welcomed by the European Commission and represents an action for prevention of functional decline and frailty. *I2FRESCO* aims to prevent frailty and functional decline focusing on the patient outside the hospital bed and also directly in patient's environment. This initiative combined five work-streams, among which health literacy and awareness, integrated clinical interven-

CPME News

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A new issue of EuroMeds, the magazine of the European Medical Students' Association (EMSA), has been released during the EMSA meeting in Tbilisi, Georgia, 9-12 May 2013. As central topics, this issue features antimicrobial resistance and the promotion of the prudent use of antibiotics. Articles for EuroMeds have been prepared by medical students, young doctors and institutions with which EMSA has been cooperating closely. Contact regarding EMSA: olga.rostkowska@cpme.eu.

EU Institutions News

♦

The Employment, Social Policy, Health and Consumer Affairs Council meeting takes place between 20 and 21 June 2013 in Luxembourg.
To consult the agenda, please click here.

♦

On 19 June, ENVI Committee discussion of MEP Oreste Rossi (IT, EFD) draft report from the Commission to the Council on the basis of Member States' reports on the implementation of the Council Recommendation (2009/C 151/01) on patient safety, including the prevention and control of healthcare associated infections.
To follow the debate, please click here.

♦

On 20 June, the EU Level Diet Platform will jointly meet together with the High Level Group on Nutrition and Physical Activity.

♦

On 3-4 July, the Action Group of Prevention of Frailty and Functional Decline of the European Innovation Partnership on Active and Healthy Ageing will hold its progress meeting and decide steps ahead.
For further information, please click here.

♦

On 10 July, the ENVI Committee in the European Parliament is scheduled to vote on MEP Dagmar Roth—Behrendt's (DE, S&D) draft report on medical devices as well as MEP Peter Liese's (DE, EPP) draft report on IVD medical devices.

-tion and health economic business models. CPME is an active member of this consortium and is leading the work-stream on health literacy. CPME proposes a specific health literacy strategy on frailty, based on a well-structured management model of inputs and outputs. Since without content answering to the real life needs of the older population, awareness would be void of motivation and ideas, CPME proposes that the best way to answer these needs is by defining the knowledge and the awareness needed about frailty and functional decline. To do this, it has been suggested firstly to identify what are the exact informational needs of carers, patients and social networks; then, identify a set of questions that would need to be answered about frailty in the everyday real life situations of the elderly. CPME is well active in these activities and took also part in a the *I2FRESCO* Executive Committee on 19 April 2013 in Rome where Dr Jacques van der Vliet, Chairman of the CPME Working Group on Healthy ageing, presented the Health literacy program.

Another important input has been given by CPME on 18 April 2013, at the occasion of the conference "Frailty in old age, a public health concern at EU level", in the framework of the European Innovation Partnership on Active and Healthy Ageing (EIPAHA). The meeting took place in Brussels and was attended by all the actors involved in EIPAHA. On behalf of CPME, Prof Dr Gelu Onose (RO) and Dr Jacques van der Vliet (NL) attended two different Working groups as experts. Moreover, Dr Jacques van der Vliet presented on impact of frailty in health and social services. All the recommendations given by CPME during the Conference have been the result of long discussions and work with geriatrician experts who wanted to contribute to building an incisive statement of the CPME. Most of the CPME experts' inputs have been included in the final report of the conference workshop entitled "Impact of frailty in health and social services" reported during the afternoon plenary session.

The final report will be part of the European Commission publication, expected for December 2013, and will be a basis to open discussion to future guidelines on Frailty (foreseen for 2014). Maria Iglesia-Gomez, on behalf of the European Commission addresses her own thank you message, saying "I would like to thank our partners, such as the CPME, Standing Committee of European Doctors for their committed work to drive the agenda of ageing forward."

Miriam D'Ambrosio
CPME EU Policy Intern

For further information, please contact: Anamaria Corca.

Patient safety, not yet there: cooperation and monitoring still needed.

Four years after the Council Recommendation on patient safety, including prevention and control of healthcare associated infections (2009/C 151/01- link to be added) and eight years after the Declaration of Luxembourg, the landmark document on patient safety at European level, patient safety is still at the core of much needed European cooperation, with a first stage of reporting from member states having been completed and an ongoing Joint Action on Patient Safety and Quality of Care. The Joint Action is a European project bringing together national health ministries and health organisations under the tutorship of the European Commission. The Joint Action is lead by HAS (Haute Autorité de la Santé).

Last November the European Commission published a report on the implementation of the Council Recommendation (2009/C151/01) and the European Parliament followed through with its own report within the Committee for Environment, Public Health and Safety (ENVI). MEP Oreste Rossi (IT, EFD), the rapporteur on the matter published his draft report on 27 May and currently it is awaiting amendments by 27 June. The report was discussed within the committee on 19 June.

The draft report concludes that while considerable improvements were made, further progress is still awaited regarding:

1. A EU level classification for patient safety to identify, understand and analysing the factors involved in patient safety.
2. Insufficient steps to improve the provision of healthcare associated infections (HAI)-related information to patients by healthcare establishments and insufficient research support into the field of HAIs.
3. A continued collection of comparable indicators on patient safety by Member States, further cooperation on patient safety, as well as national and/or regional action in this area.

Furthermore, the rapporteur expressed also his support to draw up a second progress report in June 2014 on the Council recommendation (2009/C 151/01).
At the EU level two other initiatives are ongoing : first, the Joint Action on Patient Safety and Quality of Care which prepared for and is entering an implementation stage of safe clinical practices. The CPME has given a considerable contribution to identify such practices.
Secondly, the Platform on Patient Safety and Quality of Care reorganised its efforts to several subgroups, of which one focuses on training of healthcare professionals on patient safety and where CPME will also bring its contribution from the medical point of view in the coming months.

For further information, please contact: Anamaria Corca.

InterQuality partners look ahead to final stage of project

On 10 and 11 June CPME was pleased to welcome its partners in the International Research Project on Financing Quality in Healthcare (InterQuality) to Brussels.
Having entered into its 5th semester, the project looks into the effect of financing systems on the quality of healthcare, focusing on pharmaceutical care, hospital care, outpatient care and integrated care.
The project aims to identify policy recommendations which enable smarter spending in healthcare.
The project consortium, which is led by the Medical University of Warsaw under the coordination of Prof. dr hab. Tomasz Hermanowski, discussed the status quo of research into i.a equity in access to and expenditure on pharmaceuticals , national experiences of pay-for-performance systems for remuneration of GPs/family medicine specialists, and the cost structures for teaching hospitals as opposed to other hospitals.
Furthermore the dissemination of project outcomes was discussed. The communication of project findings shall reflect both the scientific and the policy dimension of the project. Alongside publications in journals, a conference in Brussels will provide a platform for presentation and discussion, bringing together key stakeholders and policy makers. CPME looks forward to the work ahead. One focus of CPME activities shall be the development of guidelines for the communication of healthcare reforms, in close cooperation with the European Patients' Forum (EPF).

For further information, please contact: Sarada Das.

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.

Guest commentary:

CPME values your feedback! Feel free to leave us a message by clicking here.