

# CPME Activity Report, May 2016

## Policy up-dates

# Professional Practice

On 18 December 2015, the European Medical Organisations hosted a joint conference entitle 'Continuous Professional Development for Doctors – Improving Healthcare'. The conference is taking place in Luxembourg with the support of the Ministry of Health. The final conference report is available here.

CPME is continuing action against standards for healthcare services. In terms of interaction with the European Committee for Standardisation (CEN), CPME has asked for the medical profession's opposition to CEN's activities in this area to the be acknowledged in the soon to be launched CEN Strategy on the Standardisation of Healthcare Services (CPME 2016/029 FINAL). At the same time, the European Medical Organisations are continuing to join forces to call upon the European and the Member States to actively oppose standardisation initiatives in this area (CPME 2016/028 FINAL). CPME is monitoring developments actively and seeking out opportunities and for action and alliances.

CPME is monitoring the implementation of the changes to the Professional Qualifications Directive adopted in Directive 2013/55/EU, which all Member States were to have transposed into national law by 18 January 2016. The European Commission will open procedures against Member States who have missed this deadline. The European Commission and Dutch Presidency of the Council of the EU are hosting a series of events reflecting on the process. CPME has been attending these events and will report to the membership (CPME Info 056-2016).

CPME is also continuing its participation in the Joint Action on Health Workforce Planning and Forecasting. The project's final conference took place in Mons on 3-4 May 2016. CPME presented its views for the sustainability of the project's outcomes at a stakeholder session during this event.

#### Transatlantic Trade and Investment Partnership (TTIP)

CPME action on the TTIP and other free trade agreements continues. On the occasion of the 12th round of negotiations on the TTIP in Brussels, CPME spoke at the stakeholder event to reaffirm its position, i.e. the exclusion of healthcare services and medical services from the TTIP, as well as the inclusion of robust safeguards to prevent regulatory standards being lowered (CPME 2016/013). The media reports that the negotiation talks now aim to achieve a political agreement by the end of 2016.

CPME continues to follow developments and seek expert advice to consolidate its response. Most recently, CPME has invited experts to CPME meetings to share the point of the European Commission, industry, patient groups, and Member States on the negotiations. This input has also

underlined the need for action at Member State level. Following the decision of the CPME Board at its meeting on 23 May 2015, the template letter for lobbying action on TTIP was disseminated to the CPME membership (CPME 2015/047 FINAL), which has in turn been disseminated to various ministers of health.

As in the EU-Canada Comprehensive Economic and Trade Agreement (CETA), the TTIP will include an article which allows for the development of 'Mutual Recognition Agreements' (MRA) enabling the mutual recognition of professional qualifications upon initiative of the relevant profession. Some professions, i.a. architects, are exploring the feasibility of such agreements (CPME 2016/022). At its meetings on 8-9 April 2016, CPME launched a discussion on whether further action should be taken on the topic of mutual recognition agreements (MRAs) for doctors' qualifications. This showed the need for a broader debate and consideration of the issue, which will be taken forward at the next meetings in November 2016.

At the September 2015 meeting of the European Medical Organisations' (EMOs) presidents it was agreed to launch the drafting process for a joint statement on the TTIP. A first discussion took place at the meeting of EMOs' presidents in December 2015.

#### Public health

In the context of its contribution to the EU Platform for Diet, Physical Activity and Health, CPME has concluded work on the 'Health Village' Toolbox. The 'Health Village' intervention aims to provide a framework for doctors and other healthcare professionals to bring messages on healthy lifestyles to the public outside the usual setting for healthcare services, for example by providing healthy lunch ideas at a school's summer fete or stalls with information on healthy workplaces at a company's team day. The aim is not to provide visitors with an individual diagnosis, but rather to raise their awareness for healthy lifestyle options. The 'toolbox' will offer guidance and materials which are to enable doctors to plan and implement the intervention in their local community and beyond. It is available on the CPME website for public distribution. As its next contribution to the EU Platform for Diet, Physical Activity and Health, CPME will carry out a mapping of guidelines to primary care physicians on promoting healthy lifestyles.

CPME also launched a new Working Group to prepare a CPME policy on obesity, addressing i.a. the question of recognising obesity as a disease. This is motivated by the on-going policy debate and the focus of European Obesity Day 2016, which CPME supported with a statement.

CPME has co-signed a joint letter together with the European Heart Network (EHN), Nestlé, the European Consumer Organisation (BEUC) et al. calling for a legislative limit for the amount of industrially produced trans fatty acids in foods. The Commission has announced regulatory action on this issue, the preparatory process, including an impact assessment, will be launched shortly.

CPME is also monitoring developments relating to tobacco and alcohol policy. On tobacco policy, Member States must complete the implementation of the Tobacco Products Directive 2014/40/EU by 20 May 2016; CPME will monitor the progress made. At the same time, CPME is still supporting the full implementation of the WHO Framework Convention for Tobacco Control (FCTC), in particular in terms of the involvement of tobacco industry in policy discussions. CPME will also

support a joint event led by Smoke Free Partnership to mark the occasion of World No Tobacco Day on 31 May 2016.

As regards alcohol policy, CPME is observing developments relating to European Commission action on this dossier as well as the court case on the Scottish law on minimum unit pricing of alcohol. As the European Court of Justice ruled that minimum unit pricing can be permissible as a public health measure if certain criteria are fulfilled, the law will now be examined against these criteria by the Scottish court. A hearing is scheduled for June 2016.

# Chronic conditions

CPME contributed to the REISEARCH campaign on chronic conditions and participated recently to two events: a European Commission conference addressing this to member states and stakeholders such as CPME where chronic conditions were recognised as a societal problem and the second event on 26 April organised by Atomium Culture and EISMD addressed results of the REISEARCH campaign on chronic conditions as well more generally the need to bridge the gap between science, media and society. Dr Jacques de Haller, CPME President intervened to underline that the link between chronic conditions and innovation and more generally when discussing innovation we should bear in mind that a balanced opinion requires balanced information and that the doctor is not a magician and a health in all policy approach is very much needed to address chronic conditions.

## Patient safety

Four main activities took place in the past 8 months on patient safety:

- 1. CPME presented at the EU Health Policy Forum meeting on 6 April 2016 reminding of the need to advance with preparations of a proposal for a sustainable framework on patient safety, an item asked for from the Council in its conclusions of December 2014. A summary is available here: http://ec.europa.eu/health/interest\_groups/docs/ev\_20160405\_flash\_en.pdf.
- 2. Lobbying the text of the Council conclusions on Patient Safety, 1 December 2014 CPME actively monitored and lobbied the negotiations that led to the Council Conclusions on Patient Safety, 1 December 2014. Two worrying aspects for the medical profession were taken out from the draft conclusions: point d of the draft conclusions referred to the development of voluntary guidelines on standards and the official recognition of the Expert Group on Effective Ways of Investing in Health as well as more generally formulations that extend beyond the remit of art 168 TFEU and that may require standardization of medical services done by bodies outside the medical profession.
- 3. CPME responded to a consultation from the European Commission on the Future Agenda of Patient Safety at EU level

CPME is a member of the <u>Patient Safety and Quality of Care Expert Group at EU level</u>, represented by Dr Katrín Fjeldsted, CPME President and Rapporteur on Patient Safety.

On 12 March, the Executive Committee decided on a set of amendments and comments to the European Commission consultation on the 'Future activities in the fields of patient safety and quality of care' presented to the PSQC Expert Group. The CPME underlines the need of

continuous policy in the existing framework with the explicit and meaningful inclusion of stakeholders, like professional associations. The proposal follows <u>Council conclusions on Patient Safety</u> of 1 December 2014 when the European Commission and Member States were invited to set-up, by December 2016, a framework for a sustainable EU collaboration on patient safety and quality of care, also taking into account the results of the "Joint Action on patient safety and quality of care" (PaSQ).

4. CPME contributed with policy advice on patient safety and Anti-microbial- resistance (AMR) to an EP own initiative report entitled 'safer healthcare in Europe: improving patient safety and fighting AMR'

On 2 February 2015, letters outlining CPME's position on patient safety and AMR were sent to MEP Piernicola Pedicini, MEP Margrete Auken, MEP Cristian-Silviu Buşoi, MEP Marit Paulsen and MEP Christel Schaldemose, rapporteur and shadow rapporteurs on the draft own-initiative report on "safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance" (2014/2207(INI).

#### eHealth

<u>Data protection:</u> CPME monitored the development of negotiations on the General Data Protection Regulation (GDPR). The final phase of the negotiations (trialogue) took place at the end of 2015. On 17 September 2015, the CPME adopted the 'CPME recommendations ahead of trialogue negotiations on the General Data Protection Regulation (2012/0011(COD))' (<u>CPME 2015/087FINAL</u>).

The final interinstitutional agreement on this Regulation was reached on 15 December 2015, despite the divergent views especially on the definition of consent and on further use of data for incompatible purposes.

The Regulation was formally adopted by the Council on 8 April 2016 and by the European Parliament on 14 April 2016. The official texts should shortly be published in the Official Journal of the European Union in all official languages. The new rules will become applicable two years thereafter.

<u>mHealth:</u> The European Commission published on 10 April 2014 a green paper on mobile Health and opened accordingly a public consultation to gather the views of stakeholders on the matter. On 5 June 2014, CPME adopted a response to this public consultation (<u>CPME 2014/052 FINAL</u>).

A multi-stakeholder event was organised by the Directorate-General for Communications Networks, Content and Technology (DG Connect) on 6 July 2015. The report of the meeting is available here: <a href="CPME">CPME Info 208-2015</a>.

Follow-up actions were undertaken by DG Connect with the creation of two sub-groups on assessment guidelines and on data privacy. As part of these actions, CPME commented the Draft Code of Conduct on privacy for mobile health applications on 8 December 2015 (CPME 2015/121 FINAL). In addition, CPME is represented in the working group on mHealth assessment guidelines by Dr Lucas.

Finally, the CPME Board adopted the CPME policy on mobile health on 31 October 2015 (CPME 2015/095 FINAL).

<u>CPME eID policy:</u> CPME continues to promote its policy agreement on electronic ID systems for physicians (<u>CPME 2013/039</u>). EU Policy advisor, Constance Colin, presented the policy at the multistakeholder workshop of the EXPAND project, on 28 January (presentation: <u>CPME Info 087-2015</u>). Following this event, CPME was contacted by the Directorate General for Informatics of the European Commission (DG DIGIT) as they showed interest in the CPME initiative. A meeting was organised with Alice Vasilescu, IT project officer. The report of the meeting is available here: <u>CPME Info 048-2015</u>. A second meeting took place with Dr Georgios Raptis on 30 April 2015 to further discuss the technical aspects of the policy.

# Pharmaceutical policy

Transparency of physicians-industry relationships: On 15 November 2014, the CPME Board adopted the 'CPME guidelines on the transparency of relationships between physicians and the healthcare industry' (CPME 2014/055). In order to ensure a swift communication of CPME's activities to promote ethical relationships with industry, the Executive committee agreed to give more visibility to the CPME Guidelines and to produce a leaflet which would outline the aim of the policy as well as the principles it addresses. The electronic version of the leaflet is available <a href="here">here</a>. In addition, in the framework of the <a href="platform of ethics and transparency">platform of ethics and transparency</a> and the adoption in 2012 of a list of guiding principles promoting good governance in the pharmaceutical sector, the European Commission is now planning to create a website to monitor the implementation of the List of guiding principles. CPME responded to the questionnaire developed to this aim (<a href="CPME">CPME</a> 2015/027 FINAL). A stakeholders meeting was held on 15 April 2015 in Riga to discuss the outcomes of the questionnaire. Prof. André Herchuelz attended the event on behalf of CPME.

European Medicines Agency (EMA): Prof. André Herchuelz and Prof. Wolf-Dieter Ludwig are candidates, on behalf of CPME, to the EMA Management Board for the upcoming new mandate (2016-2019). Four members from Civil Society will be appointed: two members representing patients' organisations, one member representing doctors' organisations and one member representing veterinarians' organisations. The European Commission will draw up a list of candidates to send to the Council, which will then appoint the new members in consultation with the European Parliament (December 2015).

In the framework of the Patient Safety and Quality of Care WG, CPME was consulted on the European Medicines Agency (EMA) Good Practice Guides on Medication Errors. The CPME responses to the consultation are available here: CPME 2015/062 FINAL

In the framework of the EU Clinical trials regulation (Regulation (EU) No 536/2014), the EMA adopted a new policy on the publication of clinical trials data, which entered into force on 1 January 2015 (the policy is available <a href="here">here</a> / CPME had contributed to preliminary consultation: <a href="here">CPME 2013/088</a>). Following the adoption of the EMA policy, a public consultation was launched on how transparency rules contained in the new Regulation should apply to the EMA clinical trial database. The proposals of EMA especially address what type of personal data should be covered and what is "commercially confidential information". CPME responded to the public consultation

by insisting on the need for transparency and that economic interests of drug developers should not take precedence over the public legitimate interest to be informed about the drugs available on the EU market: <a href="Mailto:CPME 2015/008">CPME 2015/008</a>). Dr Erzsébet Podmaniczky, Chair of the CPME Pharmaceuticals WG and CPME representative at the HCP WP in EMA, attended a meeting on biosimilars (5 March 2015: <a href="mailto:agenda">agenda</a>). Dr Podmaniczky was also involved in the activities of the HCP WP of EMA. The annual report of this WP is available here.

Antimicrobial resistance (AMR): As a follow-up to previous commitments of CPME in the field of AMR, CPME issued jointly with the Federation of Veterinarians of Europe (FVE) and the Council of European Dentists (CED) a leaflet on the responsible use of antibiotics. The <u>leaflet</u> directly addresses Doctors, Dentists and veterinarians, and is available in all EU languages <u>here</u>.

CPME continues its close collaboration with the European Centre for Disease Prevention and Control (ECDC) in preparation of the annual European Antibiotics Awareness Day (EAAD).

CPME has also taken action with regard to the European Parliament's draft own-initiative report on "safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance" (2014/2207(INI).

<u>Biosimilars</u>: On 6 October 2015, the European Commission's Directorate-General for Internal Market, Industry, Entrepreneurship, and SME's (DG Growth) organised a workshop on the uptake of biosimilars in Europe. Prof. Herchuelz presented the <u>CPME position on biosimilars</u> and moderated the discussion on doctors' views and perspectives on biosimilars. Representatives from national medical associations and from the World Medical Association also attended the event.

A second stakeholder event on biosimilar medicinal products will be held by the European Commission on 20 June 2016 in Brussels. This workshop will end with the launch of the updated Q&A for patients and for healthcare professionals.

CPME is currently involved in this process of Q&A revision as a follow-up to the publication in 2013 of the Consensus Paper "What you need to know about biosimilar medicinal products". This paper was drafted by the Working Group on biosimilars, under the leadership of DG Growth.

## Healthy ageing

On 30 April 2015, CPME and its partners released a study on health literacy of functional decline and frailty of doctors and older people.

The present study generated data **for the first time** on the levels of health literacy of functional decline and frailty for doctors and older patients (60+ years old) in Latvia and Romania. Furthermore, the study tackles not only the lack of data on the topic but it provides insight from two EU member states, a Central-Eastern and a Baltic member state, that (also) struggle with the decrease in fertility coupled with high percentage of outward migration predominantly within the early working age population. Projections on the aging of the population in Latvia and Romania are particularly worrying as the decrease in fertility, migration and life expectancy that is below that of the EU-15 member states, since these developments accelerate the impact of the projected demographic challenges at an unprecedented rate. Please find <a href="here">here</a> the Executive Summary, Policy Recommendations and the full study.



# Medical devices

Upcoming trialogues to discuss the legislative proposals on medical devices are expected in May 2016. CPME is closely monitoring the negotiation process with a view towards patient safety and the need for vulnerable groups included in clinical investigations to benefit from the results.

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#### Communication activities

## External communication:

- <u>CPME Newsletter</u>: This is a quarterly publication disseminated to EU policy-makers, EU media, CPME members, Health NGOs, EMOs and main stakeholders of interest (please, find <u>here</u> the newsletter section on the CPME website).
- <u>CPME Press releases</u>: Every year CPME issues different press releases on relevant decisions made by the CPME or specific events in the health sector. They are duly published on the website in a specific section (link available <u>here</u>) and sent to an active media network across Europe.
- <u>CPME in the media</u>: The CPME is actively collaborating with national and international press and TV channels. The CPME President, the Vice-presidents and the Secretary General are quite often invited to release statements, interviews or write opinion articles and scientific pieces. The Secretariat created also a special sector on the website with the aim to collect all the media materials regarding the CPME. Please, click here to visualise it.
- <u>CPME video</u>: Since 2013, the CPME produces videos and recently decided to invest more on audio-visual material. For this reason, on the CPME website has been activated a new section (here) completely dedicated to the videos produced from the Secretariat.
- <u>CPME communication campaigns</u>: in order to achieve the best results for its policies, CPME is making use of different media campaigns, planning series of newspaper articles, press releases, social media activities, etc. Recent campaigns include:
  - 1) Participation to the European Antimicrobial Awareness Day (#EAAD)
  - 2) Participation to the REISearch media campaign (#science4health)
  - 3) In January 2015, CPME decided participation to the EPF Patient empowerment campaign (#patientsprescribe). Support was offered by participation to several Steering Group meetings along with other stakeholders such as pharmacists (PGEU) and nurses.
- <u>CPME leaflets and Manifesto</u>: The CPME produces all the necessary material to introduce its mission statement and main policies during every formal or informal meeting. With the occasion of the 2014 European elections, for instance, the Secretariat following the directives of the CPME members created the CPME Manifesto, available <a href="here">here</a>. In April 2015, the CPME produced also a leaflet about the guidelines on transparency, reachable <a href="here">here</a>.
- <u>CPME conferences and meetings</u>: The CPME is active in public relations activities. Every year, at least one big conference is organised, focused on relevant policies and attended from CPME members, experts, main stakeholders and EU institutions' representatives. <u>Recent conference</u>:
  - 1) Luxembourg, 18 December 2015: joint conference on 'Continuing Professional Development for Doctors Improving Healthcare'.

- <u>Social media</u>: CPME is equally present on social media, through Twitter since December 2012. The CPME twitter account is daily updated and is carefully followed by the European Institutions, in particular the DG SANTE, DG EMPL, DG GROWTH, European Parliament, Mr Martin Schulz (President of the European Parliament) and from the main stakeholders in the healthcare sector. The CPME Secretariat staff makes active use of this social media to share messages and for lobbying purposes. Please, click here to follow.
- <u>CPME website external section</u>: The CPME website is daily updated under its different sections. In particular it has a section completely dedicated to the CPME policies where externals can reach the latest development of the CPME activities. CPME uses the website to promote its activities and policies.

#### Internal communication:

- <u>CPME Monthly Bulletin</u>: The CPME Monthly Bulletin is a periodical e-mail disseminated among the CPME members. The aim of this tool of communication is to keep the CPME members informed on the main decisions taken from the CPME Executive Committee and on the most important policies' updates. For your reference, please find here the April 2016 issue.
- <u>CPME website internal section</u>: The CPME website presents a public version and a version entirely dedicated to the CPME members, accessible by using username and password, where all the documents are reachable by the searching function. Moreover, to facilitate the communication with CPME members and to better organise the dissemination activity, a new section has been created, entirely dedicated to <u>surveys</u>. On September 2015 a new calendar section accessible only for CPME members has been created to inform the CPME membership about external activities carried out by the Secretariat. The calendar is located under 'members section' and available here.

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## Internal Affairs

At the meeting of the CPME General Assembly and Board in Brussels on 9 April 2016, CPME welcomed the Georgian Medical Association as an observer to CPME.

On the same occasion, Ms Annabel Seebohm was appointed CPME Secretary General. She started on 1 May.

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## **Adopted policies**

CPME Statement on classifications of professional qualifications and practice
 On 12 May 2016, the CPME Executive Committee adopted the 'CPME Statement on classifications of professional qualifications and practice' (CPME 2016/055 FINAL)

- CPME contribution to WHO Expert Group of the Commission on Health Employment and Economic Growth

On 8 April 2016, the CPME Executive Committee adopted the 'CPME contribution to WHO Expert Group of the Commission on Health Employment and Economic Growth' (CPME 2016/043 FINAL).

- CPME Policy on Sex and Gender in medicine
   On 9 April 2016, the CPME Board adopted the 'CPME Policy on Sex and Gender in medicine' (CPME 2016/036 FINAL).
- CPME response to public stakeholder consultation on next phase of EU-US cooperation in eHealth/Health IT

On 15 March 2016, the CPME Executive Committee adopted the 'CPME response to public stakeholder consultation on next phase of EU-US cooperation in eHealth/Health IT' (<u>CPME 2016/026 FINAL</u>). The objective of this consultation is to gather comments and inputs which will be used by the European Commission to finalise its roadmap.

- CPME Comments to the Draft Code of Conduct on privacy for mobile health applications

  On 21 January 2016, CPME welcomed the opportunity to comment on the <u>Draft Code of Conduct on privacy for mobile health applications</u>. The purpose of this code is to foster justified trust among users of mobile applications which process personal data that includes data concerning health.
- Memorandum of Understanding for future cooperation between CPME and the European Region of the World Confederation for Physical Therapy/Physiotherapy

  On 21 January 2016, the Presidents of CPME and the European Region of the World Confederation for Physical Therapy/Physiotherapy signed a Memorandum of Understanding for future cooperation. The Memorandum highlights the benefits of interprofessional collaboration for the quality of care in Europe. It identifies a series of topics of common interest relating to patients' rights, professional practice, healthcare and education. CPME looks forward to the implementation of these objectives.
- Consensus Statement of the European Medical Organisations on Continuous Professional Development, Luxembourg, 2015

On 18 December 2015, the European Medical Organisations the AEMH (European Association of Senior Hospital Doctors), CEOM (European Council of Medical Orders), CPME (Standing Committee of European Doctors), EANA (European Working Group of Practitioners and Specialists in Free Practice), EJD (European Junior Doctors), EMSA (European Medical Students Association), FEMS (European Federation of Salaried Doctors), UEMO (European Union of General Practitioners) and UEMS (European Union of Medical Specialists) adopted the 'Consensus Statement of the European Medical Organisations on Continuous Professional Development'.

 CPME Response to the Public consultation on Standards in the Digital Single Market: setting priorities and ensuring delivery



On 10 December 2015, the CPME Executive Committee adopted the 'CPME Response to the Public consultation on Standards in the Digital Single Market: setting priorities and ensuring delivery' (CPME 2015/115 FINAL).

- CPME Commitments to the EU Platform on Diet, Physical Activity and Health 2016-2017
  On 19 November 2015, the CPME Executive Committee adopted the 'CPME Commitments to the EU Platform on Diet, Physical Activity and Health 2016-2017' (CPME 2015/103 FINAL).
- CPME Comment on consultation on Directive 92/83/EEC Structures of excise duty on alcohol and alcoholic beverages
  - On 19 November 2015, the CPME Executive Committee adopted the 'CPME Comment on consultation on Directive 92/83/EEC Structures of excise duty on alcohol and alcoholic beverages' (CPME 2015/114 FINAL).