

To: CPME members

Brussels, 29 January 2019

CPME Strategy Meeting 9 January 2019 and call for expression of interest

Dear Members,

Our very best wishes for 2019. We hope you had pleasant holidays and a good start to the new year. On 1 January 2019 the new Executive Committee (EC) started its term. In a strategy meeting 9 January 2019, the EC discussed the political and organizational outlook for this term.

1. Policy Priorities

The EC ranked all policies within four clusters: Professional practice and patients' rights, E-health, Public health and disease prevention, Pharmaceuticals and healthcare products. The policies within these clusters were classified as 'active dossiers', 'passive monitoring' and 'silent dossiers'. Policies ranked under 'passive monitoring' are only served if there is capacity, as 'active dossiers' are priority dossiers. Members are updated on 'passive monitoring' dossiers when appropriate in the Monthly Bulletin and working group mailings. When classified as 'silent dossiers' all activities are suspended. Please consult the ranked policies within the four clusters attached.

2. Call for Expressions of Interest

The EC kindly invites all CPME Members to express their interest in playing an active role within CPME. Please find in Annex 1 an overview. Current Rapporteurs and Working Groups Chairs are considered to continue.

Please note that all expressions of interest which are also possible on spot will be submitted to the Board during the CPME meeting in Valletta, Malta in April 2019.

3. Role of Vice Presidents

The EC is of the opinion that the four Vice-Presidents should have a more prominent role in supervising CPME policies as outlined in Art. 11 of the Rules of Procedures by constituting a bridge between Rapporteurs and Working Groups Chairs. All policies are grouped into four clusters to which a supervisory responsibility is assigned as follows:

- <u>E-health</u> : Dr Ray Walley
- <u>Pharmaceuticals and healthcare products</u>: Dr Christiaan Keijzer



- Professional practice and patients' rights: Dr Daiva Brogienė
- <u>Public health and disease prevention</u>: Dr Ole Johan Bakke.

Matters related to the general EU political outlook are supervised by the Executive Committee.

We hope the EC deliberations will be beneficial to the CPME policy work and processes. Certainly, we remain at your disposal for suggestions or questions.

Yours sincerely,

- K

Prof. Dr Frank Ulrich Montgomery President

Annexes:

- 1. Overview
- 2. Tables with ranked policies

Annabel Seebohm, LL.M. CPME CPME Secretary General

Active dossiers

-	Vaccination Alcohol, Diet, Nutrition, Physical Activity and Tobacco Policy Climate change and medicine	CPME Rapporteur on Vaccination: Dr Jacques de Haller CPME WG on Healthy Living – Chairperson: Dr Patrick O'Sullivan CPME Rapporteur on Climate change and medicine: Dr Martin Balzan
-	Health system, European Semester, financing and tax policy, health inequalities	CPME Rapporteur on Health Systems: Interest expressed by Prof. Dr Frank Ulrich Montgomery and Dr Jacques de Haller
-	Collaborative practice/Skill mix, Health workforce, Working time Professional Regulation & qualifications	CPME Rapporteur on Collaborative practice: Interest expressed by Dr Jacques de Haller CPME WG on Professional Practice – Chairperson: Prof. Dr Frank Ulrich Montgomery
-	Patient Empowerment & Health Literacy	CPME Rapporteur on Patient Empowerment: Dr Katrín Fjeldsted
-	Antimicrobial resistance (AMR)	CPME Rapporteur on AMR: Dr Maciej Hamankiewicz
-	Access to medicines and drug shortages	CPME WG on Pharmaceuticals – Chairperson: Dr Erzsébet Podmaniczky
- - -	Health Technology Assessment (HTA) Artificial Intelligence Data protection eHealth	CPME Rapporteur on HTA: Dr Bernard Maillet CPME Rapporteur on Artificial Intelligence: To be appointed CPME Rapporteur on Data protection: Mr Sjaak Nouwt CPME WG on eHealth – Chairperson: Dr Bernard Maillet

Passive monitoring dossiers

-	Refugee health	CPME WG on Refugee Health – Chairperson: Dr Marily Passakiotou
-	Defensive medicine	CPME Rapporteur on Defensive medicine: Dr Daiva Brogienė
-	Standardisation	CPME Rapporteur on Standardisation: Prof. Dr Frank Ulrich Montgomery / External expert: Prof. Dr med. Johann Wilhelm Weidringer
-	Self-Care	CPME Rapporteur on Self-care: Dr Jacques de Haller
-	Patient safety and quality of care	CPME Rapporteur on Patient safety and quality of care: Dr Katrín Fjeldsted
-	Transparency and ethics	CPME WG on Pharmaceuticals – Chairperson: Dr Erzsébet Podmaniczky
-	Clinical Trials	CPME Rapporteur on Clinical trials: Prof André Herchuelz
-	Biosimilars	CPME WG on Pharmaceuticals – Chairperson: Dr Erzsébet Podmaniczky
-	Off-label use of medicines	CPME WG on Pharmaceuticals – Chairperson:
	and drug repurposing	Dr Erzsébet Podmaniczky
-	Falsified medicines	CPME WG on Pharmaceuticals – Chairperson: Dr Erzsébet Podmaniczky
-	Personalised medicine	CPME WG on Pharmaceuticals – Chairperson: Dr Erzsébet Podmaniczky
-	Pharmaceuticals in the environment	CPME WG on Pharmaceuticals – Chairperson: Dr Erzsébet Podmaniczky

- Information to patients
- Medical devices
- mHealth
- Environmental and Occupational Health
- Mental Health
- Healthy and Active Ageing
- Chronic conditions management

- CPME WG on Pharmaceuticals Chairperson: Dr Erzsébet Podmaniczky
- CPME Rapporteur on Medical devices: Dr Katrín Fjeldsted
- CPME Rapporteur on mHealth: Mr Sjaak Nouwt
- CPME Rapporteur on Environ. and Occupational Health: Dr Jacques de Haller
- CPME Rapporteur on Mental Health: Dr Jacques de Haller CPME Rapporteur on Healthy and Active Ageing: Prof. Dr Gelu Onose
- CPME Rapporteur on Chronic conditions management: Prof. Dr Gelu Onose



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Public Health and Disease Prevention Supervised by CPME Vice-President Dr Ole Johan Bakke

CPME Rapporteur on Vaccination: Dr Jacques de Haller

CPME Rapporteur on Mental Health: Dr Jacques de Haller

CPME WG on Healthy Living – Chairperson: Dr Patrick O'Sullivan

CPME Rapporteur on Climate Change and Medicine: Dr Martin Balzan

CPME Rapporteur on Healthy and Active Ageing: Prof. Dr Gelu Onose

CPME Rapporteur on Chronic Conditions Management: Prof. Dr Gelu Onose

CPME Rapporteur on Environmental and Occupational Health: Dr Jacques de Haller

Active dossiers

- Vaccination
- Alcohol; Tobacco; Diet, Nutrition and Physical Activity
- Climate change and Medicine

Passive monitoring dossiers

- Environmental and Occupational Health
- Mental Health
- Healthy and Active Ageing
- Chronic conditions management

Silent dossiers

- Action against cancer

For a full overview of past activities relating to the dossiers below, please consult CPME 2018/051.



'Active dossiers'

Information on dossier	Objective	Current input	CPME Secretariat Recommendation for Future Activities	
	Vac	ccination		
 High priority at EU level CPME has a clear position that the prevention of communicable diseases through vaccination is safe and effective CPME cooperates with the European Centre for Disease Prevention and Control (ECDC) 	→ Increase vaccination coverage in Europe, tackle vaccine hesitancy	 Monitor the developments and, where appropriate, promote the CPME policies on vaccination Participation in the new EU joint action on vaccination (EU-JAV) and its stakeholder forum Participation in the annual WHO World Immunization Week and the European Immunisation Week by supporting different communication activities Providing and briefing speakers Internal communication: EC briefing, CPME bulletin / External communication: CPME newsletter, Press Release, Twitter 	 Participation in the EU-JAV, its selected work packages, and its stakeholder forum Active participation in the WHO World Immunization Week supported by appropriate communication activities Continuation of communication activities Monitor the Commission's proposal to convene a Coalition for Vaccination to bring together European associations of healthcare workers 	
Alcohol				
 CPME has a long-standing commitment to tackling alcohol- related harm both in direct patient contact and through their NMAs. 	 → Alcoholic beverages should be labelled the same way as non-alcoholic products → Minimise the exposure of children and youth to alcohol marketing 	 Briefing of CPME WG Chair and CPME WG on Healthy Living Contributing to the ongoing alcohol labelling negotiations (meetings with The Commission and MEPs); working 	 Promote the CPME policy on alcohol labelling to end the exemption of alcoholic beverages from EU Regulation 1169/2011 	

 CPME has adopted policies on labelling of alcoholic beverages and on raising awareness i.a. for the dangers of drink-driving, the implications of alcohol-related harm for children and young people, and the impact of alcohol at the workplace. Moreover, CPME contributed to the revision of the Audio-Visual Media Services Directive, to protect children from commercial communications for alcohol and unhealthy food. 		 together with an informal coalition of health NGOs and with other EMOs. CPME co-signed a joint letter to MEPs on wine labelling under the Common Agricultural Policy (CAP). CPME, together with other NGOs, is invited to re-join the European Commission's European Alcohol and Health Forum. The future of the Forum was discussed in June 2018 but the Commission has made no progress to re-start the work. Internal communication: EC briefing, CPME bulletin / External communication: CPME newsletter, media coverage EU, Twitter 	 advertising and self-regulation Monitoring Commission's forthcoming assessment of the alcohol industry's commitment to develop self-regulation on labelling of the list of ingredients and the nutrition declaration for alcoholic beverages, including communication activities together with a coalition of health NGOs Continuation of communication activities CPME intends to engage with other Brussels health NGOs in the framework of a European alliance aimed at minimising the exposure of children and youth to health-harmful marketing, in particular of alcohol and unhealthy foods WG on Healthy Living plans to draft a 	
			policy paper on healthy living	
Diet, Nutrition and Physical Activity				
 CPME's focus is on preventing disease by promoting healthier choices. We also call on policy- makers to follow the evidence- base for creating a regulatory 	 → Reduce obesity in Europe and make Europeans eat better and move more → Encourage doctors to promote healthy lifestyles with healthy diets and adequate exercise 	 Monitor the developments and, where appropriate, promote the CPME policies on obesity and self- regulation and advertising of unhealthy food 	 Finalising the current commitment and submitting a new one to the EU Platform for Action on Diet, Physical Activity and Health 	



 framework which ensures the best possible information to consumers. CPME has recently adopted policies on trans fats and obesity CPME is part of the EU Platform for Action on Diet, Physical Activity and Health to tackle current trends in diet and physical activity. 		 Briefing of CPME WG Chair and CPME WG on Healthy Living Participation in the in the work of the European Commission's EU Platform for Action on Diet, Physical Activity and Health. Being a stakeholder at European Food Safety Authority (EFSA) to provide strategic input to EFSA's work plans and future priorities, present and discuss their own work, and network with other stakeholders. Internal communication: EC briefing, 	 CPME intends to engage with other Brussels health NGOs in the framework of a European alliance aimed at minimising the exposure of children and youth to health-harmful marketing, in particular of alcohol and unhealthy foods WG on Healthy Living plans to draft a policy paper on healthy living Continuation of communication activities
		CPME bulletin / External communication: CPME newsletter, media coverage EU, Twitter	
	Toba	cco Policy	
 CPME is strongly in favour of effective regulatory action, both at national and EU level, to ensure that access to and consumption of tobacco products as well as their promotional information is strictly regulated with a view to progressively achieving a total prohibition. CPME also discusses doctors' roles in encouraging smoking cessation 	→ Reduce smoking in Europe, increase tobacco taxation	 Briefing of CPME WG Chair and CPME WG on Healthy Living Processing of news & information and dissemination to members Cooperation with the Smoke Free Partnership (SFP) on tobacco taxes and illicit trade of tobacco products Participation in the event organisation of the annual WHO World No Tobacco Day Giving responses in consultations Internal communication: EC briefing, CPME bulletin / External 	 WG on Healthy Living plans to revise the CPME Position on nicotine delivery products including electronic systems (e-cigarettes) WG on Healthy Living plans to draft a policy paper on healthy living Continuation of communication activities Active participation in the World No Tobacco Day supported by appropriate communication activities



and foster the exchange of good practices.		communication: newsletter, Twitter; communication activities related to the World No Tobacco Day	- Provide the medical profession's perspective in future EU activities;
	Climate Char	nge and Medicine	
 CPME action on environmental health addresses the health impact of factors such as air, noise or water pollution to work towards a containment and roll-back of damage to the environment. CPME also contributes to the debate on climate change, in particular on global warming and the loss of biodiversity, to highlight the implications for health. 	→ Encourage doctors to raise awareness of environmental issues → Provide the medical profession's perspective	 Briefing of CPME Rapporteur and other specialists including the preparation for media requests Processing of news & information and dissemination to members Cooperation with the Health and Environment Alliance (HEAL); possible participation in their delegation at the UN climate change conferences (COP); reviewing and endorsing their reports and studies CPME published the Briefing for EU Policymakers of the Lancet Countdown 2018 Report Internal communication: EC briefing, CPME bulletin / External communication: media coverage EU, Twitter 	 Continuation of communication activities Possible future cooperation with HEAL on air quality Provide the medical profession's perspective in future EU activities

PURPOSE: For discussion		
CONCERNING: CPME Activities		
AUTHOR: CPME Secretariat		

'Passive monitoring'

These dossiers are only served if there is capacity, active dossiers take precedence. Members are updated when appropriate in the Monthly bulletin/Working Groups.

Environmental and Occupational Health			
 Since 2011, CPME has been member of the 'Healthy Workplaces' partnership hosted by the EU Agency for Health and Safety at Work (EU-OSHA). The surrent 2018 2010, Healthy Workplaces, Compaign is artitlad. Managenetic activities of the surrent set of the s	\rightarrow Passive monitoring and ad hoc reaction \rightarrow Organise one EU-OSHA campaign-related activity (e.g. conference, seminar, workshop or training)		
- The current 2018-2019 Healthy Workplaces Campaign is entitled Manage Dangerous Substances			
Mental	l Health		
 CPME has focussed on the specific implications of mental health in various thematic contexts, including workplace settings, in connection with ageing and in relation to the medical profession itself. CPME is a member of the Expert Platform on Mental Health, a multi-stakeholder. 	→ Monitoring and ad hoc reaction, e.g. endorsing a call to action to improve patient empowerment and self-management of care in mental health		
Healthy and A	Active Ageing		
- CPME is a member of the European Innovation Partnership on Active and Healthy Ageing (EIPAHA) at EU level and participates in the action group meetings on integrated care and prevention of frailty and functional decline.	\rightarrow Monitoring and ad hoc reaction \rightarrow Participation in the EIPAHA meetings		
Chronic conditions management			
- CPME is partnering in the EU joint action CHRODIS+ to implement good practices for chronic diseases.	\rightarrow Monitoring and ad hoc reaction \rightarrow Participation in the JA CHRODIS+ work package on communication		



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Silent dossiers

All activities are suspended on these topics.

Action Against Cancer

- CPME continues to attend some selected cancer-related events in order to stay updated on the developments in the field.



Professional Practice and Patients' Rights

Supervised by CPME Vice-President Dr Daiva Brogienė

Active dossiers			
- Health systems, health inequalities, European Semester, financing and tax policy	CPME Rapporteur on Health Systems: Interest expressed by		
	Prof. Dr Frank Ulrich Montgomery and Dr Jacques de Haller		
 Collaborative practice/Skill mix, Health workforce, Working time 	CPME Rapporteur on Collaborative practice: Interest expressed by		
	Dr Jacques de Haller		
- Professional regulation & qualifications	CPME WG on Professional Practice – Chairperson:		
	Prof. Dr Frank Ulrich Montgomery		
- Patient Empowerment & Health Literacy	CPME Rapporteur on Patient empowerment: Dr Katrín Fjeldsted		
Passive monitoring dossiers			
- Refugee health	CPME WG on Refugee Health – Chairperson: Dr Marily Passakiotou		
- Defensive medicine	CPME Rapporteur on Defensive medicine: Dr Daiva Brogienė		
- Standardisation	CPME Rapporteur on Standardisation: Prof. Dr Frank Ulrich		
	Montgomery / External expert: Prof. Dr med. Johann Wilhelm		
	Weidringer		
- Self-care	CPME Rapporteur on Self-care: Dr Jacques de Haller		
- Patient safety and quality of care	CPME Rapporteur on Patient safety and quality of care: Dr Katrín		
	Fjeldsted		

- Silent dossiers
- Ethics
- TTIP and other FTAs
- Sex and gender

For a full overview of past activities relating to the dossiers below, please consult CPME 2018/051.



'Active dossiers'

Information on dossier	Objective	Current input	CPME Secretariat Recommendation for Future Activities
	Health systems, health inequalities, Euro	opean Semester, financing and tax policy	
 CPME continues to monitor the various debates on health systems and their organisation and financing. This includes in particular the European Semester and related processes, such as the annual 'State of Health in the EU' analyses. Within DG SANTE, discussions within the Expert Panel on Effective Ways of Investing in Health (EXPH) and the Expert Group on Health System Performance Assessment shape soft policy debates on reforming health systems. CPME engages with these groups as appropriate. WHO-Europe promotes discussion on health system reform, e.g. the elaboration of primary care in 	 → shape EU discussion on health systems to limit negative impact on medical profession (e.g. as regards scope of practice) → build members' knowledge of and engagement in European Semester 	 (Proactive) Monitoring and ad hoc reaction, limited pro-active outreach Support to CPME Rapporteur on Healthcare systems, Financing, and Tax Policy Systematic monitoring and reporting to members Reaction to institutional policy activities, such as consultations, DG SANTE Expert Panel activities Internal communication: EC briefing, CPME bulletin / External communication: CPME newsletter, Twitter 	 Pro-active policy discussion, pro- active outreach Launch CPME policy discussion on trends in healthcare systems and appropriate policy statements Nominate CPME Rapporteur Improve CPME's and members' engagement in relevant processes Communication activities to support action as appropriate



context of the renewal of the Alma Ata declaration.			
on the Joint Action on Health in	→ confirm CPME positions on health hequalities in reaction to institutional olicy activities	 Monitoring and ad hoc reaction, no pro-active outreach Support to CPME Rapporteur on Health Inequalities Systematic monitoring of Commission/WHO policy action and reporting to members Sporadic reaction to institutional policy activities, such as consultations or stakeholder requests for support Participation in events e.g. Patient Access Partnership (PACT) activities Internal communication: CPME bulletin, EC briefing / External communication: CPME newsletter, Twitter 	- Continuation of activities
	Collaborative practice/Skill mix,	Health workforce, Working time	
interchangeably with terms such as pr skills mix, new roles, upskilling, → advanced roles, without any do	 → consolidate role of doctor in care rovision → reinforce collaboration between octors and other professionals, e.g. harmacists and nurses 	 (Pro-active) Monitoring and ad hoc reaction, no pro-active outreach Support to CPME WG on Professional Practice and CPME Rapporteur on Health Workforce Systematic monitoring and reporting to members Reaction to institutional policy 	 Pro-active policy discussion, pro- active outreach Launch CPME policy discussion and drafting process for standalone CPME policy, e.g. terminology Nominate CPME Rapporteur Internal communication: E0 briefing, CPME bulletin / External



Pharmaceuticals there have been extensive discussions on the interprofessional collaboration between doctors and pharmacists i.a. on medication.		 Liaison with other stakeholders, e.g. EMOs, health professions, WMA, including co-signature of EMOs' statement on the role of medical doctors, and communicated it i.a. to WHO. Internal communication: EC briefing, CPME bulletin / External communication: CPME newsletter, Twitter 	Twitter, potentially articles in HPCB, presentations at external meetings
 DG SANTE has commissioned the tender <u>Support for the health</u> workforce planning and forecasting <u>expert network (SEPEN)</u>, which CPME is a consortium member of. There are continued policy debates on the topic, e.g. in the context of an OECD-WHO-ILO event on mobility. At EU level there are few policy developments in this area since the DG SANTE Expert Group on Health Workforce was suspended, however there are discussions e.g. on workforce mobility in DG Employment & Social Affairs. 	tender (end date: September 2020) → confirm CPME positions in reaction	 Monitoring and ad hoc reaction, limited proactive outreach Support to CPME WG on Professional Practice / CPME Rapporteur on Health Workforce / SEPEN experts Systematic monitoring and reporting to members Reaction to institutional policy activities, such as consultations Response to requests from members Participation in SEPEN meetings and activities Sporadic meetings with stakeholders and institutions Internal communication: EC briefing, CPME bulletin / External communication: CPME newsletter, Twitter 	- Continuation of activities



 The Interpretative Communication on the Working Time Directive sets out the acceptable framework for transposition of the Directive into national law. At the same time the 'Social Fairness Package' in under negotiation, which will include i.a. the establishment of a European Labour Authority, and the adoption of Council Recommendations on access to social protection for workers and the self-employed. In addition, there are on-going negotiations on the proposal for a Directive on Transparent and Predictable Working Conditions. 	ework inpro-active outreachctivities on-CPME WG on Professional Practice	- Continuation of activities
Profe	ssional regulation & qualifications	
 The Proportionality Directive 2018/958/EU (<u>CPME Info 185-2018</u>) must be transposed into national law by June 2020. There are various policy developments relating to professional regulation, e.g. the impacts of the DG GROW study on professional regulation and 	to limit reaction, limited pro-active	 Continuation of activities Launch of more pro-active action in case of implementation problems, review activities, further challenges to doctors' regulation On-going communication of CPME position and policy developments in EC briefing, CPME bulletin, Twitter



 behavioural economics, and on national rules on advertising regulations. The implementation of the Professional Qualifications Directive 2005/36/EC is on-going, well past its January 2016 deadline. Its review is also underway, e.g. in the form of exploratory projects on changing Annex V. 		 policies Coordination with other professions, e.g. liberal professions Outreach to EU institutions, especially European Commission Participation in events, e.g. DG GROW Single Market Forum Internal communication: EC briefing, CPME bulletin / External communication: CPME newsletter, article in HPCB newsletter, media coverage EU (e.g. Politico), joint press release with CED and PGEU, Twitter 	
	Patient Empowerm	ent & Health Literacy	
 In order to achieve optimal results from treatment, a good patient- doctor relationship is essential. One of the prerogatives is patient empowerment and this requires an informed patient. CPME was partnering in the EMPATHIE EU tender on empowering patients in the management of chronic diseases. CPME also commented the EPF Charter of Patient Empowerment and a multi-stakeholder Roadmap for Action. 		 Monitor the developments in this field Participating in the advisory board meetings of the CEmPaC (Centre for Empowering Patients and Communities) network Processing of news & information and dissemination to members Internal communication: CPME bulletin 	 Provide the medical profession's perspective in the CEmPaC project supported by communication Additional communication activities when appropriate



CPME is a member of the Health Literacy Coalition (HLC) which has developed an infographic and a consensus paper on health literacy. In addition, the coalition has organised events at the European Parliament and workshops at the Gastein Forum.	field, and participate in the actions of the Health Literacy Coalition	 Monitor the developments in this field Participating in the Health Literacy Coalition's (HLC) meetings Internal communication: CPME bulletin 	 Participate in the Health Literacy Coalition's (HLC) possible future actions Additional communication activities when appropriate
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'Passive monitoring'

These dossiers are only served if there is capacity, active dossiers take precedence. Members are updated when appropriate in the Monthly bulletin/Working Groups.

Refugee health	
 The EU level and international discussions on migration continue, most recently at UN level in the adoption of the Global Compact for Safe, Orderly and Regular Migration in December 2018. At EU level the negotiations on the revision of the Dublin II Regulation continue (CPME is not lobbying on this dossier). 	\rightarrow up-date CPME policies on non-discriminatory refugee health and safe integration of refugee doctors to ensure \rightarrow confirm CPME positions in reaction to institutional policy activities
Defensive medicine	
- CPME discussions on defensive medicine continue under the lead of the Rapporteur.	ightarrow creation of CPME policy in follow-up to CPME survey
Standardisation	
 CEN acknowledged the opposition to its standardisation of healthcare services agenda and abandoned its immediate activities focussed on this area. On-going CEN projects which may be relevant include the creation of a CEN-CENELEC Focus Group on Artificial Intelligence (AI), and the drafting of a standard for a European format for 	 → stop Commission activities on standardisation of healthcare services → stop CEN activities on standardisation of healthcare services: achieve sustainable commitment from CEN that no



electronic health records (EHRs).	activities shall be undertaken → create awareness for issue in national ministries and standardisation bodies
Self-care	
 CPME has engaged in European self-care projects such as the Promotion of Self-Care Systems in the European Union (PiSCE) and the Pilot project on Promoting Self-management for Chronic Diseases in the EU (PRO-STEP). 	\rightarrow Provide the medical profession's perspective in European self-care initiatives
Patient safety and quality of care	
 CPME has been working on patient safety for many years and been involved in a series of European projects such as SImPatIE, EUNetPaS and PaSQ. 	→ Monitor the developments in this field → Providing speakers to conferences when relevant
- At institutional level, CPME was a member of the European Commission Working Group on Patient Safety and Quality of Care. This was however discontinued by the Commission although CPME tried to maintain its existence by publishing a joint statement with over 20 health organisations.	

Silent dossiers

All activities are suspended on these topics.

	Ethics	
-	CPME continues to engage in activities on ethics as appropriate. Most recently, CPME hosted a session on refugee doctors are the UNESCO Chair in Bioethics	
	13th World Conference on bioethics, medical law and health law.	
-	CPME has provided support to members facing challenges to medical ethics, in particular the Turkish Medical Association.	

TTIP and other FTAs

- The EU is engaging in negotiations on a variety of free trade agreements, most importantly with Japan.
- The future relationship between the UK and the EU is likely to be in the format of a free trade agreements, therefore it is useful to monitor horizontal trade policy developments, e.g. in relation to the creation of a Multilateral Investment Court.

Sex and gender

CPME has adopted a policy on sex and gender in medicine (<u>CPME 2016/036</u>). This policy provides recommendations in various areas in which a S&G sensitive approach should be incorporated, from the different research fields to medical education and training, as well as disease prevention.

Pharmaceuticals and Healthcare products

Supervised by CPME Vice-President Dr Christiaan Keijzer

Active dossiers

- Antimicrobial resistance (AMR)
- Access to medicines and drug shortages
- Health Technology Assessment (HTA)

Passive monitoring dossiers

- Transparency and ethics
- Clinical Trials
- Biosimilars
- Off-label use of medicines and drug repurposing
- Falsified medicines
- Personalised medicine
- Pharmaceuticals in the environment
- Information to patients
- Medical devices

Silent dossiers

Pharmacovigilance

CPME Rapporteur on AMR : Dr Maciej Hamankiewicz CPME WG on Pharmaceuticals – Chairperson: Dr Erzsébet Podmaniczky CPME Rapporteur on HTA: Dr Bernard Maillet

CPME WG on Pharmaceuticals – Chairperson: Dr Erzsébet Podmaniczky CPME Rapporteur on Clinical trials : Prof André Herchuelz CPME WG on Pharmaceuticals – Chairperson: Dr Erzsébet Podmaniczky CPME WG on Pharmaceuticals – Chairperson: Dr Erzsébet Podmaniczky CPME WG on Pharmaceuticals – Chairperson: Dr Erzsébet Podmaniczky CPME WG on Pharmaceuticals – Chairperson: Dr Erzsébet Podmaniczky CPME WG on Pharmaceuticals – Chairperson: Dr Erzsébet Podmaniczky CPME WG on Pharmaceuticals – Chairperson: Dr Erzsébet Podmaniczky CPME WG on Pharmaceuticals – Chairperson: Dr Erzsébet Podmaniczky CPME WG on Pharmaceuticals – Chairperson: Dr Erzsébet Podmaniczky CPME WG on Pharmaceuticals – Chairperson: Dr Erzsébet Podmaniczky

For a full overview of past activities relating to the dossiers below, please consult <u>CPME 2018/051</u>.

'Active dossiers'

Information on dossier	Objective	Current input	Secretariat Recommendations for Future Activities
	Antimicrobia	l resistance (AMR)	
 CPME position paper on antimicrobial resistance adopted in 2013 (CPME 2013/020 FINAL). Involvement in the stakeholder forum of the joint action on antimicrobial resistance and healthcare-associated infections (EU-JAMRAI). Collaboration with the European Centre for Disease Prevention and Control (ECDC), notably on the annual <u>European Antibiotics</u> <u>Awareness Day (EAAD)</u>. 	→ Reducing antimicrobial resistance across Europe	 Briefing CPME Rapporteur on AMR; Processing of news & information and dissemination to members; Reaction to institutional policy activities, such as consultations; Response to requests from members; Participation in the annual European Antibiotics Awareness Day (EAAD): Preparatory meeting with ECDC, incl. the Technical Advisory Committee; Production of materials (such as statement, PR) in preparation of the EAAD; Participation in the twitter activities. 	 Providing input to the EU-JAMRAI stakeholder forum basing on CPME policy and contributing to the WP7 (appropriate use of antimicrobials) and WP8 (awareness-raising and communication) within EU-JAMRAI Internal and external communications activities (e.g. joint press release, newsletter article and twitter activities). Monitoring the developments in EU policies on AMR; According to policy developments, additional policy and communication activities with ECDC, including the production of materials and social media activities
	Access to medicir	nes and drug shortages	
 The Commission's studies on pharma incentives (available here) and Max Planck Institute studies on legal aspects of SPCs (available here) were released in May 2018. The latter one was published in parallel to the Commission's proposal on supplementary 	→ Assuring patients' right to healthcare and to receive the best treatment available, regardless socio-economic conditions.	 Briefing CPME Chair of the working group on pharmaceuticals; Processing of news & information and dissemination to members; Reaction to institutional policy activities and response to requests from members; Monitoring of other developments, 	 According to EU policy developments on access to medicines, appropriate policy and communication activities will be defined; Pursuing CPME's involvement in EMA's activities, in particular as member of the Healthcare

protection certificates (SPCs).

- Commission's consultations on the paediatric regulation and on orphan medicinal products are concluded.
- On 19 November 2016, the CPME Board adopted a policy on access to medicines and pharmaceutical pricing (<u>CPME 2016/063 FINAL</u>) in the context of the ongoing EU discussions on the affordability of new drugs.
- In 2016, the European Medicines Agency (EMA)'s management board and scientific committees were renewed. As a result, Prof. Wolf-Dieter Ludwig was appointed as a member of the EMA <u>Management Board</u> for the upcoming new mandate (2016-2019) and the mandate of Dr Podmaniczky within the <u>Healthcare</u> <u>professional Working Party</u> (<u>HCPWP</u>) was also renewed for the term 2016-2019.
- CPME currently doesn't have a specific policy on drug shortages.
- Among the health stakeholders, the hospital pharmacists (EAHP) are very much involved in this topic. In this respect, CPME - represented by Dr de Haller - has taken part in the COST Action on Medicines Shortages, aiming at encouraging

e.g. to the EMA adaptive pathways;

- Participation in the Commission Expert Group on 'Safe and Timely Access to Medicine for Patients' (STAMP) meetings.
- Internal communication: EC briefing, CPME bulletin / External communication: CPME newsletter, and Twitter activities.

Involvement in EMA activities :

- Participation of the CPME representative (or alternate) in the EMA Healthcare professionals working party (HCPWP) twice a year;
 Participation in different EMA
- workshops either by one CPME representative or by CPME secretariat;
- Providing *ad hoc* contributions in the activities of HCPWP of the EMA.

professionals' working party (HCPWP).

Where appropriate, EC and WG members will be updated on EU initiatives.

systematic sharing of information and research about past, ongoing and future shortages of medicines.	Health Technolo	pgy Assessment (HTA)	
 The European Commission published a legislative proposal on HTA in January 2018. The legislative file is now highly debated in the Council of the EU and the European Parliament. CPME has been actively involved in the providers group of the stakeholder forum of the European network for Health Technology Assessment (EUnetHTA) and is now a member of the new HTA network stakeholder pool; Adoption of CPME position on the HTA (CPME 008/2018 FINAL) in April 2018. 	→ Establishing the EU framework on HTA in line with CPME policy to guarantee independence and transparency of procedure and outcomes, as well as meaningful involvement of healthcare professionals in the process	technology assessment;	 Provide the medical profession's perspective in the context of future EU activities on HTA, in particular in the case of a legislative proposal. According to EU policy developments on HTA, appropriate policy and communication activities will be defined;

'Passive monitoring'

These dossiers are only served if there is capacity, active dossiers take precedence. Members are updated when appropriate in the Monthly bulletin/Working Groups.

Transparency and ethics		
 The 'CPME guidelines on the transparency of relationships between physicians and the healthcare industry' were adopted by the Board in November 2014 (<u>CPME 2014/055</u>). In addition, a <u>leaflet</u> was produced in 2015 to give more visibility to these guidelines. The revision of the CPME-EFPIA joint declaration has been postponed during CPME meeting in November 2018 in Geneva. Mental Health Europe (MHE) decided to launch a one-year project to pursue its work on transparency. As part of its '<u>Shedding Light' project</u>, CPME was invited to join the project stakeholder working group on transparency. 		
Clinica	al trials	
 The Clinical Trials Regulation (Regulation (EU) No 536/2014), was adopted on 16 April 2014. CPME followed closely the negotiations on the directive and is now monitoring its implementation. Since then, the EMA adopted a new policy on the publication of clinical trials data and undertook several public consultations related to the transparency of clinical trial data under the EU database and on access to documents. CPME responded to the different public consultations on this issue. 		
Biosi	milars	
 In 2017, the EMA has launched a new initiative which aims at developing a guide for healthcare professionals on biosimilars. To that end, a topic group on 'biosimilars' – in which CPME was represented by - was established within the Healthcare Professional Working Party (HCPWP). The final document was presented during the third workshop on biosimilars, which was held on 5 may 2017. Also in 2017, CPME received an invitation from the EMA Biosimilar Medicinal Products Working Party (BMWP) to take part in an interested parties meeting and to share ideas for future collaboration and focus. 		

Off-label use of medicines	
 Adoption of a CPME policy on off-label use of medicinal products in April 2017 (<u>CPME 2017/006 FINAL</u>). The Commission published in February 2017 a <u>study report</u> on the off-label use of medicinal products in the EU, which provides a factual analysis of the current situation in the EU member states. 	\rightarrow Monitor potential developments in this field and, where appropriate, promote the CPME policy.
Falsified r	nedicines
 The <u>Falsified Medicines Directive</u> was adopted on 8 June 2011 and had to be transposed into national law at the latest by 2 January 2013. In preparation of its implementation, the Commission adopted a <u>delegated regulation</u> in October 2015 to further detail the characteristics of the safety features and the verification process. CPME hasn't undertaken specific actions in this field since the adoption of the directive. In 2016, CPME was approached by <u>ASOP EU</u>, the Alliance for Safe Online Pharmacy, to raise awareness about the threat posed by falsified medicines in the context of illegal online sales of medicines. The Executive Committee decided not to undertake proactive actions for the time being. 	→ Monitoring potential developments which could have an impact on the medical profession.
Personalised medicine	
 Many events are regularly organised at EU level to promote the development of personalised medicine while acknowledging the current barriers (data protection rules limiting the collection of Big data, clinical trial models which are not suitable for new therapies, etc). CPME currently doesn't have a CPME policy on personalised medicine. However, some CPME policies touch on related topics (data protection, clinical trials, etc.) 	→ Monitoring the developments in this field, especially when it comes to the discussions on Big Data.
Pharmaceuticals in the environment	
 Early 2018, the Commission carried out a public consultation with the view of developing the EU strategic approach to pharmaceuticals in the environment. CPME participated in a stakeholder meeting in February 2018, which aimed at collecting the views of healthcare professionals. The strategic approach was expected to be adopted before summer 2018. 	→ Monitoring potential developments in this field.

Nevertheless, according to some sources, the dossier would be currently blocked in the Commission and it is unclear if the communication will be published before the elections of the European Parliament in 2019.	
 In 2010 CPME published a <u>response to ENVI Committee vote on the</u> <u>'Information to Patients' report by MEP Fjellner</u>, as well as <u>comments on the</u> <u>EP draft report on info to patients on medicinal products subject to medical</u> <u>prescription</u>, In 2017, EMA published an action plan to improve medicinal product information. Among all identified actions, EMA intends to focus primarily on electronic product information. 	Assuring that patients benefit from high quality and independent information on prescription-only medicines.
 Strict surveillance and tight controls over medical devices is of utmost importance according to CPME's policy and mission of patient safety and high quality healthcare. Following the discovery of fraudulently manufactured and sub-standard medical devices, CPME believes action must be taken and will closely follow and monitor the legislative developments at European level. Therefore, CPME contributed to the negotiations of the new Medical Device Regulations which were adopted by the European Parliament and the Council in April 2017. 	 → Provide the medical profession's perspective to the implementation of the new MDR → Medical Devices Coordination Group (MDCG) Participating in the MDCG meetings as an observer member. MDCG provides advice to the European Commission and assists it and the Member States in ensuring a harmonised implementation of MDR. → JA on Market Surveillance of MD Participating in the advisory board meetings of the Joint Action on Market Surveillance of medical devices, coordinated by the Medicines & Healthcare products Regulatory Agency (MHRA)
	→Participate in the Commission's work to establish expert panels in the context of the on-going implementation of MDR. These panels would include health care professionals to advice the Notified Bodies before placing devices on the market.

'Silent dossiers'

All activities are suspended on these topics.

	Pharmaco	vigilance
-	In 2011 CPME published a response to the EMA consultation on the design of	
	web-reporting forms for healthcare professional reporting of adverse drug	
	reactions,	



eHealth Supervised by CPME Vice-President Dr Ray Walley

Active dossiers

- Artificial Intelligence
- Data protection
- eHealth

Passive monitoring dossiers

- mHealth

Silent dossiers

- Professional electronic ID Card for Doctors

For a full overview of past activities relating to the dossiers below, please consult CPME 2018/051.

CPME Rapporteur on Artificial Intelligence: To be appointed CPME Rapporteur on Data protection: Mr Sjaak Nouwt CPME WG on eHealth – Chairperson: Dr Bernard Maillet

CPME Rapporteur on mHealth: Mr Sjaak Nouwt

'Active dossiers'

Information on dossier	Objective	Current input	Secretariat Recommendations for Future Activities
	Artificia	l Intelligence	
Commission put forward a <u>European approach to artificial</u>	→ Ensure the development of an adequate regulatory and ethical framework for AI-based technology in the health sector	 Map current EU initiatives in the field of artificial intelligence Identify ongoing groups/initiatives for CPME to participate Contact responsible Commission unit 	 Appoint a Rapporteur on Artificial Intelligence Draft CPME policy on Artificial Intelligence Provide CPME expertise to influence the AI ethical and regulatory development. Internal and external communications activities to be defined.
Data protection			
 <u>Regulation (GDPR)</u> came into force on 25 May 2018. <u>CPME Members' Briefing</u> prepared 	\rightarrow High level protection of all citizens' health and medical data by its storage with the appropriate security standards, for purposes of proof of medical treatment and for future patient's safety	 Briefing CPME Rapporteur on data protection; Processing of news & information and dissemination to members; Participation in events' panel discussions and meetings on health data (EDPS event, EC meetings, 	 Promotion of the WMA declaration of Taipei in different fora (eHealth stakeholder group, eHealth week in Malta, eHealth conference in Tallinn); Take part in the development of an EU code of conduct for the medical profession on the ethical use of health data for research purposes (BBMRI-

 legislation and how these changes will impact the healthcare sector. CPME's endorsement of the WMA Declaration of Taipei on ethical considerations regarding health databases and biobanks in April 2017. Involvement in drafting <u>BBMRI-ERIC code of conduct for health research</u> 		 stakeholders' events such as EFPIA and COCIR); Participation in panel discussions Reaction to institutional policy activities Response to requests from members; Internal communication: EC briefing, CPME bulletin / External communication: CPME newsletter, and Twitter activities 	ERIC). - Where appropriate, additional communication activities.
 Membership in the <u>eHealth</u> <u>stakeholder group (eHSG)</u> since 2012. Monitoring of the activities under the <u>eHealth joint action (JAseHN)</u> which supports the <u>eHealth Network (eHN)</u>. Participating in the Commission consultation on the Electronic Health Records exchange format 	→ Ethical and sound sharing of data in healthcare as well as building trust in and acceptability of new communication technologies for patients and health care providers	 Briefing CPME Chair of the eHealth working group; Processing of news & information and dissemination to members; Reaction to institutional policy activities, such as consultations; Response to requests from members; Involvement in the eHSG: CPME Representative in the eHSG; Participation in the eHSG meetings twice a year; Participation to web meetings and email exchanges in the context of sub-groups' activities. Involvement in JAseHN activities: Monitoring of JAseHN deliverables; Updating the CPME WG on eHealth 	 Provide the medical profession's perspective on the policy developments in the eHealth field. Deliver an input on Electronic Health Records initiative Continuation of the different activities (involvement in the eHSG, JAseHN and ongoing EU projects). Periodical update of the CPME WG on eHealth;

	on JAseHN activities; - Providing comments on certain deliverables on a case by case basis.
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'Passive monitoring'

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mHealth			
- Involvement in the European Medicines Agency (EMA)'s topic group on digital media and health.	ightarrow Monitor the developments in this field and, where appropriate, provide the medical profession's perspective.		
- Participation in a Commission's workshop on the safety of non embedded software in the healthcare sector in April 2018, in order to provide CPME's perspective on mHealth policy.			

'Silent dossiers'

All activities are suspended on these topics.

Professional electronic ID Card for Doctors		
 In 2013 CPME adopted a policy on "Ensuring the secure use of telemedicine and e-health applications in an integrated Europe – Towards a Common Policy Agreement on Electronic ID Systems for Physicians" 		

CPME NUMBER: CPME 2018/091 DATE: 09 January 2019

EU political outlook Supervised by the Executive Committee

- Brexit _
- The future of EU health policies

EC – No Rapporteur / BMA EC - No Rapporteur

One Health _

EC -	NU	napporteur
EC –	No	Rapporteur

Information on dossier	Objective	Current input	Secretariat Recommendations for Future Activities
	I	Brexit	
 CPME has been following the negotiations and intervening with letters. All action is coordinated with the BMA. 	→ continued free movement for doctors/researchers and application of related tools e.g. alert mechanism, and cooperation mechanisms on crossborder health threats	change	 Continuation of activities Communication on Brexit via CPME Health Check 2019 EP event on 27 February 2019 (tbc) Follow-up meetings with taskforce 50 including BMA and EMOs.



PURPOSE: For discussion CONCERNING: CPME Activities AUTHOR: CPME Secretariat			CPME NUMBER: CPME 2018/091 DATE: 09 January 2019
	The future of	f EU health policies	
 CPME is coordinating its activities with other stakeholders (i.e. Council of European Doctors, Pharmaceutical Group of the European Union) and sent a joint open letter to Juncker. CPME has followed the political debate on the next European budget (Multiannual Financial Framework - MFF) and on the future of health within the budget. In the next MFF, it is proposed to skip a separate health programme and to replace it by the health strand in the overarching European Social Fund Plus 2021-2027. It is not clear that DG SANTE will remain in place. If not maintained, there is the risk that health will be lower on the agenda and allocated to other DGs resulting in industry-oriented policies. 	 → Highlighting the importance of keeping health policy high on the European Agenda → Keep DG SANTE as a standalone service in the next Commission mandate. 	 Meetings with Presidencies and MEPs highlighting CPME (CED-PGEU) position as presented in the open letter to President Juncker. Internal communication: EC briefing, CPME bulletin / External communication: CPME newsletter, CPME website, Twitter, joint press release, specific item on the CPME Health check 2019. 	 Proactive lobbying action for policy change: meeting with MEPs and Commission policy-makers. Organise an EP event with PGEU and CED if there is indication that the new Commission will give up on DG Santé.
'One Health'			
- Collaboration with the Federation of Veterinarians of Europe (FVE) and the Council of European Dentists (CED) in the context of their	→ Underlining the importance of interdisciplinary training and creating a 'One Health' culture among all future health professionals	- Sending the joint letter to the Deans of medical, dental and veterinary schools to support the inclusion of	 Pursue the collaboration with FVE, CED and students' organisations on the 'One health approach'.



COMITÉ PERMANENT DES MÉDECINS EUROPÉENS STANDING COMMITTEE OF EUROPEAN DOCTORS 🖉

PURPOSE: For discussion CONCERNING: CPME Activities AUTHOR: CPME Secretariat		CPME NUMBER: CPME 2018/091 DATE: 09 January 2019
Memoranda of Understanding (<u>CPME-FVE MoU</u> and <u>CED-CPME</u> <u>MoU</u>) to jointly act in recognition of the concept of the 'One Health' approach.	the One Health ap undergraduate education - Organization of 'On conference on 5 Decemb Paris - Preparation of the repo Health' event - Internal communication: CPME bulletin / communication: CPME and Twitter activities.	he health' ber 2018 in press release, newsletter article and twitter activities). - Organization of one regional workshop on 'One Health' per year. - Potentially a rapporteur to be appointed External