On 15 November 2014, the CPME Board adopted the 'CPME policy on the Transatlantic Trade and Investment Partnership Agreement (TTIP)' (CPME 2014/076 FINAL)

CPME policy on the Transatlantic Trade and Investment Partnership Agreement (TTIP)

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.¹

The Transatlantic Trade and Investment Partnership Agreement (TTIP) between the United States of America and the European Union aims to achieve the reciprocal liberalisation of trade in goods and services as well as rules on trade-related issues. CPME welcomes the commitment shown by the European Union and the United States of America to facilitate transatlantic trade and investment with the objective of supporting economic activity and thus promoting economic growth. CPME is convinced that economic stability in both public and private sector and sustainable high quality healthcare are mutually dependent. Investment in healthcare yields direct returns for the economy.

With regard to the TTIP's impact on healthcare and healthcare systems however, and this applies also to other free trade agreements, such as the Comprehensive Trade and Economic Agreement (CETA), CPME wishes to highlight the following considerations with the objective of safeguarding equitable high quality healthcare for every patient in the European Union:

- Article 168 of the Treaty on the Functioning of the European Union reaffirms that a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities. It also provides that the Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care, which includes the management of health services and medical care and the allocation of the resources assigned to them.
- The Charter of Fundamental Rights of the European Union, which is legally binding on the institutions of the European Union and the Member States as to the implementation of Union

¹CPME is registered in the Transparency Register with the ID number 9276943405-41. CPME has also adopted the '<u>CPME response to the public consultation on investment protection and investor-to-state dispute</u> <u>settlement (ISDS) in the Transatlantic Trade and Investment Partnership Agreement (TTIP)'</u> and the '<u>CPME</u> <u>response to the public consultation for the own-initiative inquiry of the European Ombudsman towards the</u> <u>European Commission concerning transparency and public participation in relation to the TTIP negotiations</u>'. More information about CPME's activities can be found under <u>www.cpme.eu</u>

legislation, establishes in Article 35 a right for everyone to access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. It goes on to provide that a high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.

- In the Union legislative framework, there is an acknowledgment for the fact that healthcare services are subject to subsidiarity and cannot be equated to services delivered in a purely commercial context. Healthcare and pharmaceutical services are therefore exempted from the scope of application of Directive 2006/123/EC on services in the internal market.
- The provisions of the TTIP, insofar as they have a legal base in Union law, must respect the provisions of treaty, legislation and charter and must exclude any provisions which risk infringing the rights and competences set out therein.

In particular, CPME underlines the following:

- It is not consistent with the Union's obligation to ensure a high level of human health protection in all its policies that the TTIP does not acknowledge the special nature of healthcare and healthcare systems, but rather foresees that the protection of citizens' rights is dependent on the European Commission and Member States taking individual and specific action to ensure existing and future legislative and regulatory frameworks affecting the healthcare system are also applicable to trade and investment in the scope of the TTIP. By requiring the European Commission and Member States to bear the burden of justification for measures which can be challenged as deviating from the TTIP's objectives or as running contrary to the legitimate expectations of the investor adopted in the scope of their respective competences, the rights and competences established by Union and national legislation become vulnerable.
- As regards trade in goods, the objective of promoting regulatory compatibility or harmonisation may in no way result in provisions that aim to establish a high level of protection of public health, patient safety or quality of care being circumvented or weakened.
 - As regards pharmaceutical products, for example, Regulation No 536/2014 on clinical trials on medicinal products for human use and the recently adopted European Medicines Agency (EMA) policy on clinical trials data disclosure, have set up a robust transparency framework which will allow individuals to better access safety and efficacy information about the drugs they use. The safety and transparency processes related to medicinal products put in place by Union law cannot be questioned as non-tariff-barriers (NTBs) which can be removed for the benefit of economic growth. They must remain unchallenged as essential provisions safeguarding the health of patients in Europe. The new EU rules applicable to clinical trials should in no way be circumvented by the TTIP.
 - Similarly, Member States' competence to adopt laws affecting the trade of goods with the objective of protecting public health must not be weakened. In implementation of Directive 2014/40/EU on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of

tobacco and related products, for example, Member States have the right to maintain or introduce further requirements in relation to the standardisation of the packaging of tobacco products.

 As regards services, the division of competences between Member States and the Union, as illustrated above, does not allow for a liberalisation as envisaged by the TTIP, since Member States' competences relating to health policy and healthcare services must not be circumvented.

Therefore

- The TTIP must not put in question the rights and regulations established by Union legislation and Member States' laws regulating healthcare and healthcare systems and in particular must not subject them to potential challenges by governmental bodies or investors, in particular the proposed investor-to-state-dispute settlement mechanism. The TTIP must therefore explicitly acknowledge the agreement may not encourage trade or investment by lowering standards, policies or legislation at Union or national level aimed at safeguarding high quality healthcare and healthcare systems, nor may it deter the Union or Member States from maintaining existing or adopting new standards, policies and legislation to this end.
- In light of the division of competences between Union and Member States, CPME calls for healthcare services to be granted a carve-out from the TTIP's scope of application.
- The widest possible public access to documents relating to the TTIP negotiations should be ensured, in accordance with Regulation 1049/2001 regarding public access to European Parliament, Council and Commission documents, and the judgment of the European Court of Justice in Case C350/12 P. The agreement's importance warrants a public consultation of the draft final text of the TTIP.