



This issue

Message from the CPME President page 2

LATEST NEWS

The Commission invites the alcohol industry to label their products better page 3

Standardisation of healthcare services - health stakeholders' views are not accepted page 3

European Semester's country reports highlight health and healthcare conditions across Europe page 4

Brexit: a challenge for the European medical profession page 4

What future for doctors' professional regulation? CPME examines Proportionality Directive page 5

Health Technology Assessment: quo vadis? page 6

Update on biosimilars page 6

Draft medical device regulation is soon to become EU law page 7

NEWS FROM CPME MEMBERS

Norwegian Medical Association - human rights work page 7

New steps for health protection in the Czech Republic page 9

Electronic Health Cooperation Service Space – the Hungarian national e-health project page 10

CPME NEWS

CPME news Page 11

EVENTS

Institutional news Page 11

SAVE THE DATE! - CPME Meetings 2017



7- 8 April
2017, Vilnius

24 - 25 November
2017, Brussels

MESSAGE FROM THE CPME PRESIDENT

Dear Colleagues and friends,

Welcome to the 22nd edition of the CPME newsletter. The following pages present the latest developments in health politics at EU level and recent CPME activities.

This edition highlights in particular the position of CPME on the EU framework on Health Technology Assessment (HTA) and on the future strategy for the standardisation of healthcare services by the European Committee for Standardisation (CEN).

This issue also includes CPME's perspective on the UK withdrawal from the EU and the challenges for the European medical profession that this will represent. While we respect the political decisions of the UK, as representative of the European physicians we call on 'Brexit' negotiators to safeguard some important principles like patient safety, freedom of movement of the health workforce and high standard in medical education and training during and after the long process of 'Brexit'.

Also, a special emphasis is placed in this Newsletter on the proposal for a Directive on a proportionality test before adoption of new regulation of professions. As health professionals we are very supportive of the regulatory measures the new Professional Qualifications Directive has introduced in 2013 to improve patient safety, mainly the alert mechanism and controls on language knowledge. We therefore regret that the Commission's own efforts to make professional practice safer are now being threatened by the draft Directive for proportionality tests on professional regulation. For this reason, we call for an exemption of health professions from its scope.

Finally, the CPME newsletter will inform you of recent news from CPME members, featuring articles from the Norwegian Medical Association, the Czech Medical Chamber and the Hungarian Medical Chamber.

I hope you enjoy reading this edition and wish you a pleasant spring time.

Yours sincerely,



Dr Jacques de Haller, President of CPME



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THE COMMISSION INVITES THE ALCOHOL INDUSTRY TO LABEL THEIR PRODUCTS BETTER



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On 13 March 2017, the European Commission published a [report](#) on the mandatory labelling of the list of ingredients and the nutrition declaration for alcoholic beverages. Currently, such labelling is not obligatory for alcoholic drinks, unlike for other drinks and foods. In the new report, the Commission invites the industry to respond to consumers' expectations to get

more information.

However, instead of regulatory actions, the Commission furthermore invites the alcohol industry to develop self-regulation on labelling. The industry is expected to offer a harmonised approach aiming to provide consumers with information within a year. In case the Commission will not be satisfied with the industry proposal, it will launch an impact assessment which would consider both regulatory and non-regulatory options.

The alcohol labelling report, which was supposed to be published already in December 2014, is based on data collected by the Commission through Member States and stakeholders consultations. It has been long-awaited because the European Parliament, the World Health Organisation (WHO), as well as consumer and public health organisations all have been asking for new labelling rules for

*For further information, please contact:
[Markus Kujawa](#), EU Policy Adviser*

STANDARDISATION OF HEALTHCARE SERVICES - HEALTH STAKEHOLDERS' VIEWS ARE NOT ACCEPTED

Building on long-standing discussions, European health stakeholders, including CPME, have submitted a new joint statement to the debate on a future strategy for the standardisation of healthcare services by the European Committee for Standardisation (CEN). In their statement, the International Association of Mutual Benefit Societies (AIM), the Council of European Dentists (CED), the European Hospital and Healthcare Federation (HOPE), the European Federation of Public service Unions (EPSU), the European Social Insurance Platform (ESIP), the European Trade Union Confederation (ETUC) and CPME presented several criteria to identify the value added of CEN action on healthcare services, as key conditions for any action – meaning that if they are not met, standardisation initiatives should not go ahead. The statement also described the scope for standardisation activities which would result from the application of these criteria. A preliminary discussion of the joint statement at a CEN focus group meeting on 21-22 March 2017 showed that other actors, including CEN and several CEN members, do not agree to restrict the scope of standardisation thus, moving the perspective of potentially reaching a consensus further out of reach.

CPME shall evaluate the outcomes of the CEN focus group meeting to determine further action.

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

EUROPEAN SEMESTER'S COUNTRY REPORTS HIGHLIGHT HEALTH AND HEALTHCARE CONDITIONS ACROSS EUROPE

On 22 February 2017, the European Commission published the 2017 [country reports](#) which form an integral part of the European Semester process. The reports describe in detail the current state of each Member State's economy in particular in relation to public spending as well as presenting data on key indicators across all economic sectors. They also look at the implementation of the previous years' country-specific recommendations to assess what progress has been made. From addressing the rates of air pollution, to commenting on levels of public spending on health, the reports puts Member States' conditions in the context of EU averages.

It also remarks on trends and reform progress made. Looking at the implementation of the 2016 country-specific recommendations, for example, the Commission provides positive feedback on the contribution of Malta's new Health Act to improving the effectiveness of the healthcare system, on Ireland's success in negotiating a new framework for prices of pharmaceuticals and on Romania's law establishing health centres and teams in underserved areas. The next step of the European Semester will see the consolidation of national plans in reaction to the country reports. CPME shall monitor this process and support CPME members in engaging with policy-makers.

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BREXIT: A CHALLENGE FOR THE EUROPEAN MEDICAL PROFESSION

The UK's decision to leave the EU has created great uncertainty around the future immigration status of the thousands of EU medical professionals currently living, working, or studying in the UK, as well as creating insecurity for UK doctors living in other EU states. It is vital that all of these colleagues are given the clarity and reassurance they need regarding their future status, rather than being used as bargaining chips in Brexit negotiations.



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In the UK, EU nationals account for 5 per cent of the NHS workforce and 6 per cent in adult social care. They play a vital role in the delivery of health and social care, and a key role in medical research. Without them, the UK health service would be unable to cope, but this is not just about the numbers nor only the UK: the exchange of medical expertise and experience between other European countries and the UK is invaluable and of great benefit to patient care across the continent. The mutual recognition of professional qualifications ensures that medical professionals working across the EU and in the UK are fully qualified and highly skilled with an attendant improvement in patient safety.

For example, some doctors who trained and qualified abroad, currently work one week a month in England. This is in order to develop their skills and bring expertise back to their hospital and is of great benefit to the patients they care for. Future immigration rules must not prevent this exchange of expertise from taking place.

Also, the ongoing political uncertainty surrounding the future of UK and EU nationals living and working in different jurisdictions will likely lead to some choosing to return 'home'.

To provide stability to these individuals, doctors and academic staff from across Europe should be granted permanent residence in their current location. This is also important given the collaborative nature of most medical research and the key role medical academics play in educating and training doctors and other healthcare professionals. Equally, it is essential that UK researchers are able to gain experience in other EU nations.

Both measures, the possibility of permanent residence and the freedom of movement, are essential for continued collaboration in medical research, and ensure that optimal cooperation between UK and EU academics continues to help shape the European research and innovation agenda.

Dr Jacques de Haller, President of CPME

WHAT FUTURE FOR DOCTORS' PROFESSIONAL REGULATION? CPME EXAMINES PROPORTIONALITY DIRECTIVE

Having been heavily involved in the 2013 revision of the Professional Qualifications Directive, CPME has monitored its implementation closely. The most recent initiative to build on that Directive is the [proposal for a Directive on a proportionality test before adoption of new regulation of professions](#), published on 10 January 2017 as part of the 'Services Package'. CPME is now examining the proposal.



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During the preparation of the proposal, in particular in the context of the outcomes of the transparency and mutual evaluation exercise on professional regulation, CPME adopted a [consultation response](#) and a [joint statement](#) with the Council of European Dentists (CED) and the Pharmaceutical Group of the European Union (PGEU) on the topic. Here, CPME called for an exemption of health professions from the scope of a future Directive. The initial examination of

the proposal for a Directive showed that the concerns raised in the preparatory phase have not been taken into account and there is still a fundamental conflict between the approach the Directive takes and the specificities of the regulation of the medical profession.

CPME underlines the importance of effective regulatory frameworks for the health workforce. Regulation regarding education, training or professional practice should not be considered 'red tape' per se, but rather seen as a crucial tool to protect patient safety and quality of care. The proposed Directive however places a high burden of proof on Member States to provide evidence as to the suitability and proportionality of new regulations, failing which a regulatory measure may be deemed disproportionate and would have to be withdrawn. With much ambiguity about the modalities of justifying regulation in accordance with the Directive's provisions, the question remains what problem the new framework is aiming to solve when it comes to doctors. The economic rationale the Directive is based on, i.e. that slimmer regulation of professions will increase employment, mobility and growth, does not sit easily with the medical profession's situation, neither in terms of priorities by which economic considerations can never take precedence over patient safety concerns, nor in terms of real-life application, with doctors already being the most mobile of the regulated profession. The on-going discussion within CPME will explore how European doctors' concerns can be translated into a better legal proposal.

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HEALTH TECHNOLOGY ASSESSMENT: QUO VADIS?

At the end of last year, the European Commission opened a [public consultation](#) on strengthening EU cooperation on Health Technology Assessment (HTA). While the third Joint Action on HTA (EUnetHTA) will end in 2020, the Commission is looking ahead to next steps and exploring different scenarios from a status quo to the establishment of a sustainable EU framework.

In its response, CPME favours a sustainable EU framework on HTA, based on voluntary participation and mandatory uptake, to enhance evidence-based decisions taken at both decision-makers and physicians level. Indeed, it would not only support evidence-based and equitable decisions at national level but also facilitate doctors' access to reliable, timely and objective information on medical technologies to take better informed decisions with their patients on the best treatment. Ultimately, it could help ensure fairness and reduce inequalities in access to medical treatments between and within countries.

In order to ensure trust in the system, principles of independence and transparency must prevail when establishing this sustainable framework. The recourse to internal and/or external expertise and the management of conflicts of interest must rely on a clear set of rules on independence. In addition, the methodologies and processes should be transparent and the results of the assessment made public and easily accessible for all the relevant actors. The CPME response is available [here](#).

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UPDATE ON BIOSIMILARS

On 23 January 2017, the European Commission published a [new Q&A on biosimilar medicines](#) for patients who want to know more about biosimilar medicines. Available in seven languages, this Q&A document offers a short introduction to what a biosimilar is, what the similarities and differences with other biological products are and what the regulatory framework for these products is.



This document is the continuation of the work performed by the Commission's working group on access to biosimilars between 2010 and 2013. Established under the 'Process on Corporate Responsibility in the Field of Pharmaceuticals', the working group had identified the need for clear and unbiased information from an independent source as a key element for an adequate and informed uptake of biosimilar medicines. This led to the development in 2013 of a first information document entitled '[What You Need to Know about Biosimilar Medicinal Products](#)'. Rather than being

a technical document on biological products, the new Q&A provides updated information on biological products to the patient in a language that is easy to understand despite the complexity of the concept.

In May 2017, the Commission will organise a third multi-stakeholder workshop on biosimilar medicines that will focus on the role of healthcare professionals. A new information guide on biosimilars prepared by the European Medicines Agency and the European Commission targeting healthcare professionals will be launched at this occasion.

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DRAFT MEDICAL DEVICE REGULATION IS SOON TO BECOME EU LAW

The law proposal on medical devices and in-vitro diagnostics were adopted by the Council of the EU on 7 March 2017 and the European Parliament Committee on Environment, Public Health and Food Safety (ENVI) on 21 March 2017. The vote in the European Parliament plenary is scheduled for April.

The new regulations will apply three years after publication as regards general medical devices and five years as regards *in vitro* diagnostic medical devices. The objective of the revisions is to ensure a high level of health and safety protection for EU citizens who are using the devices and the free and fair trade of the products throughout the European Union. Also EU legislation is adapted to the significant technological and scientific progress in this sector.

For further information, please contact:
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NORWEGIAN MEDICAL ASSOCIATION - HUMAN RIGHTS WORK



**The Norwegian
Medical Association**
DEN NORSKE LEGEFORENING

Human Rights and Medicine

There are several reasons why medical associations should engage in human rights issues. In some countries, doctors have been accessories to torture; in others they have actively opposed violations of human rights. It is essential for medical associations to support colleagues who are exposed to human

rights violations and help promote human rights internationally.

Health as bridge to peace

Health can be a good basis for establishing contact between the parties to a conflict, and doctors and medical associations may well play a role in promoting peace. This is stated in, for example, the document '[Health as a bridge to peace](#)', adopted by the World Health Organization (WHO) in 1998. Moreover, doctors are ethically obligated to treat all patients equally, irrespective of their ethnicity and nationality. Against this background the Norwegian Medical Association (NMA) contacted all the medical associations in the new republics of former Yugoslavia and invited those to a meeting in Oslo in 1993. The intention of the meeting was to provide assistance to re-establish contact between the associations and discuss the humanitarian situation for the civilian population during the armed conflicts. Several meetings were arranged during the 1990, the last one in Ohrid in FYROM in 1997. Over this period we could observe that the cooperation between the parties gradually improved between some of the medical associations, but for some others the wounds were too deep, and they needed longer time.

In cooperation with the World Medical Association, the Turkish Medical Association and the Human Rights Foundation of Turkey we tried to use the same model in the Middle East. However, it soon became clear that a process similar to the one in former Yugoslavia would be difficult to achieve, mainly because some of the medical associations had decided to not cooperate with the Israeli Medical Association as a matter of principle, although the ISMA committed to medical cooperation without conditions.

Human Rights and Psychiatry

Psychiatry is a field where human rights dilemmas arise, for example in situations involving coercion. In cooperation with the Chinese Psychiatrist Association and Peking University Institute of Mental Health we have arranged annual seminars on ethics and human rights in psychiatry since 2004. An educational programme has been developed that includes annual sessions with 50–60 participants each over a three-year period. In total, nearly 800 psychiatrists have participated in these seminars.

The participants come from all of China's provinces, where they occupy key positions in regional psychiatry. Topics such as patients' rights, human rights and ethics related to coercion have been discussed. Case histories, Norwegian as well as Chinese have served as the basis for these discussions, which have been conducted with openness. Western psychiatry also faces challenges, and the seminars have provided an opportunity for exchange of experience and mutual learning.

Doctors and Torture

Since 1997 the Norwegian Medical Association has engaged in cooperation with the Turkish Medical Association and the Human Rights Foundation of Turkey (HRFT) on various human rights related projects. Our collaborative projects have included efforts ranging from seminars on rehabilitation of persons with mental traumas to symposiums on healthcare in prison. Solidarity with colleagues in Turkey is more important than ever. The use of torture, especially by the police, has increased and freedom of speech has been curtailed. According to the HRFT, these changes have been caused by new legal regulations. The situation is especially difficult in the Kurdish areas.

Society of Medical Doctors, Malawi

In 2015 the Norwegian Medical Association entered into a three year long collaboration with the Society of Medical Doctors of Malawi (SMD). The aim of the project is to strengthen the Society of Medical Doctors' membership services in general, to facilitate the role of the organisation as an arena for discussion of professional practice and ethical issues, and to improve quality of care as well as doctors' own welfare. Malawian doctors will also have a formal channel of communication with policy-makers and thus perform an important role in the civil society. Measures to maintain the organisational capacity in the long-term is also an integral part of the project.

Conclusion

Doctors share a set of core values that extend across national and ethnic interests. This value basis is embedded in shared codes of conduct formulated by the profession itself, for example in the World Medical Association's Declaration of Geneva. This means that doctors and medical associations have a particular responsibility for ensuring equal access to health services, including in wars and other armed conflicts. In our collaborative projects we have sought to emphasise mutual trust and equality. We have invited participation in projects in which we believed that everybody could learn from each other. In such projects, taking a long-term view is equally important.

All projects except the project in Malawi have received financial support from the Norwegian Ministry of Foreign Affairs.



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The Secretariat of SMD: Isaac Wana og Mazikosi Grace Lupeska
Photo: Bjørn Oscar Hoftvedt

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Bjørn Oscar Hoftvedt and Ole Anders Stensen, the Norwegian Medical Association

NEW STEPS FOR HEALTH PROTECTION IN THE CZECH REPUBLIC



Finally, the Czech Republic belongs to the western European countries – at least in one important regard. As president of the Czech Medical Chamber, I have always advocated strongly for complex and strict anti-smoking legislation. Certain measures concerning health protection entered into force in 2005. The law, however, did not include an absolute ban on smoking in all in-door premises so far.

Our fight for the new anti-smoking bill took a long time also due to the huge impact of the tobacco lobby on political decision-making processes. Many factors, including influence of various stakeholders and initiatives, hindered reasonable progress at the legislative level. The effort paid off on 14 February 2017 when the president of the Czech Republic Milos Zeman signed the new government bill on the Act of Protection from the Harmful Effects of Addictive Substances.

We really welcome that from 31 May (World No Tobacco Day) onwards there will be a smoking ban for all in-door premises – transit areas at international airports, shelters and waiting rooms, public transportation, medical establishments, schools, zoos, all premises of all sport grounds and all internal premises of restaurants and establishments providing catering services with the exception of water pipes and electronic cigarettes. Further good news is that there is also a considerable progress on health warnings on cigarette packs – a measure which is already in force. The packages containing pictorial health warnings, are a good step forward. Although the best way would be in my opinion plain packaging, it significantly improves the protection especially of young people, against the harmful impact of tobacco advertising.

The fight against smoking is an essential topic for the Czech Medical Chamber. A conference of our organisation concerning this theme will take place in the Senate of the Parliament of the Czech Republic in June 2017.

Dr Milan Kubek

It is worth mentioning the clause that allows smoking in “structurally separated premises”. This term is precisely defined (i.e. the smoke must be strictly isolated from the external environment and the premises must be clearly labelled as smoking area) and must not be used by people under 18 years. The Czech Medical Chamber also welcomes the new reimbursement system for toxicological screenings. Toxicological screenings will now also cover organisations that make certain person undergo such examinations (e.g. in case of police investigation or with regard of labour law).

The fight against smoking is an essential topic for the Czech Medical Chamber. A conference of our organisation concerning this theme will take place in the Senate of the Parliament of the Czech Republic in June 2017. We will see there whether politicians take the fight for fresh and health air seriously. One matter remains undoubtedly clear – the tax on tobacco should be considerably higher in the Czech Republic. It is logical that when smokers voluntarily damage their health, there should be higher payment directly to the health system that provides healthcare for diseases caused by smoking. People smoke more than 20 million of cigarettes every year in our country. If we transferred 20 crowns from each cigarette to the healthcare system there would be 5 billion more for the public health. The next development within this field is hopefully just a matter of time!

For further information, please contact:

Dr Milan Kubek, President of the Czech Medical Chamber



ELECTRONIC HEALTH COOPERATION SERVICE SPACE – THE HUNGARIAN NATIONAL EHEALTH PROJECT



The Electronic Health Cooperation Service Space (EESZT) is the largest IT development of the Hungarian healthcare. The new system was developed by the National Healthcare Service Center (ÁEEK) to transform the paper-based national healthcare system to a modern, service focused and up-to-date, nation-wide eHealth

system which meets all the requirements related to data protection. The cloud-based centralised platform enables information systems and health professionals in the sector to work together. It allows different healthcare providers, emergency ambulance services, physicians and pharmacists to access and update health data in order to ensure the continuity of patient care.

The new system's main object is to provide personalised patient care and increase patient safety at national level. By using the new services like eDoctor's referrals and ePrescriptions access to health care services becomes easier and patients' recovery time becomes faster. Physicians and pharmacists will be able to see their patients' healthcare data, exact medical history, chronic diseases, blood-type, laboratory test results and any allergy related information they may have through their e-profile. Patients will not only be able to download their electronic documents and doctors' medical reports but also the imaging results of any CT or X-ray scans. They can access their medical documents anytime and anywhere. This means less paper, less queuing and a shorter patient journey.

*The system is protected by parallel multi security solutions. Patients data can only be accessed by the authorised doctor or specialist and the pharmacist.
(Patients) can decide which of their personal data can be accessed.*

Ms Renata Tar

The system is protected by parallel multi security solutions. Patients data can only be accessed by the authorised doctor or specialist and the pharmacist (depending on their qualification and authorisation by their workplace) after logging in to a two factor authentication system. Patients need to complete a self declaration form when setting up their eProfile where they can decide which of their personal data can be accessed. eProfile settings can be changed anytime.

The pilot mode of the system will end in August 2017. Publicly financed health institutions will be able to join on a voluntary basis from September onwards. Joining will be mandatory from November 2017. By the end of 2015 the National Healthcare Service Center (ÁEEK) had invested HUF 7.2 Billion (EUR 23 Million) in 191 public financed health institutions to develop an IT infrastructure that will allow 69% of hospitals, 72% of general practitioners and 85% of pharmacies to join immediately.

The Hungarian government calculates HUF 1.2 Billion (EUR 3.9 million) a year to support the Electronic Health Cooperation Service Space (EESZT).

For further information, please contact:

[Ms Renata Tar](#), International Relations – Hungarian Medical Chamber



CPME NEWS

On 2 December 2016, CPME President Dr Jacques de Haller and CPME Secretary General Annabel Seebohm attended the Plenary Meeting of the European Council of Medical Orders (CEOM) in Paris.

On 8 December 2017, CPME Vice President Dr Bernard Maillet participated in the 3rd annual COCIR eHealth Summit in Brussels. Please find more information [here](#).

On 27 January 2017 CPME President Jacques de Haller attended the Conference of INGOs at the Council of Europe in Strasbourg. Please find the highlights from the conference [here](#).

On 8 February 2017 CPME Vice-President Dr Patrick Romestaing was at the OECD Stakeholder Consultation meeting for the feasibility study on health in workplace skills assessment in Paris.

On 15 February 2017 CPME Vice-President Prof. Dr Rutger Jan van der Gaag participated at the European Commission Vaccine Hesitancy event. Streaming of the event available [here](#).

On 27-28 February 2017 CPME Secretary General Annabel Seebohm took part in the final conference of the Joint Action on Addressing Chronic Diseases and Healthy Ageing across Europe (CHRODIS) entitled "Towards better prevention, management and care" in Brussels. Please find more information [here](#).

On 17 March 2017 CPME President Jacques de Haller took part in the Final Conference on PISCE in Brussels. Please find more information [here](#).

On 21-23 March 2017 CPME President Jacques de Haller and Secretary General Annabel Seebohm attended UNESCO Chair in Bioethics 12th World Conference in Limassol, Cyprus. More information can be found [here](#).

On 29-30 March 2017, CPME Past President Dr Katrín Fjeldsted attended the 2nd Global Ministerial Summit on Patient Safety in Bonn, Germany. More information can be found [here](#).

EU INSTITUTIONAL NEWS

15 December 2016	The December European Council discussed migration, security, economy and youth, and external relations. Please find more information here .
1 January 2017	On 1 January 2017 Malta took over the rotating six-month presidency of the Council of the European Union from Slovakia. More information on the presidency's priorities can be found here .
17 January 2017	The Italian MEP Antonio Tajani (EPP, IT) was elected new President of the European parliament with 351 votes in a final face-off with Gianni Pitella (S&D, IT), who secured 282 votes.
1 March 2017	As announced in President Juncker's 2016 State of the Union speech, the European Commission presented a White Paper on the Future of Europe which forms the Commission's contribution to the Rome Summit of 25 March 2017
15 February 2017	The EU-Canada Comprehensive Economic and Trade Agreement (CETA) was approved by the European Parliament. The landmark trade deal could apply provisionally from as early as April 2017.
10 March 2017	The European Council re-elected Donald Tusk as its president for a second term, from 1 June 2017 to 30 November 2019. Donald Tusk was also re-appointed as President of the Euro Summit for the same period.
29 March 2017	The European Council President Donald Tusk was handed over the official letter by the UK government to evoke the Article 50 TEU.

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Thank you

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Guest commentary

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