

FLASH n°118 - January 2014

Feature Stories



European Mutual Statute

Commissioner Tajani announces a proposal for mutuals at Social Entrepreneurs Conference



Commission launches Consultation on investorto-state dispute settlement



Clinical Trials

Council and Parliament adopt common position on Clinical Trials



Data Protection

Data Protection delayed to end of 2014

Contents:

AIM and You	2
European Institutions	2
Council of Ministers	2
European Commission	2
European Parliament	4
Pharmaceuticals and Medical Devices	3
European Affairs	5
Mutuals	5
Health and Long-term care	5
Health Events in Europe	7

Next Meeting and visit dates



Pharmaceuticals and Medical 7 February Devices WG

At AIM offices

Pensions WG 3 March

At AIM Offices

Committee on the revision of AIM 6 March

Statutes

At AIM Offices

Fraud WG 12 March

At AIM offices

Internal Audit Committee 30 April

At AIM offices



AIM @AIM_Healthcare · 16 janv.

■AntonioTajaniEU announces an initiative on the #EUMutualstatute after 22.01 #mutuals4u #livetweet from the #SocEntEU Conference



AIM @AIM_Healthcare · 16 janv.

MEPs engaged for #social #economy,@toiapatrizia discusses with personalities from the #mutual sector #mutuals4u pic.twitter.com/ksBwWOQMa1



AIM @AIM_Healthcare · 16 déc.

#TTIP talks- 3rd round to start in Washington D.C. today, Key issues:

bit.ly/1k7Guvw @EU TTIP team

AIM and you

> AIM Activities

AIM Meetings:

20 January: European Affairs Working Group

23 January: Mutuals Working Group

Events AIM attended:

On 14 January AIM Secretariat attended the meeting of the Education and Solidarity Network.

On 16-17 January, AIM Secretariat attended the EU Commission Conference 'Social Entrepreneurs: Have your Say'. *For more information, read the dedicated article.*

On 30 January, AIM Secretariat attended the Annual Event of Prescrire about Medicines Victims. More information is available on Prescrire's website (FR).

> AIM Staff



We have the pleasure to inform you that we are welcoming two new members of staff at AIM this month: Romain Chave and Athina Pantelidou.

Romain Chave is joining AIM as Junior Project Manager. He is in charge to support the Secretariat on European Affairs, and other working groups, such as Mutuals. He will also provide support for Communications and for logistics (statutory meetings). Romain speaks English and German, with French as mother tongue.



Athina Pantelidou is joining AIM as Intern until 15 April 2014. She is studying an advanced master programme in European Social Security in KU Leuven (Katholieke Universiteit Leuven). She is from Greece, Thessaloniki and speaks Greek as a native, English, German and Dutch. Contact Romain and Athina.

European Institutions

Council of Ministers

EU Greek presidency: The priorities of the Greek presidency in the EU Health policy.

The Greek Presidency published the official programme for her presidency in EU from 1 January to 30 June 2014. The three main non-legislative health priorities of the presidency are: Economic crisis and health care, Migration and Public Health and Healthy diet and physical activity.

Within legislative priorities, importance will be given to the progress of the proposals on medical devices and in-vitro diagnostic devices but also to the proposal for a Regulation on fees payable for Pharmacovigilance activities. The next goal will be the progress on a transparency Directive on pricing and reimbursement of medical products.

Council Conclusions on health and the economic crisis are also planned. Key Greek Presidency events will include the e- health forum 2014, the second High-Level e-Health Experts Conference and also a High-Level Conference on nutrition and physical activity.

One objectives of the Greek presidency, the revision of the EU Tobacco law is already closed to be achieved with a Compromise between the Council and the Parliament that was validated this month by the Health Committee in the Parliament. For more information visit the dedicated page on the official website gr2014.eu.

> European Commission

Chronic Diseases: EU Commission launches new Joint Action on Chronic Diseases

On 29 January, the Joint Action for chronic diseases "CHRODIS" was launched at a kick - off meeting in Madrid. Joint actions are activities carried out by the European Union and one or more Member States or by the EU and the competent authorities of other countries in the frame of the Health Programme. This Joint action includes 38 organisations from 22 Member and this is the first action co-financed by the EU Health Programme under the 2013 plan.

2

CHRODIS Joint Action works in order to promote a mechanism of exchanging good practice among the member states with respect to tackle chronic diseases. It also aims at health promotion and prevention and particularly with issues such diabetes and persons with several long-term conditions.

The joint EC/OECD "Health at a Glance: Europe 2012" reported that in 2011, 30 million people suffered from diabetes in Europe. The absence of exercise, bad nutrition, smoking and alcohol, and exposure to chemical substances are proved to be dangerous factors for causing a chronic disease.

For more information please refer to this page of the European Commission.

TTIP: Commission launches Consultation on investment dispute settlement in Transatlantic Trade and Investment Partnership (TTIP)

The Commission is to consult on new rules for investment dispute settlement in the investment provisions of TTIP. In early March, EU Trade Commissioner Karel De Gucht will launch a public consultation on a proposed EU text for the investment part of TTIP which will include sections on investment protection and on investor-to-state dispute settlement, or ISDS. This draft text will be accompanied by clear explanations for the non-experts.

The draft will would include new and improved rules, including a code of conduct, to ensure arbitrators act impartially and are chosen fairly. Citizens across the EU will then have three months to comment.

For more information see the <u>Press Release</u> and the <u>Factsheet on Investor State Dispute Settlement</u>. The consultation will be published on the <u>DG Trade Website</u>.

TTIP: A group of experts to advise the European Commission

A stakeholder advisory group will provide the EU negotiating team with expert advice in the areas being negotiated in the Transatlantic Trade and Investment Partnership (TTIP) talks.

The fourteen members of the group, representing different interests, will meet every 2 months in between negotiating rounds. They come from environmental, health, consumer and workers' interests and different business sectors (for instance: European Public Health Alliance, the European Consumers Association, BEUC or the European Services Forum). The group has a consultative role and will have access to negotiating documents. The first working session will be held on 25 February 2014. For more information, see the Press Release and visit the Website of the expert Group.

TTIP: Regulation on financial services

On 27 January the European Commission published its proposals for the creation of a framework for regulatory cooperation on financial services in the TTIP.

The Commission is to establish, within the TTIP, an institutional framework of EU and US regulators which would ensure that the EU and US rules work together and would avoid regulatory arbitrage and duplicative application of rules. The Commission's opinion includes joint work to ensure implementation of internationally-agreed standards and a supervision examination of the existing rules to examine whether they create unnecessary barriers to trade.

Insurance and healthcare services are included into the financial services part of TTIP.

Find the opinion of the Commission here. The 4th Round of TTIP negotiations will be held 10-14 March in Brussels.

Insurance: Report on the Recast of the insurance mediation directive adopted by Economic Committee

The parliamentary committee Economic and Monetary Affairs (ECON) voted on the draft report on 22 January 2014. The new text aims at improving regulation in the retail insurance market.

The new directive relative to insurance mediation should expand the scope of application of the previous directive (IMD1) to all distribution channels, clarify the exercise of the freedom of establishment as well as simplify the procedure for cross-border entry to insurance markets across the EU.

Insurance mediation carried out by statutory systems of social security governed by public law should be excluded as an amendment in this sense was proposed and accepted. The text will now be voted in plenary on 22 February 2014.

> European Parliament

Public Procurement: New European rules adopted

On 15 January 2014, a new Directive regarding public procurement was approved by the European Parliament.

The main novelties are the introduction of award criteria promoting environmental considerations, social aspects and innovation when choosing a contractor. The bidding procedure will be simplified aiming at reducing the administrative burden by over 80% according to the Commission.

A new simplified regime will be created for social, health, cultural and assimilated services with a threshold increased to 750 000 €. The Directive should not affect the social security legislation of the Member States which are free to organise the provision of services of general interest including social services. To fight against social dumping, the new laws will include rules on subcontracting: Contractors and subcontractors that do not comply with EU labour laws will be excluded from bidding. Member states will have 24 months to implement the new rules into national law. More details can be found in the Parliament Press Release.

E-health: e-health Action Plan 2020 supported by the European Parliament

On 14 January, Members of the European Parliament voted on a resolution in support of the eHealth Action plan 2014-2020 presented by the European Commission in 2012. Considering that the development of e-health could improve the efficiency of healthcare systems and the wellbeing of patients, the European Parliament urged the Commission and the member states to promote the development of user-friendly, safe and accessible e-health services across the European Union. This development should be



fostered by a sustainable funding model and involve all stakeholders: health insurance funds, national health institutions, healthcare professionals. The e-health action plan 2020 launched by the Commission aims at empowering patients and healthcare systems and promoting the utilisation of devices and technologies to provide more efficient health services and optimise healthcare spending. More information can be found in the Parliament Press Release.

Pharmaceuticals and Medical Devices

Clinical Trials: Council and Parliament find agreement in the revision of EU rules on clinical trials.

On 20 December the Council and the Parliament reached an agreement on the revision of the Directive 2001/20/CE on clinical trials. The new regulation aims at simplifying and accelerating the authorisation procedure and deals with other issues such as transparency, ethic committees and tacit agreement.

The new regime for the application procedure provides that clinical trials will be introduced at a single entry point. Under the current directive an application must be submitted to each member state where the clinical trial will be conducted.

Regarding new transparency procedures, member states will now be obliged to publish every clinical trial results within a year, in a publicly accessible database managed by the European Medicines Agency. Member states have a deadline of 60 days to respond to an application. If not, then authorisation is given automatically. Moreover as for ethic committees, each member state will make their independent assessment of ethical issues. You can find more information in the Council Press Release.

European Affairs

Data Protection: Adoption postponed until end of 2014

On 22 January, a political agreement was reached by Commissioner for Justice, Ms Reding and the Greek Presidency and upcoming Italian Presidency of the Council with the aim to find an agreement on the data protection proposal before the end of 2014.

More than a date a roadmap has also been elaborated to get to this agreement by the end of the year. Yet, the implementation of the roadmap and the deadline will very much depend on member states' progress in the Council.

For the moment the state-of-play is still not clear. Several states continue to oppose a regulation among which, the United Kingdom, Denmark, Hungary and Slovenia.

In the Parliament, the vote in the Plenary is scheduled for March or April 2014 in order to validate the final Report of the main Committee and thus to have an official common



©EU Council

position of the EP. For more information about the current state, please refer to this article by EU Observer.

Clinical data: National Health Service patient data: accessible to drug and insurance firms in the UK

In the United Kingdom, drug and insurance companies will be able to purchase from March patients' data from a unique medical database.

This data includes mental health conditions and diseases such as cancer of even smoking or drinking habits. Companies that are interested can apply to the new Health and Social Care Information Centre (HSCIC) and pay to extract the information which will not remain completely anonymous (the so called "pseudonymisation" procedure).

On the one hand advocates of this new initiative claim that it will save lives and support he health system by making drug side effects or the performance of the hospital surgical units more transparent. On the other hand, privacy experts warn that the extracted information will contain NHS numbers, date of birth, postcode, ethnicity and gender. Mark Davies, the centre's public assurance director, indicates there is a "*small risk*", that certain patient data could be re-identified due to their former existing medical data. More details can be found in the Guardian's article.

Fraud: First Commission Study on Fraud in Healthcare

The study which was published in December 2013, is the first study of this scope giving an accurate picture of fraud in healthcare in all EU member states.

The <u>study</u> begins with recognizing that citizens of the European Union spend the remarkable figure of over 1 trillion euro a year on healthcare, while the healthcare sector is one of the areas that is particularly vulnerable to corruption. The study aims at identifying the scope of fraud in the healthcare system as well as the capacity of member states to prevent and tackle fraud cases. The study further identifies 6 various typologies of corruption: bribery in medical service delivery; procurement corruption; improper marketing relations; misuse of high-level positions; undue reimbursement claims; fraud and embezzlement of medicines.

Another delivery of the study is to establish that all member states are concerned by the problem of fraud, though the pattern of fraud based on different typologies does differ. In conclusion, the study also lays down several best practices to counter fraud in healthcare. These are for example anti-bribery legislation, the centralization of procurement, the setting up of control mechanisms in the healthcare system or the introduction of transparent waiting lists. For more information, also report to the Executive Summary of the Study.



©EU Commission, Extract from the Executive Summary

Mutuals and Social Economy

European Mutual Statute: A proposal for mutuals announced by Commissioner Tajani

During the Conference of Strasbourg, the European Commissioner Tajani announced a proposal for mutuals.

After the positive results of the Consultation on the creation of a statute for mutual in September 2013, the Commission had ordered a study to assess the possible impacts of a regulation. This impact assessment is to be concluded by the end of February. Commissioner Tajani already announced on 16 January 2014, at the Conference on social entrepreneurship, the very likely positive outcome of the study and declared that a proposal would be made before the end of the current legislation of the Commission (October 2014). AIM and all the mutual stakeholders welcomed very warmly this declaration and remain mobilised to ask for a prompt proposal from the Commission. See the AIM Press Release for more information.

Social Economy: Mutuals gathered at the Social Entrepreneurs Conference in Strasbourg #mutuals4u

AIM participated in a Conference organised by the European Commission on Social entrepreneurship on 16 and 17 January 2014 in Strasbourg.

This Conference aimed at assessing the European initiatives and actions regarding social enterprises, preparing the future policies and giving the opportunity to the stakeholders to exchange.

AIM, its members as well as European partner associations have been representing the European mutual movement on a stand entitled #Mutuals4U. This stand involved the International Cooperative and Mutual Insurance Federation (ICMIF), the



Association of Mutual Insurers and Insurance Cooperatives in Europe (AMICE), the Mutualité Française, the Regional Unions of Alsace, Lorraine and Burgundy, and various European mutuals (MGEN and Harmonie Mutuelles - France, Solidaris and ANMC - Belgium, Knappschaft - Germany). Specific examples of social innovation projects carried out by mutuals were such as the impact of environment and air on health. Commissioner Barnier, Andor and Tajani were speaking at this Conference and various key personalities visited the Stand (see picture with Commissioner Barnier) This conference ended with the release of the Strasbourg Declaration pointing the key role played by social enterprises (among which Mutuals) to create inclusive and sustainable growth for the European Union.

Throughout the whole conference, a live tweet was animated around the hashtag #mutuals4u: all key messages of the Conference can be found by using this <u>hashtag</u>. Find more information on the <u>Website</u> of the Conference.

Health and Long-term care

> Trends in health system

WHO: WHO director calls to action on Non-communicable diseases

The New OECD report gives more figures about the impact of the crisis on the health sector

Zsuzanna Jakab, Director of the WHO declared that "the cost of action to counteract non-communicable diseases and tobacco is far lower than the cost of inaction". In Europe, the central and eastern parts of the region are characterised by the greater figure of premature mortality caused by NCDs, whereas the western parts of the region have a larger proportion of people living with NCDs.

The director reminded that in 2003, the framework convention on tobacco control (FCTC) was signed as the very first World Health Organisation (WHO) international treaty. More will have to be done in many countries to meet the global voluntary NCD target for a 30 per cent relative reduction of tobacco use by 2025. In particular, the director referred to the necessary toughening of tobacco control legislation in Europe, while member states are in the process to adopt a new Directive on Tobacco products.

For more information on this, you can read the article from The Parliament.

> Call for proposals, Consultations

Public consultation on patient safety and quality of care

04.12.2013 - 28.02.2013

http://ec.europa.eu/health/patient_safety/consultations/patient_safety_quality_care_cons2013_en.htm

Public consultation on VAT legislation on public bodies and tax exemptions in the public interest 14.10.2013 – 25.04.2014 (new deadline)

http://ec.europa.eu/taxation_customs/common/consultations/tax/2013_vat_public_bodies_en.htm

State aid: Commission consults on draft Communication on State aid to promote Important Projects of Common European Interest

28.01.2014 - 28.02.2014

http://europa.eu/rapid/press-release_IP-14-84_en.htm?locale=en

Studies, Videos

Cross-border Healthcare

EU Commission: Seeking healthcare in another EU Member State

http://bookshop.europa.eu/is-bin/INTERSHOP.enfinity/WFS/EU-Bookshop-Site/en GB/-/EUR/ViewPublication-Start?PublicationKey=ND0313476

Environment

WHO: Health and environment- communicating the risks

http://www.euro.who.int/__data/assets/pdf_file/0011/233759/e96930.pdf

Ageing

Attitudes about Aging: A Global Perspective

30.01.2014

http://www.pewglobal.org/2014/01/30/attitudes-about-aging-a-global-perspective/

Palliative Care

WHO: Worldwide Palliative Care Alliance: First ever global atlas identifies unmet need for palliative care 28.01.2014

http://www.who.int/mediacentre/news/releases/2014/palliative-care-20140128/en/

Crisis and Health

EU Health Observatory: New website Health and Finance Crisis Monitor

http://www.hfcm.eu/

Health Systems

EU Health Observatory: New Website: Health Systems and Policy Monitor

http://www.hspm.org/mainpage.aspx

Cross-border hospital collaboration in border regions - mechanisms and motivations

EU Health Observatory

http://www.euro.who.int/en/about-us/partners/observatory/news/news/2013/11/cross-border-hospital-collaboration-in-border-regions-mechanisms-and-motivations

WHO, Research for universal health coverage

World health report 2013

http://www.who.int/whr/2013/report/en/index.html

	Health events in Europe
13-14 February	European Council Brussels
6-7 March	Justice and Home Affairs Council Meeting
10 March	Employment, Social Policy, Health and Consumer Affairs Council Meeting (EPSCO)
20-21 March	European Council Brussels
March 2014	Greek Presidency Nutrition and physical activity Conference Greece
28-29 April 2014	Informal Meeting of Health ministers Greece
May 2014	World Health Assembly
20 June	Employment, Social Policy, Health and Consumer Affairs Council Meeting (EPSCO)

The monthly AIM Flash is compiled by Blandine Cassou-Mounat, Romain Chave and Athina Pantelidou.

Realisation & Layout: Blandine Cassou-Mounat

26-27 June

For more information on one of the topics mentioned above, please contact the AIM Secretariat.

'AIM Flash' © monthly publication of the AIM Secretariat

European Council

Brussels

AIM asserts copyright in all the text of this publication. Reproduction of short extracts is welcome provided the source is quoted. Reproduction of complete articles requires written permission in advance from the AIM office.