

Feature Stories



Medical Devices

Positive Breakthrough for medical devices' safety with adoption of ENVI Report



AIM-MLOZ Cross-border Workshop

Implementation of Cross-border healthcare directive remains challenging



Long-term Care Conference

Health mutuals and paritarian institutions commit to international cooperation



Tobacco Products Directive

Adoption of the report for stricter regulation of Tobacco products

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Next Meeting and visit dates

- 30 October** Fight against Fraud Working Group
At AIM offices
- 29 November** Pharmaceuticals and Medical Devices Working Group
At AIM offices
- 4-6 December** AIM General Meetings
In Hamburg
- 20 January** EU Affairs Working Group
At AIM offices

Top Twitts



EHMA @EHMAinfo

17 Sept

Excellent [#CBworkshop](#) this morning by [@AIM_Healthcare](#) and MLOZ: CBC seems to be largely transposed, but patients beware!

Retweeté par AIM

Ouvrir



AIM @AIM_Healthcare

5 h

[#Tobaccodirective](#) on 8.10, Debate 9h, vote 12h, press conf 14h w/ [@LindaMcAvanMEP](#), plenary Amendments [bit.ly/RyJOCR](#) [@EP_Environment](#)

Ouvrir



AIM @AIM_Healthcare

26 Sept

AIM welcomes positive breakthrough for safety of [#medicaldevices](#) in ENVI Committee. See our Press Release: [bit.ly/15tNHlf](#)

AIM and you

➤ *AIM Activities*

AIM activities:

29 August: Mutuals' Working Group

13 September: Education and e-learning Working Group

16 September: European Affairs Working Group

17 September: AIM-MLOZ Cross-Border Workshop: *"How far are we in the implementation of the Cross-border Healthcare directive"*

18-20 September: Conference *"Evolution of health systems regarding the challenges of Long-Term Care"*
Co-organised by AIM, AEIP, MGEN, RES

30 September: Pharmaceuticals and Medical Devices Working group

Events AIM attended:

On 11 September AIM Secretariat attended the EU Health policy Forum.

On 2nd October, AIM Secretariat attended the Seminar «Social Entrepreneurship in the European Agenda» organised by Social Economy Europe.

European Institutions

➤ *European Council*

Greek Presidency: Priorities of the Greek Presidency at the EU Health policy Forum

As well as finalising the various files before the elections, Greece announced three non-legislative priorities this month: Economic crisis and healthcare, Migration and Healthy diet and physical activity

On 11 September, Mr Antonio Lanas presented for the first time the Priorities of the Greek presidency. Regarding Health the task of the Greek Presidency will be to try and advance as much as possible on Tobacco, Clinical Trials and Medical Devices.

The non-legislative priorities of the Greek Presidency will be three-fold: Economic crisis and healthcare, Migration and Healthy diet and physical activity.

The future Greek Presidency plans to have Conclusions on economic Crisis and health as well as Healthy diet and physical activity. Specifically on Healthy diet and physical activity, the Greek Presidency is planning to hold a Presidency Conference in mid-March in Greece.

➤ *European Commission*

Social Policy: Commission publishes a Communication on the Social dimension of the Economic and Monetary Union

On 2nd October, the Commission released a communication which focuses on issues that are directly relevant for the well-functioning of the EMU, while fully respecting the general social agenda for the wider EU.

The flagship measure in the communication is to create a new scoreboard to allow for better and earlier identification of major employment and social problems in the framework of the European Semester, the EU's yearly economic policy-making cycle.

The Communication focuses on three areas: Reinforcing surveillance of employment and social challenges and strengthening policy coordination under the European Semester; Enhancing solidarity and reinforcing job mobility; Strengthening social dialogue. For more information read the Commission [Press Release](#). The Communication does not get a unanimous support: Martin Schulz, the President of the European Parliament already indicated that the measures proposed did not go far enough.



Commissioner Andor presents new Communication at Press Conference ©EC Audiovisual Services

➤ **Pharmaceuticals and Medical Devices**

Medical Devices: Adoption of a positive report for the safety of medical devices

On 25 September, a crucial report of MEP Dagmar Roth-Berendt for the future safety of medical devices in Europe has been adopted with 52 votes in favour, 12 against and 3 abstentions in the Health committee in the European Parliament.

AIM has welcomed in a press release the improvement of the safety and benefit of high-risk medical devices like implants or heart valves.

According to the report, the assessment of high-risk medical devices should go through special notified bodies designated by the European Medicines Agency. Other advances in this report include improvements on transparency of clinical data: the restriction of use of the abusive claim of “commercial sensitivity” should also remain an exception. MEPS also approved that innovative medical devices should be tested against a comparator i.e. the existing reference treatment. Finally, Manufacturers would need to ensure that they are covered by an appropriate liability insurance to cover insolvency and any damages to patients caused by a faulty device. The vote in Plenary on this topic is scheduled at the end of October.

For more information, please consult the [Press Release](#) of the ENVI Committee.



Medical Devices: implementation regulation and recommendation to improve the safety of medical devices

On 24 September, the European Commission adopted two measures announced in the Joint Plan for immediate action agreed between the Commission and the EU Member States following, amongst others, the Poly Implant Prothèse (PIP) breast implants scandal.

The new rules are a Commission Implementation Regulation clarifying the criteria to be met by notified bodies, which are responsible for inspecting manufacturers of medical devices, and a Recommendation clarifying audits and assessments in the medical devices sector. Most of the actions agreed upon have now been implemented or are under implementation. The overall progress will be presented in a Commission Staff Working Document to be published in October. In addition, a pilot project of joint audits of notified bodies undertaken by auditors from several Member States and the Commission was launched earlier this year. 11 such audits have taken place and 8 more are planned before the end of the year. These actions have already, before the adoption of today's measures, resulted two notified bodies been obliged to temporarily stop issuing certificates until deficiencies have been corrected.

For more information, read the Commission [Press Release](#).

Clinical Trials: Waiting for the mandate to negotiate from the Council

The Clinical trials report was voted in May in the European Parliament. Rapporteur Glenis Willmott (S&D, UK) is now waiting for the negotiating mandate to start informal negotiations with the Council on the basis of the report. The mandate could finally be issued on 30 October by Lithuanian Presidency. Time is running out to find an agreement on this important file for the publicity of all trials in Europe.

Euractiv reported that the pharmaceutical industry is trying to 'mobilise' patient groups into lobbying against EU plans. Tim Reed, from the non-profit group Health Action International, said denouncing industry lobbying practices: "*industry uses [patient groups] to say we're not going to get innovative medicines if the industry is deterred from investing by having to be transparent about their clinical trials*". More information on lobbying by the industry is available in the related Euractiv [article](#).

Clinical Trials: EMA policy on clinical trials could help save lives

The Agency established advisory groups to help develop a policy on publication of and access to clinical-trial data, which has recently been released for public consultation.

In its draft, the EMA proposes “proactive publication of clinical-trial data” submitted in support of a marketing-authorisation application. Many elements from clinical study reports (CSRs) would finally become publicly available. This is a step in the right direction, as there is currently a lack of public access to the full body of available scientific evidence about the effects of medicines on human health.

Read the [Press Release](#) by AIM, and its partners MiEF, HAI and ISDB.

➤ AIM Events

Cross-border Healthcare: Implementation of Cross-Border Healthcare Directive remains challenging

On 17 September, at the initiative of AIM and MLOZ, over 50 stakeholders gathered at the Cross-border Healthcare Workshop to discuss the status of implementation of the directive.

At the end of October, on 25 October, the deadline of implementation for member states will be over. The workshop chaired by Christian Horemans from MLOZ showed that some challenges remain in the implementation of this text.

First, implementation seems to vary widely from country to country: for instance, while Belgium is almost ready, implementation is still at an early stage in Croatia and the Czech Republic.

Key challenges for the implementation discussed by stakeholders were for example the streamlining of all legal tools on cross-border healthcare and the necessity to inform patients well about their rights.

Presentations in the event included member states' perspectives from 3 countries, but also from pharmacists, hospitals, national health authorities and European institutions.

For more information on the outcome of the event, read the AIM-MLOZ [Press Release](#).

🐦 See all Tweets relevant to this workshop: [#CBWorkshop](#)



Long Term care: Health mutuals and paritarian institutions commit to international cooperation to improve management of long-term care

From 18-20 September, MGEN welcomed the AIM-AEIP-MGEN-RES Conference in Paris on the "Evolution of health systems regarding the challenges of Long-Term Care".

The conference was attended by over 150 representatives of health mutuals, provident societies and public authorities from about 20 different countries.

This conference, organised by AIM, the MGEN group, the Education and Solidarity Network, and AEIP (European Association of Paritarian Institutions of Social Protection), was also supported by Kemporen (National Federation of Health Insurance Societies, Japan) and the NCCMP (National Coordinating Committee for Multiemployer Plans, United States).

AIM President Mr Jean-Philippe Huchet also contributed at the event. At the end of this conference, mutuals and paritarian institutions signed a [declaration](#) marking their mobilisation in favour of ensuring long-term care in health systems is taken into account to a greater extent. For more information, read the Common [Press Release](#).



➤ EU Affairs

Data Protection: Data Protection in the Council and in the Parliament

In the Council, no general approach could be found on the first three chapters. No agreement has been reached either on the legislative form of the text: regulation or directive.

On 5 September 2013, Lithuanian Justice Minister Juozas Bernatoniš met with Commissioner of Justice Viviane Reding and Chair of the responsible Committee (LIBE) Juan Fernando Lopez Aguilar.

Lithuanian justice Minister declared: "A number of ministers stated that quality of the legal act should not be sacrificed to speed, and emphasized that there was still much work to be done by the experts from 28 Member States.

Therefore, Lithuania, holding Presidency over the EU Council, is following this approach". In October during the Justice and Home Affairs Council the important input of Ministers in the negotiations on these issues is expected.

In the European Parliament, the vote in the main Committee, LIBE which has been postponed several times now, should take place on 21 October.

EU-US TTIP: Preparing the Second Round of Negotiations

The second round of the Transatlantic Trade and Investment Partnership (TTIP) negotiations will take place in Brussels from 7 to 11 October 2013. Answering to fears of deregulation- including in the healthcare sector, Commissioner of DG Trade Karel De Gucht declared *“The goal here is not a transatlantic, deregulatory free-for-all”* [...].

We will try to make the technical aspects of EU and US regulations more compatible – while leaving the political choices about the level of protection firmly intact.”

An [article](#) by Corporate Europe Observatory establishes that already 119 meetings have taken place with industry lobbyists at the European Commission and warns of an ‘*Industry-dominated advisory group*’.

For more information on the position of the Commission on the TTIP you can consult this [summary](#) of the European Commission on the [Regulatory Part](#).



©EU Commission

Tobacco directive: Adoption of the Report and Postponing of the Vote in Plenary to 8 October

Over the last three months, important progress has been achieved on the tobacco Products Directive.

The most positive move is the adoption in July of the progressive [Report](#) of MEP Mc Avon (S&D, UK) was adopted in the ENVI Committee, though the plenary vote was delayed. The report validates the most important points of the Commission proposal including bigger warnings on tobacco packaging, the ban of flavourings, better ingredients regulation, tighter measures against illicit trade as well as the prohibition of cross-border sales. The obligations for tobacco packages to display at least 75% of health warnings as well as the ban of flavourings are two measures which aim to deter younger generations to start smoking (see also the [Press Release](#) of the Committee).



The next step in the European Parliament is the plenary vote on the text which will take place on 8 October in Strasbourg. In the Council, a [General Approach](#) had been reached in June, the main difference with the adopted report being a display of health warnings representing 65% of the package.



Also linked to the topic of tobacco prevention, the European Commission has launched its ‘Ex-smoker Campaign’ featuring celebrities on the occasion of the Ex-smoker day on 26 September. More information is available on the Ex-smoker [website](#).

Social Dimension to EMU: Commission proposes ideas to deepen social integration

The Commission released a [communication](#) on the Social Dimension of the Economic and Monetary Union.

The flagship measure in the communication is to create a new scoreboard to allow for better and earlier identification of major employment and social problems in the framework of the European Semester, the EU's yearly economic policy-making cycle.

The scoreboard would gather indicators such as: unemployment level and changes; youth unemployment rate; at-risk-of-poverty rate of working age population. The Communication focuses on three areas: Reinforcing surveillance of employment and social challenges and strengthening policy coordination under the European Semester; Enhancing solidarity and reinforcing job mobility; Strengthening social dialogue.

DG Employment and Social Affairs will also be holding a Conference on Social dimension of the EMU on 10th October. For more information you can read the Commission [Press Release](#).

European Semester: Still much room to improve the European semester, say MEPs of the ECON Committee

The ECON Committee points to room for improvement in the resolution on the EU semester.

Warnings and requests are set out in the committee's annual resolution on the latest developments in the European Semester, the process whereby EU member states coordinate their budgetary and economic policies. Drafted by Elisa Ferreira (S&D, PT) and approved by 30 votes to 2, the resolution welcomes the fact that some concerns previously raised by Parliament have been addressed but notes that there is still ample room for improvement.

MEPs have called for legislative proposals to give the Economic and Monetary Union (EMU) a social pillar and set up a “*social pact for Europe*”, referring to recent consequences of austerity policies on the welfare systems.

The resolution will be put to a vote by the whole house towards the end of October. It will provide Parliament's input for 2014 coordination process, which the Commission is to launch in November. See the full [Press Release](#)

Single Market Month: Online debates with Commissioners on Social Rights

The European Commission has organised the Single Market Month this year to bring closer citizens to Institutions through online interactive debates and events. Throughout the Single Market Month, the forum hosts successive debates on four themes: Jobs, Social Rights, Banks, and e-Commerce.

One week was dedicated to social protection rights from 30 September to 2

October. Commissioners Tonio Borg, Lazlo Andor and Michel Barnier answered citizens' questions on social rights online. To see the discussions in the chat with Commissioner for Health Tonio Borg, you can visit this [page](#). The results of these debates will also be summarised into a final report to provide new ideas to the European Commission.



Public procurement: Adoption of the Report in main Committees

On 5 September the main Committee IMCO backed 3 deals on procurement and concessions on greener, more social & innovative procurement.

The provisional deals struck with Council in July on three directives (on "classic" procurement, "utilities" and "concession contracts") would enable authorities to consider not only the price, but also environmental or social benefits or innovative ideas offered by a bidder.

The draft directives provide for "innovation partnerships" enabling authorities to call for tenders to solve a specific problem without prescribing a solution. The new directives would include tougher rules on "abnormally low" bids and subcontracting, so as to ensure compliance with labour laws and collective agreements.

As for concession contracts, public authorities use concession contracts to hire private firms to supply services or to perform works, such as building roads, bridges or sports arenas.

New EU-wide rules would apply to public contracts worth €5 million or more. They would also give authorities more scope to pick the best offer, relying not only on the lowest price criterion, but also on environmental, social or innovation-related ones. The final plenary vote on the three agreements is scheduled for November.

For more information you can read the Parliament [Press Release](#) or read the [Press release \(FR\)](#) in French by Rapporteur MEP Tarabella.

Open Data: Consultation on best ways to open up more public data

The Commission is asking for help in drawing up guidance and practical advice for boosting the re-use of weather data, traffic data, publicly funded research data, statistics, digitised books, and other types of public sector information (PSI). Commission Vice President Neelie Kroes said: *"The open data revolution is all about individuals and entrepreneurs and that includes the giving them a role in policy design."*

Interested parties can contribute until 22 November 2013, and with their input help ensure effective implementation of the newly revised PSI Directive, which aims to ensure public authorities release more information at little or no cost to users. The results of this consultation will support guidelines to be published in 2014. For more information read the [Press Release](#).

Professional qualifications: European Commission and Member States to assess barriers restricting access to regulated professions

On 2nd October 2013, the European Commission adopted a communication announcing the start of an evaluation of national regulations on access to regulated professions. Regulated professions are professions to which access is conditional upon the possession of specific qualifications or for which the use of a specific title is protected, e.g. pharmacists or architects.

This communication implements requirements as set out in the revised Professional Qualifications Directive.

Each Member State will have to report the list of professions it regulates, including those at regional level. The Commission will then publish this list in the form of a European map of regulated professions that will clearly display which professions are regulated and for which countries, to support mobility of workers. See the [Press Release](#).

➤ Trends in health system

Universal Health Coverage: Health research is essential for progress towards universal health coverage

At the launch of the "World health report 2013: Research for universal health coverage", WHO today called on countries to continue investing in local research in order to develop a system of universal health coverage tailored to each individual country's situation. With universal health coverage, countries can help ensure that citizens obtain the health services they need without suffering financial hardship when paying for them.

Dr Margaret Chan, Director-General of WHO, describes universal coverage as "*the single most powerful concept that public health has to offer*". In launching the "World health report 2013: Research for universal health coverage", Dr Chan says "*universal coverage is the best way to cement the health gains made during the previous decade. It is a powerful social equalizer and the ultimate expression of fairness.*"

➤ Call for proposals, Consultations

EU Commission, Consultation on best ways to open up more public data

30.08.2013

<http://ec.europa.eu/digital-agenda/en/news/consultation-guidelines-recommended-standard-licences-datasets-and-charging-re-use-public>

➤ Studies, Videos

European Commission DG Connect, Improving health for all EU citizens- the EU explained

02.10.2013

http://ec.europa.eu/health/health_policies/docs/improving_health_for_all_eu_citizens_en.pdf

European Commission, DG Connect, New study on the eHealth Interoperability Framework

20.08.2013

<http://www.ehealthnews.eu/download/publications/3595-ehealth-interoperability-framework-study>

European Commission, Report on Health inequalities: gaps in life expectancy and infant mortality narrow across the EU

09.09.2013

http://europa.eu/rapid/press-release_IP-13-823_en.htm?locale=en

European Commission, DG EMPL, Demand for healthcare workers grows, while recruitment of professionals declines for the first time since 2010

04.09.2013

<http://ec.europa.eu/social/main.jsp?langId=en&catId=89&newsId=1968&furtherNews=yes>

EMA, European Medicines Agency publishes a video explaining the concept of medicines under additional monitoring

01.10.2013

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/09/news_detail_001900.jsp&mid=WC0b01ac058004d5c1

WHO, Research for universal health coverage

World health report 2013

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

EPPOSI, Consumer Perceptions of Self Care in Europe

<http://selfcare.epposi.org/pdfs/EPPOSI-Self-Care-Barometer-Report-2013-EN.pdf>

Health events in Europe

30 Sept- 4 Oct Week dedicated to Social Rights in the “EU Single Market Month” (EU Commission, DG MARKT)

9-11 November Mont Blanc Meetings

“Changing the course of globalization through social and solidarity economy: Towards post 2015 Millennium Development Goals”

Chamonix, [Information](#)

19-20 November Lithuania’s Presidency Conference “Sustainable Health Systems for Sustainable Growth in Europe” Vilnius

22 November Open Info Day - Horizon 2020 'Health, demographic change & wellbeing'

Brussels, [Information](#)

25 November EU Conference of Partners of EU Innovation Partnership on Active and Healthy Ageing

Brussels, [Information](#)

28 November Argus de l’assurance : « Mutuelles, Avec quelle stratégie se préparer aux évolutions du marché», *With the participation of AIM President, Mr Jean-Philippe Huchet*

Paris, [Information](#)

16-17 January DG Markt Conference Social Entrepreneurs Have your Say'

Strasbourg, [Information](#)

March 2014 Greek Presidency Nutrition and physical activity Conference

Greece

28-29 April 2014 Informal Meeting of Health ministers

May 2014 World Health Assembly

20 June EPSCO Health Council

Brussels

The monthly AIM Flash is compiled by Blandine Cassou-Mounat.

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

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