

Feature Stories



European Mutual Statute

Commission publishes results of the Consultation and Synthesis Report



Medical Devices

EU Parliament missed needed improvements in the medical devices legislation



Tobacco Products Directive

AIM deplores weak outcome of vote on Tobacco Products Directive



Cross-border Healthcare

Cross-border healthcare directive enters into force

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Next Meeting and visit dates

21 November	Mutuals WG <i>At AIM offices</i>
29 November	Pharmaceuticals & Medical Devices WG <i>At AIM offices</i>
4-6 December	AIM General Meetings <i>In Hamburg</i>
6 December	Workshop Fight against Fraud <i>In Hamburg</i>
16-17 January	Social Entrepreneurs Conference <i>In Strasbourg</i>
20 January	EU Affairs WG <i>At AIM offices</i>

Top Twitts



AIM @AIM_Healthcare

From the Synthesis Report of @EU_enterprise "There is strong support amongst the majority of the respondents to promote a #EUMutualStatute"



José Manuel Barroso @BarrosoEU

Health care systems remain national responsibility. But #EU can improve context & support MS action. #WorldHealthSmt

Retweeted par AIM



AIM @AIM_Healthcare

Article @Parlimag #EU medical devices directive a 'missed opportunity' #medicaldevices @AIM_Healthcare bit.ly/16q6tuw

AIM and you

➤ *AIM Activities*

AIM activities:

9-10 October: Presidium meeting in Paris

28 October: Committee on the revision of AIM Statutes

30 October: Fight against Fraud Working Group

Events AIM attended:

On 8 October, AIM Secretariat attended the Renewing Health User Advisory Board.

Publications:

AIM published a [Press Release](#) on the plenary vote on Tobacco products

AIM published a [Press Release](#) on the plenary vote on Medical devices.

AIM's Vice-President, Christian Zahn, made a statement in '[The parliament.com](#)' on Medical Devices.

European Institutions

➤ *European Council*

European Council: Digital economy, innovation and services

European heads of states gathered on 24 and 25 October at the European Council in Brussels on the topic of digital economy, innovation and services.

On 24 and 25 October, the European Council focused on the digital economy, innovation and services, to maximise their potential for growth and jobs. The issue of Data protection is addressed in their conclusions in these terms: "*the timely adoption of a strong EU General Data Protection framework and the Cyber-security Directive is essential for the completion of the Digital Single Market by 2015*".

Furthermore the Council welcomed the Social Dimension of the Economic and Monetary Union with the introduction of an employment and social scoreboard, coordination of social policies and improvement of social dialogue.

For more information, please refer to the European Council [Conclusions](#).

➤ *Council*

Clinical Trials: Council approves mandate to negotiate clinical trials

The Committee of Permanent Representatives officially mandated the Lithuanian Presidency to enter into negotiations with the European Parliament and the Commission with the aim to reach an agreement at first reading on the Proposal for a Regulation on Clinical trials.

The aim of the proposed regulation is to facilitate the authorisation procedure for clinical trials and as a result to increase the number of clinical trials in the European Union. The Presidency compromise text was presented to the Committee, found a very broad support and will serve as a starting point for negotiations with the European Parliament. The first informal trilogue will take place on 6 November.

More information on what is happening at Council level on the Lithuanian Presidency [website](#).

For the European Parliament, Rapporteur Glenis Willmott (S&D, UK) highlighted in the Parliament's position the necessity to publish all trials results and at least the clinical study report. AIM supports this major advance for transparency and the necessary information on the medicines already available and transparency of all trials in Europe (for more information, refer to [AIM and its partners' Letter](#)).



➤ **European Commission**

Medical Devices: Consultation on the Opinion of the Scientific Committee on the safety of PIP Breast Implants

This month, the 2012 Opinion of the Scientific Committee, SCENIHR, proposed its update with new data of its first Assessment on the safety of Poly Implant Prothèse (PIP) Silicone Breast Implants and submitted it to consultation. At the time of the opinion in 2012, data on the Poly Implant Prothèse (PIP) implants were still limited. While in its 2012 Opinion, the SCENIHR concluded that the health risk for women with PIP silicone breast implants was low, it was not possible to make a general risk benefit statement at that time.

In the newly published opinion, the Committee sticks to its former recommendation that the risk-benefit assessment needs to be based on a patient by patient basis by the aesthetic surgeon, bearing in mind the time since the implantation and the psychological state of the patient.

The SCENIHR Committee still acknowledges that: *“PIP silicone gel filled breast implants (PIP implants) are reported to have a higher prevalence and incidence of implant ruptures than other silicone breast implants, and that ruptures also tend to occur earlier in the implant life than is the case with other implants.”*

All interested parties can contribute to the Consultation until 3 January 2014 under this [link](#).

For more information, read the Committee's [New Opinion](#)



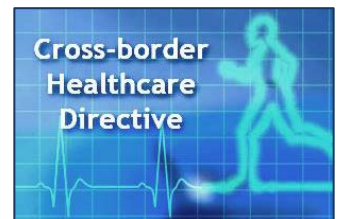
Cross-border Healthcare: Cross-Border Healthcare Directive enters into force

25 October marks the end of the transposition period for all member states.

Commissioner for Health Tonio Borg summarised the impact of the directive in these terms: *“For patients, this Directive means empowerment: greater choice of healthcare, more information, easier recognition of prescriptions across-borders. The Directive is also good news for Europe's health systems, improving cooperation between Member States on interoperable eHealth tools, the use of health technology assessment, and the pooling of rare expertise.”*

At this occasion the Commission reminded that they will also monitor carefully the implementation of the text. For citizens, the Commission has published a [Question and Answers](#) on the Directive. To learn more on the implementation, you may also look at [AIM-MLOZ Press Release](#) with all lessons from the Cross-border workshop of mid-September.

AIM Member, MLOZ, also published a [Press Release](#) (FR) this month, inviting its members to ask their mutual for information before receiving care abroad.



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Personalised Medicines: New Commission Staff Working document

The report published on 31 October focuses on the potential and issues with the use of -omics technologies in the research and development of personalized medicine and current EU research funding in the area.

The report concludes that personalized medicine will offer new treatment opportunities for the benefit of the patient. The European Commission will continue to monitor the developments of personalized medicine in the coming years and maintain a fruitful dialogue with stakeholders while continuing to support this field with funding under Horizon 2020. For more information you can consult the full Document [here](#).

The EU has already put up a framework, which supports the development of personalized medicines like the regulatory framework for pharmaceuticals, for example including therapies. On 10 December 2008, the European Commission had already published a [Communication](#) “Safe, Innovative and Accessible Medicines, a Renewed Vision for the Pharmaceutical Sector”.

➤ **Pharmaceuticals and Medical Devices**

Medical Devices: EU Parliament missed needed improvements in the medical devices legislation

On 22 October, the European Parliament voted in the plenary on the report of MEP Roth-Berendt as adopted by the ENVI Committee on the regulation of Medical Devices.

While the Report of MEP Roth-Berendt had managed to introduce more



transparency on clinical data and the ENVI Committee proposed stricter rules for assessment before certain high-risk medical devices can reach the market (novelty of the device, safety concerns), MEPs in the plenary largely watered down this compromise. AIM members and other partners such as Drug Bulletins and the Medicines in Europe Forum warn that the opportunity to prevent large-scale scandals such as the hip implants case should now be seized by the Council.

Christian Zahn, AIM Vice-President and President of the European region summed up the AIM position on the website [The Parliament](#): “Medical devices should not only guarantee technical performance and safety but bring a health benefit to the patient”. He concluded that this vote was really a “missed opportunity”.

For more information on AIM’s position, please consult the AIM and its partners’ [Press Release](#). More detailed information on the results of the vote is available in the [Press Release](#) of the European Parliament.

Clinical Trials: EMA argues that sharing of detailed trial results would increase efficiency in drug development
In a Paper published this month EMA’s Director says that sharing of detailed trial results would increase efficiency in drug development.

The debate on publicity of clinical trials results between the industry and the European Medicines Agency is going on. EMA’s director declared in the New England Journal of Medicine on Monday 21st October data secrecy will be “a boon to drug developers”. Instead of reducing the incentive to invest in drug research, releasing data from clinical trials would help drug company scientists hunting for new medicines.

This article comes in the middle of the trial with pharmaceutical companies AbbVie and Intermune over the publication of some of their trials’ results. In April, AbbVie and InterMune won an interim ruling preventing the agency from releasing documents, pending a final court decision.

EMA’s view is also shared by the ENVI Committee which aims at publishing the Clinical study report. In member states, the Germany’s Institute for Quality and Efficiency in Health Care complains that EMA measures do not even go far enough. For more information, you can read the [Article](#) on Euractiv.

Patient Safety: Adoption of the Report on Patient Safety in the Plenary

MEPs called member states to reinforce their measures on patient safety in hospitals particularly in an own-initiative report.

MEPs have voted to adopt parliament’s [own initiative report](#) on patient safety in their Strasbourg plenary session.

The report notes that insufficient attention is given in the member states to these complications, as well to side effects. In the European Union, 8 to 12 % of patients treated in a hospital on average suffer from adverse events.

Rapporteur Oreste Rossi (EPP, IT) presented the most important measures as preparing the medical and nursing staff to comply with the best sanitary conditions and instructing patients on proper standards of conduct.

MEP Rossi wants to push member states to action. He declared in an article: “it is vital to continue efforts towards the introduction of European classifications on patient safety or the definition of European guidelines on patient safety. Also, with regard to HAIs, certain specific actions recommended by the council to prevent and control them have only been implemented by a limited number of countries”. To read the whole article, visit ‘The Parliament’s [website](#).



Professional Qualifications: Members of the European Parliament approve Professional Qualifications’ Directive with a broad majority

The draft directive was approved with a vast majority of 596 votes but still has to be formally approved by EU member states.

Main improvements of the text include a European professional card and establishing common training frameworks.

For instance, the EU Professional card should ease the recognition process, as professionals will be able to ask their home country to arrange the recognition, rather than having to apply to the host country, as at present. The system will be based on the existing electronic information exchange system between member states’ administrations.

To fight against fraud, the directive also aims to prevent health professionals, who have been convicted of a relevant crime or face disciplinary action, from transferring their practice to another EU member state.

More information in the European Parliament [Press Release](#)

➤ European Affairs

Data Protection: MEPs approve data protection regulation report in main Committee

On 21 October, the long-awaited vote on Data Protection finally took place and validated the agreement found between all groups on the Compromise Amendments.

The main Committee, LIBE Committee, managed to find an agreement on Data Protection this month.

The text also concerns health data and takes into account processing of health data in the social security context.

More broadly, the proposal aims at harmonising and updating the various European laws on data protection that followed the previous European Directive dating back to 1995.

Main changes also aim at stepping up the protection of personal data with higher sanctions in case of violation of the Regulation, a right to erasure for the person, a simpler explanation of operations on their data.

MEPs also voted to adopt a mandate for negotiations with the Council so that the Rapporteur has the chance to find a compromise with the Council still in this term. Rapporteur Albrecht said that whether negotiations are successful or not, a vote in Plenary should take place in April 2014.

The [Press Release](#) of the LIBE Committee gives a detailed summary of the vote. The Commission welcomed the results of the vote in a [Speech](#) of Commissioner Reding. In the health sector, you may also read the reaction of the [NHS](#) and the [opinion](#) of the European Association of Doctors, the CPME.

EU-US TTIP: Consumers start debating the Impact of TTIP on health before Second Round of Talks

The EU and the US will hold a second round of the Transatlantic Trade and Investment Partnership (TTIP) talks in Brussels from Monday 11th – Friday 15th November 2013.

The second round of talks over the Transatlantic Trade and Investment Partnership (TTIP) had been supposed to start in Brussels today (7 October), but were postponed due to the government shutdown in the United States.

The European Commission will organise a briefing session for stakeholders during the second round of the negotiations on Friday 15 November. More information on this event is available on the Commission's [page](#).

Preparing the impact that the TTIP might have on the health sector, Gastein Forum and a TACD event already enabled health stakeholders to discuss the issue.

Speaking at the European Health Forum in Gastein, Austria, on 3rd October, Detlev Ganten, the president of the World Health Summit, said the key question was whether free-trade agreements restrict local government's ability to choose their own political, social and cultural systems – including public health. To preserve its protective healthcare and social model, Ganten declared the EU should push to maintain a high-level of safety during the negotiations – both on food and chemicals, especially the endocrine disruptor Bisphenol A, used in some plastics and resins.

For more information on this event you can read the related Euractiv [article](#).

Tobacco directive: Weak outcome of the Vote on Tobacco

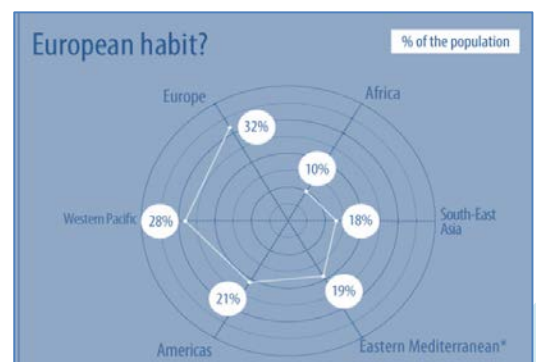
MEPs have made a small step in the approval of the Tobacco directive and some of them gave in to heavy tobacco industry lobbying.

The overall results of the vote in the Plenary are a setback on the objectives of the ENVI MEPs with smaller health warnings of only 65% of the package, a delayed ban on menthol cigarettes and no ban of slim cigarettes.

The only really positive point is that Council negotiations were opened. Given the intensive and overwhelming lobbying actions of the Tobacco industry which already caused the proposal's delay, the absence of blocking of the report is actually an achievement. Another positive point is warnings at the top edge of tobacco packages which ensures better visibility (more information in the [AIM Press Release](#)).

Rapporteur Linda Mc Avon reminded that Europe is not a pioneer on tobacco control and lags far behind the United States and Australia with a substantially higher number of smokers in the European Union than in these countries.

More information on the results of the vote is available on the Parliament's [Press Release](#).



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Extract of the Infographic, A lung lung story

➤ **Mutuals**

European Mutual Statute: Commission publishes results of the Consultation and Synthesis Report

On 4 November, the Commission published the responses received from the Consultation as well as a synthesis report.

Overall, the European Commission received 305 responses coming from 16 Member states.

The synthesis points out that a strong support amongst the majority of the respondents exists to promote a European Mutual Statute as a possible solution to the inability to engage in cross-border activities.

The consultation running from March to June should be followed by an Impact Assessment before the Commission makes a proposal of legislation. AIM members have already called for a timely impact assessment before the end of the term. For more information, please see the [page](#) of the Commission with all results of the Consultation and the [Synthesis Report](#).

Health and Long-term care

➤ **Trends in health system**

Universal Health Coverage: Health systems for health and wealth in the context of Health 2020

On 17 and 18 October, ministers gathered in Estonia at the occasion of the follow-up of the Tallin charter, which called for greater investment in health systems.

Ministers, experts and delegates from 38 Member States and representatives of the European Commission, the Organisation for Economic Co-operation and Development (OECD), the World Bank among others explained the steps they had taken to implement the Tallinn Charter.

The reorganization of health services to offer a more coordinated provision of care and promotion of health in general have been outlined as some key priorities. To learn more about this event, you can refer to the dedicated [page](#) on the WHO website.

➤ **Call for proposals, Consultations**

Consultation on VAT legislation on public bodies and tax exemptions in the public interest

14.10.2013 - 14.02.2013

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

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**

Video by European Parliament on Data Protection

21.10.2013

<http://europartv.europa.eu/en/player.aspx?pid=c5510828-2f37-4ef5-8fcb-a25e0112bd8d>

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, 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

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

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

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