



Feature Stories




European Mutual Statute
[Participate in the Consultation on a European Mutual Statute](#)



Clinical Trials
[Clinical Trials: Transparency in non-commercial clinical trials](#)



VAT
[Results of the Conference on "VAT rules in the public sector and their exemptions in the public interest"](#)



Medical Devices
[Parliament debates on Medical Devices Report by Rapporteur Roth-Berendt](#)

Contents:

AIM and You	2
European Institutions	2
<i>EU Commission</i>	2
<i>Pharmaceuticals and Medical Devices</i>	3
<i>European Mutual Statute</i>	4
Health and Long-term care	5
Health Events in Europe	6

Next Meeting and visit dates



17 May	Communications Task Force at AIM Offices
21 May	EU Affairs Working group at AIM Offices
29 May	Health System Reform Study Trip in Lisbon
31 May	Pharmaceuticals and Medical Devices Working Group
13 June	General Assembly and board in Gent
14 June	Fraud Working Group in Gent



AIM @AIM_Healthcare
Latest @EU_Social Publication on Social Economy highlights the revival of #mutuals in Europe #ESS: bit.ly/13G13FZ
Ouvrir

1 h



AIM @AIM_Healthcare
Access to healthcare with EU Health Insurance card endangered, via @PSEurope_News bit.ly/XGooXa, #EHIC cross-border #healthcare
Ouvrir

19 Avr



AIM @AIM_Healthcare
#AIM at @EU_Health policy forum: Commissioner Borg presented Investing in #Health, part of #socialinvestment package
Ouvrir

9 Avr

➤ *AIM Activities in April*

AIM activities:

10 April: Mutuals Working Group

Events AIM attended:

On 9 April, AIM attended the EU Health Policy Forum.

On 17 April, AIM attended the Steering group of EU Access to medicines platform in Dublin.

From 17 to 19 April AIM attended the Conference on “VAT in the public sector and exemptions in the public interest” in Venice.

European Institutions

➤ *European Commission*

Active Ageing: High level conference addresses frailty in old age

In the frame of the European Innovation Partnership (EIP) on Active and Healthy Ageing, the Commission organised a High level Conference on frailty in old age on 18 April 2013.

The key objective of the conference was to initiate a policy debate on frailty guidelines, and showcase the commitments being implemented in the frailty action group. “Frailty in old age” has covered is functional and cognitive decline, screening and effective interventions, and risk factors such as malnutrition.

Introducing the topic, Commissioner for Health Tonio Borg outlined that frailty attracted 158 commitments of the stakeholders in the EIP. The Commissioner also acknowledged a shift away from reactive disease management towards prevention of functional decline.

For more information, you can read the [Press Release](#) and Commissioner's [speech](#).

Medical Devices: Adoption of Commission Recommendation on a common framework for a unique device identification system for Medical Devices

On 5 April the European Commission published the Commission Recommendation on a common framework for a unique device identification system of medical. The recommendation establishes the ‘Unique Device Identifier’ as the best way to ensure effective and harmonised traceability of medical devices in the European Union. The ongoing revision process of the current Directives on medical devices should empower the Commission to adopt detailed traceability requirements. Once the future European databank on medical devices, Eudamed, is established, information related to device identifier will be centralised at European level via a European UDI electronic system which will be part of the future Eudamed.

Read the full Commission [Recommendation](#).



Pensions: Commission launches consultation of third pillar retirement products

The European Commission is today launching a public consultation on third pillar retirement products (individual pension plans). The consultation focusses on consumer protection, more specifically on the pre- and post-contractual information given to consumers as well as the selling practices covering marketing, inducements and advice given in the sector. The consultation is open to all stakeholders and will be available in all EU languages. It will run for 12 weeks until 19 July 2013. Pension funds are a very important and fundamental choice in the life of a consumer. Currently there are no specific EU rules for such products which may take on various legal forms ranging from "life insurances" to "investment products". This leads to legal fragmentation which does not allow the consumer to be protected in a consistent way in all EU countries.

The results of the consultation will be taken into account for the preparation of possible future initiatives in this field.

Link to the [consultation](#)

➤ **Pharmaceuticals and Medical Devices**

Medical Devices: Parliament debates on Medical Devices Report by Rapporteur Roth-Berendt

MEPs discussed the necessity to have centralised market authorisation and the possible delays it causes, external experts in notified bodies and reprocessing.

In Introduction Rapporteur Roth-Berendt reminded that “*Patient safety is as important as patient access*” in the ENVI Committee. As in previous occasions she insisted on the necessity to have a centralised authorisation procedure and clinical trials for High-risk medical devices of Class III. The time changes in the procedure were also addressed specifically with a difference of only one month in the case of centralised procedure with the Commission proposal. Shadow MEPs Mc Guinness and Krahmer expressed a different opinion on a centralised pre-market assessment. MEP Parvanova from ALDE also expressed support for centralised authorisation with a restricted amount of high-risk medical devices.

AIM is in favour of a centralised marketing authorisation for Class III Medical devices, to make sure that all medical devices such as implantable devices have proved their efficacy when they are used by patients. The answers to key aspects of the review are still controversial: Check out our [press release](#) to read some true facts about medical devices.

Clinical Trials: Transparency in non-commercial clinical trials

On 10 April, Glenis Willmott MEP held an event on the transparency of non-commercial clinical trials which was the opportunity for all stakeholders to express on transparency, a key element in the revision of the directive on clinical trials.

Participants in the panel were the British National Health System, the NHS, the British Medical Journal, the BMJ, the Nordic Cochrane Centre and the European Organisation for the Research and Treatment of Cancer, the EORTC. In the debate it was discussed that academics do not publish all their data currently. This is one of the reasons why transparency needs to be established as principle at EU level through the publication of the full Clinical study report.

Speakers also highlighted the ethic arguments why clinical trials results need to be public relying on the Declaration of Helsinki. The 1964 text revised in 2008 is a cornerstone for medical research and stipulates the need for research published to be full and balanced. The Director of publication of the BMJ, Trish Grove emphasised the need for datasets to be public in order to allow researchers to repeat a study with different subjects but the same methods (replication). The different panellists also debated the pros and cons of the scope of the publication: raw data, Clinical study reports or only a summary of the data. They all have an implication in terms of transparency and administrative burden as well as data protection.

AIM together with 11 organisations has signed a [letter](#) to support full transparency of clinical trials. The vote on all amendments and the Report in the ENVI Committee is scheduled for 29 May.



Platform on Access to Medicines: EU Platform on Access to medicines is coming to an end

Since 2010, AIM has been involved in the EU platform on access to medicines, an initiative of the European Commission that is coming to an end this year with a report in each of the 5 working groups.

On 17 and 18 April the last Steering group of the platform on Access to Medicines has been held after three years of work in five different working groups. The main objective of the Platform set up by DG Enterprise and Industry is to “*facilitate, within the current legal framework, the pricing and reimbursement of innovative treatments*”.

AIM members have contributed to the drafting terms of references on three key topics: biosimilars, non-prescription medicines and managed entry agreements.

The Deputy Head of Unit for the Unit in charge, Mr Heynisch called stakeholders to submit their suggestions to the Commission on the follow-up activities of this platform. A conference is already planned for October.

You can find more information on the final reports of the platform on the Commission’s [website](#).

VAT: Stakeholder conference on “the VAT rules in the public sector and their exemptions in the public interest”

At this event organised by the EU Commission and the Italian tax administration in April in Mestre, the EU Commission announced the publication of an impact assessment and a new proposal to review the current system of VAT rules in the public sector in 2014.

This conference is a follow-up of the [Green Paper](#) of 2010 and the [Communication](#) of 2011 on VAT Future, referring to a possible deletion of existing taxation exemptions in the field of health. Representatives of the Member States' tax administrations and various stakeholders as well as AIM and ESIP participated in the conference. During the conference, the EU Commission emphasized three main points of shortcomings in the current rules: A lack of neutrality a lack of harmonization and the complexity of rules.

Indeed, a lack of neutrality causes distortions of competition between the public and the private sector. Moreover, the current rules also lack harmonization, which gives Member States a wide discretion to define notions as public bodies or to determine the scope of exemptions.

The Copenhagen Economics Study of 2011 has also been discussed, which pointed out four possible reform options: The full taxation, the refund system, deletion of Article 13 and keeping exemptions in the public interest and option 3 with an option to tax. Experts also presented the VAT systems of New Zealand, Australia, South Africa and Canada. In most of these countries all supplies of services or goods are taxed including health care and education. The EU-Commission pointed out, their main primary focus is waste, postal services and broad casting.

For more information on the event, please consult the Commission [page](#).

➤ **Mutuals and Social Economy**

European Mutual Statute: Public consultation

The public Consultation on Mutual Societies is running now and until 14 June 2013. All mutuals and federations are invited to reply to the public consultation.

In some states, health mutuals and insurance mutuals are not allowed to operate due to the lack of existing legal framework, and have limited possibilities for cross-border activities with mutuals in other countries. The study contains details on characteristics, legal frameworks, corporate governance, and economic importance, as well on barriers that these enterprises face in Europe, when they wish to engage in activities across borders or to create groups. Period of consultation is from 11 March to 14 June 2013. The [questionnaire](#) of the Consultation is already available.

*Follow all news on the European Mutual Statute on Twitter under the Hashtag (Key word) **#EUMutualStatute***

➤ **African Region**

2nd International Days of Mutuals: 3rd and 4th April AIM-UAM Conference in Rabat



On 3-4 April 2013, over 120 representatives of mutuals coming from 15 African countries and representatives of mutuals and umbrella associations of mutuals from Europe and Latin America took part in these 2nd days of mutuals, placed under the high patronage of His Majesty King Mohammed VI. On 3 April the African mutuals updated their priorities and the action plan 2012-2014 of the African and Middle East mutual at the invitation of the AIM in collaboration with the UAM. On 4 April at the invitation of UAM, AIM gave a progress report on the role of the mutuals in the development of the social economy. Mr. Abdelmoumni, President of the General mutual of the personnel of the public administrations

(MGPAP) and Vice-president of the AIM was re-elected for a second consecutive mandate, to the presidency of the African Union of Mutuals (UAM).

For more information, please log in to the dedicated AIM [page](#).

➤ *Trends in health system*

WHO Europe: Oslo expert conference on impact of economic crisis on health

Taking stock of the effects of the economic crisis on the healthcare system in the European Region, the WHO brought together senior policy-makers from ministries of health, finance and health insurance funds, as well as patient organizations, international partners and researchers, to review the situation across the Region today.

The conference held on 17–18 April 2013 reviewed how health systems have been affected and reviewed the various responses. Disease prevention, strengthening primary health care, cost-effectiveness to reduce inefficiencies and increase the use of generic medicines and streamlining benefit packages have been enhanced by participants as the steps to reform healthcare systems. These measures echo the European Commission measures proposed in the 'Investing in Health' document part of the Social Investment Package. More information is available on the WHO [website](#).



➤ *Call for proposals, Consultations*

EIP AHA: New round of Invitations for Commitment launched: your chance to join in the work of the European Innovation Partnership on Active and Healthy ageing

<https://webgate.ec.europa.eu/eipaha/news/index/show/id/302>

➤ *Studies*

EU Commission: Social economy and social entrepreneurship - Social Europe guide / Volume 4, (cf. p.23-24 about mutuals)

<http://ec.europa.eu/social/BlobServlet?docId=10027&langId=en>

OECD: Briefing-Strengthening Health Information Infrastructure

<http://www.oecd.org/fr/els/systemes-sante/strengtheninghealthinformationinfrastructure.htm>

This study was communicated by Cornélia Federkeil-Giroux (FNMF, FR)

European Policy Centre: Economic governance: helping European healthcare systems to deliver better health and wealth?

http://www.epc.eu/pub_details.php?cat_id=3&pub_id=3497

Report by DG Research and Innovation: Rare diseases, How Europe is meeting the challenges

http://ec.europa.eu/research/health/pdf/rare-diseases-how-europe-meeting-challenges_en.pdf

International Journal of Integrated Care, Jan-March 2013

<http://bit.ly/YwryQb>

EU Commission: EU Employment and Social Situation Quarterly Review – March 2013

<http://ec.europa.eu/social/main.jsp?langId=en&catId=89&newsId=1852&furtherNews=yes>

EU Commission: Social Europe: Current challenges and the way forward Annual Report of the Social Protection Committee (2012) p.115-123 Healthcare systems

<http://ec.europa.eu/social/BlobServlet?docId=9760&langId=en>

Doctors of the world: Access to healthcare in Europe in times of crisis and rising xenophobia

<http://www.mdm-international.org/spip.php?article1205>

Health events in Europe

- 13-15 May** eHealth week
Dublin, [Website of the event](#)
- 16 May** EPHA Event “Can EU Citizens Afford their Medicines? The Economic Crisis and Access to Medicines in Europe”
Brussels, [Information](#)
- 30 May** HOPE Event: “1st European Forum of Public Procurement of Innovation for Health Hospital Purchasers: Relevant Stakeholders of the European Industrial Innovation”
Paris, [Information](#)
- 7 June** REVES Event: Best examples of partnership between public authorities and social & solidarity economy
[Information](#)
- 20 – 21 June** EPSCO Council
- 9-11 November** Mont Blanc Meetings
“Changing the course of globalization through social and solidarity economy: Towards post 2015 Millennium Development Goals”
Chamonix, [Information](#)
- 28 November** Argus de l’assurance : « Mutuelles, Avec quelle stratégie se préparer aux évolutions du marché »
With participation of AIM President, Mr Huchet
Paris, [Information](#)

*The monthly AIM Flash is compiled by Blandine Cassou-Mounat with the Contribution of Corinna Hartrampf.
Realisation &Layout: Blandine Cassou-Mounat
For more information on one of the topics mentioned above, please contact the AIM Secretariat.*

'AIM Flash' © monthly publication of the AIM Secretariat

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.