Feature Stories

**AIM Workshop on Resilience of Health Systems to austerity Measures in Lisbon**

**Clinical Trials**
Clinical Trials: ENVI MEPs vote for more transparency

**MEPs vote a Motion for the opening of the Transatlantic Trade and Investment Partnership**

**Take part in the Consultation on a European Mutual Statute**

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Next Meeting and visit dates

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<td>11 June</td>
<td>Disease Management Workshop on Alzheimer In Gent</td>
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<td>EU Affairs Committee In Gent</td>
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<td>16 September</td>
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<td>27 September</td>
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AIM Activities in May

AIM activities:
- 17 May: Communications Task Force
- 21 May: European Affairs Working Group
- 29 May: Health Systems Reform Workshop in Lisbon
- 31 May: Pharmaceuticals and Medical Devices Working Group

Events AIM attended:
On 16 May, AIM attended the EPHA joint Event on Access to medicines in the European Parliament with the presence of our partners, HAI and Prescrire.

European Institutions

European Commission

Data Protection: LIBE Press Seminar

On 15 and 16 May, The parliament held a press seminar on data protection. This event was the occasion to hear again most rapporteurs express their point of view on this topic. MEPs are holding shadow meetings in the view of the adoption of the Report in LIBE Committee on 8 or 9 July. They are looking to converge on the parliament’s final draft before it goes to an orientation vote in the civil liberties committee. Some voices among MEPs oppose to additional bureaucracy for companies such as for instance MEP Ludford (Article of EU Observer). Jan Albrecht expressed his fear for the proposal to be watered down in the EU Observer. "We promised the people that we will help give a proper legislation that will better enforce their rights, better protect their interest … and in the end, the only thing that we are doing - and this is not excluded – is to water down existing law. That is not what people would like to see” he said.

Social Investment Package: Motion for Resolution

On 30 May, MEPs of the EMPL committee voted on a motion on the Social Investment Package calling the member states to set real investment targets and have a reinforced control mechanism to implement EU 2020 objectives. The Motion on the Social Investment Package was adopted by 34 votes to 3 with 3 abstentions. It stresses the importance of targeted social investments and asks the Commission to develop a scoreboard of common social investment indicators. The adopted motion for resolution, in parallel with an oral question to the Commission is expected to be subject of the plenary discussion and vote in June. Read the Motion for Resolution.

Access to Medicines: EPHA Event and Declaration on Access to Medicines with the Crisis

On 16 May, the European Public Health Association together with 5 other organisations and the S&D group held a one-day event on Access to Medicines in Europe with the impact of the economic crisis. The debate covered a broad range of topics: the Shortages in all countries hit by the crisis but also in most Eastern EU countries, High prices of innovative medicines, Delays to market of generics and lack of transparency of prices. Discussing affordability of medicines, MEP Marian Harkin (ALDE, IE) for instance pointed to the excessively high cost of drugs in her native Ireland. "In spite of having several big pharma firms based in the country, the cost of many drugs in Ireland is up to three times the price paid in other European countries."
In the second part of the event, academia and regulators discussed various systems of price setting for medicines and the need for new medicines to bring therapeutic added value.
For more information read the Joint Press Statement and see the video and presentations of the event.

**Health and safety at work:** Commission opens public consultation on future EU policy framework
The European Commission has launched a public consultation to gather insights and contributions from the public further to results of the evaluation of the European Strategy on Safety and Health at Work 2007-2012.
This should help identify current and future challenges in the occupational safety and health area, and identify solutions to address these challenges.
All citizens and organisations are welcome to contribute to this consultation, which will be open from 31 May 2013 to 26 July 2013. Link to the consultation.

**EU-US:** MEPs give a conditional go-ahead to EU-US trade talks
Following the debate in the European Parliament, MEPs voted on 23rd May on a hard-fought resolution to back the launch of negotiations on a transatlantic trade agreement.
MEPs stressed the negotiating mandate should include public procurement and financial services, but exclude culture. Except for the Greens, most MEPs have backed going ahead with the negotiations on the so-called Transatlantic Investment and Trade Partnership (TTIP), but reiterated their concerns on a number of issues, especially cultural diversity and health.

The European Commissioner in charge of trade, Karel De Gucht, explained that cultural diversity as enshrined in the EU Treaty and in the UNESCO Convention on cultural expressions was a guiding principle of the Commission’s actions, including trade. This said, he insisted that excluding audiovisual services from EU commitments in the TTIP, as advocated by some MEPs, was neither necessary nor justified. For more information, read the Parliament Press Release.

**Cross-border healthcare:** Commission expresses concerns about refusals by Spanish public hospital to recognise EHIC
The European Commission has requested information from Spain about complaints that Spanish hospitals providing public healthcare are refusing to recognise the European Health Insurance Card (EHIC).
The Commission is concerned that Spain might be failing to fulfil its obligations under EU law to provide emergency healthcare to temporary visitors from other Member States on the same terms and conditions as are available to Spanish nationals under the public healthcare scheme.
The Commission’s request for information follows an increasing number of complaints it has received concerning hospitals providing public healthcare services, mainly in tourist areas of Spain, which refuse to treat citizens on the basis of their European Health Insurance Card and instead request a travel insurance policy and credit card details.
Public healthcare is generally free of charge in Spain and the European Health Insurance Card entitles its holder to be treated on the same terms as Spanish nationals. More information in the Commission Press Release.

**ECJ:** European Commission refers the UK to Court for incorrect application of EU social security legislation
The European Commission decided on 30 May to take the UK to court over its social security tests for foreigners. The EU Commission says security benefits have been refused to potentially tens of thousands of EU nationals. According to UK figures, there were 42,810 applications for social security benefits between 2009 and 2011 from citizens from the EU as well as Norway, Liechtenstein and Iceland. Of these, around 28,000 (or 64 percent) were turned down.
The commission said it was a “fair assumption” that a “significant proportion” of those refused social security were actually entitled to it.
For more information, read the EC Press Release and the EU Observer Article.
Pharmaceuticals and Medical Devices

Clinical Trials: More transparency supported by all MEPs of the ENVI Committee
The report for a regulation on clinical trials by Rapporteur Willmott was adopted in the ENVI Committee on 29 May. MEPs supported a major breakthrough of the legislation on transparency of all clinical trials through the publication of the Clinical study Report on an EU Database.
Clinical trials had been recognised by the European Commission as a priority after the fall in the number of clinical trials in Europe.
On transparency, the suggestion of the Rapporteur was adopted as a compromise between the publication of only a summary and the publication of all raw data. Other important measures are the introduction of low-intervention clinical trials with fewer requirements.
The final vote in plenary is expected on 8 October 2013. For more information on the outcome of the vote, read the ENVI Press Release or watch the Parliament video.

Biosimilars: New Guideline for the Consultation on Biosimilars
The European Medicines Agency (EMA) has recently published an updated biosimilars guideline for consultation that outlines the general principles that industry must take into account when developing a product and making an application to the agency. The 2 April 2013 proposed revision will ultimately result in a new guideline to replace the current Biosimilars Guideline from October 2005.
With the aim of facilitating the global development of biosimilars and to avoid unnecessary repetition of clinical trials, the guideline explains that it may be possible for an applicant to compare its biosimilar in certain clinical studies and in vivo non-clinical studies with a comparator authorised outside of the EEA. For more information, visit the related EMA page.

Pharmacovigilance: European Medicines Agency issues six key recommendations to tackle the issue of medication errors
Medication errors are unintended errors in the prescribing, dispensing or administration of a medicine while in the control of a healthcare professional, patient or consumer.
Since July 2012, the EU pharmacovigilance legislation has required reporting of all suspected adverse drug reactions resulting from medication errors to EudraVigilance, the EU database of adverse drug reactions. The EU regulatory workshop on medication errors, which was attended by 240 participants representing various stakeholder groups, aimed to gather the available expertise in this area.
Six key recommendations resulted from the discussions:
- the harmonisation and further development of terminologies and definitions of medication errors
- Closer collaboration between national patient safety authorities, national regulators, EMA and the Commission;
- the development of data pooling and analysis to identify medication errors;
- the systematic assessment and prevention of the risk of medication errors through the EU risk-management planning process;
- active engagement and capacity building with patient and consumer groups and healthcare professionals to improve safe medication practices;
- Support to research into safe medication practices.
These proposed actions will now be prioritised by the Agency together with the Commission and the EU regulatory network by considering their potential benefit and resource implications. The Agency, in collaboration with the European Commission and the EU regulatory network, will now develop an action plan, which it will publish before the end of the year. Find more information on the EMA 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

**Mutuals and Cooperatives: Adoption of an Own-Initiative Report on the contribution of cooperatives to overcoming the crisis**
The own-initiative [report](#) by MEP Patrizia Toia (S&D, IT) stresses the exceptional resilience of cooperatives, just as mutuals to the economic crisis and the need to promote this form of entrepreneurship. In-built capacity for resilience should be strengthened by paying proper attention to cooperatives in all EU policies designed to contribute to smart, sustainable and inclusive growth. The report calls on the Commission to bolster its services responsible for cooperatives by creating a Directorate focused on cooperatives and other social-economy organisations (such as mutuals) within DG Enterprise, with a unit working solely on the restructuring of industrial and service enterprises in crisis or without a successor into cooperatives. A plenary vote is scheduled for 10-13 June.

For more information read the [press release](#).

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Health and Long-term care

**Trends in health system**

**AIM Health System Reform Workshop: Resilience of a health system to austerity measures in Lisbon**

On 29 May, the Health Systems working group of AIM chaired by Jean Hermesse, Secretary General of the Christian Mutuality organised a workshop about the resilience to austerity measures in Portugal hosted by Montepio Geral. 40 people from Portugal, Luxembourg, Slovenia, Estonia, Belgium, Germany and Poland participated to the workshop. The focus was on the type and the impact of measures taken in Portugal to respond to the crisis.

The measures in reaction to the crisis have been presented by representatives of the ministry of health. Measures include one-off measures such as the increase of co-payments and the reduction of health expenditure in the budget. Consequences on the health status of the Portuguese population are a reduced access to healthcare and a rise in mental problems. Health actors explained on the other hand that there needs to be continuous investments in health with the example of a health mutual providing affordable healthcare. A concluding report will be available to AIM members.

**Call for proposals, Consultations**

**New EMA Guideline for the Consultation on Biosimilars**


**Studies**

Maastricht University et al., **New Overview of public health capacity in EU Member States:**

**World Health Statistics 2013**
http://apps.who.int/iris/bitstream/10665/81965/1/9789241564588_eng.pdf

**EU Observatory of Health Policies**, Health in All Policies Seizing opportunities, implementing policies

**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)

### Health events in Europe

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<td>7 June</td>
<td>REVES Event: Best examples of partnership between public authorities and social &amp; solidarity economy</td>
<td>Information</td>
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<td>20 – 21 June</td>
<td>EPSCO Council</td>
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<td>27-28 June</td>
<td>IPSE Meeting: “Faced with an enduring crisis: actions, proposals and solutions”</td>
<td>Munich, Information</td>
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<td>18-20 Sept</td>
<td>AIM International Conference on Evolution of health systems with long-term care with MGEN, Education and Solidarity Network and AEIP</td>
<td>Paris, Information</td>
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<td>9-11 November</td>
<td>Mont Blanc Meetings</td>
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<td>“Changing the course of globalization through social and solidarity economy: Towards post 2015 Millennium Development Goals”</td>
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<td>28 November</td>
<td>Argus de l’assurance : « Mutuelles, Avec quelle stratégie se préparer aux évolutions du marché »</td>
<td>With the participation of AIM President, Mr Huchet</td>
<td>Paris, Information</td>
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*The monthly AIM Flash is compiled by Blandine Cassou-Mounat.*