Featured Stories

**Resignation of the Commissioner**
Health Commissioner John Dalli resigns due to fraud investigation

**Commission Programme**
New Commission Work Programme 2013 published on 23rd October

**Public Procurement**
Debate around the application of public procurement to social security

**Pharmacovigilance**
Council adopts Pharmacovigilance revision

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Next Meeting and visit dates
5-6 November E-health Study trip in Berlin
Open to all AIM Members

28-29 Nov. European Affairs Committee
AIM Board of Directors meetings

29 November Conference on healthy ageing
Health System Reform WG in Brussels

30 Nov. Fight against fraud WG in Brussels

7 December Pharmaceuticals and Medical Device Working Group in Brussels

12 December European affairs WG in Brussels

NOVEMBER 2012: AIM Events' Calendar

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**TF:** Task Force

**WG:** Working Group
 AIM and you

- **AIM Activities in September**
  On 3rd October AIM President Mr Jean-Philippe Huchet participated in a Conference of the European Social and Economic Committee Conference on "Social Enterprises and the Europe 2020 Strategy". From 17th to 20th October, AIM attended the 40th Congress of mutuality in Nice. On 19th October, AIM published a joint position paper with ESIP on Data Protection Regulation proposal. On 22nd October, AIM published a joint position paper with ESIP, MiEF, ISDB and ESIP on the Medical Devices Regulation proposal. On 25th October, AIM attended the EU Health policy forum.

- **Members’ news**
  Mr Jan Van Emelen from the Belgian Member MLOZ represented AIM at the Think-tank European Policy Centre Event “Role of ICT in supporting active healthy ageing: possibilities and barriers?” on 16 October.
  An important AIM delegation attended the 40th FNMF Congress:
  Ms Eleni Spanopoulou (OATYE, GR), Vice-President of AIM, Mr Pedro Bleck Da Silva (Montepio, PT), Chairman of the Mutuals Working Group Mr Alain Coheur (UNMS, BE) and among international members: Mr Georges Sakr (UMS, Libanon), Mr Ghassan Daou, President (UMS, LB), Mr Atoue Abdel Hamid, Secretary (UMS, LB) and (If you would also like to communicate information about your activities in the Flash, please contact the Secretariat).

- **AIM secretariat**
  Ms Corinna Hartrampf started working for AIM on 1st October 2012. She replaces Ms Rita Kessler as Project Manager. She is mainly responsible for the coordination of the Working Group on European Affairs and the Pharmaceutical and Medical devices Working Group.
  You can contact Corinna Hartrampf at: corinna.hartrampf@aim-mutual.org

European Institutions

- **EU Council and Presidency**
  **Health and Safety at Work**: Cooperation for improving occupational health and safety at work
  Leadership and worker participation for improving occupational health and safety at work was the main topic on the agenda in discussions facilitated by the Cyprus Presidency during a Conference on Health and Safety at Work. The Conference was organised by the Department of Labour Inspection, in cooperation with the European Agency for Safety and Health at Work, and was held in Lefkosia (Nicosia) on October 18, 2012. It was attended, among others, by representatives of the European Employers and Workers Organisations and members of the Board of the European Agency for Safety and Health at Work.
  The new European Strategy on health and safety at work 2013 - 2020 is currently under discussion, at the priority-setting phase. A document prepared by the Advisory Committee on Security and Health at Work for the European Commission, makes particular reference to the importance of consultation on management of occupational safety and health, considering employee participation to be a further key factor in successful health and safety at work-related risk management. See the Press Release.

- **European Commission**
  **Commissioner**: Health Commissioner John Dalli resigns due to fraud investigation
  Commissioner Dalli had to resign due to an OLAF investigation establishing that he would have been informed of a Maltese lobbyist selling contacts to him to the Tobacco industry. The complaint was lodged by the Tobacco industry Swedish Match. Ex-foreign Affairs Minister in Malta, Tonio Borg should replace him on 1st December 2012 once approved by the Council and Parliament.
This resignation comes as a surprise for many stakeholders and has turned to a heated debate over the cause of the resignation, some journalists referring to the affair as ‘Dalligate’.

The ex-Commissioner himself declared he did not want to resign and was forced to do so. For the Commission, it was a political decision but the OLAF investigation did not establish any corruption, while Anti-tobacco associations denounced a manipulation of tobacco companies to delay yet again the publication of the proposal that was said to be strict with companies. The Commission said its decision was not influenced by anyone. The concern of some MEPs and anti-smoke NGOs is that the position on the Tobacco Product Directive that was favourable to blank packages and strict measures against tobacco industry will be watered down. The Commission has denied that this will change its position. At least one consequence is certain: a delay of one month minimum for the publication of the proposal of the Tobacco Products Directive (already delayed of one year since April 2011).

The European Commission Vice-President Maroš Šefčovič is appointed on a temporary basis until the arrival of the new Maltese Commissioner.

To read the official Commission position published on 16 October, see the Press Release. For an extensive summary of the affair, read the article of La Tribune from PressEurop of 26 October. About the need for tighter lobbying rules, read the European Voice article of 18 October.

**Commission Work programme 2013**
The Commission Work Programme 2013 was published on 23rd October with the list of initiatives the Commission aims to publish in 2013. The Work Programme mentions the health sector several times for its growth potential and new job opportunities.

A few initiatives should concern health and social policy:

- **Horizon 2020:**
  Proposals for reinforced partnering in research and innovation under Horizon 2020 through the renewal and creation of Public-Private Partnerships in key industrial sectors, such as pharmaceuticals, and for example the Renewal of European & Developing Countries Clinical Trials Partnership (Roadmap).

- **Communication on Social Investment for Growth and Cohesion Package:**
  in order to provide guidance on increasing efficiency of social protection systems; improving activating and enabling of social policies. This communication should absorb the project of Communication on Long-term Care. The Communication will feed into the Europe 2020 strategy and the European Semester to foster a social dimension in structural reforms and support the design of social investment in the National Reform Programmes and assist Member States in making best use of EU funds, ESF in particular.

  In the social sector, a reform concerning pensions is foreseen:

- **Review of the Directive Effective Institutions for Occupational Retirement Pensions:**
  One of the aims of the review is to facilitate cross-border supply: the aim is to reduce the legal, regulatory and administrative complexity for the setting-up of cross-border pension schemes (Roadmap of the Review).

  Last but not least at horizontal level, a Review of the current VAT rates structure is indicated as legislative proposal:

- **Review of the current VAT rates structure:**
  The review of the VAT rates structure is one of the priority actions mentioned in the Communication on the future of VAT, the objective being a proposal presented by the end of 2013. The review might as well impact the health sector, though it is not mentioned specifically in the Roadmap.

  An impact Assessment has started in 2012 with some in-house preparation involving all policy DG’s. An Impact Assessment Steering Group including almost all DGs and also DG SANCO will be set up early 2013.

  See the full list of initiatives 2013 and the Commission Work programme.

- **Pharmaceuticals and Medical Devices**

  **Pharmacovigilance:** Council adopts Pharmacovigilance revision

  Today the Council gave its approval to the amended legislation on Pharmacovigilance. The new rules will come into force by the end of 2013.

  Even though the rules on pharmacovigilance were improved in 2010, potential weaknesses were brought to light in 2011. Therefore, the Commission promptly ran a "stress-test" of the rules and proposed further amendments to the legislation. They will lead to strengthened monitoring of
additional categories of medicinal products. Patients and health professionals will recognise these medicines thanks to a standard black symbol, and an explanatory statement about the product's characteristics. That statement will encourage all users to report suspected adverse reactions to these medicinal products. For more information see the Press Release and the Memo published on 4 October on Pharmacovigilance.

**Medical Devices:** Creation of Umbrella organization Medtech Europe for In Vitro Diagnostics and Medical Devices in Europe.

MedTech Europe, the alliance of European medical technology industry associations, was launched on 10 October at the European MedTech Forum in Brussels.

Founded by the European Medical Technology Industry Association Eucomed and the European Diagnostic Manufacturers Association EDMA, the alliance will collaborate closely on common policy interest areas. MedTech Europe will focus on the medical device and in vitro diagnostics legislative frameworks, the medical technology industry 5-year strategy, health technology assessment, patients & safety and environmental issues. Future topics of collaboration will be determined by the MedTech Europe Board. To support MedTech Europe, a new website - www.medtecheurope.org has been created with an additional Newsletter. See the Press release of EDMA and Eucomed and visit the new website.

**Health System**

**Public Health:** Panel of independent experts to work on the improvement of health care systems

The call for experts, provided by the decision was launched on 15 October. Deadline for applying is 23rd November. Members of the panel are appointed by the Commission on the basis of their expertise in one or more of the fields of expertise and collectively cover the widest possible range of disciplines. The fields of expertise are set out in detail in Annex I to Decision 2012/C 198/06 and include: health planning and budget prioritization; health services research; hospital and health care management; health care provision, and health education and promotion.

All the information about application, selection criteria and process, Independence, Workload and indemnities is available under this link.

**Cross-border health threats:** Stepping up EU preparedness

On 10 October, MEPs backed plans to provide EU-wide early warning of health threats and inserted a provision enabling member states to club together to buy vaccines, building on the E.Coli infection in 2011 or the influenza H1N1 pandemic in 2009. Allow states to make joint purchase orders at a lower price, strengthening of the European coordinating body, competency to declare European Emergency are some key step forwards that the text will enable. The draft legislation will be put to a plenary vote in November in Strasbourg.

In the proposal reviewed by the adopted ENVI report, the Early Warning and Response System (EWRS), hosted by the European Centre for Disease Prevention and Control in Stockholm (ECDC) would extend its scope to all cross-border threats to health, to allow for an EU-wide coordination and response. MEPs also included human zoonotic infections (which can be transmitted from animals to humans), and ask EU member states for coordination of their communications campaign.

Moreover, the text would introduce the possibility of recognising a European "health emergency" to accelerate the provision of medication while so far the EU needs to wait for the World Health Organisation to declare an international emergency across continents. The new law would also allow member states to purchase medicines jointly, thus enabling more equitable access to vaccines at a better price.

MEPs added a provision on the independence and the transparency that the experts involved in the system must display. EWRS experts would therefore have to declare the presence, or absence, of any: direct or indirect interests which might be considered prejudicial to their independence.

See the Press Release.
Organ transplantation: Adoption of Commission Implementing Directive laying down information procedures for the exchange, between Member States, of human organs intended for transplantation

The Commission adopted on 9 October a new piece of legislation to facilitate EU cross-border exchange of information about organs and their donors.

In 2011, 30,000 organs were transplanted in the European Union, and many of them were shipped across borders. It is therefore of utmost importance to ensure EU-wide traceability of organs, particularly to cover cases where recipients suffer from adverse reactions to donated organs. The newly adopted legislation will aim to foster cross-border transmission of valuable information about: organs and donors (e.g. types of organ, donor's age, gender, health history); the traceability of organs once exchanged, in compliance with confidentiality and data security measures; reporting of serious adverse events and reactions to specific organs, which allows the doctors to take appropriate measures if needed. The new Directive makes it mandatory for national authorities to exchange and store information on cross border organ exchanges and to provide a 24/7 service in case of serious adverse reactions or events. This will allow the medical teams to take appropriate and timely action and to ensure safety of patients. Read the full text of the Directive. Read more about the Implementing Directive on the European Commission page.

Environment

Survey: EU biomonitoring shows mothers and children exposed to harmful chemicals

Analysis of 4,000 urine and hair samples in 17 European countries suggests all mothers and children have chemicals in their bodies that should not be there.

The findings of a first-ever biomonitoring survey reveal that the human body is contaminated with small levels of mercury, cadmium, cotinine (a measure of exposure to environmental tobacco smoke) and five phthalates (which are endocrine disrupting chemicals used in plastics). Six of the 17 countries involved also tested people for bisphenol A, parabens and triclosan, which are also endocrine disrupting chemicals (EDCs). The human biomonitoring projects “COPHES” and “DEMCOPHES”, which prove that a European wide measurement of chemicals in people across Europe using a coordinated and harmonised approach is feasible, provide comparable results for the first time.

HEAL, the Health and Environment Alliance, where AIM is a member highlighted in a press release that although the project concluded that the levels found are not of high concern, they do represent an important threat to public health. “The truth is that none of these chemicals belong in our bodies” Ms van Vliet declared. “More worrying is that endocrine disrupting chemicals are all linked to serious health problems ranging from premature puberty in girls and birth defects in baby boys’ genitals to increased risk of hormone related cancers, such as breast and prostate”.

In addition, the levels found are only a part of picture. The timing of exposure, such as in the womb or during infancy, may be just as crucial and exposure to mixtures of chemicals is important because combined exposures may be more harmful than each of these chemicals alone.

For more information see HEAL Press Release and the Press Release of the Cypriot Presidency.

Insurance

Public Procurement: Debate around the application of public procurement to social security

The national social security services of European Union member states could be opened up to private sector competition according to the terms of a proposed European Commission directive on public procurement. Commissioner tried to reassure stakeholders otherwise after a Mediapart article pointing the unnoticed Annex.

The directive, presented in December 2011 by Michel Barnier, European Commissioner for Internal Market and Services, Michel Barnier, and due to be examined on 5 November and voted in Committee on 29 November, seems to require governments to launch a yearly invitation for tenders to manage sectors of their compulsory social security services, most of which until now have been managed according to the principle of social solidarity (Mediapart Article, 12 October 2012). Surprisingly, the proposal, contained in an annexe of the 246-page text of the directive, was unnoticed by MEPs until October.

Michel Barnier, declared in response to this article he would be against such a change (Commissioner Press Release 18 October 2012). The proposal of the European Commission in the field of public procurement rules would “not put
into question the national organization of social security services, and does not open social security to the private sector” in his words.

Imposing a condition of privatization of its social protection system would be contrary to the Treaty and the case law, as stated firmly by MEP Tarabella, Rapporteur on Public Procurement, who would be strongly against the possibility of privatization of social security (MEP Tarabella Press Release, 17 October 2012).

The Council in its Working document on 2nd October reduces the impact of the Annex to contracts but does not delete the controversial annex (Council Working document, 2 October 2012).

“(3a) It should be recalled that the provision of services should be covered by this Directive only in so far as it is based on contracts; consequently, the provision of services on other bases, such as law or regulations, or employment contracts, should not be covered. In some Member States, this might for example be the case for compulsory social security services”.

➤ Members’ events

**FNMF: 40th Congress of Mutuality in France**

From 18th to 20th October the French member of AIM, the Fédération Nationale de la Mutualité Française, FNMF, held its 40th congress of Mutuality. The event is one of the biggest in size in Europe for mutuality gathering over 2,500 politics working in French mutuals in presence of President François Hollande, the minister for health and the minister for social economy. The French spirit of mutuality gathered in the Concert hall Acropolis in Nice for four days discussing access to healthcare, mutual values and the European Mutual Statute notably. The theme of this year’s Conference was “Access to healthcare; what role for Mutuality? What role for mutuals?”

AIM has supported and contributed to this event through the presence of a representative delegation: Ms Eleni Spanopoulou (OATYE, GR), Vice-President of AIM and Chairwoman of the Communications Task Force, Mr Pedro Bleck Da Silva (Montepio, PT), Chairman of the Mutuals Working Group and Mr Alain Coheur (UNMS, BE), Director of EU Affairs and head of the cross-border project of the Belgian mutual Solidaris with the French Student Mutual LMDE, Mr Ghassan Daou, President, Union des Mutuelles Santé au Liban (UMS, LB), Mr Atoue Abdel Hamid, Secretary (UMS, LB), Mr Georges Sakr, President (CMS, LB), Mr Djikiné Babassa, President (UTM, MA).

See the AIM Press Release on the FNMF Congress.
French Minister for Social Economy Mr Benoît Hamon supports the European Mutual Statute

An AIM delegation with Mr Pedro Bleck Da Silva (Montepio, PT), Chairman of the Mutuals Working Group together with AIM President Mr Jean-Philippe Huchet and the FNMF team had the occasion to stress the importance of the European Mutual Statute with Minister for Social Economy Mr Benoît Hamon. The minister acknowledged AIM’s strong wish for a European Mutual Statute and guaranteed its support in the promotion of the statute in Europe.

See the [AIM Press Release](#) on the FNMF Congress.

### Trends in health system

**WHO Europe: Health systems must reorient services to meet new challenges**

Recognizing that non communicable diseases (NCDs) represent the greatest health burden for countries in the WHO European Region requires service-delivery systems to shift towards more people-centred care.

Speaking at the World Health Summit, held in Berlin, Germany on 21–24 October, Dr Hans Kluge, Director of the Division of Health Systems and Public Health at WHO/Europe, described how some countries adapted their health systems to take account of the NCD epidemic and an ageing population, in the face of falling growth rates for health expenditure.

Lithuania and the Republic of Moldova, for example, introduced new financing arrangements so that a fall in health-insurance payroll contributions triggers general budget transfers to compensate. This enables the countries to maintain services and support vulnerable groups unable to contribute financially. Latvia initiated budget cuts and structural reform concurrently, shifting priority to primary health care, coverage of essential medicines and outpatient specialist services. Improving efficiency is key, noted Dr Kluge, to reduce the adverse effects of the financial crisis and to secure popular and political support for future spending. Efficiency measures include eliminating ineffective and inappropriate services, improving the rational use of drugs and allocating more to primary and outpatient specialist care and less to hospitals.

**WHO Europe: Can fiscal policies reduce non-communicable diseases?**

Governments increasingly turn to fiscal policies to address risk factors – tobacco use, harmful use of alcohol and unhealthy diet – associated with non communicable diseases (NCDs). Specifically, these policies focus on raising taxes on tobacco and alcohol to reduce consumption, and introducing food taxes and subsidies to promote a healthy diet.

One of the goals of the Action Plan for Implementation of the European Strategy for the Prevention and Control of Non communicable Diseases 2012–2016 is to “to use fiscal policies and marketing controls to full effect to influence demand for tobacco, alcohol and foods high in saturated fats, trans fats, salt and sugar”.

WHO/Europe has put together a package of supporting documents on fiscal policies, and advised decision-makers in health policy, most recently at an international training seminar in Lithuania on 24–26 September 2012.

For more information, consult the WHO [webpage](#).
Studies

EU Parliament: Reforming the Data Protection Package, September 2012


EU Commission: A selection of successful projects funded by the EU Health Programmes

Notre Europe Study: “The mutualist economy: what is their foreseeable future in the Single Market?”

Annual report 2011 of European Medicines Agency
European Medicines Agency - The Annual report shows continuously high level of activities

Active Ageing Report
http://ec.europa.eu/social/main.jsp?langId=en&catId=89&newsId=1632&furtherNews=yes

Sustainability of Ageing- LEPAS
http://ec.europa.eu/social/main.jsp?langId=en&catId=89&newsId=1639&furtherNews=yes

Health events in Europe

5-6/11, Paphos Meeting of the Platform on Access to Medicines
Henk Eleveld (ZN, NL) and Corinna Hartrampf (AIM) will represent AIM

27/11, Brussels Friends of Europe Event
“Why health is crucial to European recovery”
Agenda

5/12, Brussels EPPOSI Event,
An Optimal European Chronic Care Model: Towards Implementation and Benchmarking
Agenda

6/12, Brussels Employment, Social Policy, Health and Consumer Affairs Council (EPSCO)

10/12, Nicosia Cypriot Presidency Conference
Closing Conference for the European Year for Active Ageing, and Solidarity between Generations
Françoise Troublé Uchôa (FNMF, FR) will represent AIM

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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