



## Featured Stories



**European Mutuals' Statute**  
Intervention of Pedro Bleck Da Silva to defend AIM's position in the EMPL Hearing  
 MEPs and stakeholders gather for the statute.



**Pharmaceuticals and Medical Devices**  
Council and Parliament found an agreement for greater medicine safety.



**Pharmaceuticals and Medical Devices**  
PIP Implants: MEPs keep a strong line for a change on Medical Devices Regulation.



**Cypriot Presidency: The President of the Republic of Cyprus presents Presidency Programme in Strasbourg**  
Active Ageing and Social Europe high on the Agenda

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## Next Meeting dates

<b>25 July</b>	<b>Fight against fraud WG in Brussels</b>
10 September	European affairs WG in Brussels
19 September	Pharmaceuticals WG in Brussels
26 September	Mutuals' Statute WG in Brussels
28-29 Nov.	AIM Board of Directors meetings and Conference on healthy ageing
30 Nov.	Health System Reform WG in Brussels Fight against fraud WG in Brussels
12 December	European affairs WG in Brussels

TF: Task Force  
 WG: Working Group

## JULY 2012: AIM Events' Calendar

Mon.	Tue.	Wed.	Thu.	Fri.	Sat.	Sun.
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25 <b>Fraud WG</b>	26	27	28	29	30	

## AIM and you

### ➤ AIM Activities

On **20 June**, Pedro Bleck Da Silva, Chairman of the Working Group on Mutuals Statute, represented AIM in the panel of experts at the Employment Committee Hearing on a European Mutual Statute (More information p. 5)

On **28 June**, Philippe Swennen from the Secretariat spoke on behalf of AIM in the Annual [Conference](#) of AEIP, the European Association of Paritarian Institutions, "Building for the Future: Tackling Together the Global Challenges of Social Protection".

### ➤ Working Groups

#### **European Mutual Statute Meetings: AIM-AMICE TF, Mutuals' Statute WG, Hearing on EMS**

AIM and AMICE gathered on 19 June to finalise the programme of the Conference on the European Mutual Statute taking place on 26 September. The Mutuals' Statute Working Group discussed AIM amendments on Ms Bastos Opinion on the Own-Initiative Report on the European Mutual Statute. Finally the Hearing was the occasion for AIM to explain to MEPs of the EMPL committee why mutual societies need a statute.

#### **European Affairs Working Group Meeting on 15 June**

On the agenda were notably the follow-up of a simulation event on the Cross-Border Healthcare Directive organised by AIM and other stakeholders with the presence of Mr John Rowan from the Commission and a presentation of the Report of the event by Christian Horemans. Ms Caroline Hager from the Commission also presented the EU Health Workforce Action Plan. Members have been working as well on Data Protection to be continued through a political paper.

#### **Pharmaceuticals and Medical Devices WG on 28 June**

Topics on the agenda were the Consultation on HTA for which members have drafted an answer, the Transparency directive and the related preparation of an AIM position as well as a presentation by Laure Lechertier (FNMF) on the new French legislation for Pharmacovigilance after the Mediator scandal in France.

### ➤ Members' news

#### **British member Benenden healthcare opens doors to all**

[Watch Benenden's Video on You tube](#)



Benenden Healthcare Society believes that there is a role to play for non-profit, low-cost, ethical business models in the provision of public services has taken a huge leap to be part of that provision. UK residents are set for greater choice in healthcare provision as Benenden Healthcare Society's annual conference voted to remove the last of its membership eligibility restrictions. Membership of Benenden Healthcare up until today had been restricted to current or former public sectors workers as well as members of credit unions, co-operatives and charities.

Now, any UK resident aged 16 or over, will be able to join the Society and benefit from its mutual, not-for-profit ethos. For more information, please consult the full [Press Release](#) on Benenden Healthcare's website.

#### **FNMF French Member publishes its yearly review of drugs expenditures in France**

You can consult the brochure in French under this [link](#).

(If you would also like to communicate information about your activities in the Flash, please contact the [Secretariat](#)).



## European Institutions

### ➤ EU Council

#### **Cypriot Presidency: The President of the Republic of Cyprus presents Presidency Programme in Strasbourg**



On this 1<sup>st</sup> July the Presidency of Cyprus is taking over after the Danish Presidency. On Wednesday July 4, 2012, at the European Parliament's plenary session in Strasbourg, the President of the Republic of Cyprus, Mr Demetris Christofias will present the Cyprus Presidency programme. At the plenary session the MEPs will have

the opportunity to ask the President questions about the Presidency ([Press Release](#)). The programme gives all health priorities of the Council: Active and Healthy Ageing with two conferences dedicated to this topic in Nicosia

and Cross-Border Health Threats (for the full list of priorities in the health sector, please refer to Page 38 of the [programme](#) of the Cypriot Presidency).

The next Council meeting of health ministers on 10 July will discuss voluntary blood and tissue donation as well as cross-border health threats (for more information, please report to the [agenda](#)).



DANISH PRESIDENCY OF THE COUNCIL  
OF THE EUROPEAN UNION 2012

### **Pharmacovigilance: Council and Parliament found an agreement for greater medicine safety**

On 20 June, the European Parliament and the Commission agreed on a Directive and a Regulation that will strengthen the monitoring of medicine safety (pharmacovigilance). As a result of the new rules, pharmaceutical companies will be obliged to let the authorities know the reasons behind a decision to stop the marketing of a product in order to prevent that serious safety concerns are kept secret hidden by a voluntary decision to withdraw a product from the market. The monitoring is also strengthened in other ways: an urgent union procedure will be initiated in case of serious safety concerns with regard to a medicinal product, and more medicinal products will automatically be put on a special monitoring list which is made publically available.

The Commission put forward its proposals for a Directive and a Regulation in October 2011 and February 2012. The proposals have been negotiated between the EU Member States in the Council and in the European Parliament. The political agreement is subject to final approval by the European Parliament, the Commission and the Council. See the [Press Release](#)

### **Cross-border health threats: EU ministers call for cooperation across borders**

On 21 June, Health Ministers showed commitment to continue and strengthen the fight against antimicrobial resistance which is a serious and increasing problem in the EU and the rest of the world. Every year 25,000 European citizens die due to antimicrobial resistance. The Ministers agreed to draw attention to reducing the use of antibiotics and to more cooperation between the human and veterinary sectors (*for more information on the Council Conclusions on AMR, read the article below*). The Ministers also discussed the Commission's Health Security Initiative from December last year regarding how to cooperate at EU level when responding to future flu pandemics, outbreaks of E.coli or other cross-border health threats.



During the lunch Ministers discussed the possibilities for joint procurement of vaccines or other medical countermeasures. The negotiations on the Health Security Initiative will continue under the Cyprus Presidency. Furthermore, the Council reached agreement on the new Health Programme for 2014-2020. See the full [Press Release](#).

### **Antibiotics: Council conclusions on the impact of antimicrobial resistance in the human health and veterinary sector**

On 22 June the Danish Presidency of the Council has moved forward in one of its objectives for health policy in Europe: Antimicrobial Resistance (AMR). The Council published [Council Conclusions](#) linking the human health and the veterinary sector. The conclusions call upon the member states to develop and implement national strategies or action plans for countering AMR. The Council also called upon the Commission to follow up on its Communication of 15 November 2011 through concrete initiatives to implement the 12 actions indicated in the Communication, and to present a timeline for the implementation of the initiatives. Besides it expand the existing food and veterinary working group on AMR to fully involve the human health sector to support the implementation of a comprehensive approach against AMR.

#### **➤ Pharmaceuticals and Medical Devices**

### **Pharmacovigilance: European Medicines Agency finalises first set of guidelines on good pharmacovigilance practices**

The European Medicines Agency has published the first set of finalised modules of the guideline on good pharmacovigilance practices (GVP) today. The finalisation of these seven modules is a key deliverable of the 2010 pharmacovigilance legislation, which will apply from Monday 2 July 2012. Each of the modules covers one major process in the safety monitoring of medicines. For the complete list of modules and more information please connect to the EMA [website](#).

### **PIP Implants: MEPs keep a strong line for a change on Medical Devices Regulation following the PIP case.**

In a resolution adopted in the Plenary on 16 June by a show of hands, MEPs argue that the PIP case "has shown a malfunctioning at European and national levels, notably a lack of cooperation by a show of hands, MEPs argue that the PIP case "has shown a malfunctioning at European and national levels, notably a lack of cooperation (...), and a lack of traceability of raw material used for medical devices". EU legislation in this area is to be revised this year. The Parliament has asked the European Commission to switch to a pre-market authorisation system for certain medical devices, including breast implants ([Press Release](#)).

Individual MEPs continue to engage for stronger change as shown in this [article](#) of the Parliament Magazine of 25 June.

### **Prices: President of EFPIA voices concerns of industry on decrease in drug prices due to the crisis**

Sir Andrew Witty, CEO of GlaxoSmithKline and President of EFPIA, the body representing the research-based pharmaceutical industry in Europe, called today for a better collaboration between governments, the European Commission and the pharmaceutical industry in order to ensure that pharmaceutical innovation plays a full role in improving the health of European citizens and in supporting a growth agenda for Europe. This follows a letter sent by Sir Andrew on behalf of EFPIA members to European political leaders last week, in advance of the this week's European Summit. A key concern is the cross-border impact of measures taken. Most importantly, the practice of referral to other countries when setting prices for medicines, results in inefficiencies and sometimes in limited supplies. Where the industry has agreed to temporary price cuts to bridge funding gaps (e.g. in Greece or Portugal) other countries not subject to the same financial pressure automatically lower their prices. The impact of a price cut in Greece resonates across the EU and globally – the implications for the R&D-based industry are clear. See the full [Press Release](#) (also reported in the French *Le Monde* of 27 June).

### ➤ **Active and Healthy Ageing**

#### **European Innovation Partnership: 261 Projects submitted in the call for commitments**

The 261 projects were submitted by groups of stakeholders spanning the public and private sector. In addition, 54 regions and municipalities offered themselves as 'reference sites', to exchange good practice and to share knowledge and experience on past successes in this domain. The commitments were submitted by a wide array of stakeholders, with particular high participation of universities and research groups (37%), public authorities (17%) and health providers (8%). Six meetings are being held this month in Brussels, in which stakeholders are starting to define the implementation details of the specific actions. They will form action groups for each specific action, which will be tasked with agreeing action plans to be presented at the Conference of Partners to be held on 6 November. The first indicators of the process will also be available later this year. The Partnership will assess the results of its work, and the first report will be published in 2013. For more information please consult the EC's [Press Release](#).



### ➤ **Health System**

#### **Crisis: MEPs lead urgent plea from health community to prevent health crisis in Europe**

For the first time 9 MEPs, 65 leading trade unions, civil society organisations, health organisations, and industry associations have united in an open letter attached calling on European leaders to stop cutting essential health and welfare systems and focus on ordinary people living in Europe coping with the dire impact of a financial crisis of which they are the first victims. The toll on physical and mental health is becoming unbearable, and health systems are at breaking point. The coalition is led by the European Public Health Alliance, whose recent briefing note summarises the evidence of the devastating impact of the financial crisis on human health. The evidence in rising suicides, mental health problems, rates of infectious disease are warning signs that current policies are hurtling Europe in a dangerous direction. See full [Press Release](#).

#### **Health Programme: MEPs of the ENVI Committee ask for a more elderly and chronic disease-focused EU health programme**

Compared to the former Health Programme 2008-2013, MEPs have proposed a stronger focus on access to healthcare and vow to promote "health literacy" to boost prevention, ageing populations and chronic illnesses. In its report, the committee says the EU's third multiannual health programme, to run from 2014, must tackle "the health-related, social and economic challenges posed by the ageing of populations and the increasing number of chronic illnesses". It should add value to national health policies in order to "improve physical and mental health and access to healthcare for all EU citizens and reduce health inequalities". The €446 million budget is indicative and will be confirmed when the EU's overall budget plan for 2014 to 2020 is adopted. The report drafted by Françoise Grossetête (EPP, FR) was adopted unanimously. The schedule for plenary vote is linked to the ongoing discussions on the Multiannual Financial Framework (MFF), the EU budget for 2014 to 2020. See the [Press Release](#).

### **Research: Horizon 2020: a major step for Europe's competitiveness**

On 31 May the Council reached an agreement on the main elements of "Horizon 2020" – the draft EU framework programme for research, development and innovation for the period 2014-2020. A large majority of member states supported the compromise proposal on Horizon 2020 drafted by the Danish Presidency. This agreement allows the Council to start negotiations with the European Parliament on the final adoption of the text. The programme's budget will be decided in the context of the EU's next multiannual financial framework (for 2014-2020). "With this agreement the member states have shown that in a time of very hard crisis and austerity we are willing to take the necessary steps to invest in Europe's



future, prosperity and growth, said Morten Østergaard, the Danish Minister for Science, Innovation and Higher Education.

The framework programme itself and three other elements of the research and innovation package – the specific programme implementing Horizon 2020, the rules of participation and dissemination, and the Euratom programme on nuclear research activities – should start running from January 2014.

See the [Press Release](#).

### **Voluntary Blood Donation: Health MEPs oppose paid donation of tissues and cells**

In the resolution, adopted on 21<sup>st</sup> June by 54 votes to 4, with 2 abstentions, MEPs call on all EU countries to ban financial incentives for donation and to clearly define the conditions under which financial compensation may be granted, for example to reimburse travel expenses or loss of earnings. A minority of EU countries currently have guiding principles on compensation or incentives.

The resolution highlights the value of bilateral agreements that help countries to meet general tissue or cell shortages or to find a donor match when they cannot do so domestically. But it says patients could benefit further if EU countries work more closely with Eurocet, the European registry of tissues and cells. See the [Press Release](#).

### **Health Day: World Blood Donor Day - Blood donors, all heroes!**



On 14 June, World Blood Donor day, under this year's motto of "Every blood donor is a hero", the European Commission stressed the importance of safe blood supplies and encourages all European citizens to join the ranks of responsible voluntary donors. Today more than 500 million EU citizens depend on blood donated by less than 15 million donors. This is not enough to meet the needs of all the Europeans who depend on blood to survive from an emergency or to live with a chronic disease that

requires regular transfusions. For more information please see the Commission [Press Release](#).

### **Rare Diseases: 1,000th designation of an orphan medicinal product: improving the lives of patients**

Over 30 million European citizens suffer from a rare disease. The small numbers of patients affected by a single disease and the fragmentation of knowledge about rare diseases translates into difficulties for people to get the right diagnosis, the right medical advice and the right medicine. In many cases, the medicine they need has not yet been developed. Today's 1000th designation of an orphan medicinal product marks a tremendous success in improving this situation. For more information please consult the [Press Release](#).

### **m-health: smartphone app to ensure stress-free travel this summer**

The European Commission has launched an application for smartphones explaining how to use the European Health Insurance Card. The Card gives people access to state-provided healthcare in case of illness or an accident during travel and temporary stays in 31 European countries. The Card is available – free of charge - from national health insurance providers. It guarantees access to urgent treatment under the same conditions and at the same cost (free in some countries) as people insured in that country.

See the [Press Release](#).

#### **➤ European Mutuals' Statute**

### **EMPL Committee Public Hearing on a European statute for mutuals by Pervenche Bérès on 20<sup>th</sup> June**



Pedro Bleck da Silva, Chairman of the Statutes Working Group represented AIM at the hearing alongside Gérard Andreck the President of MACIF group and Grégor Pozniak, Secretary General AMICE.

The European Parliament EMPL Committee reports on the Hearing on its [website](#):

“Experts all agreed that mutuals need a European statute that allows them to work at a European level, which would facilitate their development across Europe, the establishment of cross-border groups, to benefit of the single market and strengthen

the competition for the users' benefit, but also the European social model”. [...] “The diversity among the mutuals is not an obstacle for a Statute, but rather an enrichment. The diversity consists in the legal framework in terms of definitions and ideas of what mutuals want: identity, brand recognition for the cross-border transactions etc. The Statute would ensure to avoid discrimination and would guarantee equal treatment in the single market and a fair and competitive market. Even those Member States without a system of mutual societies are not against a European Statute, but rather they lack interest in having one”. To read the full report on the EMPL committee, please go on the Committee's [home page](#) (last item).

## ➤ **Social Services**

### **Social Business Initiative**

The EMPL Committee had a second discussion of the draft report by Mr Becker (EPP- AT) on the Commission communication "Social Business Initiative - Creating a favourable climate for social enterprises, key stakeholders in the social economy and innovation". Further to his [draft report](#) Mr Becker acknowledged the need to better define "social business", based on already existing definitions and other EP reports. Consideration of amendments and vote are set to take place on 10 July in the EMPL Committee.

### **VAT: European Commission calls on France to limit the reduced VAT rate to domestic care services**

On 21 June, the Commission has asked France in a reasoned opinion to ensure that certain "personal services" should be subjected to the normal VAT rate. Indeed, France applies a reduced VAT rate to "personal services", a much broader category which covers, for instance, gardening, home lessons (different from school support), computer and internet assistance at home, maintenance services, and maintenance and temporary guarding of main and secondary residences. This rate also applies to the services of intermediaries operating in the sector. The Commission considers that applying a reduced VAT rate to these services is not compatible with European Union law. [Press Release](#)

## Health and Long-term care

### ➤ **Trends in health system**

#### **Bi-national Cooperation in public health: Creation of the first Franco-German Public Health Institute**

The department for Research and Teaching of the Parisian University Sorbonne Paris Cité and the Medizin fakultät in Berlin announced the creation of a Franco-German Health institute *beginning June*. The two partners are currently determining the objectives and steps of this structure that will offer research and training. The institute will be formally inaugurated in January 2013. One of the innovative aims of the Institute is to promote a bi-national approach of public health questions and to start thinking on efficient health crisis management. Main topics in the institute will be the relations between migrations and health, determinants and health inequalities and health systems reform. The institute's final location is still debated but could be in Paris in the Hôtel-Dieu. For more information please see the [article](#) (fr) published on the French University website, and a related [Press Release](#) in German on the Charité's website.



*(Article suggested by the French member FNMF. For any suggestions of articles, e-mail the [Secretariat](#)).*

#### **AMR: Europe to boost development of new antimicrobial drugs**

There are several reasons why development of new antimicrobial drugs has stalled in Europe (and in fact worldwide). Among them is the difficulty to develop antibiotics targeting pathogens endowed with antimicrobial resistance. In addition, the regulatory environment within Europe is such that new drugs need to show non-inferiority in clinical trials within a margin of 10% as compared with current gold standards; this is quite challenging since many participants in a clinical trial may not be infected with the bacteria being targeted by the new drug. As these drugs are taken for limited courses not for life, this also restricts possible profitability. These factors have coalesced to make development of new antimicrobials a largely unattractive prospect for drug companies. "Only two new classes of antibiotics have been developed and launched in the last 30 years. This reflects the difficulties we face—the science is very complex and the risk and investment required is high yet antibiotic discovery has a higher attrition than other therapeutic areas", says David Payne, Head of Antibiotic Discovery at GSK. See the full article on [The Lancet website](#).



#### **African Region: The role of Mutual Societies in the extension of health protection in Africa**

Mutual benefit societies in Africa can play a role in providing health protection to their members. This was the strong message which came out of a conference in Abidjan, Cote d'Ivoire, in February this year, organised by the International Association of Mutuality and the Union of African Mutuality. In countries where the majority of the population is not covered by compulsory health insurance, people face very high health expenses. Mutual benefit societies can help in many ways.

The financial contribution, even reduced, remains the principal barrier to their membership. A 2005 report for the International Labour Organization found for example that in Ghana, despite a 75% subsidy towards premium costs, many people could not even carry the costs associated with the photograph needed for the insurance card. For more information you can look up on AIM African member [MUGEF-CI website](#) (fr).

#### **AIM Vice-President José-Maria spoke at the RIO+20 Summit in the Meeting of Rencontres du Mont Blanc**



The International Forum of the Social and Solidarity Economy Entrepreneurs (MBM-IFSSEE), chaired by Thierry Jeantet, held a side event at the Rio+20 Summit on last Tuesday June 19.

Mr José-Maria Garriga presented on social economy at this occasion. The room was overcrowded to attend the only meeting of the Summit dedicated to the Social and Solidarity Economy.

Brice Lalonde, co-coordinator of the Rio+20 Summit, reiterated its support and wishes the international recognition of the SSE. For more information, please consult the [Press Release](#) of the Meeting.



## Health events in Europe

### ➤ *Danish EU Presidency*

21-22/06, Luxembourg [Meeting of Employment, Social Policy, Health and Consumer Affairs \(EPSCO\)](#), Council of the European Union

### ➤ *Other events*

- 5/07, Nicosia [Conference on Cross Border Health Threats](#) in the EU and its neighbouring countries-focus on communicable diseases
- 22-28/07, Venice [Observatory Venice Summer School 2012](#) on performance assessment, European Observatory on Health Systems: to marshal the evidence on performance, to review what it means for health systems and to share experiences of responding through policy and in practice.
- 10-11/07, Nicosia Informal Meeting of Ministers for Employment, Social Policy, Health and Consumer Affairs  
[Agenda](#)
- 5-6/09, Nicosia High Level Conference on Healthy Ageing across the Lifecycle
- 18/10, Nicosia Conference on Occupational Safety and Health
- 21-24/10, Berlin [World Health Summit](#)
- 10/12, Nicosia Closing Conference for the European Year for Active Ageing, and Solidarity between Generations

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*The monthly AIM Flash is compiled by Ph. Swennen, R. Kessler and 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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