

FLASH n°108 – November-December 2012

New Year edition

Featured Stories



Irish Presidency of the Council

- -Irish presidency priorities
- -Trio Programme of Irish, Lithuanian and Greek presidencies



European Mutual Statute

Adoption of the Opinion in the EMPL Committee and Meeting with Commissioner Barnier



Transparency of prices

Adoption of Report in ENVI on 18 December



Public Procurement

Adoption of the Report of MEP Tarabella

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JANUARY 2013: AIM Events' Calendar

Next Meeting and visit dates

21 January	AIM Presidium, Brussels				
25 January	Pharmaceuticals & Medical Devices WG, Brussels				
28 January	European Affairs Working Group, Brussels				
11-12 March	E-health study Trip to Barcelona Agència d'Informació, Avaluació i Qualita en Salut (AIAQS)				
13-14 June	General Assembly and board Meetings Gent				
WG: Working G	Group				

Mon.	Tue.	Wed.	Thu.	Fri.	Sat.	Sun.
	1 Happy New year!	2	3	4	5	6
7	8	9	10	11	12	13
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21 Presidium	22	23	24	25 Pharma WG	26	27
28 EU Affairs WG	29	30	31			

AIM and you

> AIM Activities in September

- 5-6 November: e-health Study Trip in Berlin with EHTEL. Presentations should be available soon on the AIM website.
- **9 November and 14 December**: Mutuals Working Group gathered in AIM and decided to organize a cocktail in the Parliament to be held on 21 January. Article on the EMS
- 14 November: AIM Participated to the Hearing on medical Devices organized by ALDE. Article about Medical devices
- 16 November: AIM participated to the EU Health policy forum
- **28-30 November**: AIM held its Board Meetings with European Affairs Committee, Board of Directors, International Conference on Healthy Ageing and Health Systems Reform working group and Fraud Working group.
- 6 December: AIM delegation met Commissioner Barnier to discuss the European Mutual Statute.
- 10 December: AIM participated to the Closing Conference of the Year on Active Ageing in Cyprus

The contribution to EUnetHTA was confirmed for Joint Action 2 and drafted by Irina Odnoletkova (MLOZ, BE), Chairwoman of the AIM HTA Working group.

Members' news



AIM would like to welcome two new members approved by the members of the Board of directors: HZZO, Croatian Institute for Health Insurance as associate partner¹



<u>MUSPO</u>, Mutuelle Santé Prévoyance Obsèques from Democratic Republic of Congo as corresponding member

AIM now represents 48 organisations in 27 countries.

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

- Benenden Healthcare's new structure was published by Health Insurance Magazine: Article

> AIM secretariat

AIM is now on Twitter! Follow us on Twitter: @AIM healthcare

- > Learn about the latest News in Europe (from MEPs, institutions and journalists)
- > Get to know what AIM and our members are doing



European Institutions

> EU Council and Presidency

Priorities of the Irish Presidency: People-centred recovery, designed to last

The official document of priorities of the Irish Presidency will only become public in January 2013 but they are already summarised in speeches and on the presidency dedicated <u>page</u> on the new Presidency <u>website</u>. *In general:*



The Irish Prime Minister or 'Tánaiste' (in gaelic) presented the priorities on 17 December as follows:

"The attention must now focus on the challenge of getting the European economy back on track by improving the EU's global competitiveness, promoting economic growth and creating jobs. This will be the central theme of the Irish Presidency"

¹ Croatia will also become the 28th Member State of the EU on 1 July 2013

In the health sector: The Irish Presidency will focus mainly on medical devices and clinical trials. Tobacco directive, Cross-border healthcare and Health Programme are also on the agenda. Transparency of pricing and reimbursement of medicines is left to the decision of the Council but should not be the priority.

The Irish, Lithuanian and Greek Presidencies Trio Programme

The 18-month work plan of the 3 next presidencies has been released. Ireland's Presidency Trio partners are Lithuania (July-December 2013) and Greece (January-June 2014). The main objective for the trio remains to stimulate growth, create jobs to tackle the economic crisis.

On the side of health, the Trio programme mentions: Health and Safety at Work, Social investment, Cross-border health threats, Medical Devices, IVD Directive, Clinical trials and also Transparency on prices of medicinal products and a proposal for a revision of the fees payable to the European Medicines Agency.

Especially on social security systems, the programme states "Attention will also be paid to the issues of the financing of the social protection systems and adequate access to services as well as the potential responses to the ever increasing need for long-term care".

The Presidencies will also resume the negotiations on the proposal for a Directive on improving the portability of supplementary pension rights (the so-called "Portability Directive").

For health priorities see p.59-63 in the Trio Programme.

Round-up of the European Year 2012 for Active Ageing and Solidarity between Generations

The aim of the European Year 2012 for Active Ageing and Solidarity between Generations was to raise awareness of these issues and promote measures that create more and better opportunities for older:

The year has had a political impact among others with an Austrian Federal Plan for Senior Citizens, the Irish Age-Friendly County Programme running until end 2013 with public consultations with older people at town and village level, a Germany campaign of 2012 as Year Against Age Discrimination under the slogan "Im besten Alter. Immer" (Always in the best age), the Polish Government Programme for Senior Citizens Social Activity" with a dedicated budget and finally a new Belgian federal advisory council for the elderly.



Commissioner Laszlo Andor and Sotiroula Charalambous, Cypriot Minister of Labour

The EY 2012 Awards have also enabled to select European best practices in Healthy Ageing.

Other deliveries of EY2012 that continue to thrive in 2013 are:

- The European Innovation Partnership on Active and Healthy Ageing, see the Memo on latest Conference of Partners This includes the EU covenant of mayors for Age-friendly cities (lead by the AGE platform)
- The Active Ageing index.

Council Conclusions on Healthy Ageing

In the <u>Council Conclusions on Healthy Ageing</u>, member states, as well as the European Commission, are invited to engage on this issue by making healthy ageing a priority for the coming years.

In the <u>Council Declaration</u> on the European Year for Active Ageing and Guiding principles for active ageing, the Council remarks that "The active ageing perspective should be mainstreamed across all relevant policy areas".

The guiding principles stress 3 priority areas: employment, social participation and independent living of older people. For a summary of the guiding principles, please click here.



Also read the AIM Declaration on Healthy Ageing and Press Release.

Council Conclusions on Organ Donation & Transplantation

Organ transplantation saves lives and drastically improves the quality of life for patients. 30 300 organs were transplanted in the EU in 2011. However latest records (from 31 December 2011) show that more than 61 000 patients in the EU are on a waiting list for an organ. The Cyprus Presidency of the European Union set organ donation & transplantation as a priority, reiterating support for the Commission's "Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States", which is now half-way.

The Action Plan addresses three main challenges supported by the <u>Conclusions</u>: (1) to increase organ availability; (2) to enhance the efficiency and accessibility of transplant systems; and (3) to improve quality and safety.

More information on the Commission's <u>website</u>

> European Commission

Commissioner: Tonio Borg appointed new commissioner for health and consumer policy



On 28 November, the former foreign minister of Malta, Tonio Borg, has been approved as the new Commissioner for Health. His predecessor John Dalli had to leave the Commission after a scandal involving the new tobacco directive.

After the Commission proposal, a vote of the European parliament resulted in 386 votes to 281 against.

Liberal, Green and leftist MEPs chose to oppose Mr Borg because of his conservative views on gay rights and abortion. The EU ministers approved Tonio

Borg one week after the vote.

The controversial tobacco directive which brought down Mr Dalli will be revised, Mr Borg said.

He provided MEPs with written assurances that he would respect the European Charter of Fundamental Rights, the rights of women and gay rights. See the Official decision.

European Year 2013: 2013, 'European Year of Citizens'- "It's about Europe. It's about you. Join the debate"

"After 20 years of EU citizenship, much has been achieved. It is time to reflect on where we stand and what the future should bring," said Vice-President Viviane Reding, EU-Commissioner responsible for Justice and Citizenship. The European Year of Citizens coincides with the 20th anniversary of the introduction of EU Citizenship, when the Maastricht Treaty came into force in 1993. 2013 will also be the year when the Commission adopts its next EU Citizenship Report (see the 2010)



<u>Press Release</u>), which will present further targeted EU initiatives to remove the remaining obstacles that hinder citizens from fully enjoying their rights. One year before the European elections 2014, it is also the right moment for a broad debate about the future. As part of the Year, politicians have started holding debates with citizens directly about the future of Europe. Such debates will be held all across the Union over the course of 2013. Everyone will be free to join the debates. The European Year of Citizens will be officially launched by a debate with citizens in Dublin on 10 January 2013, coinciding with the start of the Irish presidency of the Council.

See the Press Release and the dedicated campaign website for more information.

Patient safety: Commission publishes report on state of play in the Member States

The report focuses on the state of implementation of a number of actions to increase patient safety agreed to by the EU's member states in 2009. Patient safety means that patients are not exposed to unnecessary harm or potential

harm associated with healthcare, including the prevention and control of healthcare associated infections. The report concludes that Member States have implemented various measures such as embedding patient safety in public health polices and identifying competent authorities on patient's safety; however more effort is needed towards actions targeting patients, e.g. patient empowerment, and health professionals, e.g. more education and training. The report also shows that the economic crisis slowed down the implementation because of changing public health priorities.



See the Report and the detailed Commission Staff Working document

Publication of e-health Action Plan: Putting patients in the driving seat: A digital future for healthcare



The new <u>e-health Action plan</u> foresees new steps to reach interoperability of services, and e-health deployment. Concrete actions should include an e-health interoperability framework, consultation on electronic health records and green paper on mHealth.

Released on 7 December, this second action plan builds on the first e-health action plan on e-health dating back to 2004 and the establishing of the "eHealth network"

with article 11 of the Directive on the application of patients' rights in cross-border healthcare adopted in 2011.

The Action plan identifies main objectives to the development of e-health which has been much slower than the evolution in the rest of ICTs. These objectives are interoperability, deployment, and also cooperation at global level and innovation in the e-health sector.

Interoperability is the first challenge the Commission wants to address and gives priority in terms of legislative action. The Commission plans:

- An e-health interoperability framework by 2015 that will be based on guidelines on a dataset for patient summary records;
- A study on national legislations covering electronic health records for 2013;
- Green paper on mHealth and health and wellbeing applications by 2014 and
- Guidance on application to health services of the future legislation on data protection.

Legal issues are more specifically developed in the <u>Commission Staff Working Document</u> accompanying the Action Plan.

Facilitating Research and development is the second challenge defined by the Action Plan, which the Commission wants to respond to with 'Horizon 2020', the Commission programme dedicated to research.

Third, deployment and cooperation should be facilitated by developing new e-health indicators and also through Health Technology Assessment so as to measure the added value of e-health in a clearer fashion.

See the Press Release.

Cross-border health threats: Commission proposes effective measures to better protect citizens from a wide range of cross-border health threats

The European Commission adopted on 8 December a legislative proposal on the means to address serious cross border health threats. Building on lessons learned with recent crises such as the H1N1 pandemic in 2009, the volcanic ash cloud in 2010 and the outbreak of E. coli in 2011, the Commission is proposing to strengthen the means to prepare for and to address such crises. The main measures proposed include:

- to extend the existing co-ordination mechanism for communicable diseases to all heath threats caused by biological, chemical or environmental causes;
- to reinforce the mandate of the Health Security Committee;
- to strengthen preparedness for crises e.g. by enabling joint purchasing of vaccines;
- to provide the means to recognise a European "health emergency situation" for the purpose of making medicines available faster;
- and to agree on European wide emergency cross border measures when a crisis results in large scale mortality and national measures fail to stop the disease from spreading.

See the Press Release.

Health Programme: Annual work plan for 2013

The annual work plan 2013 for the health programme was adopted on 28 November 2012.

Main priorities for 2013 will be: Active and healthy ageing – focus on chronic diseases, effective ways to invest in health – also health workforce, patients' rights and safety and advice and data, particularly on sustainable health systems. The work plan will also support the implementation of legislation in the following areas: Safety and quality of tissues, cells and blood, Cross-border healthcare, Pharmaceuticals and medical devices. See the Work Plan and more information online.

Pharmaceuticals and Medical Devices

Medical Devices: Is new legislation on medical devices sufficient to protect patients? On the 14th of November 2012, the ALDE-Group was hosting a conference on the new proposal of the European Commission for a regulation on Medical Devices. The main issue was how to improve patient safety by setting up a pre-market authorization system and by improving the market surveillance, the vigilance, and the accreditation and assessment of notified bodies. Professor Alain Fraser from the European Society of Cardiology reported that just like in the case of pharmaceuticals, proof of efficacy for the Medical devices is also needed. For the time-being, medical devices only need to prove their 'performance'. Hans-Heiner Junker, a representative of the German notified bodies remarked that the more players are involved in the evaluation of a medical device, the broader the interpretation is. Some additional thinking also needs to be done to avoid a repetition of the PIP scandal



which points to some major lacks in the current regulatory system, though being a fraud case. On this last point, Ilaria Pasarani from the European Consumers' Organisation BEUC brought the testimony of one of the victims of PIP to the audience. For more information on the event see the ALDE website.

Medical Devices: ENVI Workshop on Medical Devices and IVDs on 26 February

A two-part ENVI Workshop on Medical devices and In Vitro Diagnostic Medical Device will take place on 26 February organised by ENVI Rapporteur for Medical Devices Dagmar Roth-Berendt and by ENVI Rappoerteur for In Vitro Diagnostics MEP Liese. The workshop will consist of an exchange of views with representatives of EU institutions, healthcare professionals associations, patients' organisations, industry, notified bodies, academics and other stakeholders. A first agenda will be available in January. See announcement on ENVI homepage.

Transparency of prices: Adoption of Report in ENVI

On 18 December, ENVI MEPs have adopted the Report of Rapporteur Parvanova on Transparency directive for pricing and reimbursement of medicinal products.

Main measures adopted include:

- Keeping a 90 day time-limit for pricing or reimbursing with a total 180 day time-limit for inclusion in health
- 60-day time limit for inclusion of generic medicines in order to speed up the availability of these cheaper products.

These deadlines include all the procedural steps and any applicable health technology assessment.

- Increased transparency with for example disclosure of names and the declarations of interests of their experts and members, and publication of the list of the medicines covered by the public health insurance with prices, once a year.
- -The countries still have the right to re-assess efficiency of medicines and ask for data that was used in the marketing authorisation
- -The new text also specifically includes biosimilars
- -finally the text deletes the possibility to impose fines on member states when not respecting time limits which was going clearly beyond the scope of the text.

See the Press Release.

> Cross-Border Healthcare

Cross-border prescriptions: Publication of Implementing directive on European prescription rules

The implementing directive results from Article 11 paragraph 2 of the Cross Border Health Care Directive (2011/24/EU) requesting member states to adopt measures to facilitate the recognition of medical prescriptions. The new rules on Prescriptions take the form of an Implementing Directive. They introduce a common set of descriptive elements to help identify prescribers, patients and prescribed products. They do not, however, deal with the appearance, format or language of the prescription. Nor do they preclude further elements, in line with local practices, being added by prescribers. These common elements are limited to cross-border prescriptions requested by the patient, not prescriptions used within a country (unless a Member State so chooses). National Contact Points, established under the Cross-border healthcare Directive will inform patients on the right to travel with a cross-border

prescription when visiting another Member State as well as the minimum list of elements that it should contain. See the <u>Press Release</u> and for more information click <u>here</u>.

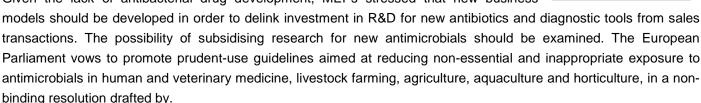
Regarding the implementation of the cross-border healthcare directive, a <u>consultation</u> is going on until 22 February 2013 on European Reference Networks.

> Health System

Anti-Microbial Resistance: EU must tackle the rising threat of microbial resistance, says health committee

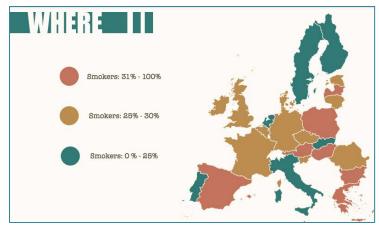
The Report on the Microbial Challenge – Rising threats from Antimicrobial Resistance by Anna Rosbach (ECR, DK) was adopted unanimously and will be voted in plenary in December in Strasbourg.

Given the lack of antibacterial drug development, MEPs stressed that new business



See the Press Release and Report.

Tobacco: Revision of the Tobacco directive



Map of Smokers in Europe, Extract of Commission's infograph features to combat illicit trade.

On 19 December, the EU-Commission published its proposal to revise the new Tobacco Products Directive. The new proposal foresees to strengthen the rules of the manufacturing of tobacco products, the way they are presented and sold. It bans the use of cigarettes, roll-your-own tobacco and smokeless tobacco products with characterizing flavors. The use of large pictorial health warnings mandatory on cigarettes and roll-your-own tobacco will be mandatory. The new proposal will also regulate the cross border sale and plans to implement technical

The main change is in labelling and packaging. Indeed all cigarette and roll your own packages must contain a combined picture and text health warning covering 75% of the front and the back of the package. Promotional elements are not allowed on the package. There will be an information message on the side of the pack that tobacco smoke contains more than 70 substances causing cancer. Member States can also choose plain packaging in duly justified cases. The ban on oral tobacco products (snus) is maintained, except for Sweden which has an exemption. See this very visual representation of smoking consequences and more information online.

Data Protection: Publication of the Report in January

On the topics of data protection, Rapporteur Jan Albrecht published an update of the dates for the coming year:

- -Publication of the report is still foreseen on 10 January 2013.
- Deadline for Amendments is on 27 February
- An Orientation vote will take place end of April 2013
- from May 2013, the trilogue could already begin

New position paper from EPF; EU Observer article on the state of play

Insurance

Public Procurement: Adoption of the Report of MEP Tarabella

On the 18 December 2012, the Committee on the Internal Market and Consumer Protection of the European Parliament (IMCO) has adopted the report of Marc Tarabella (S&D, Belgium) of public procurement with 23 votes in favor, 8 against and 7 abstentions.

Members of the IMCO Committee of the European Parliament decided that the Directive will apply to "Compulsory social security services". But services will not be covered by this Directive when they are organized as non-economic services of general interest. Member States are also free "to organize the provision of compulsory services or of other services of general interest or as non-economic services of general interest" (see footnote of annex XVI). The report of MEP Tarabella (S&D, BE) clarifies that this Directive "will not affect the social security legislation of the Member States or deal with the liberalization of services of general economic interest reserved to public or private entities, nor with the privatization of public entities providing services."

Furthermore, the Directive only applies to public contracts for social and other specific services listed in Annex XVI with a value of 750 000 €. The Commission originally proposed an amount of 500 000 € (Article 4 (d)).

The Compromise Text of the Cyprus Presidency, which was discussed in the Competitive Council on the 10/11 December 2012 heads the same direction. The Directive "should not affect the social security legislation of the Member States or liberalize services of general economic interest, reserved to public or private entities".

The coordinators of the IMCO Committee will decide at a later stage, when they will open the negotiations with the Council of the European Union. Both institutions need to come to an agreement before the directive of Public Procurement will come into force.

Social Economy and European Mutual Statute

European Mutual Statute: Adoption of the Opinion in the EMPL Committee and Meeting with Commissioner Barnier

The EP Committee on Employment and Social adopted on 6 December by a large majority its opinion for the Committee on Legal Affairs on the "Statute for a European mutual society" 2012/2039(INI), Rapporteur for the opinion MEP Regina Bastos (Opinion). The report on EMS by MEP Luigi Berlinguer is scheduled to be voted in the Legal Affairs Committee on 22 January while the provisional date for the vote in the plenary is 7 February 2013. In February, the European Commission will launch a public consultation on the results of the study on "Current"

situation and prospects of the mutuals in Europe" published in November 2012.

On 6 December, An AIM delegation composed of 5 European countries met the Commissioner Barnier who expressed its support for a European Mutual Statute. The delegation was composed of AIM President Jean-Philippe Huchet, the Chairman of the Mutuals Working Group, Pedro Bleck da Silva (PT), Lawrence Christensen from Benenden (UK), Sabrina Luise from FIMIV (IT), Christian Horemans from MLOZ (BE).

A cocktail will be organized on 21 January in the European Parliament to promote the European Mutual Statute.



Social Business: Adoption of the Report on Social Business Initiative

On Tuesday, November 20th the European Parliament has adopted its report on the EU Social Business Initiative. It stresses the necessity of adequate financial support of social enterprises which promote quality employment and combat social exclusion. Across Europe there are about 2 million enterprises like cooperatives, foundations, associations and mutual societies with at least 11 million employees.

New measures include: asking for a comparative study on the different applicable national frameworks, and simplifying the regulation on the Statute for a European Co-operative Society as well as support for the European Foundation Statute and a European Mutual Statute. Read the Report on Social Business Initiative.

Health and Long-term care

Trends in health system

Public expenditure: The Quality of Public Expenditure in the EU

According to the Report, the main reform measures are:

- 1. Ensuring a sustainable financing basis to the sector, a good pooling of funds and a resource allocation that is not detrimental to more vulnerable regions;
- 2. Adjusting existing cost-sharing systems so they encourage a cost-effective use of care;
- 3. Ensuring a balanced mix of different staff skills and preparing for staff needs;
- 4. Improving and better distribute primary health care services and reducing the unnecessary use of specialist and hospital care;
- 5. Increasing hospital efficiency through increasing use of day-case surgery and concentration of some hospital services;
- 6. Ensuring a cost-effective use of medicines (e.g. greater use of generic medicines) while allowing for innovation
- 7. Improving the general governance (by ensuring coherence of decision-making, clear priorities and goals and improved management skills) of the system;
- 8. Improving data collection and information channels and using available information to support performance;
- 9. Using health technology assessment more systematically to help decision-making processes;
- 10. Improving population's life-styles and access to more effective health promotion and disease prevention. (see p.24-26 and 43-52 for Efficiency of healthcare expenditure)

Health Indicators Report: Health spending in Europe in 2010 fell for the first time in decades

The Report published on 16 December indicates that health spending per person and as a percentage of GDP fell across the European Union in 2010. This is one of the many findings in the "Health at a Glance: Europe 2012", a new joint report by the OECD and the European Commission. From an annual average growth rate of 4.6% between 2000 and 2009, health spending per person fell to -0.6% in 2010. This is the first time that health spending has fallen in Europe since 1975. See the Press Release

Studies

Publication of Report "EU in the World": Statistics for Health p.41, for Social Protection p.71 http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-30-12-861/EN/KS-30-12-861-EN.PDF

Last Eurohealth Issue page 21-23, Information on Clinical Trials

http://www.euro.who.int/__data/assets/pdf_file/0008/179729/Eurohealth_v18n4.pdf

EU Parliament: Reforming the Data Protection Package, September 2012

http://www.europarl.europa.eu/document/activities/cont/201209/20120928ATT52488/20120928ATT52488EN.pdf

WHO Europe's work 2010-2011: Report of the Regional Director on the work of WHO in the European Region in 2010–2011

http://www.euro.who.int/en/what-we-publish/abstracts/what-weve-achieved-together-report-of-the-regional-director-on-the-work-of-who-in-the-european-region-in-20102011

EU Commission: A selection of successful projects funded by the EU Health Programmes http://ec.europa.eu/health/programme/docs/success_stories_full_en.pdf



Health events in Europe

20 January Health Minister of Ireland presentation in the ENVI Committee

26 February ENVI Workshop on Medical Devices and In Vito Diagnostics

More information on the Committee homepage

4 February EPPOSI Event

Building a Framework for Societal Benefits Approach to Health Technology Assessment

Brussels, Programme and Registration

4-5 March Informal meeting of Health Ministers

May 2013 eHealth week

20 – 21 June EPSCO Council

The monthly AIM Flash is compiled by Blandine Cassou-Mounat with the contributions of Corinna Hartrampf and Philippe Swennen. Realisation & Layout: Blandine Cassou-Mounat

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

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