AIM FLASH—N° 103 – April 2012

Featured Stories

European Mutuals’ Statute
Conference on a European Mutuals’ Statute
26 September: Save the Date for MEP Berlinguer’s Conference in the European Parliament

Pharmaceuticals and Medical Devices
MEPs draw conclusions of the PIP scandal
EP Resolution was adopted on Defective PIP Breast Implants with the support of all MEPs.

Active and Healthy Ageing
EIP for Active and Healthy Ageing moves from Plan to Action
EC presented on how to get involved.

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Next Meeting dates
4 May: Communications TF in Brussels
30 May: AIM-AMICE Joint TF in Brussels
31 May – 1st June: XXXth General Assembly in Brussels
15 June: European affairs WG in Brussels
28 June: Pharmaceuticals and MD WG in Brussels
25 July: Fight against fraud WG in Brussels
6 September: European affairs 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

MAY 2012: AIM Events’ Calendar

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TF: Task Force
WG: Working Group
AIM and you

- **Position Papers**

**Pharmaceuticals and Medical Devices: Consultation on Safety feature for pharmaceuticals**
AIM responded to the European Commission public consultation on detailed rules for a unique identifier for pharmaceuticals (safety feature). The aim of the unique identifier is to avoid that falsified medicines enter into the legal supply chain.

**HTA: Joint letter on stakeholders’ involvement**
AIM co-signed a joint stakeholder letter on stakeholders’ involvement in the second EU Joint Action on health technology assessment which was sent to the European Commission and EUnetHTA on 26/04.

- **Working Groups**

**Joint AIM-AMICE task force on European mutual society**
The joint task force met on 2/05 to discuss and support the on-going preparation of the EP own-initiative report on mutuals, including MEP Berlinguer’s (S&D, I) conference on 26/09 in Brussels. More information is available from the AIM Secretariat.

- **Members’ news**

ZN is inviting AIM members to the event ‘Open house 2012’ on 8-9 May presenting the Dutch system of Fraud in Healthcare in Zeist in the Netherlands. The event will be in English.

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**European Institutions**

- **EU Council**

**Informal Health ministers meeting pushes for innovation and chronic diseases management**
On 23-24/04 on the occasion of an informal Health Council meeting, European Ministers for Health have discussed how to make room for innovation in the health systems both at national and European level. They also pushed forward the agenda on chronic diseases in the discussion on patient empowerment. Ministers also discussed medical devices and agreed to use the Health Security Committee as a platform for crisis management in the field of medical devices (More information on the Danish Presidency’s [website](#)).

- **Pharmaceuticals and Medical Devices**

**MEPs draw conclusions of the PIP scandal**
Motion for resolution on "Defective silicone gel breast implants by French company PIP" has been adopted by unanimity in the ENVI Committee in the European Parliament on 25 April. The main points of the resolution aim at correcting this ‘failure of the notification system’. In the resolution, MEPs call for a shift to a pre-market authorisation system for some devices, more transparency in the functioning of notified bodies and a breast implant register ([Press Release](#)). The motion seeks to push for modifications in the Commission’s proposal of the Recast of the Medical Devices Directive to be published in the coming months. Although there is a broad consensus of MEPs on the need to reform the authorization system to avoid a similar case in the future, the European Association for Medical Devices demonstrated its criticism in its [reaction](#) to the motion.

**Parliament discusses the Commission changes to Pharmacovigilance after Mediator case**
At the next ENVI committee meeting on 8 May, the committee should vote on the report of MEP Linda McAvan (S&D, UK) welcoming the changes proposed by the Commission to close the current loopholes in the Pharmacovigilance legislation that were revealed by the Mediator case in France. The main and undisputed changes should be: the urgent procedure would be automatic in some cases; Companies would have to declare specifically if a product is withdrawn for safety reasons and the list of medicines monitored has been extended. Rapporteur Linda McAvan expressed her wish to see the text adopted as quickly as possible so it can start being implemented still in 2012.

**European Commission offers €2 million prize for a leap forward in vaccine technology**
On 16/04 the European Commission offered a €2 million prize to encourage inventors to overcome one of the biggest barriers to using vaccines in developing countries: the need to keep them stable at any ambient temperature. Vaccines are often rendered ineffective by temperature variations in these regions during transport and storage, long before they can be administered. The WHO estimates that half of all supplied vaccine doses are wasted. Since most of this waste is caused by an inadequate cold-chain, there is an urgent need for alternatives to, or cost-effective improvements on existing technologies. You can find more information on DG Research’s [webpage](#).
EMA: a robust global framework for conduct and oversight of clinical trials
The European Medicines Agency published a reflection paper on ethical and good clinical practice (GCP) aspects of clinical trials of medicinal products for human use conducted outside of the European Union (EU)/European Economic Area (EEA) and submitted in marketing authorisation applications to the EU regulatory authorities (Press Release).

Active and Healthy Ageing
European Partnership for Active and Healthy Ageing moves from Plan to Action
DG SANCO and DG INFSO have presented the development of the European Innovation Partnership for Active and healthy Ageing in a Conference in Brussels on 3rd April. Three ways to get involved in projects are provided to target current funding tools:
- Committing to action in one of the 6 areas outlined (prescription adherence, frailty, integrated care of chronic diseases...);
- Becoming a ‘Reference site’ thus sharing solutions with other partners;
- Joining the Market Place of Ideas to look for like-minded partners and share ideas.
You will find more information on the EIP website, on commitments, on the reference sites and on the marketplace for ideas. Please be aware that the commitment or expression of intent to be a reference site can only be submitted until 31 May 2012.

More information is available on the EIP’s website. (Slide from Presentation by Maria Iglesia, DG SANCO, available on request)

Health System
Action Plan for the EU health workforce adopted as part of the Commission Communication for a job rich recovery in Europe
On18 April, the Commission adopted a Communication "Towards a job rich recovery" which sets out a range of measures to encourage employment and strengthen economic growth in Europe. It also identifies healthcare as one of three key sectors with a high employment potential and includes an Action Plan for the EU health workforce (Press Release). Healthcare is highly labour intensive and one of the largest sectors in the EU, accounting for about 17 million or 8% of all jobs in the EU. Despite the economic downturn, the sector continues to grow and, with an ageing population and the rising demand for healthcare, will remain a key driver for jobs with an estimated 8 million job openings between 2010 and 2020. However, the sector faces major challenges at a time of severe budget constraints, including health workforce shortages and skill mismatches in many countries (see accompanying staff working document). The Action Plan aims to assist Member States to tackle these challenges and sets out actions to foster European cooperation and share good practice to help improve health workforce planning and forecasting, to anticipate future skills needs, to improve the recruitment and retention of health professionals while mitigating the negative effects of migration on health systems.
More information is available on the Commission’s website.
Public consultation on stakeholder consultation in the voluntary Health Technology Assessment network
(Feature Story)
The European Commission Directorate General Health & Consumers launched on 2nd May a stakeholder consultation on “Modalities of stakeholder consultation in the voluntary Health Technology Assessment network” to be established under Directive on patient’s rights adopted in 2011 (article 15). The Directive states that the purpose of the HTA network shall be to support and facilitate cooperation and exchange of scientific information among Member States. Although the network will consist of Member State representatives, the Directive also specifies that stakeholder consultations on the Network's activities should take place. The deadline to provide input is 1st August 2012.

High-level conference on EU Health Programmes
On 3rd May, DG SANCO organized a high level conference on EU health programmes: results and perspectives. The conference highlighted the successes of the first and second Health Programmes but also looked at the third ‘Health for Growth Programme’ (2014-2020) currently being debated by the Council of Ministers and the European Parliament (Press Release).

HEIDI: A new way of sharing and storing health information in the EU
HEIDI (Health in Europe: Information and Data Interface) has been launched by DG SANCO. As an internet based wiki that presents comparable data about health in the EU (for example on health status, health determinants, systems and policies), Heidi has been set up by the Commission but its contents are written by European health experts. The experts are responsible for their contributions and can directly upload and edit information.

➤ European Mutuals’ Statute

Conference on a European Mutuals’ Statute
MEP Luigi Berlinguer (S&D, IT), rapporteur for the EP JURI committee on the own-initiative report on mutuals will organize a conference in relation to his own-initiative report in the EP in Brussels on Wednesday, 26 September, from 15.00 till 18.00. SAVE the date!

Simplification of European Cooperative society - SCE
On 23/04/2012 DG Enterprise and Industry organized with the Association „Cooperatives Europe”, a large conference on ‘Co-operative contributions to the EU 2020 strategy’ with more than 200 participants. The objective was to celebrate the 2012 UN International Year of Co-operatives, and to highlight the strengths of the cooperative business model as an alternative means of doing business for a sustainable socio-economic development.

One of the questions discussed was the need for simplification of the European Cooperative Society (SCE) Regulation 1435/2003. On this issue the Commission presented a list of three main categories of provisions that may be revisited and amended if appropriate. All interested parties are invited to send their opinions and comments on the list of articles by 29 June 2012 (Press Release).

➤ Social Services

Services of general economic interest (SGEI): Commission adopts de minimis Regulation
The European Commission has adopted a Regulation that exempts from EU state aid rules aid of up to € 500 000 per company over a three-year period that is granted as compensation for the provision of services of general economic interest (SGEI). Compensation of this magnitude is deemed unproblematic because it is too low to have any impact on trade and competition. This is the last pillar of a new package of state aid rules for SGEI, the bulk of which has been adopted in December 2011 (Press Release and MEMO/11/929).

Employment package: Commission presents new measures and identifies key opportunities for EU job-rich recovery
On 18/04 the Commission has come forward with a set of concrete measures to boost jobs. The proposal focuses on the demand-side of job creation, setting out ways for Member States to encourage hiring by reducing taxes on labour or supporting business start-ups more. It also identifies the areas with the biggest job potential for the future: the green economy, health services and ICT. The policy communication underlines the need for a stronger employment and social dimension to EU governance and lays down ways to involve employers’ and workers’ representatives more in setting EU priorities.

Among others, Member States are invited to improve health workforce planning and forecasting to match the demand and supply of health professionals better while offering them long-term job prospects and stimulate exchange on innovative and effective recruitment and retention strategies for health workers. The Commission is also launching a consultation on employment opportunities in personal and household services (see below). (Press Release)
Public consultation on employment potential of personal & household services (including healthcare & social services)
The European Commission services (DG EMPL) launched a public consultation on exploiting the employment of the personal and household services. This also includes healthcare, residential care, long term care, care for elderly, social services and child care. The deadline to respond is 15/07/12.

Health and Long-term care

➢ Trends in Health Insurance
German Krankenkassen score record surplus
German public health insurers made €4 billion in surplus in 2011, bringing their total reserves to more than €10 billion, compared to a loss of €390 million in 2010, according to The Local.de (en). According to the insurers, the surplus is due to the fact that expense estimates were too high. The news has re-opened a debate on what to do with the extra cash: Hospitals want the government to use the surplus to spare them in the latest budget cuts, but Health Minister says the insurers should pay money back to contributors. Others want the €10 quarterly fee for visiting a doctor to be scrapped, while Finance Minister would prefer to use the high surpluses as an occasion to cut the €14 billion tax subsidy to public health insurers. The insurers, meanwhile, point out that the cost of healthcare is continuing to rise and that any subsidy-saving measures could put them in a precarious financial position in the future.

Spanish Central Government threatens regions to seize control of their healthcare budgets
The Spanish central government has announced plans to cut health and education spending by €10bn, according to the online Wall Street Journal. If the regions do not agree to do this, then the central government will take control of their operations and enforce cuts. But there is a deeper problem. As with Greece, there has been systematic corruption. One insider says that no one knows how many people are employed in public sector healthcare in any of the regions. He adds that no one, including the government, has a coherent healthcare strategy. These measures will increase the cost of subsidized drugs for Spanish residents, look to reduce waste and also try to make it cheaper for the regions to buy drugs from pharmaceutical suppliers by setting up a centralized administration that will purchase drugs for all.

➢ Trends in Healthcare
Spain plans to save €1bn by charging EU countries for their citizens’ health expenses in Spain
The Spanish government plans to save €1bn by more efficiently billing health tourists’ countries of origin, according to the BMJ. At the moment Spain misses out on the money because of an incorrect interpretation of European Union regulations on healthcare provided to foreigners, concludes a recent report of the Court of Accounts. The report says that the wrong interpretation of the EU directive 2004/38 on the free movement of citizens within the EU cost Spain €917m in 2009 for healthcare it provided to 700,000 foreigners, for which regional governments failed to extract reimbursement from the home countries.

What can be learned from China’s health system in 2012?
China has accomplished near universal coverage in a very short time, according to The Lancet. A recent survey showed that medical insurance coverage has increased from 29.7% in 2003 to 95-7% in 2011. However, this has not yet been effective in reducing patients’ financial risks, as both health expenditure and out-of-pocket payments continue to rise rapidly. Reform of public hospitals is essential to control health spending because such institutes deliver more than 90% of the country’s health services. Many hospitals remain profit-driven with doctors’ bonuses tied to that profit. In terms of primary care, their gate-keeping and referral roles have not yet been fully established. For the first time in 2012, the Chinese urban population outnumbered its rural residents. This growing urbanisation not only offers great opportunities in the improvements of health-care access and basic health infrastructure, but also poses substantial risks, including changing diets and lifestyle, air and water pollution, and occupational and traffic hazards.

Experts consider how to tackle overtreatment in US healthcare
The first randomised study of coronary artery bypass surgery was not carried out until 16 years after the procedure was first developed, quotes the BMJ reporting on a conference on overtreatment in US healthcare. When the results were published, they “provided no comfort for those doing the surgery,” as it showed no mortality benefit from surgery for stable coronary patients. This is a typical example of surgeons embracing an expensive and invasive technique before it had been properly evaluated. Experts met to explore what drives overtreatment and how to reduce it, and acknowledged that overtreatment and avoidable care cost lives, harmed patients, and consumed up to 30% of the $2.5 trillion healthcare budget in the US.
Health in the EU27 in 2010
Eurostat
According to statistics published by Eurostat in April, at the age of 65, both women and men are expected to live a further 9 years in a healthy condition.

The future of healthcare in Europe,
University College London - European School

WHO report - Health systems financing: the path to universal coverage
WHO
In this report, the World Health Organization maps out what countries can do to modify their financing systems to sustain affordable health.

Health systems and the financial crisis
European Observatory on Health Systems
A window for health reforms (Czech Republic), Crisis reforms and the road to recovery (Estonia), The health system in a time of crisis (Greece), Coping with austerity (Ireland), Professional Qualifications Directive (the Netherlands) Pharmaceutical market reforms (Portugal), The evolution of obesity (Spain), Performance in chronic care (Denmark)

New HiT Health system review 2011 on Poland
European Observatory on Health Systems
Extensive reform efforts have taken place since 1989. The system is now a decentralized system of mandatory health insurance complemented with financing from state and territorial self-government budgets. The health status of the Polish population has improved substantially, but challenges remain. Prioritizing primary care and adopting new payment mechanisms such as DRGs, have been introduced in recent years but need to be expanded to other areas and intensified. Limited financing seems to be the biggest barrier in achieving accessible and good quality of health care services and in improving patient satisfaction with the system.

Ageing population is not a drain on economy of NHS
University College London
Rising numbers of older people should not be blamed for economic problems or for increasing pressure on the NHS. The effects of population ageing on the health sector are limited because older people are staying fitter, and this group is likely to contribute a substantial proportion to the UK economy provided that they are well looked after, it concludes.

Communicable Diseases
ECDC special report: European Commission’s HIV action supports expanded Services for key populations.

EU-wide overview of community-based initiatives to reduce childhood obesity
European Commission

The diabetes epidemic and its impact in Europe,
OECD, Background document of the European Diabetes Leadership Forum, Copenhagen, 25-26 April 2012

Diabetes Management
European Commission - New data on policy frameworks for Diabetes and economic costs available.

Diabetes: The key to successful prevention is lifestyle changes
The more goals are achieved, the lower the incidence of type 2 diabetes. Achieving all five of the lifestyle goals* prevented diabetes onset for minimum 7 years in the Finnish Diabetes Prevention Study.

The tougher the better: The effect of an increased performance threshold on the performance of general practitioners,
Office of Health Economics (OHE)
In 2006, Scotland’s general practitioners (GPs) were required to meet new, higher thresholds on quality and outcomes indicators to receive maximum levels of payment. This paper examines whether this change improved GP performance, and whether the impact differed across regions.

Personalised Medicine in European Hospitals,
HOPE
This report by the European Hospital and Healthcare Federation, and PWC identifies key elements in the ongoing hospital-based development of personalised medicine in Europe. It compares the evolution of personalised medicine in six European hospitals located in Denmark, Finland, France, Hungary, Slovenia and Spain.
Health events in Europe

**Danish EU Presidency**
- 07–09/05, Copenhagen: High Level eHealth Conference 2012, Ministry of Health, National Board of eHealth and National Board of Health
- 23–24/05, Copenhagen: Informal meeting of the Committee for Orphan Medicinal Products, Ministry of Health and Danish Medicines Agency
- 24–25/05, Copenhagen: Informal meeting of the Committee for Advanced Therapies (CAT), Ministry of Health and Danish Medicines Agency
- 24–25/05, Copenhagen: MISSOC Network Meeting, The Ministry of Social Affairs and Integration
- 21–22/06, Luxembourg: Meeting of Employment, Social Policy, Health and Consumer Affairs (EPSCO), Council of the European Union

**Other events**
- 07–09/05, Copenhagen: ehealth week 2012 organised by the Commission, Danish EU Presidency and WoHiT.
- 23/05, Brussels: ESIP European conference 2012 "Active and healthy ageing and solidarity between generations: role of the social insurances"
- 23–24/05, Brussels: 8th Annual World Health Care Congress-Europe Sharing global innovation in health (with Thomas Ballast, CEO vdek Germany, Pieter Hasekamp, DG ZN The Netherlands, Roger van Boxtel, Chairman Menzis The Netherlands, as guest speakers)

In partnership with AIM: get a 25% discount by using promotional code CFX532

- 19–20/06, Longbotten (SE): Arctic light ehealth conference - From policy to action: ehealth to anyone, anywhere, at anytime.

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

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