

Featured Stories



European Mutual Statute

[AIM cocktail on the European Mutual Statute at occasion of vote on Own-Initiative Report](#)



Clinical Trials

[Glenis Willmott publishes Draft Report on Clinical Trials](#)



Data Protection

[Jan Albrecht publishes Draft Report on Data Protection](#)



Access to scientific Data

[French journal Prescrire holds Annual Conference on access to medicines' data](#)

Contents:

AIM and You	2
European Institutions	2
<i>EU Council</i>	2
<i>Pharmaceuticals and Medical Devices</i>	3
<i>Health System</i>	5
<i>European Mutual Statute</i>	7
Health and Long-term care	7
Health Events in Europe	8

Next Meeting and visit dates



6 March	Fight against Fraud Working Group
12-13 March	E-health study Trip to Barcelona
18 March	European Affairs Working group
22 March	Pharmaceuticals and Medical Devices Working group
13-14 June	General Assembly and board Meetings Gent



AIM @AIM_Healthcare
RT @EU_eHealth "A Tweet a day keeps the doctor away"
Good infographic on Social media: what role for healthcare?
bit.ly/UAu7cv
Ouvrir

< Learn how Twitter is used in the health sector



AIM @AIM_Healthcare 22 Janv
@marctarella Thank you for a successful event. Support for a #EUMutualStatute necessary to preserve solidarity & #mutuals in Europe!
Ouvrir

< Follow News about the #EUMutualStatute



AIM @AIM_Healthcare 28 Janv
@EMA_News to review 3rd- and 4th-generation combined oral contraceptives after death cases in France: bit.ly/VrWcLJ
@mutualite_fr
Ouvrir

< See what the European Medicines Agency does about pharmacovigilance

AIM and you

➤ *AIM Activities in January*

21 January: AIM organized a cocktail in the European Parliament on the European Mutual Statute. -> Read the [article](#)

25 January: Pharmaceuticals and Medical Devices Working Group at AIM

28 January: European Affairs Working Group at AIM

Visit: From 14 to 18 January, AIM received and accompanied the Delegation of [CMS](#), Council of Medical Schemes from South Africa

Event: AIM attended the Yearly Conference Pilule d'Or of our French Partner [Prescrire](#): 'Medicines and health products: no security without access to scientific data' -> Read the [article](#)

Publication: On 4th February, AIM published its [Position](#) on Clinical Trials. -> Read the [article](#)

➤ *Members' news*



Our British Member **Benenden Healthcare** went through rebranding with a new logo and tagline as well as a new website. This change follows the opening up of their membership last year.

Find out why 'Life is Precious' and visit the new Benenden Health [website](#).

➤ *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*

Justice and Home Affairs meeting on Data protection

On 17 and 18 January, the Informal Justice and Home Affairs meeting discussed data protection. The Irish Presidency sees in the data protection package an opportunity for growth but also the chance for citizens to increase trust online.

Speaking about the proposed reforms, Minister Shatter declared:

"The proposals aim to improve individual's control of their personal data, including the "right to be forgotten", whereby an individual no longer wants his or her information processed on the internet. This new right will go some way to address the possible reputational, financial and psychological risks associated with social networking and internet based sites".



➤ *European Commission*

Revision of EU Commission guidelines on Good manufacturing Practice Medicinal Products

On 17 January, the European Commission launched a public consultation of the following revised guidelines on good manufacturing practices: This includes Chapter 3: Premises and Equipment, Chapter 5: Production and Chapter 6: Quality Control and Chapter 8: Complaints, Quality Defects and Product Recalls.

More information on the Commission's [page](#)

Also on 23 January, the Commission published an Implementing decision on the assessment of a third country's regulatory framework applicable to active substances of medicinal products for human use and of the respective control and enforcement activities pursuant to Article 111b of Directive 2001/83/EC of the European Parliament and of the Council (Directive relating to medicinal products for human use). Read the [Decision](#) and the [Questions and Answers](#).

➤ **Pharmaceuticals and Medical Devices**

Clinical Trials: State of Play on the proposal of Clinical trials

AIM published its [position](#) on Clinical Trials together with the Medicines in Europe Forum, The International Society of Drug Bulletins and Wemos, a Dutch NGO and Rapporteur gave the first lines of her Report.

Clinical trials are studies on humans aimed at testing the safety and efficacy of medicines. The revision of the current Clinical Trials Directive from 2001 takes place in the context of a drop in the number of clinical trials conducted in the European Union (EU) which is attributed to this directive. The new proposal adopted on 17 July 2012 pursues the following objectives: Simplifying the authorisation process, A lighter regime for 'low risk' trials, Enabling co-sponsorship and the Compensation for damages as well as Simpler safety reporting thereby modifying the role of Ethics Committees. Subsequently, rapporteur Glenis Willmott (S&D, UK) published her [Draft Report](#) on 31 January. The Rapporteur goes some way to increase transparency measures, a point that she also presented in the ENVI committee in January ([Video](#)).

AIM and its partners want to point out to the necessity for more transparency, for a clarification on definitions and the need to keep former definitions; the need to better protect trial subjects with limitation for the new 'low-intervention' clinical trials. More information on Clinical trials on the [page](#) of the Commission

➤ **Health System**

Access to scientific data: Prescrire's annual event on "Efficacy or Adverse Drug effects: confidential or public interest data"

This year Prescrire, the independent journal, a partner of AIM, had invited the Academic Pr. Peter Götzsche Head of the Cochrane Institute in Denmark and Florent St Martin, Associate professor at Science Po in public health to debate on publicity of scientific data of medicines.

Peter Götzsche declared Pharmaceutical industry was party and judge at the same time in authorisation procedures and gave many examples of fraud cases in the sector. As researcher at the Cochrane Institute, the professor pointed out the selective publication of clinical trials by the industry which makes it possible to hide adverse side effects.

On a more political note, Florent St Martin put forward the positive evolution for the past five years on transparency and conflicts of interest. He warned that conflicts of interest have still been revealed lately mentioning the phenomenon of revolving doors between the management of the European Medicines Agency and the industry.

Both speakers come to the conclusion that reinforcing transparency of data and of the health system in general is a necessity. Read the full speeches of speakers in French [here](#).

Prescrire also published its black list of medicines 2012 at this event. The black list is available on their [website](#).

Cancer: 10 Facts on EU Action to Fight Cancer on World Cancer Day

On the occasion of the World Cancer Day, the Commission reminded all actions going on in the cancer field.

One of the initiatives is "[The European partnership for action against cancer](#)", where AIM is a member.

The Commission also organizes her action around: tackling the risk factors such as tobacco and pollution; cancer Research, screening guidelines and a European Code of Cancer.

Particularly on risk factors the Commission addresses tobacco and environmental factors. An ambitious tobacco control policy with a new Proposal for regulating tobacco products and prohibiting the advertising and sponsorship of such products; In the same area, the Commission organized an award winning pan-EU campaign "Ex-smokers are unstoppable".

The Commission further contributes to cancer prevention by addressing environmental factors such as exposure to carcinogenic and mutagenic substances both indoors (including in the workplace) and outdoors. It does so mainly by developing and implementing legislation on air, soil and water quality and on general chemical exposure (ie. in water, waste and organic pollutants). See the [Press Release](#)

Modernisation of Professional Qualifications: Adoption of Report in ENVI Committee

MEPs of the Internal Market Committee on 23 January voted a Report on a new draft law on recognition of professional qualifications. MEPs also backed plans for an EU- wide alert system to prevent doctors or nurses who are barred from their profession in one EU country from exercising it in another.

The draft law would enable professions to opt for European professional qualifications cards which would be granted by a member state. The system would be based on the existing electronic information exchange system between

member states administrations. This should save time and ease the recognition process, because professionals could ask their home country to arrange the recognition, rather than having to apply to the host country, as at present.

"Key changes to current rules, and notably the professional card, are a real EU added-value, improving a common European understanding and European citizenship", declared the Rapporteur Bernadette Vergnaud (S&D, FR).

The new rules also aim to prevent health professionals, such as doctors, nurses or veterinary surgeons, who have been convicted of a crime or face disciplinary action from transferring their practice to another EU member state. All EU member states should be informed of such convictions or decisions to discipline a professional within 48 hours, says the text. To ensure that easing doctors' mobility does not harm patient safety, MEPs voted to enable EU member states to opt to test their knowledge of the language used where they are apply to get a job. Doctors should also be obliged to update their skills through continuous professional education and training.

See the [Press Release](#).

Health and environment: MEPs call for better protection from hormone-affecting chemicals

On 22 January a Report from Swedish Social Democrat MEP Åsa Westlund was adopted in the ENVI Committee

The report calls for a number of specific measures, including:

- Fast measures to protect vulnerable groups such as children, young people and pregnant women
- Development of horizontal criteria for deciding which substances are endocrine disruptors and which are not
- Addition of tests identifying endocrine disruptors to existing EU legislation on chemicals
- Treating Endocrine disruptors as substances of very high concern in REACH regulation

See the [Press Release](#)

Health Journalism: EU Prize awards excellence in health journalism for the 4th time

The EU Health Prize for Journalists, now in its fourth run, aims to raise awareness on important health issues affecting the lives of people from across the EU – issues that the European Commission addresses through legislation or other initiatives. It also sets out to encourage and award excellent health journalism across Europe. The winners of the fourth EU Health Prize for Journalists were announced by Tonio Borg, European Commissioner for Health and Consumer Policy at an award ceremony in Brussels yesterday evening. The winning articles, selected from 557 submissions from journalists across the EU, cover issues related to healthcare and health services - with an additional "special prize" on smoking cessation. Journalists awarded this year come from the Czech Republic, Ireland and Italy and talk about nurses in psychiatric hospitals, Cancer screening and umbilical cord banks. See the [Press Release](#) for further details and links to the articles.

Data Protection: MEP Jan Albrecht publishes Report on Data Protection

On 8 January, MEP Jan Albrecht (Greens, DE) published his [draft report](#) on the data protection regulation.

The Report has some implications in the health sector as it includes in Article 81, the exceptions under which health personal data can be processed. Rapporteur Jan Albrecht also added in Article 82a the possibility of providing specific measures for public institutions and departments in the social security context. However delegated acts are still foreseen so far in the Rapporteur's report. Jan Albrecht also introduces the use of icons to give data subjects a clear view of how their personal data will be processed.

For a short [overview in 10 points](#) of the regulation, refer to this Background Information from the Greens published in December.

Regarding Committees for opinion, the IMCO Committee already adopted its [opinion](#) on 23 January with the addition of the precision that some national derogations on Mobile-health. The opinion also foresees the possibility to keep health data of Article 81 longer in article 5 (e). JURI Committee has adopted its opinion as well and should publish it shortly.

ICON	ESSENTIAL INFORMATION	FULFILLED
	No personal data is collected beyond the minimum necessary for each specific purpose of the processing	
	No personal data is retained beyond the minimum necessary for each specific purpose of the processing	
	No personal data is processed for purposes other than the purpose it was provided for	

Example of Icons

© Alexander Alvaro 2012

➤ Insurance

Cross-border trade: Commission to examine legal obstacles to cross-border trade in insurance and life insurance

The European Commission is set to examine barriers to cross-border trade in insurance products including life insurance caused by different contract laws in the EU's Member States, after today launching a call for experts to look into the problem. The expert group will identify to what extent contract law differences hinder cross-border distribution and use of insurance by European businesses and consumers. For example, a citizen moving to work in another EU country may be forced to take out a new car insurance policy, or face problems having their rights under a private pension plan recognised if taken out in another EU country. And businesses with branches in several EU countries may be forced to get separate policies under different conditions in each country instead of a single policy for all their property. The group will report at the end of 2013, after which the Commission will decide on any possible follow-up actions.

The Expert Group on Insurance Contract Law will bring together key stakeholders, including insurance providers, representatives of consumer and business users, academics and legal professionals. It will assist the Commission in examining whether differences in insurance contract laws hinder cross-border distribution and use of insurance products. See the [Press Release](#).

➤ VAT

VAT in health sector: ECJ condemns Reduced Spanish VAT rates on medical products

The EU Court of Justice said the reduced VAT rates in Spain on medical products breached EU rules in a ruling on 17 January. "By applying reduced rates of VAT beyond what is authorized under the VAT Directive, Spain has failed to fulfill its obligations under EU law," judges stated in their judgment.

The Court considered that the application of a reduced rate of VAT to medicinal substances which can be used habitually and suitably in the production of medicine is contrary to the VAT Directive. The directive authorizes the application of a reduced rate of VAT only to finished goods which may be used directly by final consumers, other than goods which may be used in the production of medicinal products, which normally require further processing.

Read full [Press Release](#) of the European Court of Justice.



➤ Mutuels and Social Economy

Mutual Statute: AIM Cocktail on European Mutual Statute

The cocktail in the European Parliament on 21st January was the occasion for AIM to celebrate and thank the broad commitment of the members of the Committee on Legal Affairs and the Committee on Employment and Social Affairs of the European Parliament to support the Statute for a European Mutual Society.

MEP Marc Tarabella (S&D, BE) host of the cocktail, underlined the major role that health mutuels are playing in the European Union's economy by providing health coverage and social services to over 160 million European citizens. He reminded the audience that: "Solidarity is the last protection against inequalities" and that therefore mutuels are an essential part of social Europe and should be encouraged in promoting solidarity.



From left to right : Abdelmoula Abdelmoumni, MEP Marc Tarabella, Jean-Philippe Huchet, Christian Zahn, Eleni Spanopoulou, Pedro Bleck da Silva

Mutual Statute: Adoption of the Own-Initiative Report on the European Mutual Statute

On 22 January the Legal Affairs Committee of the Parliament adopted the Own-Initiative Report on the European Mutual Statute with 22 votes in favour and 1 against. The indicative plenary date is 14 March 2013.

The Report's main points are: the acknowledgement that the creation of a European Mutual Statute is necessary. This new tool would be only optional and should not affect obligatory social security schemes or national laws. The European mutual society should be managed democratically and financed collectively for the benefit of its members. The draft Report of MEP Berlinguer was adopted as a whole without voting on the amendments.

See the [Draft report](#) for more details.

Mutual Statute: European Added Value assessment on 'A Statute for European mutual societies'

In January the European Commission also published a European Added Value assessment on the European Mutual Statute. This paper has been undertaken by the European Added Value Unit of the Directorate for Impact Assessment on request of the Committee on Legal Affairs. The document aims at pointing out the main benefits of a statute for a European mutual society from a social, economic and legal perspective.

It is calculated that today mutual societies provide healthcare and social services to 230 million European citizens and represent about 180 billion euros in insurance premiums. **Almost 70% of the total number of insurance companies in Europe are mutual societies.** There is a nearly unanimous agreement among stakeholders that a statute for European mutuals would increase the visibility and the recognition of mutual societies at European level and would unfold for them the advantages of the internal market.

Read the Whole [Assessment](#).

Health and Long-term care

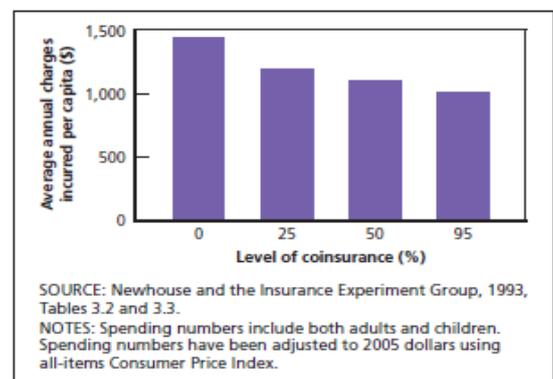
➤ **Trends in health system**

Health System: User fees increase does not ensure better use of health services

Governments increasingly look for solutions to reduce healthcare spendings but increasing user fees turns out to be counterproductive.

The RAND [Health Insurance Experiment](#), the largest and most rigorous study of user fees to date, found that the more patients had to pay for care, the less they used it (see graph). Less care led to lower costs, but it didn't mean greater efficiency, because sometimes people received fewer services when they actually needed more. Patients did reduce their use of less-effective care, but there was a decrease in the use of effective care as well. The RAND findings also showed that the proportion of inappropriate hospital stays and admissions was the same with or without user fees. Another American [study](#) came up with similar results: It involved insured seniors through U.S. Medicare found that raising user fees for physician visits and prescriptions increased Medicare costs. As in Quebec, many patients stopped taking their medications and ended up in the hospital. Look up the whole article [online](#).

Figure 3
Participants with Cost Sharing Spent Less on Health Care Services



WHO: Speeding up access to quality medicines in Africa

Ten African countries have joined a WHO initiative that aims to speed up access to medicines and develop local expertise in medicines' regulation.

The "accelerated registration" pilot project is a new collaboration between medicines regulators in developing countries and international experts working with WHO's Prequalification of Medicines programme.

The project encourages national regulatory authorities to fast track the registration of medicines that have already been assessed and approved by WHO's stringent prequalification procedure. This means that they have been evaluated for quality, safety and efficacy – based on information from manufacturers and close inspection of

manufacturing and clinical sites. WHO's list of prequalified products is a vital tool for United Nations agencies and other organizations involved in bulk purchasing of medicines.

Read whole article on the WHO [website](#).

➤ *Call for proposals*

Horizon 2020: Call for expressions of interest for Experts for Horizon 2020 Advisory Groups

http://ec.europa.eu/research/horizon2020/index_en.cfm?pg=h2020-experts

EIP AHA: New round of Invitations for Commitment launched: your chance to join in the work of the European Innovation Partnership on Active and Healthy ageing

<https://webgate.ec.europa.eu/eipaha/news/index/show/id/302>

➤ *Studies*

WHO Europe Report on cancer:

New report assesses national capacity for the prevention and control of non-communicable diseases

<http://www.euro.who.int/en/what-we-do/health-topics/noncommunicable-diseases/cancer/news/news/2013/02/new-report-assesses-national-capacity-for-the-prevention-and-control-of-noncommunicable-diseases>

EU Employment and Social Situation Quarterly Review

<http://ec.europa.eu/social/BlobServlet?docId=9319&langId=en>

<http://www.hi-mag.com/health-insurance/product-area/pmi/article413037.ece?page=1>

(This study was recommended by Benenden healthcare)

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-we-ve-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

- | | |
|---------------------|---|
| 19 February | <i>Stakeholder event</i> "The Battle against tobacco, cancer and heart disease"
In the European Parliament, Event Co-organised by MEPs against Cancer, European Public Health Alliance and European Cancer Leagues
Invitation |
| 26 February | <i>ENVI Workshop</i> on Medical Devices and In Vito Diagnostics
More information on the Committee homepage |
| 4-5 March | <i>Council:</i> Informal meeting of Health Ministers
Agenda is expected to focus on patient safety and MS experience with policies, childhood obesity, children with learning disabilities (particularly autism) and the impact of the crisis |
| 13-15 May | eHealth week
Dublin, Website of the event |
| 20 – 21 June | EPSCO Council |

The monthly AIM Flash is compiled by Blandine Cassou-Mounat.

Realisation &Layout: Blandine Cassou-Mounat

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

'AIM Flash' © monthly publication of the AIM Secretariat

AIM asserts copyright in all the text of this publication. Reproduction of short extracts is welcome provided the source is quoted. Reproduction of complete articles requires written permission in advance from the AIM office.