

FLASH n°123 - June 2014

Feature Stories



Christian Zahn elected as AIM new President



Council discusses safety of medical devices



AIM publishes Position Paper



Health system

Council conclusions on the economic crisis and healthcare

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What's next?



Top Tweets



28 August

Presidium

5 September

Prevention WG

6 October

European Affairs WG

8 October

Fraud WG

12-14.11

General Assembly

AIM @AIM_Healthcare · 30 juin

AIM has a new president! @ChristianZahn Read our Press Release: bit.ly/RsRskD



AIM @AIM_Healthcare · 20 juin

#mutuality in Europe: What are the priorities? Colloquium at the CIN. bit.ly /1sszbFk



AIM @AIM_Healthcare · 18 juin

Reducing exposure to EDCs would allow EU health savings. @HealthandEnv launches report. bit.ly/1ijPKyJ

AIM and you

Press Release: Christian Zahn elected as AIM new President

26 June - At the occasion of its XXXII General Assembly in Bruges AIM member organisations elected Mr. Christian Zahn, President of the Verbands der Ersatzkassen e. V (vdek), as new President of the Association Internationale de la Mutualité.

Among his priorities, Mr. Zahn wants to unify and consolidate the global mutual movement to promote the values of solidarity, universal access to healthcare and democracy. AIM will make every effort to help its members to make their specificities and activities recognised at regional level in Africa and Middle-East, Latin-America, and Europe. In the latter, the presence of AIM in the European institutions and national parliaments will be strengthened to promote mutual interest in the European Union.

In Germany, Mr. Zahn is President of the Verband der Ersatzkassen e. V., the German association which gathers six statutory health insurance funds (*Krankenkassen*) and covers 26 million of people. Mr. Zahn is alternating chairman of

the administrative Board of the German National Association of Statutory Health Insurance Funds (GKV) and was until now Vice-President of AIM and Chairman of the European Affairs Committee.

Next to Mr. Zahn, the other delegates elected in the AIM Presidium are Mr. Luc Carsauw (Belgium) as Treasurer and Mrs. Matthias Savignac (France), Theo Hoopenbraouwers (the Netherlands) and Abdelaziz Alaoui (Morocco), and Mrs. Ana Maria Silva (Portugal) and Elisa Carolina Torrenegra (Colombia) as Deputy Presidents. This new Presidium will meet in August to draft a working programme for the next three years.



Communication: AIM has a brand new leaflet



The AIM leaflet was designed over the past few months. The image of the tree, centre of the layout, symbolises stability, strength and support, which are traits which characterise the AIM, just as the values of democracy and solidarity in which it is rooted. Promoting universal access to healthcare, fostering the exchange of best practices, promoting health protection based on solidarity and democracy, strengthening social innovation and promoting both the mutual model and the social and solidary economy are presented as AIM's key missions. The leaflet shows the advantages and

benefits of being part of the AIM: As a platform, the association facilitates the exchange between members, spreads information on important issues in the field of healthcare and allows its member organisations' voices to be heard. The brochure will be published in four languages (English, French, German and Spanish) and was distributed in Bruges at the General Assembly in June 2014.

You can download the leaflet on AIM Website.

TTIP: AIM publishes Position Paper

The AIM published a position paper which underlines the impact which the Transatlantic Trade and Investment Partnership (TTI") between the EU and the US could have on healthcare in case these negotiations are not handled correctly.

In its paper, the organization raises awareness on the issues of transparency, the exclusion of services of mutual benefit societies/health insurance funds, the Investor-to-State Dispute Settlement (ISDS), Public Procurement and Pharmaceuticals. AIM calls for a greater involvement of the public in the negotiations through the publication of concrete provisions and key documents, as well as for the exclusion of health and social services carried out by mutual benefit societies and other not-for-profit organisations. As far as public procurement is concerned, AIM wants commitments to be made binding for ALL Member States and EVERY US State in order to safeguard EU markets. These commitments should be established by a "positive list".

In order to protect MS governments from being sued by US investors, the AIM wants ISDS to be kept outside TTIP or, in the case it were included, to exclude IPR from negotiations and to include strong provisions whose aim will be to safeguard the public interest. The sectors of investment should again be mentioned through a "positive list". On the topic of pharmaceuticals, AIM asks for pricing and reimbursement not to be subject to TTIP and for reimbursement procedures not to be shorten, as these measures would limit the access to affordable and cost-effective medicines. Moreover, advertisement should consist only in objective information independent from the manufacturer and direct to consumer pharmaceutical advertising must be excluded from the partnership. In the same vein, Member State's strong conditions for Internet sales should be maintained and clinical trial data transparency guaranteed.

To allow greater access to affordable medicines -thanks notably to the use of generics- Member States must be given the option to exclude patents on medical procedures. AIM thinks the EU must protect its healthcare systems from invasive reforms which could have a negative impact on citizen's health and well-being, but it should also welcome changes which would improve the latter. The organization thus requests the inclusion of the issue of medical devices premarket approval in TTIP negotiations as the U.S has proven to have higher standards which better protect patients' safety.

The AIM also answered the consultation on ISDS in TTIP which ended on 6 July 2014. With as main objective defending solidarity and access to healthcare for all, the next steps will be a close follow-up of the 6th round of talks of TTIP negotiations which will take place from 14 to 18 July in Brussels.

For more information on the topic, read AIM's Position Paper.

Activity Report: Three years of actions put together in a report

The General Assembly adopted in Bruges in June 2014, the AIM annual report which makes a summary of the activities carried out by AIM and its members over the period 2012-2014. The activity report is available on AIM <u>Website</u> in English. It will be translated in French and German during the summer.



AIM Activity Report 2012-2014



AIM Activities

AIM Meetings

25 June Meeting of the Latin American Region

Bruges

25 June Meeting of the African Region

Bruges

25 June Presidium Meeting

Bruges

26 June European Affairs Committee

Bruges

26 June General Assembly and Board

Bruges

27 June Health Systems Reform Working Group

Bruges

27 June Fight against Fraud Working Group

Bruges

27 June Chronic Disease Management Working Group

Bruges

European Institutions

Council of Ministers and European Council

Data Protection: EU Justice Ministers achieved a partial general approach

6 June - The Council reached a partial agreement on specific issues of the Data Protection Regulation.

Three main issues were discussed in Luxembourg by the Council composed of the Member States Justice Ministers:

- the territorial scope (Article 3(2)): Ministers agreed on the territorial scope of the data protection regulation. In simple words: EU data protection law will apply to non-European companies if they do business on our territory
- the transfer of personal data to third countries or international organisations (Chapter V). Three possibilities were deifined roads to secure data transfers to third countries and international organisations.
- the "one-stop shop" principle according to which there should be one decision by one single data protection regulator when it comes to cross-border services involving data processing.

Article 81 related to the processing of personal data concerning health, which integrates AIM's demands (Chapter IX) was not discussed so far.

More Information Here.

Health System: Council conclusions on the economic crisis and healthcare

20 June - The Council has adopted conclusions on the impact of the economic crisis and healthcare services. Many of the recommendations and statements converge with Mutuals' positions and have been stressed for months by AIM. The council reminds that the European Union has the mission to ensure a high level of human health protection in all of its policies and activities. It recognizes the necessity of investing in health promotion, HTA, e-health, the need to reduce pharmaceutical expenditure (especially innovative medicines) to enable universal access to high quality healthcare.

The impact of the crisis and the budget cuts in healthcare are underlined with high concern, as it is reckoned that cuts in healthcare services can affect access to care for all and have economic, social and health consequences. Therefore, the Council proposes to improve the effective use of European Funds and other Instruments for health investments.

These recommendations are only guidelines proposed to the Commission and Member states which stay unfortunately on surface and are really followed.

You can find the whole text Here.

> European Commission

Health Programme: Commission Adopts Annual Work Plan for 2014

26 May – The European Commission adopted the annual work plan 2014 for its third EU health Programme which seeks to implement EU health strategy and ensure that human health is protected.

The programme is implemented by means of annual work plans, the last of which was published at the end of May. Through it, the Commission announced a contribution of over €58,500,000. The various actions scheduled for 2014 will focus, mainly on the financing of grants for projects or procurements in the following fields: management and

screening of chronic diseases, frailty and integrated care, statistical data in the area of medicinal product pricing, improvement of the situation of people with dementia, Support to eHealth Network, EU Health Policy Forum or similar cross cutting stakeholder activities, implementation of the Cross-border Healthcare Directive, Financial contribution to the functioning of non-governmental bodies...

Call for proposals will soon open. For more information, please visit the **Commission's Webpage**.

European Commission: Country-specific Recommendations 2014

2 June – The European Commission adopted a series of economic policy recommendations to individual Member States in order to address urgent problems resulting from the crisis and to support sustainable growth and employment.

The Commission stresses the necessity of continual structural reforms of the economies in order to tackle urging issues like unemployment, inequality and poverty; to shift taxation from labour to more current property, consumption and environmental taxes; to strengthen tax compliance and fight tax fraud; to boost private investment; to make economies more competitive; and to bring down debt.

Concerning healthcare, 19 countries out of 26 are asked to limit the expenses and improve cost-efficiency of healthcare systems. EU leaders and ministers will discuss these recommendations in June and they will be formally adopted by the EU's Council of Finance Ministers on 8 July.

For more information on the topic, please read the Press Release.

To find out more about the country specific recommendations, please visit the **Commission's Webpage**.

EU Commission: Expert group on cancer control established

3 June – The European Commission adopted a decision which establishes an expert group on cancer control. The expert group is made up of representatives of EU, European Economic Area (EEA) and European Free Trade Association (EFTA) countries, representatives of patients' organisations, European professional or scientific associations and one representative of the International Agency for Research on Cancer. It will be solicited by the Commission in order to help in the preparation of guidelines on cancer data and draw up guidelines and recommendations on cancer control. It will also assist in the preparation of legal instruments and policy documents. For more information on this topic, please visit the Commission's Webpage.

EU Commission: Tonio Borg delivers speech

3 June – Tonio Borg, European Commissioner for Health, delivered a speech on "Fostering an innovative agenda in healthcare".

The EU Commissioner shared his vision on how innovation can be supported by EU policies and legislation and on how work in this area is meant to evolve in the future. The new legislation on clinical trials was the first example chosen by Mr Borg. According to him, these new measures should save institutions and companies carrying out clinical trials some €800 million per year in unnecessary regulatory costs. The progress reached in pediatric and orphan medicines was highlighted, just as the constant struggle to make drugs safer and more accessible. As other main challenges of healthcare in Europe, improving notably the access to Advanced Therapy and personalized medicine, as well as fostering therapeutic innovation, and giving patients timely access to innovative treatments are on the "to-do" list of the Commission. Commissioner Borg confirmed the support of the Commission to Member States to deal with the difficulties involved in the pricing of pharmaceuticals and to foster dialogue between them in order to reach agreements in HTA, an area in which safe and quicker access to beneficial innovation can be achieved. Finally, Mr Borg congratulated some MS on their work on eHealth, which could represent a solution to improve the efficiency of the health system and improve care to all EU citizens.

For more information, please read Commissioner Tonio Borg's <u>Speech</u>.

EU Budget for 2015: increase of 20% to protect Europeans' health and consumers

The European Commission drafted a budget for 2012 consisting of an increase of 2.1% in commitments (legal promises to spend money on certain projects, contracts, research) and 1.4% in payments (refers to the money that the EU actually expects to pay out).

Almost 60% of the proposed commitment is dedicated to programmes that support Europe's research and innovation, youth and businesses.

The lion's share of payment appropriations goes to areas that boost Europe's economic growth and jobs (+29.5% compared to 2014) such as research (Horizon 2020) or the Youth Employment Initiative. Budget dedicated to health protection and consumers has been increased by 20%

The functioning cost of the EU remains stable at around 4.8% of the total budget. The draft budget also includes the third 1% staff reduction in three years.

Following adoption by the Commission of the 2015 draft budget, the Council (Member States) will adopt its position on it, followed by the European Parliament. This will be followed by a 21-day conciliation period to find a compromise agreement between the Council and the Parliament (expected by the end of the year).

Online Medicines: European Commission introduces logo for medicines sold online

24 June -The European Commission adopted an implementing Regulation which sets out the design for a common logo for online pharmacies, and the technical requirements for ensuring its authenticity.



When buying medicine online, one should click to check if the online pharmacy is legally operating according to the national regulator.

The Regulation should enter into force in the next four to six weeks. Member States have one year to prepare for its application. The European Commission is providing national authorities with a Communication Toolkit to support them with the preparation of national awareness campaigns which are required by the Falsified Medicines Directive. More information Here.

TTIP: Social and Health Rights must not be wipe out

25 June – The think tank solidar published a psotion on the risks of TTIP for European citizens' social and health rights.

TTIP promises more job opportunities and better consumer choices but if the negotiations are not handled correctly, "TTIP could wipe out hard-fought milestones in social protection at the stroke of a pen". The authors warn that the liberalization of the EU-US trade, services and investment market might strongly weaken the provision of vital public services. According to them, some Member States have even already tried to evade rules which are the pillar of universal access to quality services. The inclusion of an investor-to-state-dispute-settlement (ISDS) mechanism could be dramatic as it would enable international firms and corporations to sue governments outside the regulation applied to future profits. Just as alerting is the lack of transparency which characterises the negotiations, impeding Europeans to become aware of decisions which will have a social and health impact on their lives. The TTIP is all the more



important as it will set a precedent in the way further international negotiations will be carried out. It is high time for the Commission and MS to understand that "Health and services cannot be run as a business".

For more information, read the complete article.

> European Parliament

Lobbying: AIM memorandum to the new elected Members of Parliament

For the elections of the European Parliament in May 2014, AIM drafted a memorandum. It is 3 page paper addressed to the new European Parliament presenting AIM's expectations for the upcoming legislation. With this memorandum, AIM aims at strengthening its network with MEPs and calling for their support as well as pushing our concerns and propositions forward in the parliamentary agenda.

In its memorandum, AIM calls for:

• a European Mutual statute



- the setting up of a new European Parliament Social Economy Intergroup
- the creation of a unit dedicated to social economy within the European Commission
- the pursue of the social investment package actions.
- the development of health promotion
- affordable and available medicines
- safe and reliable medical devices
- · the improvement of clinical trial data transparency
- the Exclusion of health protection, healthcare and social services from US-EU Free Trade agreement (TTIP)
- the preservation of the existing VAT system in the health sector

You can download the Memorandum in AIM Website.

Who's who in Parliament: the Bureau of Presidents

1 July – MEPs elected Mr Martin Schulz as President of the European Parliament for a renewable term of two and a half years.

Martin Schulz is a Member of the European Parliament since 1994 and has served on several committees (e.g. the sub-committee on Human Rights, the Committee on Civil Liberties and Home Affairs). From 2000, he was elected Vice-Chair of the Socialist MEPs. He later became leader of the Socialists and Democrats in the European Parliament and fought for "social justice, promoting jobs and growth, reforming financial markets, fighting climate change, championing equality and creating a stronger and more democratic Europe." Together with him, 14 vice-presidents were selected for the same period.



For more information on the President and Vice-presidents, please visit the Parliament's Webpage.

Pharmaceuticals and Medical Devices

Clinical Trial: European Medicines Agency agrees policy on publication of clinical trial data with more user-friendly amendments

12 June - After an alarming backpedaling on publication of Clinical trials data (see AIM Press release Backpedalling on EMA's "proactive publication of clinical-data" draft policy: Was it all just a window-dressing exercise? Who or what is the EMA afraid of? – 20.05.2014), EMA said on 12 June that measures will be taken to allow the Agency to proactively publish clinical trial data that are submitted as part of marketing authorisation applications, but also give the possibility to download, save and print the trial data for academic and non-commercial research purposes. This proposition should be adopted by mid-July 2014, and will be effective from 1 October 2014.

Documents adopted will be available on the Agency's Website. AIM secretariat will carefully monitor this issue.

Medical Devices: Council discusses safety of medical devices

20 June - The Ministers of Employment, Social Policy, Health and Consumer Affairs met in Luxembourg to discuss the issue of Medical devices.

After the European Parliament voted on a new law concerning medical devices, the Council is expected to reach an agreement. The new regulation aims at setting up scrutiny of products before they enter the market and tightening surveillance after they become available.

Ministers exchanged views on 3 issues:

- the designation and monitoring by EU countries of the so-called "notified bodies" in charge of certifying certain medical and in vitro devices before they enter the market
- the participation of businesses in the surveillance of the safety of devices placed on the market
- the responsibilities of the medical devices coordination group

Following the discussion, the Council asked its preparatory bodies to continue work in order to establish a Council position on the package in autumn. The Council is very slow because of the different positions of the member states. AIM has supported a pre-marketing authorization for high-risk medical devices. However this option seems to be off the table.

Medical Devices: Action Plan after the PIP scandal tightened control in Europe

20 June- In 2012, the European Commission and the Member States set up an action plan aiming at improving the control on the basis of existing legislation. The Council made a review of the four key areas of the Plan: the functioning of notified bodies; market surveillance; coordination in the fields of vigilance; communication and transparency.

The Plan has resulted in substantial progress, in particular in the following areas:

- Member States have re-assessed the qualifications and the scope of activities of their notified bodies. This
 resulted in corrective measures or limitations in the scope of activities of notified bodies
- audits of notified bodies have been carried out in 22 out of 23 In one case, the notified body is no longer able
 to issue certificates.
- Notified bodies have reported that they now are carrying out or are in the process of launching unannounced audits of manufacturers. However, no reliable information is available so far on the number of unannounced audits or their effects.

The Document contains a detailed analysis of these elements as well as other points as:

- A Commission Recommendation on the use of a specific system for traceability of medical devices adopted in April 2013
- ongoing discussion on improving product registers
- Member States reports on their market surveillance activities as basis for further improvement
- discussions on incident reporting from medical practitioners and patients.

More information on the **Staff Working Documents**

> Events where AIM attended

Colloquium Mutuality in Europe: what are the priorities?

AIM held a presentation on 20 June 2014 on public health challenges for mutual societies at a colloquium organised by the Collège Intermutualiste National (National College of Belgian Mutuals) on the Topic: La Mutualité en Europe: Quelles priorités? (Mutuality in Europe: what are the priorities?)

Corinna focused her speech on key issues for mutual societies in Europe such as:

- Transatlantic Trade and Investment Partnership
- Reform of VAT regime
- Long-term care
- E-health
- And European Commission Country specific recommendation

You can find the presentation on AIM Website.

National Health Policies

WHO: Work in the European Region - 2012-2013 Report

5 June – WHO publishes the report "Realising our Vision" of the Regional Director on the work of WHO in the European Region in 2012-2013.

In 2010, a five year vision to improve health in the WHO European Region was adopted. The 53 countries served by WHO agreed on a roadmap and showed commitment and will to cooperate and make efforts to secure better health fir every European citizen. The published report focusses on the second two years of this vision and shows how all parties made it a reality.

For more detailed information, read the report.

Burkina Faso: MSA involved in the creation of health mutuals

15 June – Over the past five years, AIM French Member MSA, (Agricultural workers' and farmers' mutual benefit fund) has carried out a project to help the creation of a network of agricultural health mutual societies in Burkina Faso. The initiative dates back to 2005, in the frame of a partnership with the Network of Support to Health Mutuals in Burkina (Rams) and the French Embassy in Burkina Faso for the creation of a first health mutual which opened in 2007 in Karangasso-Sambla (Houët Province). The project itself, financed by the European Commission, started in 2009 with, as objectives, the building up of three new health mutual societies and the reunion of the four in a network at the regional level. These are occupationally based mutuals, opened at first exclusively to cotton producers and their families and then to other farmers of the area. In this context, MSA has provided agents to help with the administration, the establishment of the care package and the conditions of assistance in health centers, the animation (help to hold boards and general meetings, awareness rising activities...). The project is a success as a whole as it revived solidarity, allowed the adhesion of cotton producers to mutualistic principles, contributed to the improvement of producers' and their families' health, and, above all, to the fight against poverty in rural areas. For more information on the topic please read the Article on "Le Bimsa" Magazine webpage. (FR)

PASS: putting force together to develop the mutualist model worldwide

The Mutualist Strategy Development Support Program (PASS) will be launched in West Africa in January 2015.

In this region, the concept of a social protection floor is rising. Mutual societies have the chance to be part of this process and to promote their values and specificities against a for-profit sector which is interested in taping the market. The creation of universal health coverage is an already on-going process in many Western African Countries (Burkina, Ivorian Coast). Moreover, the Western Africa Economic and Monetary Union (WAEMU), gathering 8 African Countries, foresees a community regulation related to mutual societies. In this context, PASS will have the mission to help mutual societies to grow and contribute to the setting-up of a solidarity-based universal social protection coverage. In a way, it will put into practice the 2013 ISSA report "Mutual benefit societies: A tool for developing social protection worldwide, particularly in the health sector".

The first objective of the program is to accompany the development of the African mutual movement, for instance, by supporting the creation and expansion of mutual societies, organizing the training of workers and representatives or enhancing cooperation between players. Secondly, it aims at developing the economic environment by creating investment opportunities, technical and financial partnerships for European and African organizations in supply of healthcare, insurance or credit services for example.

The program will be financed by a consortium of French mutual-type organizations. It will be hosted in Abidjan, Ivory Coast, in the MUGEF-CI offices. PASS will accompany the opening of the first African Mutuality Union's (UAM) regional office and UAM's members in their development. Eventually, it will have to become an auto financed technical platform within 6 years, integrated to the UAM.

If PASS seeks to contribute to the development of the mutualist model worldwide and especially to ensure its long-term sustainability, its final objective is to accompany a new-born African middle class to fulfill its expectation in terms of well-being and social progress. The lead of PASS will be taken by AIM former President Jean-Philippe Huchet. His offices will be in Abidjan, Ivorian Coast. AIM will support the project.

More information available on AIM Website.

Health and Long-term care

Trends in health system

OECD: Health expenditure remains weak in Europe

30 June - The Organisation for Economic Cooperation and Development's interactive database shows that health spending has risen again after stagnating or even falling in some OECD countries.

The database covering the period 1960 to 2013 allows a comparative analysis of health care resources and utilization, risk factors to health, health status, and health expenditure and financing. Data shows that health spending continued to fall in Europe in 2012 whereas countries like Mexico or Chile underwent strong growth. As far as pharmaceutical spending is concerned, almost two thirds of OECD countries experiences real falls, due to price cuts and a growing share of the generic market, which can be explained by patent expirations for some brand name drugs and policies meant to promote the use of cheaper generic drugs.

For more information on this topic, read the article.

The monthly AIM Flash is compiled by Romain Chave and Jessica Carreño Louro.

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

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