

FLASH n°121 – April 2014

Feature Stories







Access to healthcare

Make this issue a priority for the forthcoming

European Parliament

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What's next?

19 May	European Affairs Working Group <i>At AIM Offic</i> es
25 May	European Elections
25-27 June	Meeting of the XXXII AIM General Assembly in Bruges



AIM @AIM_Healthcare · 10 avr.

European Commission publishes Green Paper and launches Consultation on #mHealth. bit.ly/1gOAYce @EU_Commission @EU_Health

AIM @AIM_Healthcare · 4 avr.

Following Parliament Vote this week #clinicaltrials rules to change by mid-2016 in the EU, Q&A by @EU_Commission, bit.ly /QKZ0zQ

AIM @AIM_Healthcare · 4 h

Final Countdown to #EP2014. 30 days before making your voice heard... @EuParlement bit.ly/1ca8Hvc

AIM and you

> AIM Activities

AIM Meetings

4 April Mutuals Working Group

Lisbon

11 April Pharmaceutical Working Group

At AIM Offices

28 April Prevention Working Group

At AIM Offices

30 April Internal Audit Committee

At AIM Offices

Events AIM attended:

- the Chronic Disease Summit held in Brussels on 3 and 4 April, with the participation of Sinisa Varga (HZZO – Croatia) (read our article)

- the event "Universal Access to Health Your Voice in the 2014 EU Elections" welcomed by AIM and the European Generic Medicines Association on 8 April (read our article)
- the workshop on Patient Empowerment on 15 April, attended by Mr Geert Basyn and Mr Xavier de Béthune de l'Alliance Nationale des Mutualités Chrétiennes on behalf of the AIM

European Institutions

Council of Ministers and European Council

Solvency 2: Council approves amending rules for the insurance industry

14 April - The Council approved amendments to EU rules for the insurance companies within Solvency 2.

The amendments include notably the provision of specific tasks for European Insurance and Occupational Pensions Authority (EIOPA) and the European Securities and Markets Authority (ESMA). They clarify the role of EIOPA in ensuring harmonised technical approaches for the calculation of technical provisions and capital requirements for insurance companies. These amendments were agreed during the negotiation of the Directive Omnibus 2, which was voted on by the European Parliament in March 2014.

Please find more information in the Press Release.

> European Commission

Integrated care: INCA launches New European Project

1 April – The Inclusive Introduction of Integrated care (INCA) has launched a new European project aiming mainly at improving the quality of care and reducing clinical costs through the coordination of socio-sanitary services. The project supported by the European Commission gathers four member states (Croatia, Cyprus, Latvia and Spain) and contributes to progress in chronic disease management going beyond the clinical vision of care and rather focusing on social aspects. INCA also makes a step forward towards patient empowerment by enabling them to communicate directly with their circle of care. Browser-based, the programme also facilitates the flow of and access to information through Internet. By the end of 2014, the five pilot sites will be implemented, an implementation which will be followed by an evaluation of the model's impact in order to consider its future applicability in other countries.

For more information, please read the European Commission's <u>News Article</u>.

Effective, Accessible and Resilient Health Systems: EU Commission publishes Communication

4 April - Providing quality care remains a challenge among Member States and it is their duty to provide high quality care. The Commission's communication highlights a number of initiatives through which policy makers in the Member States can be supported.

The Communication focusses on different actions:

- to strengthen the effectiveness of health systems through notably the health systems performance assessment (HSPA) which members are called to use for accountability, policy making and transparency, but also by defending patients safety and by an integration of care, particularly with regard to elderly people or people with chronic diseases;
- 2. to increase the accessibility of healthcare, that is, to ensure universality, access to good quality care, equity and solidarity. This aim is to be reached through an effective planning of the EU health workforce, a cost-effective use of medicines and an optimal implementation of the Directive 2011/24, which increases the transparency on "undue delay" when waiting for treatment;
- 3. to improve the resilience of health systems which must adapt effectively to new environments and tackle the challenges set by an economic context in which the top priority is to build growth and competitiveness and where resources are limited. This can be achieved, amongst others, through stable funding mechanisms, good governance, Information flows in the system and an adequate costing of health services.

These recommendations are in line with the ones addressed to Member States in the context of the European Semester. In order to achieve greater effectiveness, accessibility and resilience of their health systems, Member States are to use European funding instruments. These guidelines will undoubtedly help Member States in their fight for "adding more years to life, but also and above all more life to years".

For more information on the topic, please read the Communication.

Healthy Workplaces: Campaign to Tackle Stress at Work

7 April 2014 – The European Agency for Safety and Health at Work (EU-OSHA) launches the two-year Campaign: "Healthy Workplaces Manage Stress".



The Campaign will be coordinated at national level by EU-OSHA's national focal points in more than 30 countries and is supported by the Council of the EU, the European Parliament, the European Commission and the European social partners. In two years, it is meant to improve the management and prevention of work-related stress and psychological risks. As Commissioner responsible for employment, social affairs and inclusion, Lázló Andor, underlines, managing stress at work is a key issue to face in order to "ensure the health, safety and wellbeing of European workers". The forthcoming framework will thus encourage

a sharing of good practices to promote better mental health at work. One of its key activities is notably the European Good Practice Awards, which is to be launched on 15 April.

For more information please read Commissioner Andor's **Speech** or visit the Campaign Website.

World Health Day: Fight against Vector-Borne Diseases as Main Theme

7 April – The European Union celebrates World Health Day and highlights the fight against Vector-Borne Diseases.

More than half of the population is threatened by the "so-called" Vector-Borne Diseases -diseases transmitted by mosquitoes, bugs and other small organisms called vectors. Considering the gravity of the situation, the EU had funded research on vaccines, diagnostics and drugs, amongst others. For more information on research programmes, please read the Commission's Press Release.



In the context of World Health Day, a "Conference for Better Bee Health" was also

held to find solutions for healthy bees, apiculture, agriculture and environment and to boost "collaboration, knowledge and technology transfer between policies, science and practice." More detailed information about the Conference Here.

> European Parliament

Medical Devices: European Parliament's position settled in plenary

2 April - The European Parliament voted on its first reading of the draft legislation on medical devices.

This vote consolidates the work done so far and hands it over to the next Parliament. After the elections, the new Parliament will be able to conclude the legislative process under its next mandate on condition that the Council will be able to settle its position. The Parliament's vote endorses a stricter process involving pre-market assessments together with post-market monitoring and vigilance. It is hoped that the new regulations will be robust enough to meet the requirements that the previous legislation lacked.

Find more information on the European Parliament Press Release.

Clinical Trials: New EU new rules for more transparency

3 April - The European Parliament voted a new regulation on clinical trials aiming at addressing the shortcomings and problems brought about by the existing EU Clinical Trials Directive from 2004. The new regulation requires the publication of detailed summaries of the trial on a European database that is accessible to the public. This should tackle the non-publication of half of all clinical trials.

Along with the new rules that should improve the attractiveness of Europe as a location for clinical research and enhance EU ability to develop innovative medicines that benefit patients, the regulation is to give citizens utmost faith in clinical trials and the guarantee that authorized medicines pose no unacceptable risks for those using them. It must be reminded that people who participate in clinical trials do so to support the advancement of medical research - not for the sake of the generating corporate profits. The regulation is a progress but could have gone further by requiring comparative clinical trials which would have enabled the comparison between the new and the reference treatment, in order to ascertain its therapeutic added value.

The regulation will enter in force as law in all member states 20 days following its publication in the Official Journal of the European Union and apply six months after a EU portal for the submission of data on clinical trials and a EU database identifying each clinical trial have become fully functional. Please find further information Here.

Chronic Disease: First EU Summit calls for collaboration

3 & 4 April – Chronic Diseases represent the major share of burden of disease in Europe. The first EU Summit called for coalition between all sectors across society to enable the necessary reinforcement of resources and efforts to tackle chronic diseases. Siniša Varga, Director of the Croatian Health Insurance Fund and AIM Chairman of Disease Management and eHealth Working Group held a presentation.

At times when the sustainability of our health and social systems is a challenge in itself, investing in sustainable health



systems and reducing health inequalities must remain a priority. Considering people's health as a human capital, the Summit underlined some important actions to be undertaken in response to chronic disease, such as the strengthening of political leadership, the targeting of key societal challenges or the promotion of citizen and patient empowerment. The necessity of a more efficient use of available resources was also stressed, just as the need for strengthening evidence and information into research and development of medicine, technologies, treatment and prevention methods. These key points were supported by participants in a

series of workshops in which, amongst others, Siniša Varga, Director of the Croatian Health Insurance Fund and AIM Chairman of Disease Management and eHealth Working Group, took part. In his <u>Presentation</u> "Effective spending to reduce the burden of chronic diseases: the pressure on health and social systems", he attracted the audience attention to this often underestimated global epidemic issue and proposed policy changes to be addressed in order to improve the system.

For more information on the Summit's position, read the Conclusions.

Innovative medicines: public-private scheme for 2014-2020

17 April - The vote on the second Innovative Medicines Initiative (IMI2) took place during the final plenary session before the European Parliamentary elections next month.

IMI2 is a research programme run jointly by the European Commission and the pharmaceutical industry. The objective is to improve the process of developing new drugs and treatments by supporting cooperation in research and

development. The second initiative, spanning the period 2014-2024, has seen its budget set to approximately €3 billion. It will focus on the development of treatments that contribute to lifelong health and well-being. Some MEPs, among them the French Green MEP Michèle Rivasi, expressed their discontent, saying that the European Union is uselessly financing the global pharmaceutical industry.

Pharmaceuticals and Medical Devices

Pharmacovigilance: EMA introduces new Fee Incentives

1 April – The European Medicines Agency has introduced new fee incentives to back up micro, small and medium-sized enterprises (SMEs) in the development of medicines for humans and animals.

Aiming at answering concerns raised by SMEs about the difficulties faced by small businesses in post-authorisation procedures, the agency will grant new fee exemptions meant to support and encourage innovation. According to a recent analysis conducted by the Agency, SMEs are the source of more than 60% of the medicines authorized for the treatment of a rare disease, just as of three out of the four advanced therapy medicines approved in the European Union. EMA has developed a programme to support them financially, administratively and regulatorily.

For more information, please read **EMA's Article**.

Fight against Falsified Medicines: European Commission Launches New Project

7 April - The European Union has launched a new project to fight against the production and trafficking in falsified medicines, an issue which concerns both developed and developing countries.

Falsified medicines represent a threat to public health as they are often of bad quality and sometimes even toxic. In times when universal access to medicine and its affordability remain a challenge in themselves, developing countries seem to be particularly exposed to the dangers resulting from these drugs. The project is not only meant to update the existing legal framework to enable a better tackling of the issue, but it will also develop a national strategy and strengthen inter-agency collaboration and cross-border cooperation. Furthermore, it aims at enhancing investigation, providing training and raising awareness on this issue.

For more information on this topic, please consult the Press Release.

Clinical Trials: First European Hospital Conference

8 to 10 April – The Electronic Health Records for Clinical Research (EHR4CR) organised a conference to bring stakeholders together and discuss the deployment of a platform on clinical trials focussed on hospitals.

The EHR4CR Project has created a platform through which it aims at accelerating and optimising services for clinical trials through a connection to the Electronic Health Records (EHRs). Speeding up the process implies reducing the time taken to conduct a clinical trial and accelerating the delivery of innovative medicines to healthcare. The connection to the EHR system shall be secure and under full privacy protection.

For more information, please watch the EHR4CR Video.

> European Affairs

VAT: Public consultation to address VAT exemptions

25 April - The European Commission adopted in December 2011 a Communication on the future of VAT that sets out guidelines to modify VAT system in the EU.

One of the priorities is the review of the VAT rules on the public sector including the special rules for public bodies and the tax exemptions in the public interest. Health protection, healthcare and social services are concerned. To prepare the ground for a possible future legislative initiative in this area the European Commission launched a public consultation.

In its answer, AIM expressed its disagreement by highlighting the tremendous consequences that an increase of taxation would have on national health protection systems. Indeed, this would lead to consumer price increase, which will then in turn result in real risks for the health of European citizens. AIM backed up its opinion by providing examples of extra costs which would result from the envisaged loss of VAT exemption.

For instance, taxable inclusion would force the German social insurance system to shoulder an additional expenditure of around €34 billion in 2014. Regarding the Belgian system, a taxation of 10% on healthcare services in 2013 would have led to an increase of €1.5 billion for the Belgian Mutuals.

Alm's response will soon published on the Website.

European Semester: The Commission is about to publish Spring European Economic Forecast

5 May - the European Commission will publish its Spring European Economic Forecast.

It will cover 2013, 2014 and 2015 and will include data on Gross Domestic Product (GDP), inflation, employment and public budget deficits and debt, amongst others. These forecasts focus on all 28 EU Member States, plus the candidate countries, as well as some non-EU countries.

The European Commission's Directorate-General for Economic and Monetary Affairs produces short-term macroeconomic forecasts three times year: in Spring, Autumn and Winter. They serve as a basis for various economic surveillance procedures, such as in the context of the European Semester.

> E-health

mHealth: Commission launches Consultation

10 April – The European Commission published a green paper and launched a three-month consultation on the use of mobile health in patient care, aiming to optimize the use of mobile devices such as tablets or smartphones.

Mobile health aims at improving health and wellbeing by further empowering patients and making healthcare systems



more efficient. Moreover, it is meant to open the doors to innovative services and should allow tremendous savings in healthcare costs in Europe. The commission suggested a policy of action, which would, as the European Commissioner for Health Tonio Borg said, allow citizens to "manage their own health [...], to trigger quality of care and comfort for patients, and to assist health professionals in their work". mHealth represents a move towards prevention rather than cure and it should help reaching efficient and sustainable health systems. However, concerns about data protection and safety issues still persist. The consultation will come to an end on June 3.

For more information on mHealth, please read the Green Paper.

Events where AIM attended

Access to healthcare: Make this Issue a Priority for the Forthcoming European Parliament

8 April - AIM organised and participated in an EU Health multi-stakeholder's event on the issue of 'Universal Access to Health' at the European Parliament.

This key topic is being addressed prior to the Elections, allowing it to be given the interest and importance it deserves in the EU political agenda. This event was hosted by the MEP Andrey Kovatchev (EPP, BG), who is very active in the health arena and particularly committed to patient access to healthcare in Europe. This debate was also attended by other Members of the European Parliament: Rebecca Taylor (ALDE, UK) and Angelika Werthmann (ALDE, AT).

This unique platform was an opportunity for AIM, EGA (European, Generic Association), EPHA (European Public Health Alliance) and EPF (European Patients' Forum) to address universal access to health from their perspective on the one hand, and the Parliament's different party candidates to outline their positions and priorities on the other.

AIM had the possibility to present its priorities (solidary-based health protection system, promotion of social economy, and defense of the characteristics of European Health systems) and address some questions to the MEPs regarding VAT exemption or rocketing prices of medicines.

Find more information on the EGA's Press Release.

National Health Policies

Haiti: AIM Engaged in Promoting Quality Education through the "Education et Solidarity" Network

27 & 28 March – Partner of the "Education et Solidarity" Network of which the AIM is a founding member, the collective programme for Social Development and Dialogue in Haiti "PROCEDH-TETE ENSEMBLE" 's steering committee was held in the MGEN offices.

Coming to an end in June, the programme's main objective is to promote quality education in Haiti by mobilizing local actors. In its frame, the Network "Education et Solidarity" was in charge of coordinating an axis of work directed at social work and has worked mainly on two actions: the sensitization and mobilization around the



health social protection of education professionals, and the pilot programme of education to social protection for secondary school students, a programme which will be tested after Mai 2014 in two high schools of the Haitian capital. At the meeting, a second phase of the programme was agreed on, a stage at which both the Network and MGEN's commitment will be reinforced.

For more information on this programme, please visit their Webpage.

Ireland: Guaranteeing the Performance of Health Systems in Times of Crisis

31 March – A project funded by the Health Research Board analyses performance indicators in order to evaluate the response of the Irish Health Service to the economic recession.

Research has shown that the Irish system has successfully faced the crisis, managing to "do more with less". According to this "Resilience Project" carried out by academics in Trinity College Dublin, the system has managed to find solutions for an enhancement of the system's resilience and for its strengthening thanks to clinical care programmes, agreements between health service management and unions, reduced professional fees and drug cost savings. Considering the challenge which providing affordable and high-quality healthcare represents, the World Health Organisation and the European Health Policy Observatory intend to develop a resiliency framework to apply across the EU in similar circumstances.

For more details, please refer to the Press Release.

Greece: National Healthcare and Insurance System

11 April - During the Pharmaceuticals and Medical Devices Working Group met at AIM offices, Athina Pantelidou, intern at AIM, briefly presented the Greek National Healthcare and Insurance System.

The system was established in 1982 and aims at providing equal and free access to healthcare services for all Greek citizens. It includes a compulsory health insurance functioning under the National Organization of Health Services (EOPYY), and a complementary health insurance, which functions under private companies (mutuals and profit-oriented insurance companies). Healthcare are provided either through a national healthcare network (Primary National Health Network - PEDY), by contracted doctors, in Health Centers, Hospitals or by other family doctors, GPs and private specialists. The latter often set very high prices.

Regarding the pricing and reimbursement of pharmaceutical products, the insured patients' involvement cannot exceed a rate of 25 %. A special Committee for Pricing of Medicines sets the prices upon the agreement of the Health Minister by taking into account the three lowest prices of the medicine in European countries.

Nowadays, after the results of the economic crisis and the austerity measures applied in Greece, the healthcare system unfortunately suffers from major problems and tough reforms.

For more information please visit AIM official website

Moldavia: Teachers' Health Education

11 April – In a country where teachers' life and working conditions are extremely rough, the "Education and Solidarity" Network and the <u>UNSA Education</u> have organised a two-day training to improve the participants' health knowledge and provide them with the tools needed to discuss and reach decent living conditions.

This formation based on workshops shows teachers negotiation techniques aiming at informing, gathering information and, ultimately, convincing. Through this training, awareness on the topic of education to health at school is raised, an issue which has always been a preoccupation to <u>Education International</u>, who strongly supported this initiative. Future prospects include a further formation on the topic of social protection and the spread of this module in other countries.

For more information on this topic, please read the Article.

> Events Overview

eHealth: Forum to be held in Athens

From 12 to 14 May, a forum on eHealth will be held in Athens aiming not only at exchanging knowledge and good practices but also at fostering innovation and promoting growth and opportunities in rough times.

The current European economic state threatens the universality and affordability of healthcare. eHealth seems to embody a promising tool to tackle this key societal issue and face challenges such as the fast ageing of population or chronic diseases. Indeed, its development might pave the way towards better healthcare and a greater efficiency and sustainability of health systems. The forum to be held in May will, as the European Commissioner for Health Tonio Borg mentions, "explore the potential of eHealth for an active, healthy and prosperous Europe". The transatlantic opportunities in eHealth, the improvement of accessibility and quality of life, the personalisation of healthcare and integrated care are only some of the topics on the agenda. The forum intends to strengthen partnership through Europe to enable an optimization of the use of eHeath across the continent.

For more information visit the forum's Website and see their Programme.

Health and Long-term care

> Trends in health system

Pay and Working Conditions in Social Care: Major Survey launched

24 March – A major international survey of workers in social care has been launched across 34 countries. It will run till November 2014 and is supported by the European Federation of Public Service Unions (EPSU).

The WICARE project findings will allow them to gather information on basic pay and additional payments, working time and other employment and working conditions through online questionnaires, information they will then be able to use in order to back up their campaigning and collective bargaining work in the social care sector. As EPSU points out, this sector suffers from low pay and poor working conditions and reflects "some of the structural labour market problems behind the gender pay gap."

For more information, visit EPSU Webpage.

Call for proposals, Consultations

Public Consultation on the Preliminary Opinion on Definition Primary Care with Emphasis on Financing Systems and Referral Systems

25.03.2014 - 11.05.2014

http://ec.europa.eu/health/expert_panel/consultations/primarycare_en.htm

Public Consultation on the Green Paper on Mobile Health

10.04.2014 - 03.07.2014

http://ec.europa.eu/digital-agenda/en/public-consultation-green-paper-mobile-health

Online public consultation on investment protection and investor-to-state dispute settlement (ISDS) in the Transatlantic Trade and Investment Partnership Agreement (TTIP)

06/07/2014

http://trade.ec.europa.eu/consultations/index.cfm?consul_id=179

> Studies, Videos, Positions

Social Economy

EU Commission: Single Market News with an interview of Michel Barnier

http://ec.europa.eu/internal market/smn/index en.htm

Social Economy Europe: Memorandum for the European elections 2014

http://www.socialeconomy.eu.org/spip.php?article1930

(FR) Cahiers de l'observatoire : L'économie sociale face à la régionalisation des aides à l'emploi

http://www.observatoire-es.be/wp-content/uploads/2014/03/cahier10_WEB.pdf

Health Systems

EU Commission: Communication on effective, accessible and resilient health systems

http://ec.europa.eu/health/healthcare/docs/com2014_215_final_en.pdf

Healthy ageing

Elderly care: always aware

http://ec.europa.eu/research/infocentre/article_en.cfm?id=/research/star/index_en.cfm?p=332&calledby=infocentre&ite m=Infocentre&artid=31518

Innovation

RegioStars Awards 2014

http://urlz.fr/ISa

Working with young people

http://urlz.fr/ISc

Health events in Europe

16 May European Voice Event on Clinical Trials: Boosting competitiveness in Europe while

complying with the EU 2014 CT and data protection regulations

Paris

12-14 May eHealth Forum

Athens

19-24 May World Health Assembly

Geneva

20 June Employment, Social Policy, Health and Consumer Affairs Council Meeting (EPSCO)

Luxembourg

26-27 June European Council

Brussels

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

'AIM Flash' @ monthly publication of the AIM Secretariat

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