

# FLASH n°119 – February 2014

## Feature Stories



Parliament formally approved stricter EU tobacco rules



Social Investment

Commission updates Roadmap on Social Investment package



Pharmacovigilance

<u>Compromise on strengthened</u> <u>Pharmacovigilance fees confirmed</u>



EU Health Programme

EU Health Programme 2014-2020 approved by European Parliament Plenary

## **Contents:**

AIM and You	2
European Institutions	2
Council of Ministers	2
European Commission	3
European Parliament	3
Pharmaceuticals and Medical Devices	4
European Affairs	5
Mutuals	5
Health and Long-term care	5
Health Events in Europe	7

## Next Meeting and visit dates

3 March	Pensions WG - At AIM Offices	
6 March	Committee on the revision of AIM Statutes - At AIM Offices	Healthcare and vocial benefits for
17-18 March	AIM-EHTEL E-health Study Trip In Tallinn, Estonia	Healthcare and social benefits for
12 March	Fraud WG - At AIM offices	() ()
28 April	Prevention Working Group At AIM offices	Healthcare and vocial benefits for
30 April	Internal Audit Committee At AIM offices	



AIM @AIM\_Healthcare · 25 févr. AIM's Partner Social Economy Europe adopts position on Measurement o Impact, bit.ly/1foZSnv #ESS #socialeconomy @SocEntEU

AIM @AIM\_Healthcare · 25 févr. #AIM and #EHTEL invite to a Study Trip on #eHealth in Estonia on 17-18 March Info: bit.ly/1o3jwF2 #telemedicine

AIM @AIM\_Healthcare 4 févr.

∧ Article on @bbchealth today: Do drugs really have to be so expensive? bbc.in/1aYzvEb #UHC #Accesstomedicines @MSF\_uk

# AIM and you

#### AIM Activities

#### AIM Meetings:

7 February: Pharmaceuticals and Medical Devices Working Group

#### **Events AIM attended:**

On 11 February AIM Secretariat attended the Conference on Social Impact measurement at the European Economic and Social Committee.

On 24 February AIM Secretariat attended the meeting of the Education and Solidarity Network.

# **European Institutions**

#### Council of Ministers

#### Public procurement: Adoption of the new directive by the Council

On 11 February, the Council of Ministers<sup>1</sup> formally adopted the new directive on public procurement as voted in plenary by the European Parliament on 15 January.

The Council has adopted the legislative package for modernisation of public procurement in the EU, which is made up of a directive on public procurement; the directive on procurement by entities operating in the utilities sectors: water, energy, transport and postal services and the directive on the award of concession contracts. The Directive introduces new award criteria promoting environmental considerations, social aspects and innovation when choosing a contractor. A new simplified regime is be created for social, health, cultural and assimilated services with a threshold increased to 750 000  $\in$ . The Directive will not affect the social security legislation of the Member States which are free to organise the provision of services of general interest including social services.

After the publication in the Official Journal, Member states will have 24 months to implement the directive into national law. Find more information on the <u>Press Release</u> of the Council.

#### European Semester: Conclusions of the Council of Ministers welcome the Annual Growth Survey

The European Semester contains a clear timetable from November to July, according to which the member states receive EU advice regarding the national reform programmes. The objective is that member states take into account recommendations when they define their next year's budget.

In February, the Council of Ministers has welcomed in <u>Conclusions</u> the Commission's Annual Growth Survey 2014, setting out broad policy priorities for the EU and its Member States. The Annual Growth Survey marks the beginning of the European Semester process for 2014.

The next step will be in March, when the European Council<sup>2</sup>, has to set economic policy priorities. In June and July, the Council of ministers will then provide the country-specific recommendations.

The European Semester is in place since 2011 and has proved to include more and more recommendations in the health sector. Indeed according to <u>Euractiv</u>, in 2011, only three EU member states had received country-specific recommendations on healthcare in 2011, in addition to the four countries under the economic adjustment programme (Greece, Portugal, Ireland and Cyprus).

#### Overview of the EU semester:

- May 2014: The European Commission proposes recommendations to every country for budgetary, economic and social policies
- June-July 2014: The Council adopts the recommendations
- July 2014: Countries take into account the recommendations for the next year's national budget

<sup>&</sup>lt;sup>1</sup> Council or Council of Ministers: The Council is part of the essentially bicameral EU legislature, representing the executives of EU member states, the other legislative body being the European Parliament. The Council is composed of several configurations of the twenty-eight national ministers.

<sup>&</sup>lt;sup>2</sup> European Council: It comprises the heads of state or government of the EU member states, along with the President of the European Commission and the President of the European Council. The European Council is in charge of the general political directions and priorities of the Union. It is thus the Union's strategic, acting as the collective presidency of the EU.

In 2012, that number had gone up to six member states, and to sixteen member states in 2013. Recurrent recommendations were the reduction of home care for elderly people and hospitalisations, reduction of pharmaceutical spending and prescriptions of professional services. For the time being the European Union cannot impose any sanctions for not following the recommendations.

For more information, read the Conclusions of the Council and consult the Council scheme.

### European Commission

## Social Investment: European Commission updates Roadmap on Social Investment package

On Friday 21 February, the Commission has released a short summary of the actions implemented as a follow-up of the Social Investment Package. By the same token, the Commission updated the Roadmap on Social Investment Package. The updated Roadmap includes for instance the following actions:

- Publication of a policy makers' manual for applying innovative approaches to long-term care provision for February 2014

- Publication of a Report on efficiency and effectiveness of social spending including the financing of different social protection functions by the Social Protection Committee for June 2014.

- Setting up of a knowledge bank to share social policy experiences to be published in Mid-2014

- Publication of a joint report with OECD assessing efficiency and effectiveness of healthcare by Spring 2017

The Roadmap also includes references to special calls focusing on the Social Investment Package within Horizon 2020. Furthermore the EU Commission makes the link to the all references to social investment, health and social protection in the Annual Growth Survey 2014 in the frame of the EU Semester.

For more information, you can refer to the page of the European Commission.

#### European Parliament

#### Tobacco directive: Parliament formally approved new EU tobacco rules

On 26 February, the EU Parliament voted and adopted the revision of tobacco directive.

The Council had found a compromise about the text on 18 December. The draft legislation was approved by a strong majority in plenary with 514 votes to 66, and 58 abstentions.

The main changes in the new directive are the prohibition of all characterising flavour, Future cigarette packages from 2016 and the health warnings that cover the package back and front, will cover

65% of the packaging. The ban of menthol flavour will be given a four-year derogation until 2020.

Regarding e-cigarettes, it will be at member state's discretion to regulate them as medicines or as tobacco products... Also refillable cartridges will not be banned but member states can ban specific types of cartridges if there are safety concerns. The new Tobacco Directive is to be approved by the Council of Ministers on 14 March.

For more information you can read the Questions and Answers by the European Commission on the new Directive and the Press Release of the Parliament on the Vote.

#### Health Programme: Approval of the new EU Health Programme in Plenary

## On 26 February, the Plenary of the European Parliament has approved the new EU Health Programme for 2014-2020 with a total budget of 446 Million €.

The Health Programme aims to support Member States' action to improve people's health and reduce health inequalities, by promoting health, encouraging innovation in health, increasing the sustainability of health systems and protecting EU citizens from serious cross-border health threats. Building on achievements and lessons learned from the previous health programmes, the new programme focusses on key: strengthen action to promote health and prevent diseases; protect citizens against health emergencies; increase the up-take of innovation in health; and improve people's access to medical expertise and information for specific conditions; and improve healthcare quality and patient safety. The projects funded under the past EU Health programme facilitated mainly the exchange of best practice between member states. The candidates for funding are national health authorities, as well as public and private bodies, international organisations and non-governmental organisations with a general interest in health at EU level and which support the programme's specific objectives. More information in the Q&A of the Commission.

© EU Commission

### Financial Crisis: MEPs merge for social and employment recovery

On 13 February 2014, MEPs of the Employment and Social Affairs Committee have adopted a resolution to address the results of financial crisis. MEPs voiced concern that the recovery programmes recommended specific cuts in real social spending in fundamental areas such as pensions and basic services. Additionally the Rapporteur, MEP Alejandro Cercas accuses Troika and governments in his report of ignoring the European Social Charter and the employment conventions set up by International Labour Organization, when imposing their measures to the crisis hit countries. Several measures required as part of bailout packages contravened the EU's Charter of Fundamental Rights. Thus MEPs call for proper impact assessment and more flexibility through a recovery plan for jobs, small companies and social protection. The committee's recommendations on the issue will be voted by the Parliament's plenary in March.

For more information you can read the European Parliament Press Release.

## > Pharmaceuticals and Medical Devices

## Pharmacovigilance: Coreper approves compromise on Strengthened Pharmacovigilance rules

The Permanent Representatives Committee<sup>3</sup>, Coreper, approved a compromise of the European Parliament on 19 February on a draft regulation that aims at guaranteeing the funding of strengthened post-authorisation control of medicines for human use ("pharmacovigilance") conducted at EU level.

This approval confirms a compromise between the Presidency, Parliament and Commission from 12 February. The goal of this revision of the regulation is to finance better Pharmacovigilance activities The fees introduced by this regulation will be charged by the European Medicines Agency (EMA) and will also allow the EMA to remunerate national competent authorities for the work provided by them in the EU-wide pharmacovigilance assessment procedures. The compromise will have to be approved formally by the Council and the Plenary of the European Parliament. For more information please refer to the <u>Press Release</u> of the Council.

# *Pharmacovigilance:* European Medicines Agency and US Food and Drug Administration collaboration in pharmacovigilance

The European Medicines Agency (EMA) and the United States Food and Drug Administration (FDA) set up a 'cluster' on pharmacovigilance (medicine safety) topics in order to strengthen their collaboration and improve the exchange of information between them concerning the pharmacovigilance area.

This new project takes the form of a cluster, a regular collaborative meeting between EMA and regulators outside Europe and it is going to be performed confidentially in a monthly basis by teleconference. "*In an increasingly globalised pharmaceutical market, collaboration between medicines' regulators is essential,*" explains the EMA's Executive Director Guido Rasi. Thus clusters already exist for several issues related to biosimilars, cancer medicines, orphan medicines, medicines for children and blood-based products. The collaboration will take the form of discussions on any pharmacovigilance issue between the two agencies on a monthly basis by teleconference. For more information please refer to the <u>website</u> of the Agency.

### Innovative Medicines: Main innovators within pharmaceutical companies

An article published in the Nature Reviews Drug Discovery journal identifies the pharmaceutical companies, mainly small and medium enterprises, involved in the recent development of medicines containing new active substance.



The <u>article</u> written by staff members of the European Medicines Agency (EMA) asserts that between 2010 and 2012, 27% of innovative medicines originated from SMEs, while SMEs account for only 13% of the marketing-authorisation holders. In

comparison, 17% originate from academic institutions, public bodies and public-private partnerships. The article acknowledges SMEs as a motor for innovation in the EU. The EMA develops a programme to support SMEs throughout medicine development. For more information, you can visit the EMA <u>Website</u>.

<sup>&</sup>lt;sup>3</sup> Coreper: The Permanent Representatives Committee or Coreper is responsible for preparing the work of the Council of the European Union composed of representatives from the Member States.

#### European Affairs

#### Insurance Mediation: Public health insurance companies included in the insurance mediation directive

The European Parliament Plenary has voted on 26 February on rules on sales of life and non-life insurance products and services to level out the playing field between insurance companies and insurance "distributors".

According to the draft directive, all insurance distributors should be registered with a competent authority in their home member state. Public health insurance companies providing complementary health insurance will be concerned and should submit to the new rules as well as private distributors. In Germany for example, the "Krankenkassen" may have to register as insurance mediators and then follow the law regulating commercial and industrial business to provide complementary health insurance.

The MEPs voted on the amendments, but not on the legislation as a whole, therefore leaving open the possibility of negotiating a first-reading agreement with the Council of Ministers.

You can find more information in the Parliament Press Release.

## World Cancer Day: EU reminds flagship Actions in the fight against cancer

This year, World Cancer Day focused on "Debunking the myths" about cancer. The myths pointed out on cancer included the absence of symptoms or the impossibility to cure the disease.

At this occasion the EU Commission made an overview of EU actions in the fight against cancer. One of the biggest achievement of the EU is its 'European Code against Cancer' dating back to 1987. The code consists of 11 recommendations to fight cancer and is currently being revised. Another important EU initiative was the Joint Action "The European Partnership for action against cancer "(EPAAC) is now completed and resulted in the adoption of National Cancer Plans by several member states. Another initiative identified as a milestone is the adoption of a set of European Guidelines for quality assurance for the screening of three types of cancer (breast, cervical and colorectal cancer).

For more information, visit the Website of World Cancer Day and read the EU Press release.

## Prevention: New Action Plan on Childhood obesity adopted

On 28 February, member states announced the adoption of an <u>Action Plan</u> on childhood obesity at the occasion of the conference in Athens on Nutrition and Physical Activity. The Commission indicates the action plan includes voluntary initiatives to promote healthier environments - especially in schools, restrict marketing and advertising for children, inform and empower families as well as encourage physical activity.

The action plan aims at tackling the rising problem of obesity starting from an early age: Around one in three children aged six to nine were overweight or obese in 2010 versus one in four children in 2008. Member States estimate that treating weight-related problems accounts for 7% of their healthcare budgets.

For more information please refer to Commission Press Release.

#### TTIP: British Medical Association reassured over transatlantic healthcare market

The BMA has been given assurances that a free-trade agreement between the EU and the USA will not affect healthcare in the UK.

Talks to develop the TTIP, Transatlantic trade and investment partnership, started last July, with a fourth round of negotiations scheduled for next month.

The European Commission's director general for trade and UK minister for trade and investment responded to its concerns about healthcare opening up to bigger markets. The British Minister stated that it was up to NHS commissioners to take decisions about which providers to contract with and that the TTIP would not affect this policy. Regarding Investor State related Disputes (ISDS), the Commission told the BMA that neither the EU nor the US government has an interest in seeing their public policies successfully challenged by investors.' The upcoming consultation on ISDS proposed by the European Commission for the TTIP will also give the chance to all stakeholders to express their opinion.

For more information on the BMA's position on TTIP you can refer to the BMA article.

#### Mutuals and Social Economy

#### Social Economy: AIM attends Conference on Social Impact Measurement

On 11 February 2014 a Conference on Social Impact Measurement was held concerning the important role of social economy enterprises in today's market.

The conference was organised by a Consortium composed of social economy actors like the think-tank 'Pour la Solidarité' and SAW-B as well as by the EU Commission and the Economic and Social Committee.

The first crucial argument was the connection between social economy and the values of fair growth, equity, social cohesion and solidarity. The importance of defining few and efficient indicators to measure more accurately the social

impact has been illustrated with three main reasons: Control, visibility and improvement. The indicators must represent qualitative and simultaneously quantitative objectives. Moreover there are different types of impact of a social enterprise such as direct monetary impacts, indirect impacts and macroeconomic impacts. In conclusion it was agreed that not only the results of the social impact must be measured but also the proceeding of the project. For more information please visit saw-b's <u>official website</u>.



## > AIM Partners

*Social Economy:* Social Economy Europe adopts Positions on Social Impact Measurement and Crowdfunding In its position, Social Economy Europe argues that evaluation and measurement of social impact should be used to justify the relevance of the action of social enterprises internally as well as externally towards various stakeholders (users, public authorities, employees, funders, etc.).

Measuring the social impact should also mean paying attention to the extra-financial performance, social utility, social return on investment, and positive externalities. Apart from quantitative and economic analysis that may provide the fastest results, SEE points to the fact that qualitative and social analyses give a much more refined perspective and should also be taken into account. For more information read the full <u>position paper</u>.

#### Health and Environment: HEAL publishes new Brochures on Air Pollution

The AIM partner organisation, Health and Environment Alliance (HEAL) and the ESCAPE project have published a series of information leaflets aimed at providing individuals, health professionals and heart, lung and asthma patient groups with the latest science-based guidance on how air pollution affects health in Europe, and prevention tips.

The project ESCAPE, European Study of Cohorts for Air Pollution Effects produced new evidence on how air pollution affects cardiovascular and lung health. In 2010, air pollution was responsible for 400,000 premature deaths in Europe, with health costs of up to 940 billion €.

HEAL published 4 brochures containing tips on how to react to Air Pollution and Lung Health for

four different target groups (asthma patients, cardiovascular disease patients, lung disease patients and Chronic Obstructive Pulmonary Disease Patients).

## National Health Policies

#### Germany - Pricing and Reimbursement: Germany to introduce publication of medicines' price discounts

The German government is planning to publish price discounts on medicines, through a law which could come into force from April this year.

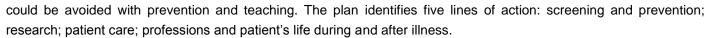
The objective of the new law will be to prevent wholesalers and pharmacies from basing their margins on list prices rather than the discounted prices. However the industry fears that the publication of the discounts could lead to an additional fall in prices elsewhere, as many healthcare agencies in Europe and Asia use the German prices as references. In particular, the pharmaceutical industry believes that German patients could miss many more new medicines because the latter will not be introduced on the German market. On the other hand the German Institute of Quality and Efficiency in Health Care (IQWIG) and the German government believe that this reform would guarantee to get the best value for money. Within the German government especially, the Social Democrats also support the proposal arguing that the poorer EU member states will not be able to afford medicine reimbursement in such high prices. For more information please refer to the <u>article</u> of Reuters



#### France - Cancer: New plan against Cancer in France

The French President François Hollande announced on 4 February the  $3^{rd}$  Cancer plan to fight against the plague that kills 150 000 persons per year in France.

This five-year plan focuses on health inequalities. Indeed, workers between 30 and 65 year old are nearly twice as likely to die from cancer as liberal professions. The plan insists on prevention and screening considering that 40% to 50% of yearly new cases



The French government allocated 1.5 billion euros to the plan which will among others finance research on rare pathologies. For more information, please refer to this <u>Page</u> (FR).

#### United Kingdom - Clinical data: National Health Service patient data plan postponed

The plan to share NHS patient data with academics, medical charities and pharmaceutical companies has been postponed for six months.

NHS England announced it would only begin collecting patient information in six months' time while the original plan was to start the collection of data in early 2014.

The NHS indicated that it would "allow more time to build understanding of the benefits of using the information, what safeguards are in place and how people can opt out if they choose to".

The data would include mental health conditions and diseases such as cancer of even smoking or drinking habits. Companies that are interested can apply to the new Health and Social Care Information Centre (HSCIC) and pay to extract the information which will not remain completely anonymous (the so called "pseudonymisation" procedure).

Advocates of this new initiative claim that it will save lives and support he health system by making drug side effects or the performance of the hospital surgical units more transparent. Nevertheless, privacy experts warn that the extracted information might contain NHS numbers, date of birth, postcode, ethnicity and gender. More details can be found in the Financial Times <u>article</u>.

# *Austria - Freedom of establishment*: Demographic criteria restriction incompatible with freedom of establishment according to the European Court of Justice

The European Court of Justice declared that the restriction in Austria regarding the opening of new pharmacies based on demographic criteria is incompatible with freedom of establishment.

In Austria, a new pharmacy cannot open if the number of people remaining to be served by the already existing pharmacy falls under 5,500. A pharmacist sued an Austrian administrative court arguing that the decision didn't take into account the specific needs of the population in this area. The Austrian court has sought a ruling from the European Court of Justice as to whether EU law precludes such national legislation.

The Court of Justice holds that the freedom of establishment precludes restrictions which do not allow the competent authorities to take into account of particular local conditions. The court recalls that the freedom of establishment does not prevent a country from adopting a system of prior authorisation for healthcare providers as long as the authorisation is adaptable to people needs.

Find further explanations on the Press Release.

#### Events Overview

#### Chronic Diseases: The first EU summit will be held in April 2014

On 3-4 April 2014 in Brussels an EU summit on chronic diseases, will be organised with the participation of 400 stakeholders, representatives from Member States, non-governmental organisations, professional groups, business operators, academics, and EU institutions.

The purpose of the summit will be to help the European Commission define its future policy on chronic diseases. Participation to the Summit is by invitation only.

For more information please refer to European Commission website



## Health Equality: "Health in Europe, making it fairer" conference

On 18 March 2014 in Brussels the conference "Health in Europe, making it fairer" will be held. The conference will address the issue of fairness and equality in health. Exchange of information on combating discrimination and proposal of common principles in order to tackle inequalities and improve access to health will be included. The conference will gather 400 persons among them representatives of Member States, non-governmental organizations and other relevant stakeholders, professional groups, academics, and EU institutions. In order to attend the conference an advance online registration is required.

For more information please refer to European Commission website

# Health and Long-term care

## > Trends in health system

#### Universal Health Coverage: Ivory Coast to create universal health coverage

The Ivorian National Parliament is to vote on a legislation providing access to care, medicines and reimbursement to every Ivorian citizen. This universal health insurance will cover everyone who is not already covered by another compulsory sickness insurance scheme. This measure should enter in force in December 2015 according to the government. Please find more information on the Ivorian National Parliament <u>website</u>.

## > Call for proposals, Consultations

Public consultation on VAT legislation on public bodies and tax exemptions in the public interest 14.10.2013 – 25.04.2014 (new deadline) http://ec.europa.eu/taxation\_customs/common/consultations/tax/2013\_vat\_public\_bodies\_en.htm

## Studies, Videos, Positions

Social Economy **Social Economy Europe: Positions on Social Impact Measurement and on Crowdfunding published** Position on Social Impact Measurement: <u>http://www.socialeconomy.eu.org/IMG/pdf/2013-</u> <u>082\_see\_position\_paper\_measurement\_and\_evaluation\_1\_-3.pdf</u> Position on Crowdfunding: <u>http://www.aim-mutual.org/fileadmin/WG/Mutuals\_WG/2013-</u> <u>081\_SEE\_Position\_paper\_Crowdfunding\_1\_.pdf</u>

Cross-border Healthcare

#### EU Commission: Seeking healthcare in another EU Member State

http://bookshop.europa.eu/is-bin/INTERSHOP.enfinity/WFS/EU-Bookshop-Site/en\_GB/-/EUR/ViewPublication-Start?PublicationKey=ND0313476

Environment WHO: Health and environment- communicating the risks http://www.euro.who.int/\_\_\_data/assets/pdf\_file/0011/233759/e96930.pdf

Crisis and Health EU Health Observatory: New website Health and Finance Crisis Monitor http://www.hfcm.eu/

Health Systems EU Health Observatory: New Website: Health Systems and Policy Monitor http://www.hspm.org/mainpage.aspx

# Health events in Europe

6-7 March	Justice and Home Affairs Council Meeting
10 March	Employment, Social Policy, Health and Consumer Affairs Council Meeting (EPSCO)
12 March	EU Commission TTIP chief negotiators' briefing to stakeholders Brussels, Information
18 March	EU Commission Conference 'Health in Europe, making it fairer' Brussels, Information
20-21 March	European Council
21 March	INAMI/RIZIV The future of social health insurance in Europe: redefining solidarity and responsibility? Brussels, Information Jean Hermesse (ANMC, BE), Ulrike Elsner (vdek, DE) and Tanel Ross (Haigekassa, EE) will be present as speakers at this Conference
26 March	EU Commission High-level conference on "The future of pensions in Europe: Taking stock and looking ahead two years after the White Paper" Brussels
2 April	EP intergroup "Social Economy" on the future of social economy policies after the Strasbourg declaration 4-6.30 pm at the European Parliament
3-4 April	EU Commission Chronic Diseases Summit By invitation only <u>Information</u> Sinisa Varga (HZZO, HR) will be present as speaker at this Conference
28-29 April	Informal Meeting of Health ministers Greece
Мау	World Health Assembly
20 June	Employment, Social Policy, Health and Consumer Affairs Council Meeting (EPSCO)
26-27 June	European Council Brussels

The monthly AIM Flash is compiled by Blandine Cassou-Mounat, Romain Chave and Athina Pantelidou. Realisation & Layout: Blandine Cassou-Mounat For more information on one of the topics mentioned above, please contact the AIM Secretariat.

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