AIM PUBLISHES DECLARATION ON EDCs p.2

EP ADOPTS ITS EUROPEAN SEMESTER PACKAGE FOR 2017 p.4

COUNCIL DISCUSSES COOPERATION TO SUPPORT ACCESS TO MEDICINES p.5

EUROPEAN COMMISSION AND INDUSTRY DISCUSS DEVELOPMENT OF DIGITAL HEALTH p.4

HIGHLIGHTS

2
AIM and You
AIM selected as a member of the European Commission’s HTA stakeholder pool
AIM publishes Declaration on EDCs

2
European Affairs
Commission adopts Annual Work Programme 2017 of the Health Programme
European Parliament adopts its European Semester package for 2017

3
Health Policies
French FNMF gathers Election Candidates to expose their social Protection and Healthcare Plans
Joint procurement of pharmaceuticals in the Netherlands

4
eHealth
The industry and the Commission discuss development of digital health

5
International
A digital library for social protection

AIM ANSWERS CONSULTATION ON EXCISE DUTIES APPLIED TO MANUFACTURED TOBACCO

AIM answered the consultation on Excise Duties applied to Manufactured Tobacco launched by the European Commission on 17 November 2016. More information Here.

Redaction: AIM Secretariat. Realisation & Layout: Jessica Carreño Louro. For more information on one of the topics mentioned above, please contact the AIM Secretariat. AIM Flash® is a 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.
AIM & YOU

AIM selected as a member of the European Commission’s HTA stakeholder pool

During the week of the 13 February, the European Commission has informed AIM that we have been selected to be part of their Health Technology Assessment (HTA) Network stakeholder pool. The pool was established to help facilitate stakeholder consultation of the HTA network. The Pool is a consultative body. Its opinions are non-binding and its members are expected to contribute to the policy developments related to HTA at EU level, to ensure that the views of different actors are reflected in the policy development and to create synergies between different stakeholders. The next meeting of the HTA Network will take place on 29 March. Please find the list of participating organisations here; the agenda of the next meeting here; and the call for expression of interest to be part of the HTA stakeholder pool here.

AIM publishes Declaration on EDCs

9 February – AIM published its Declaration on Endocrine disrupting chemicals (EDCs), calling for a more appropriate set of criteria to allow the identification and ban of (potentially) harmful substances. EDCs are probably linked to many diseases whose incidence is rising: reduced fertility, adverse pregnancy outcomes, obesity and type 2 diabetes, childhood leukemia, endocrine-related cancers... While such non-communicable diseases do indeed have both genetic and environmental components, the WHO itself recognises that increases in their rising incidence cannot solely be explained by genetics. Identifying the causative environmental factors is thus key to improving human health. On 28 February, the EU Standing Committee on Plants, Animals, Food and Feed (PAFF) will vote on the Commission’s proposal of criteria, which, at the time being, still fails to properly protect European citizens’ health.

AIM declaration calls on the Commission to put forward an appropriate set of criteria, which would be based on sound scientific evidence and enable a ranking of substances according to different weights of evidence. AIM also demands the application of the precautionary principle and asks the Commission to raise public awareness on the issue and come out with a series of evidence-based recommendation to populations and more particularly to vulnerable groups such as pregnant women and young children.

For more information read AIM Declaration on EDCs or our Editorial in Euractiv.

AIM answers consultation on Excise Duties applied to Manufactured Tobacco

13 February – AIM answered the consultation on Excise Duties applied to Manufactured Tobacco launched by the European Commission on 17 November 2016. Tobacco consumption remains one of the largest avoidable cause of mortality and premature death in the European Union, with 15% of deaths attributable to its use – that is, over 650,000 deaths a year. The negative impacts of tobacco use are already well established and smoking has been proven to be linked to several forms of cancer, cardiovascular diseases, respiratory diseases, negative reproductive effects and other negative health impact such as poor wound healing.

Tobacco taxation is an unneglectable tool which can help relieve those burdens and prevent millions of smoking-attributable deaths throughout the world while at the same time contributing to the achievement of global health objectives. In its answer, AIM recommends to increase taxation of all tobacco products which should be taxed in a comparable way as appropriate. A harmonisation of taxation rates for all types of tobacco product would also benefit vulnerable groups and help fight health inequalities. AIM also encourages the commission to adopt regulatory measures towards a EU-harmonisation of tax regimes, a purpose which a Minimum Excise Duty would particularly. Furthermore, AIM recommends to use the revenues from taxation for financing tobacco-control programmes such as awareness-raising campaigns and activities, health promotion and disease prevention, cessation services, and financing of appropriate structures for tobacco control and to include of e-cigarettes within the scope of excisable goods. Read AIM comments on the consultation Here.
COMMISSIONadoptsAnnualWork
PROGRAMME2017oftheHealth
Programme

26 January- The Annual Work Programme 2017 of the Health Programme was adopted. It gathers priorities and actions to be undertaken under the four main objectives identified: “promoting health, preventing disease and fostering supportive environments for healthy lifestyles taking into account the ‘health in all policies’ principle; protecting union citizens from serious cross-border threats to health; contributing to innovative, efficient and sustainable health systems; and facilitating access to better and safer healthcare for Union citizens.”

To support these objectives, the Commission has allocated resources to actions such as the Joint Action (JA) on Health Inequalities the JA on Vaccination, or the JA supporting the eHealth Network. It will also allocate grants to support the OECD to develop patient-reported measures and to strengthen cooperation for addressing the challenges of access to medicines. The implementation of national action plans on Antimicrobial Resistance will also be financially supported. EU market access paths for medical technologies with a focus on HTA and the stakeholders’ forum on EU collaboration on HTA are also on the list.

As far as prevention is concerned, the Commission will allocate part of its budget to support the design and implementation of national action plans on Antimicrobial Resistance. It will also allocate grants to support the OECD to develop patient-reported measures and to strengthen cooperation for addressing the challenges of access to medicines. The implementation of national action plans on Antimicrobial Resistance will also be financially supported. EU market access paths for medical technologies with a focus on HTA and the stakeholders’ forum on EU collaboration on HTA are also on the list.

For a complete list of actions, please read the Summary of Annexes from the Commission.

EUROPEANPARLIAMENTHEARSABOUTREFORMSIN
THEGREEKHEALTHSYSTEM


Dimitrios Papadimoulis (EL, GUE/NGL) and Georgios Kyrtzos (EL, EPP) both underlined that the deterioration of health systems is also observed in other countries. In particular, the question of overcharging by companies and the increase of pharma sales. The Novartis scandal in the country reveals the problems in the Greek health system too. In this regard, the measures taken in 2008 and 2009 to control costs were a mistake for Mr Kyrtzos as they focused on reducing the level of spending without paying attention to the quality of the healthcare delivered.

Dr Giannis Baskozos - Secretary General of Public Health at the Greek Ministry of Health said that in Greek there is underregulation of companies and the increase of pharma sales. The Novartis scandal in the country reveals the problems in the Greek health system too. In this regard, the measures taken in 2008 and 2009 to control costs were a mistake for Mr Kyrtzos as they focused on reducing the level of spending without paying attention to the quality of the healthcare delivered.

Mr Baskozos pointed specifically to the negative influence of corruption on healthcare, as it makes reforms impossible, for instance regarding generics penetration, which is also very dangerous for the country’s perception abroad. The Greek government also signed a memorandum of understanding end 2016 with NGOs and international organisations on prevention, vaccination. Mr Baskozos then went on to describe key features of the Greek health system as well as elements to improve:

- The new electronic prescription system is expected to support the good management of pharmaceuticals supply
- There is a need to hire more staff in the health sector
- There is a need to improve generics penetration in order to reduce therapies’ costs
- New mechanisms need to be introduced to improve the management of the drug market, such as the introduction of Health Technology Assessment
- In addition, drug prices are not transparent which hinders international comparisons
- Market failures mean that some treatments do not reach the market because manufacturers don’t expect profit
- Corruption should be addressed and lead to trials when necessary
- Greece can’t afford to hire such low levels of health expenditure and the Commission should help Greece have better deals with manufacturers

According to Panos Kanavos, Associate Professor in International Health Policy at the London School of Economics (LSE), the rest of Europe can draw very important lessons from the situation in Greece. He listed that the policies for safeguarding sustainability should focus on cost containment and efficiency improvements. This last point should be made possible thanks to value assessment frameworks and efficient purchasing practice. Monitoring and measuring performance as well as the introduction of incentives and pay-for-performance schemes are essential elements too.

Nikos Dedes, President of the Positive Voice Organisation informed participants that 12 to 14% of the Greek population have reported not having access to medicines. 22% of households said that access to healthcare is constrained by financial considerations. He also mentioned some interesting reforms, such as the merger of payers’ funds, the development of electronic prescription. However, Mr Dedes warned against the non-inclusion of patients into policies’ formulation and formation. He also signaled that it is not clear how much is spent on what drug. As a result, Mr Dedes asked for more inclusive discussions on prices and advocated for making available instruments for negotiation.

Sylvain Giraud, Head of Unit for Performance of national health systems, at the Directorate-General for Health and Food Safety (DG SANTE) presented on the EU’s role in terms of health. Mr Giraud instructed attendees that such a role focused initially on coordination and/or giving a framework for such coordination. The Cross-Border Healthcare Directive intro-
duced an element of cooperation but the European Semester was a significant development with regards to the EU’s influence on health systems. Indeed, based on economic and fiscal considerations the European Commission started to release recommendations with regards to health spending in member states, with bearing in mind the overall goal to achieve fiscal sustainability while ensuring access for all.

Rabia Khan, Policy Analyst for the OECD’s Health Division presented the outcome of its Health at a Glance report, published end 2016 and compared it with Greece’s performances. Ms Khan explained that Greece spends 8% of its GDP in healthcare, which is lower than the EU average (10%). Ms Khan also presented that a lot is actually spent on in-patient care, which is one of the most costly health spending positions. Ms Khan then advised Greece to cut waste and inefficiencies, such as overprescription of diagnostics and antibiotics. To her, the underuse of generics is problematic too.

Pascal Apostolides, President of SFEE underlined that Greece’s new ePrescription helped control more prescriptions. He also underlined the Greek pharmaceutical industry’s role in supporting health services and its contribution to sustainable health systems financing. In this respect, Mr Apostolides claimed that the industry pays back usually around a third of the total pharma expenditure.

**Active Ageing and its Implications on Mental Health**

8 February - Mental Health Europe (MHE) organized an event at the European Parliament hosted by MEP Deirdre Clune (Ireland, EPP) which aimed at discussing the importance of active ageing and why it matters to mental health.

Ageing populations constitute one of the greatest challenges for health systems and societies as a whole. Ageing goes hand in hand with other issues, which remain to be tackled in the future including increased depression rates, potential side-effects of psychotics, substance abuse, discrimination, reduced mobility and increased burden on informal carers (to mention only a few).

According to MHE, “It is crucial for Member States to address [the] implications of ageing on health and particularly mental health in a holistic and positive manner”. It was agreed by all participants that positive ageing is crucial. The Irish Minister of State for Mental Health and Older People, Helen McEntee, further underlined: “People should feel they are a valued member of and never as a burden to society”.

The European Commission also took part in the event and presented existing European and International frameworks for supporting age and mental health friendly policies such as Article 25 of the Charter of Fundamental Rights, the cross-border healthcare Directive (883), the UN Convention on the Rights of People with Disabilities, or the Madrid International Plan of Action on Ageing. Brenda O’Brien from the European Agency for Safety at work highlighted the importance of healthy working environments to decrease the burden of chronic diseases, as well as the need for joint thinking and budgetary integration.

Read MHE’s Press Release.

**European Parliament adopts its European Semester package for 2017**


The European Parliament has adopted in Plenary its report on the European Semester package for 2017. The European Semester is the yearly EU economic policy coordination exercise which begins with the adoption of a set of macroeconomic objectives by the European Commission, to which the European Parliament answers via a report, which reply is not binding on the European Commission. In this year’s European Semester social policy chapter, which was reported by Estonian ALDE MEP Yana Toom, the European Parliament specifically mentions the role of health and social services as well as social and solidarity enterprises in the contribution to sustainable and inclusive development and the creation of quality employment. In addition, the European Parliament stresses the need to invest in public health promotion and disease prevention while ensuring and improving the sustainability, safety, adequacy and effectiveness of social protection systems and the provision of quality long-term social services. The report promotes access to quality health services too.

Please find the final text here.
THE COUNCIL OF THE EUROPEAN UNION DISCUSSES VOLUNTARY COOPERATION TO SUPPORT ACCESS TO MEDICINES

3 February - The Council of the European Union's Working Party on Public Health at Senior level discussed a working paper on “Furthering a member state driven voluntary cooperation to support access to medicines”, which will be presented for adoption by Ministers of Health in June this year.

This paper follows-up on the June 2016 Council Conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States, the recent Commission consultations on HTA cooperation beyond 2020 as well as ongoing work on the impact of supplementary protection certificates and pharmaceutical incentives and rewards on innovation, availability and accessibility of medicinal products in the EU. It was also drafted in the context of joint country initiatives, between Belenux countries for instance, to assess and negotiate treatment prices. It investigates areas for future structure cooperation between health systems, such as joint horizon scanning, information sharing, voluntary pricing negotiations, waste in healthcare, HTA cooperation or market failure situations. The paper includes examples of successful cross-border cooperation in the areas listed before and seeks delegations’ feedback on drivers and challenges to voluntary structured cooperation in the area of access to medicines.

Please find the concept paper here.

PHARMACEUTICALS AND MEDICAL DEVICES

EP ENVI COMMITTEE CRITICISES THE PHARMACEUTICAL INDUSTRY IN ITS DRAFT REPORT ON ACCESS TO MEDICINES

31 January - the European Parliament’s Committee on the Environment, Public Health and Food Safety (ENVI) adopted its draft report on Access to Medicines in the EU. The report was drafted by rapporteur Soledad Cabezon Ruiz (S&D, ES).

With more than 100 paragraphs as well as explanatory statements, the report is quite lengthy, also presumably due to the high political sensitivity around the issues mentioned. It was heavily lobbied by the pharmaceutical industry, but also by health NGOs and patient groups.

In terms of content, the report welcomes the June 2016 Council Conclusions on strengthening the balance in the pharmaceutical market, which also called for a more control of medicines prices. While being less critical than the original draft report which was published in September 2016, hefty references to anti-competitive behaviour as well as free-market distortion remain in the ENVI text. The text also specifically mentions prices disproportion in comparison with a medicine’s cost structure.

In order to address affordability, including for lower- or middle-income countries, the European Parliament calls for the improvement of member states’ negotiating capacities in order to improve negotiating capacities in the EU, including through joint HTA studies, or reliance on existing HTA assessment. The report also calls for the revision of the transparency directive, especially in order to allow the timely entrance of generics and biosimilars onto the market.

The report also calls on the European Commission, the European Parliament and member states to launch a high-level strategic dialogue to establish strategies to ensure access to medicines across the EU.

The Europe of Nations and Freedom (ENF) political group tabled an alternative resolution. While the alternative resolution is also critical of the pharmaceutical industry, the ENF group is very isolated in the European Parliament and we don’t expect this resolution to be adopted.

The European People’s Party (EPP) group tabled four amendments, which rein in initial calls on other institutions to follow up on the UN High-Level Panel on Access to Medicines, reinforce the ambitions to harmonise HTA investigative tools and criteria and reassert the importance of considering the value of incremental pharmaceutical innovation.

The report should now be adopted by the European Parliament in plenary on 2 March. Being a resolution, the final report content will not be binding on the European institutions but its content can substantially influence the work of the European Commission and the Council on the topic of pharmaceuticals.

Please find ENVI’s report here.
eHealth

The European Commission and Industry Discuss Development of Digital Health

24 January - DIGITALEUROPE the technology companies’ trade association organised in Brussels an event on “e-Health: life saver or just smoke & mirrors?”. Speakers at the event included MEP Michel Boni (EPP, PL), Miguel Gonzalez-Sancho, Head of Unit for e-Health, Well-being & Ageing, at the Directorate General for Communications Networks, Content & Technology (DG CNECT) - Michele Pastore, Senior Manager for Public Affairs at Samsung and Chair of the eHealth Working Group at DIGITALEUROPE, as well as Cory Robinson, Senior Lecturer/Assistant Professor in Communication Design, Linköping University.

All speakers agreed to underline digital healthcare’s potential and significance to shape the future of healthcare in terms of treatment personalisation, continuous care, remote and constant monitoring, prevention, patients empowerment as well as adherence to treatment. However, proper development of digital healthcare should be supported by adequate infrastructures, for instance 5G infrastructure. In addition to data protection and privacy, patients and doctors’ digital literacy as well as interoperability are key to support digital healthcare development (all). Regional and local public health authorities, which are decision-makers in some countries need to be reached out too (Boni, Gonzalez-Sancho, Pastore).

For instance, while digitalisation affects all sectors, health presents its own specificities (Gonzalez-Sancho). There are serious concerns regarding the protection of personal data and privacy. In addition, data use can lead to abuse discriminatory practice from some sectors based on people’s health status (Robinson). However, if there needs to be a clear strong framework to protect patients, their privacy and data, some flexibility or specific guidelines or initiatives can also be explored (Boni, Gonzalez-Sancho, Pastore).

The industry for instance developed a Code of Conduct on mHealth, which intends to support apps compliance with data protection rules (Gonzalez-Sancho, Boni, Pastore). The Code of Conduct is currently reviewed by an all-member states high-level group in charge of supervising the protection of sensitive data.

The European Commission also tries to advance specific dossiers or aspects of digitisation as part of its Digital Single Market strategy. It has launched an initiative on a European cloud infrastructure and on freeing data flows between member states. A specific Commission expert group is also reflecting on mHealth apps’ reliability and is expected to publish its first conclusions by mid-2017.

In addition to data protection and privacy, patients and doctors’ digital literacy (Boni, Pastore) as well as interoperability are key to support digital healthcare development (all). Regional and local public health authorities, which are decision-makers in some countries need to be reached out too (Boni, Gonzalez-Sancho), especially as initiatives fragmentation is a specific challenge.

Health Policies

FNMF gathers Election Candidates to Expose their Social Protection and Healthcare Plans

21 February – Healthcare is at the centre of the political debate in France. On 21 February, FNMF, AIM’s biggest French member, organized an event in Paris inviting candidates to the Presidential Elections to present their proposals related to healthcare and social protection issues. Many journalists were on attendance and the event had a significant media coverage.

The main highlight of the meeting was centre-right candidate François Fillon’s softened position on healthcare. Indeed, Fillon seems to have changed his plans which consisted in limiting public health insurance for serious and chronic diseases. Instead, he now claims not to envisage any privatizing or lowering of coverage for public health insurance. Fillon foresees an economy of €20 billion for the healthcare system, which will notably be reached by cutting jobs in the administration. His objective of 0% out-of-pocket expenditure for the highest healthcare costs raises questions as to a possible “rocketing” of premiums. However, according to Fillon, who plans a new partnership between social security and complementary organizations, the increase in contributions will be contained.

The main highlight of the meeting was centre-right candidate François Fillon’s softened position on healthcare. Indeed, Fillon seems to have changed his plans which consisted in limiting public health insurance for serious and chronic diseases. Instead, he now claims not to envisage any privatizing or lowering of coverage for public health insurance. Fillon foresees an economy of €20 billion for the healthcare system, which will notably be reached by cutting jobs in the administration. His objective of 0% out-of-pocket expenditure for the highest healthcare costs raises questions as to a possible “rocketing” of premiums. However, according to Fillon, who plans a new partnership between social security and complementary organisations, the increase in contributions will be contained.

Other controversial issues included far-left candidate Jean-Luc Mélenchon’s proposal to nationalize healthcare competences so that 100% of healthcare costs are covered by the statutory healthcare insurance, including optical and dental care. Mr Mélenchon could not attend the meeting and sent his position in the form of a manifesto to FNMF. Socialist party candidate Benoît Hamon suggests not to “contract” doctors which would choose to work in areas already “over-provided”, in order to improve access to healthcare in so-called medical deserts. Former education Minister Hamon also advocates a renegotiation of the prices of pharmaceuticals to make expensive treatments more affordable, as well as a right to universal healthcare irrespective of the professional or personal status.

Candidate Emmanuel Macron, for his part, plans a reduction of healthcare costs of €15 billion by betting on prevention. He claimed that all “useful healthcare” will be 100% reimbursed, and that hospital organization will be improved.

The Green Yannick Jadot plans to make health a national priority. His objective will be to reorient the French health system towards prevention and proximity, fighting upstream against chronic diseases and, reaffirming the primacy of social security with regard to complementary healthcare insurance. He also aims at fighting environmental pollution (including Endocrine disruptors and air pollution).
Front National’s candidate Marine Le Pen, who was not present at the conference either, promises to guarantee social security for all French people and to fight against social fraud. She also foresees to cancel the State Medical Aid to illegal immigrants, an intention which she shares with Fillon and with Nicolas Dupont-Aignan, candidate from the right party “Débout la France”. Dupont-Aignan wants to increase reimbursement tariffs for the most expensive healthcare and, contrary to Fillon or Jadot, to put an end to the so-called generalised third-party payments. French AIM member FNMF launched its initiative “Place de la Santé”, on 1 December 2016. Its website is meant to challenge the candidates in the presidential election on health and social protection issues. The initiative helps raise public awareness on healthcare related issues and definitely contributes to putting healthcare higher on the political agenda. An example to be followed and implemented in other countries. More information here.

THE NETHERLANDS

JOINT PROCUREMENT OF PHARMACEUTICALS

The eight Dutch Academic Hospitals start with joint procurement of expensive pharmaceuticals. For the time being this experiment will be limited to immunotherapy against cancer. Such therapy costs currently ten thousands of euros per patient per year. The hospitals will also purchase anti-inflammatories.

In addition, the hospitals are planning to publish the discounts they receive. That would be something new. Pharmaceutical companies now often agree with the purchaser that such information would remain confidential. Due to the current confidentiality, hospital now not know whether they have negotiated a good price.

Costs considerably higher

Academic hospitals saw themselves in recent years confronted with significantly higher prices and costs of pharmaceutical, mainly due to new drugs against cancer. Expenditure on pharmaceuticals in the Academic hospital of Rotterdam almost doubled in the last six years, from 100 million in 2010 to 180 million last year. Several expert have mentioned recently on Dutch TV that the current model is unsustainable.

INTERNATIONAL

A DIGITAL LIBRARY FOR SOCIAL PROTECTION

In February, the Education and Solidarity Network (ESN) launched a digital library compiling educational modules, training materials, communication and advocacy, drawings, articles, reports and reference texts on solidarity-based social protection and mutuality.

This library aims to compile the rich but fragmented documentation on the subject and to make it more easily accessible and usable by all. This will also enable to develop an inventory of the documents available and, if necessary, to launch initiatives to update the existing or to co-write new media.

We invite you to send ESN any document you wish to publish in the library at this address: rchave@mgen.fr
**Call for Proposals, Consultations**

Open Public Consultation on possible activities under a ‘Commission Communication on a One Health Action Plan to support Member States in the fights against Antimicrobial Resistance (AMR)’
27.01.2017 - 28.04.2017

20.12.2016 - 20.03.2017

Public consultation on Building the European data economy
10.01.2017 - 26.04.2017

Public Consultation on the rules on liability of the producer for damage caused by a defective product
10.01.2017 - 26.04.2017

**Planned**

Evaluation of the Fee System of the European Medicines Agency
September 2017

**Studies, Videos, Positions**

New Health Technologies: Managing Access, Value and Sustainability
OECD - January 2017

NCI Tobacco Control Monograph Series 21 - The Economics of Tobacco and Tobacco Control
National Cancer Institute and WHO - January 2017

Advancing the right to health: the vital role of law
WHO - 16 January 2017

**Health Events in Europe**

**March**

1-2
Workshop on Structured Cooperation between Health Systems in Sliema (Malta)

21
The Digital Single Market: How does it benefit consumers? in St Julian's (Malta)

28
EAPM (European Alliance for Personalised Medicine) Annual Conference in Brussels (Belgium)

**April**

20
Health information in the European Union - The ERIC as a tool* in Brussels (Belgium)

24
Noise in Europe in Brussels (Belgium)

**May**

10-12
eHealth Week in St Julian’s (Malta)

28
Active and healthy ageing – Addressing the challenges of multi-medication in Europe's elderly population in Brussels (Belgium)