EU COUNCIL

HUNGARY EU PRESIDENCY

The Council officially adopted on 27/05 the Directive preventing falsified medicines from entering into the legal supply chain. The directive amends directive 2001/83 and reflects a first-reading agreement with the European Parliament reached during the Belgian presidency. The EP adopted the same text already on 16/02/2011. A main aspect to address falsified medicines concerns the use of safety features for prescription medicines to allow verification of the authenticity and identification of individual packs throughout the supply chain. The new directive also contains provisions aimed at protection patients from receiving falsified medicines through the sale of medicines via the internet. Member states have 18 months in which to transpose the new rules into national law. More

EPSCO COUNCIL MEETING, 6 JUNE

The Health ministers will have a meeting on 6 June. The main issues of the meeting are:

- The European Pact for Mental Health and Well-being: results and future action
- Innovation in the medical device sector
- Childhood immunisation: successes and challenges of European childhood immunization and the way forward
- Towards modern, responsive and sustainable health systems
The report is available here.

More from OECD

RESEARCH FUNDING

TECHNOLOGIES (FET) PROJECTS TO COMPETE FOR LONG-TERM CARE

On 18 May 2011, the OECD published a report co-financed by DG Health & Consumers entitled: “Help Wanted? Providing and Paying for Long-term Care”. It is estimated that people aged 80+ in the OECD countries (which includes the 27 EU Member States) will grow from 4% in 2010 to 10% in 2050. At the same time, family ties are becoming looser. This will challenge long-term care services and systems. The report looks at how countries can provide the necessary care for older people, despite the ageing demographic and societal changes. It is organised in 10 chapters (327 pages) and covers the following topics:

- The growing demand for long-term care in the context of ageing societies.
- Demographic projections and their implications for long-term care labour markets and expenditure.
- The role of family carers and the impact of caring on carers' mental health, poverty and labour market participation. Policies to support family carers.
- A review of employment and work conditions in formal long-term care labour markets. Strategies to attract and retain care workers to the sector.
- An analysis of public and private coverage schemes for long-term care in OECD countries.
- Financing policies to improve access while keeping costs under control.
- Options to improve value for money from long-term care services. Efficient management of the interface between health and care.

The report is available here. More from the Commission.

CONSUMER PROTECTION

SAFETY OF GOODS: FEWER DANGEROUS PRODUCTS SLIPPING THROUGH THE NET, WHILE SAFETY AT SOURCE A KEY OBJECTIVE

Thanks to the increasing effectiveness of the EU's rapid alert system for non-food dangerous products ("RAPEX"), a record 2,244 unsafe products were banned, withdrawn from the market or recalled from consumers in 2010 (up 13% compared with 2009), according to the 2010 annual RAPEX report published on 12/05. Safety at source has become a key focus – with attention now moving right back to the factory floor (design and manufacturing), and work with international partners is growing, in particular with China. FAQ - more

DIGITAL AGENDA

COMMISSION SELCTS FUTURE AND EMERGING TECHNOLOGIES (FET) PROJECTS TO COMPETE FOR RESEARCH FUNDING

The European Commission selected six research projects to compete for two top spots in the area of research into future and emerging technologies (FET). The six contenders will receive around €1.5 million each to refine their proposal for one year, after which only two will be selected. The aim of these flagship initiatives will be to deliver major breakthroughs in information and communication technologies (ICT), with the potential to provide solutions to some of society's biggest challenges. The two initiatives selected for long-term funding will run for 10 years, each with a total budget of up to €100 million per year. Here the projects which concern among others the health area:

- Guardian Angels for a Smarter Life: tiny devices without batteries that act like autonomous personal assistants, and which can sense, compute and communicate potentially even while travelling through your bloodstream.

- IT Future of Medicine: digital technology has the power to deliver individualised medicine, based on molecular, physiological and anatomical data collected from individual patients and processed on the basis of globally integrated medical knowledge.

- Robot Companions for Citizens: soft skinned and intelligent robots have highly developed perceptive, cognitive and emotional skills, and can help people, radically changing the way humans interact with machines.

More - MEMO_EN – MEMO2_EN - Speech by Vice-President Kroes "Pushing science beyond fiction"

eHEALTH

EHEALTH ACTION PLAN 2012 – 2020

End of May, AIM submitted its contribution to the public consultation on the eHealth Action Plan (eHAP) 2012-2020.

EHEALTH: CHALLENGES AND OPPORTUNITIES FOR THE FUTURE

European Commission Vice-President Neelie Kroes issued on 10/05 a stern warning to Europe's health ministers that eHealth is an essential investment regardless of budget constraints. "It would be simply unacceptable if public policymakers did not commit to giving patients access to these solutions, even if this requires investment and structural changes to our health systems" Kroes said. A recent study across The Netherlands, UK and Germany showed that home telemonitoring systems and nurse support via the telephone could improve survival rates by 15%, reduce hospital stays by 26% and make 10% overall cost savings. The eHealth Ministerial Conference 2011 in Budapest was part of the 10-12 May eHealth week co-organised by the Hungarian Presidency and the European Commission. Kroes Speech_EN

EHEALTH SURVEY SHOWS MOST HOSPITALS ONLINE BUT TELEMEDICINE SERVICES NOT FULLY DEPLOYED

More than 90% of European hospitals are connected to broadband, 80% have electronic patient record systems, but only 4% of hospitals grant patients online access to their electronic records, according to the results of a survey conducted for the European Commission. European hospitals are more advanced than US hospitals in terms of external medical
exchange, but they lag behind in using eHealth to view laboratory reports or radiology images. The survey provides useful data for the work of the EU eHealth Task Force on assessing the role of information and communications technologies (ICT) in health and social care, which is due to suggest ways for ICT to speed up innovation in healthcare to the benefit of patients, carers and the healthcare sector. The EU eHealth Task Force met for the first time in Budapest on 10th May (see IP/10/581). The deployment of eHealth technologies in Europe, with a view to improving the quality of health care, reducing medical costs and fostering independent living for those needing care, is a key objective of the Digital Agenda for Europe, which for example sets a 2015 deadline for giving patients online access to their medical data (see IP/10/199 and MEMO/10/200). More - Final report with Data annexes

EU TASK FORCE TO ADVISE HOW TO PROMOTE EHEALTH TO HELP PATIENTS AND HEALTHCARE SYSTEMS IN EUROPE

An EU eHealth Task Force to assess the role of information and communications technologies (ICT) in health and social care and to suggest ways for ICT to speed up innovation in healthcare to the benefit of patients, carers and the healthcare sector has met for the first time in Budapest on 10th May, chaired by Estonia’s President Toomas Hendrik Ilves. The high level advisory group comprises health care professionals, representatives of patients and of the medical, pharmaceutical and ICT industries, legal experts and policy makers. ICT applications already help to empower patients and address challenges faced by EU healthcare systems like an ageing population, a rise in chronic diseases, a shortage in health professionals and budget constraints by, for example, enabling remote diagnosis and treatment and secure sharing of patient records. However, there is considerable potential to develop eHealth much further in the future: allowing healthcare workers to dedicate more time to be with patients; enhancing self-help and independence of patients and elderly; and also to develop new modeling-based diagnostic techniques. More

KROES AND DALLI WELCOME COUNCIL PRESIDENCY EHEALTH DECLARATION ON DELIVERING BETTER HEALTH CARE

A Hungarian Presidency Declaration urging Member States to deploy eHealth services to the benefit of patients, healthcare workers and national healthcare systems has been welcomed by European Commission Vice-President for the Digital Agenda Neelie Kroes and Health Commissioner John Dalli. The Hungarian Presidency of the EU’s Council of Ministers presented the Declaration at the Ministerial eHealth Conference in Budapest on 10th May. The Declaration calls for patients to be able to exercise their rights to receive care in another Member State, and supports the roll-out of telemedicine and telemonitoring notably for remote management of conditions such as diabetes and to reduce the hospitalisation of chronic heart failure patients. The Declaration also refers to the role eHealth and telemedicine can play to respond to the challenges of ageing populations faced by an increase in chronic diseases and a shortage of healthcare workers.

HEALTH

A EUROPEAN APPROACH TO PERSONALISED MEDICINE

On 12 and 13 May 2011, the Commission organised for the first time a conference on personalised medicine. This is a growing field of healthcare which uses patients’ individual characteristics to better predict, prevent and treat or cure diseases. The aim was to bring together policymakers, industrial and academic researchers, patients, clinicians and other stakeholders in order to identify and prioritise future actions needed at European level to foster innovation in personalised medicine and encourage its rapid uptake in clinical practice. Conference programme – Slides of the presentations. More – John Dalli speech

OVERVIEW ON MEMBER STATES’ SMOKE-FREE REGULATIONS

According to conservative estimates, over 79,000 adults, including 19 000 non-smokers, died in the EU-25 in 2002 due to exposure to tobacco smoke at home (72 000) and in their workplace (7 300). A Eurobarometer survey of March 2009 found 84% of EU citizens in favour of smoke-free offices and other indoor workplaces, 77% in favour of smoke-free restaurants, and 61% supporting smoke-free bars and pubs. Currently, 15 EU countries have comprehensive smoke-free laws in place. Ireland, the UK, Greece, Spain and Hungary have the strictest smoke-free provisions with a complete ban on smoking in enclosed public places, on public transport and in workplaces. Detailed overview of Member States’ smoke-free regulations (As of May 2011)

HEALTH POLICY FORUM: MEETING ON 19 MAY

The Health Policy Forum held a meeting on 19 May. Following presentations were made:

- European Innovation Partnership on Active and Healthy Ageing (AHAIP)
- The activities of the Hungarian Presidency in the field of health
- Health Security in the EU – Stakeholder consultation on Health Security in the European Union

A debate took place on a Commission “Note for the Health Policy Forum on the Future of the Health Programme of the EU” post 2013”. More information is available here.

EUROPEAN WEEK AGAINST CANCER: A JOINT COMMITMENT TO PREVENT CANCER

Every year nearly 2.5 million EU citizens are diagnosed with cancer, which is also the second most common cause of death in Europe (29% of deaths for men, 23% for women). This figure is expected to rise due to the ageing European population. However, it is estimated that around one third of cancers could be prevented if people made healthier choices (or if people adopted healthier living habits). This year’s “European Week Against Cancer” held at the end of May, is one of the activities of the European Partnership for Action Against
Cancer – in which AIM participates-, focused on healthy living.  More

**COMMISSION DIRECTORATE FOR HEALTH KEY ACHIEVEMENTS 2010**

DG SANCO published a brochure on its key achievements on health policy in 2010. More

**INTERNAL MARKET**

**TAXATION: COMMISSION REFERS SPAIN TO COURT OVER REDUCED VAT RATE FOR MEDICAL EQUIPMENT**

The European Commission has decided to refer Spain to the EU's Court of Justice concerning its illegal application of a reduced rate of value added tax (VAT) to general medical equipment, appliances to alleviate animals' physical disabilities and substances used in the production of medicines. These goods do not qualify for a reduced VAT according to the rules laid down in the VAT Directive, and the application of a reduced VAT rate may distort competition within the EU. More

**PHARMACEUTICALS**

**CONSULTATION ON TRANSPARENCY DIRECTIVE**

End of May, AIM forwarded its contribution to the European Commission consultation on a possible revision of the Transparency Directive 89/105/EEC.

**CONSULTATION ON CLINICAL TRIALS DIRECTIVE**

On 12/05 the Medicines in Europe Forum (MiEF) and AIM submitted a joint contribution to the public consultation on a possible revision of the clinical trials Directive 2001/20/EC.

**RESEARCH**

**NEW EU RESEARCH INFRASTRUCTURES ON BIOLOGICAL SCIENCES WILL HELP TACKLE CLIMATE CHANGE, DISEASE AND THREATS TO FOOD SUPPLY**

Research Ministers and the Commission have given the green light to three new pan-European biological science research infrastructures. These extensive new facilities will help boost research and innovation on key societal challenges such as climate change, health and maintaining sufficient supplies of high quality food. The UK will lead in setting up an infrastructure on systems biology with applications expected in the pharmaceutical, healthcare and agricultural sectors. The new infrastructure, to be developed in France and Germany, will significantly enhance pan-European access to viruses, bacteria and fungi needed for research on infections affecting humans and crops, as well as for research on bio-security. These infrastructures are part of the new updated Roadmap of the European Strategy Forum on Research Infrastructures (ESFRI). The overall investment for their construction is about € 0.7 billion.

**SOLVENCY II**

**SUMMARY OF RESPONSES TO THE CONSULTATION ON THE SOLVENCY II LEVEL 2 IMPLEMENTING MEASURES**

A summary of the responses received to the consultation carried out on the Solvency II level 2 implementing measures was published on 5 May. The purpose of the consultation was to obtain input on the impact of the implementing measures on insurance markets, insurance products and consumers and on the wider social or economic environment. The responses show that stakeholders’ concerns relate to a small number of key issues, namely the impact on long-term products, volatility and pro-cyclicality, proportionality and limiting the reporting burden and the need for transitional measures in certain areas. The Commission Services have set up working parties to develop solutions to several of these issues. The responses together with the results of the fifth quantitative impact study (QISS) will serve as input when preparing the impact assessment, which will accompany the Commission's proposal for the level 2 implementing measures. The summary can be found here.

**EUROPEAN PARLIAMENT**

**POSTPONEMENT OF THE EUROPEAN MEDICINES AGENCY 2009 BUDGET DISCHARGE**

The EP approved on 10/05 the lion’s share of the EU's budget spending for the financial year 2009 under the 'budget discharge procedure' but decided to postpone the discharge for the Council of Ministers, the European Medicine Agency and the European Police College. As regards the European Medicines Agency (EMEA), MEPs believed there was no proper guarantee of the independence of experts hired to carry out scientific evaluations of human medicines and that some experts had conflicting interests in the case of the evaluation of the anorectic Benfluorex. The report also criticises the EMEA’s management of procurement procedures and its lack of criteria for recruiting staff. More

**DEBATE ON FUTURE OF SERVICES OF GENERAL INTEREST**

The EP Employment Committee debate and vote on the Future of Social Services of General Interest Report has been deferred to an extraordinary meeting of the EMPL committee in Strasbourg on the evening of Monday 6 June 2011. The plenary vote is foreseen, as planned, for the 22 & 23 June plenary session in Brussels.

**SOCIAL AFFAIRS**

**10TH MEETING OF PEOPLE EXPERIENCING POVERTY TO FOCUS ON THE REALITY OF WORK**

The annual European Meeting of People Experiencing Poverty took place in Brussels 13-14/05. Organised jointly by the Hungarian presidency of the EU, the Commission and the European Anti-Poverty Network, the event aimed to ensure the voices and experiences of people living in poverty are heard. Through dialogue with decision-makers, the 10th meeting focused on the situation of people experiencing poverty and employment, particularly in the current difficult climate of fiscal consolidation.
EU COURT OF JUSTICE

THE WAY FORWARD FOR CANVASSING AND COMMERCIAL COMMUNICATION FOR HEALTH PROFESSIONALS?

No 30/2011 : 5 April 2011 Judgment of the Court of Justice in Case C-119/09 Société fiduciaire nationale d'expertise comptable (es de el en fr it).

STAKEHOLDERS

COCIR POSITION PAPER ON INNOVATION-DRIVEN HEALTHCARE MODEL

Active and Healthy Ageing has been chosen for the first European Innovation Partnership (EIP) showing that it is a top-priority for the EU. In this context COCIR – the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry - launched in May a Position Paper "Towards an innovation-driven healthcare model" which highlights the major contribution of healthcare technologies to innovation and competitiveness in Europe. More

GENERAL NEWS

HEALTH INSURANCE

REFORM

27 MILLION UNINSURED AMERICAN WOMEN STAND TO GAIN BIG UNDER US HEALTH REFORM

Once it is fully implemented in 2014, the Affordable Care Act is expected to cover nearly all of the estimated 27 million working-age women in America who were uninsured for some time in 2010, a new Commonwealth Fund analysis finds. Indeed, women have greater health care needs than men, and generally play larger roles in the health care of family members. Women who seek coverage in the individual insurance market face additional hurdles—few plans offer maternity coverage and, in most states, insurance carriers charge higher premium rates to young women than men of the same age. In 2010, nearly half of women ages 19 to 64 skipped needed care because of the cost, up from one-third in 2001. Meanwhile, health care costs are swallowing a greater share of women's incomes, with low- and moderate-income women most affected, says the report. So, with the US reform, women stand to benefit from free coverage of preventive care services like mammograms, small business tax credits, new affordable coverage options and premium subsidies, and insurance market reforms, including a ban on charging women higher premiums. More

TRENDS

HEALTH INSURANCE COMPANY BUYS 28 DUTCH MEDICAL CENTRES

Zorgpunt, operating 28 medical centres, is a subsidiary of the health insurance company Menzis, which owns half the shares of Zorgpunt, says the BMJ. The remainder are owned by an investment group, Reggeborgh. Zorgpunt was launched last year by Menzis to fulfil its mission “to roll out good care better than those of its peers, says the NEJM. There are, however, health care organizations that deliver high-quality care at a cost roughly 20% lower than the average. If the rest of the U.S. health care industry followed their example, health care spending would drop from 17% of the gross domestic product to 13%. Though that would still be well above the spending level in other high-income countries, $640 billion would become available for addressing other important public- and private-sector needs. Why don’t cost-effective models diffuse rapidly in health care, as they do in other industries? The answers to this $640 billion question lie in the perceptions and behaviors of the major participants in health care. More

COST-EFFECTIVE HEALTH SYSTEM

WHY DOES COST-EFFECTIVE CARE DIFFUSE SO SLOWLY IN THE U.S.?

The U.S. health care must become more cost-effective, as it spends much more per capita on health care than do other developed countries, with broad outcomes no better than those of its peers, says the NEJM. There are, however, health care organizations that deliver high-quality care at a cost roughly 20% lower than the average. If the rest of the U.S. health care industry followed their example, health care spending would drop from 17% of the gross domestic product to 13%. Though that would still be well above the spending level in other high-income countries, $640 billion would become available for addressing other important public- and private-sector needs. Why don’t cost-effective models diffuse rapidly in health care, as they do in other industries? The answers to this $640 billion question lie in the perceptions and behaviors of the major participants in health care. More

DISEASE DEFINITION

WHO SHOULD DEFINE DISEASE?

New diagnoses are as dangerous as new drugs, according to Ray Moynihan in an article in the BMJ. “We have remarkably casual procedures for defining the nature of conditions, yet they can lead to tens of millions being treated with drugs they may not need, and that may harm them.” Last year an international panel of professional societies changed the definition of gestational diabetes. The blood glucose threshold for diagnosis was substantially lowered, more than doubling the number of women with the diagnosis. It will now encompass almost one in five pregnancies. The author highlights this as just the latest example of how the definitions of common conditions are being broadened, so much so that by some estimates, almost the entire adult population is now classified as having at least one chronic disease. And underlying the decisions to broaden disease definitions are the conflicts of

AIM Flash editor: Dr Ph. Swennen
interest embedded among the decision makers. For example, of the panel members responsible for the current set of psychiatric definitions in DSM-IV, 56% had financial ties to drug companies. So, the author proposes a panel with zero tolerance on experts with financial conflicts of interest, like in the FDA and NIH in the US or NICE in the UK. Furthermore, he proposes to broaden the panel to people representing the wider public interest, since civil society has a major stake in decisions about where normality ends and disease begins. Such panels will of course need good evidence on which to base their decisions, including evidence on the cost effectiveness of changing a diagnostic category. More

### ELECTRONIC HEALTH RECORD

**ENGLAND: NATIONAL IT SYSTEM DOES NOT OFFER GOOD VALUE FOR MONEY**

The £2.7 billion spent so far on care records systems does not represent value for money, concluded a report of the National Audit Office. And, based on performance so far, the NAO has no grounds for confidence that the remaining planned spending of £4.3 billion on care records systems will be any different. The rate at which electronic care records systems are being put in place across the NHS under the National Programme for IT is falling far below expectations and the core aim that every patient should have an electronic care record by 2010 will not now be achieved. Even where systems have been delivered, they are not yet able to do everything that the Department intended, especially in acute trusts. “This is yet another example of a department fundamentally underestimating the scale and complexity of a major IT-enabled change programme” said the NAO head. More

### EVIDENCE OF DISEASE MANAGEMENT

**GERMAN DIABETES MANAGEMENT PROGRAMS IMPROVE QUALITY OF CARE AND CURB COSTS**

Impact of disease management programs is still uncertain, according to an article in Health Affairs. A four-year study of nearly 20,000 enrollees in a diabetes management program in Germany (Barmer health insurance), where more than 14 % of total health spending is for diabetes care, overall mortality for patients, complications, frequency of hospitalisation and drug and hospital costs were all significantly lower for patients in the program compared to the control group. The German disease management program is based in primary care practices and carried out by physicians, and it draws on their personal relationships with patients to promote adherence to treatment goals and self-management. The study presents evidence supporting the fact that the reorganization and integration of chronic care into the patient care setting with physicians’ participation improves outcomes in diabetes care. More

### HEALTH WORKFORCE

**ONLY A FIFTH OF US MEDICAL STUDENTS CHOOSE PRIMARY CARE**

While the primary care workforce shortage is a bottleneck to implementation of health care reform, the US faces a the same time a declining number of medical students choosing primary care careers, a survey showed in the BMJ. Medical students are increasingly likely to be female (52%) and to graduate with greater debt: 86% of 2009 graduates owed an average educational debt of $158 000. Money figures prominently in the choices made by graduating students. The income gap between generalist and specialist doctors has widened over the years. Over a 40 year career a specialist can expect to make $3.5m more than a primary care physician. “In high performing nations around the world 50:50 is a better mix”, says the author. To encourage medical students to enter primary care, policy makers must rebalance income distribution between generalists and specialists. More

### ‘NON-PHYSICIAN CLINICIANS’ IN LOW INCOME COUNTRIES: A SOLUTION OF THE SHORTAGE OF DOCTORS

The depletion of human resources in the most deprived countries has forced to question traditional roles and responsibilities within the healthcare system, in order to reach the Millennium Development Goals for health, according to the BMJ. Much resistance remains, however, to the concept of delegating surgery to non-physician clinicians. One of the most burning topics is “task shifting” of life saving comprehensive emergency obstetric care - including caesarean sections - from conventionally trained doctors to “non-physician clinicians.” A study of the Karolinska Institute (Stockholm) in 2010 reviewed task shifting of major surgery to mid-level providers of healthcare. It found no clinically significant differences in the outcomes of caesarean section when postoperative assessment is carried out by non-physician clinicians or specialists in obstetrics. Also, the professional performance of non-physician clinicians and their high retention rates (90% after seven years compared with 0% for physicians) in rural hospitals indicate that they perform extremely well. More

### TIME TO RETHINK THE WAY FRONT LINE BACK CARE IS DELIVERED

Back pain contributes substantially to workload and healthcare costs in primary care, says the BMJ. The author raises a question: to continue to organise primary care for musculoskeletal problems around GPs or to develop the education and evidence base of physiotherapists and osteopaths to be the gatekeepers for this condition? Indeed, the first person seen by the patient with back pain is most often the GP. Surveys indicate, however, that GPs receive little training in common musculoskeletal problems and that they feel ill equipped, either relying on pharmacological management or subsequently referring patients to specialists or to osteopaths. So, one solution is for professionals other than the GP to act as first port of call for musculoskeletal problems. The minority of patients who need more extensive investigation and patients with complex health problems would be referred to the GP, improving the efficiency of general practice. More

### LONG TERM CARE

**SPENDING FOR SENIORS TO DOUBLE OR MORE BY 2050**

Spending on long-term care in OECD countries, which now accounts for 1.5% of GDP on average across the OECD, is set to double, even triple, by 2050, driven by ageing populations, according to a OECD report “Help Wanted? Providing and paying for long-term care” -
Sweden and the Netherlands today spend the most, at 3.5% and 3.6% respectively of GDP, while Portugal (0.1%), the Czech Republic (0.2%) and the Slovak Republic (0.2%) spend the least. Half of all people who need long-term care are over 80 years old. Major reforms to attract more care workers and retain them in the sector should be put in place quickly. Upgrading the status of the long-term care workforce by improving pay and working conditions is key. To meet future demand, countries will also need to attract more migrants who already make up a substantial part of long-term care workers in many OECD countries; from around one in four in Australia, the UK and the US, for example, to one in two in Austria, Greece, Israel and Italy.

Governments will need to find a balance between offering access to good-quality care and making their systems financially sustainable, the report says. Around 70% of long-term care users receive services at home, but spending in institutional care accounts for 62% of total spending. Respite care, encouraging part-time work and paying benefits to family carers can all be cost-effective policies, reducing demand for expensive institutional care. Countries have to spread the burden of such high costs, either by targeting universal benefits to those most in need of care or via public-private partnerships. Private insurance could play a role in some countries, the report notes, but is likely to remain a niche market unless made compulsory.

**Summary and conclusions**

**MEDICAL DEVICES**

**MEDICAL DEVICES MARKETING IN EUROPE: QUICKER THAN IN THE US, BUT AT THE EXPENSE OF PATIENT SAFETY**

The conditions in Europe favour medical technology companies: they can obtain regulatory approval more quickly and generate revenues faster, according to an industrial mentioned in an article in the *BMJ*. But not everyone agrees that this is the best for patients, like the US FDA which said about what happens in the EU: “We don’t use our people as guinea pigs in the US.” In Europe, decisions about marketing a new medical device are made by private notified bodies, accredited by national regulators, which can certify that a product complies with the CE marking directive (Conformité Européenne). For the highest risk devices (class III), the manufacturer must conduct some human clinical investigations, but these needn’t be randomised clinical trials or evaluate effectiveness or prove any effect on clinical outcomes. Furthermore, the information about the basis for the approval decisions is not publicly available. Lastly, post-market surveillance has not been addressed sufficiently, as company reporting is often slow and not transparent. Postmarketing studies and clinical registries to track outcomes in real time after should be the norm. There is a urgent need to review the directive on medical devices. **More**

**SAFETY OF MEDICAL DEVICES: URGENT NEED OF BETTER REGULATION AND POSTMARKETING SURVEILLANCE**

Thousands of people face painful and expensive surgery to remove failing medical devices, such as metal hip replacements and cardiovascular implants, according to investigations by the BMJ and Channel 4 Dispatches. They raise serious concerns about the regulation of medical devices and ask how well these high risk devices are tested before they come on to the market. Usually there is no need to provide proof of clinical efficacy of a medical device and the sale of devices is not usually evidence based. The investigations explore a European approval process negotiated by private companies behind closed doors and reveal a worrying lack of public information about the number of devices being used and their potential risks. They also discuss links between surgeons paid to design devices and the companies promoting them. The investigations’ findings are clear. The current system is not fit for purpose, and we urgently need better regulation to protect patients. **More in the BMJ** (with several complementary articles)

**PHARMACEUTICALS AND TRIPS**

**INDIA, MERCOSUR "MUST WITHSTAND EU PHARMA DEMANDS"**

Nations currently negotiating trade deals with the European Union (EU) have been warned that they must resist European demands which could threaten access to medicines in emerging and developing countries, According to *Pharmatimes*. During the EU-India FTA negotiations, the EU has been calling on India to enforce a stricter IP (intellectual property) regime that is provided by its national legislation and the WTO’s Trade-Related Intellectual Property Rights (TRIPs) agreement. Specifically, the EU has said that India must adopt data exclusivity provisions, which would prolong the market monopoly period for brand-name drugs. But doing so would threaten India's position as the "pharmacy of the developing world." with a generics industry which is worth more than $20 billion and exports 50% of its production, says Health Action International (HAI). HAI accuses the EU of taking “a simplistic view of IP, based on its assumptions that the more stringent the IP protection the better. It fails to consider the adverse effects of high levels of IP protection on technology transfer, innovation, development and public health for emerging and developing countries". **More**

**PREVENTION**

**PREVENTIVE DRUGS SUCH AS STATINS, ANTHYHPERTENSIVES, AND BISPHOSPHONATES: NO EVIDENCE ON EFFECTIVENESS OR COST EFFECTIVENESS**

Even if an intervention is successful in a study, it may not succeed similarly in real life settings, according to the *BMJ*. This gap between the ideal (data from randomised trials in idealised populations) and clinical circumstances raises the question of how well our most widely used preventive drugs work in real life. Thus, although there are claims that important preventive drugs such as statins, antihypertensives, and bisphosphonates are cost effective, there are no valid data on the effectiveness, and particularly the cost effectiveness, in usual clinical care. The European Medicines Agency require the drug industry to provide comparisons of all new medicines with placebo only. The author insists to put an end to this kind of gaming of the system and start to advocate true comparative effectiveness research on all preventive healthcare,
chronic non-communicable diseases, and give the systems to improve access to quality care, tackle influenza and other emergencies, strengthen health capacity of all countries to respond to pandemic.

**WHO**

**FINANCIAL AUSTERITY FOR THE WHO**

In the the Sixty-Fourth World Health Assembly, Member States reached agreements that expand the capacity of all countries to respond to pandemic influenza and other emergencies, strengthen health systems to improve access to quality care, tackle chronic non-communicable diseases, and give the

**NEWSPAPER**

**HEALTH AFFAIRS**

- May edition: Environmental Challenges For Health. The environment plays a role in nearly 85% of all disease. 
- From endocrine disruptors to nanomaterials: advancing our understanding of environmental health to protect public health.

**BOOKS - REPORTS – LINKS**

**EU LAW AND HEALTHCARE**

- “Healthcare and EU law” Asser Press 2011, 450 p. This book analyses several aspects of the impact of EU legislation on healthcare systems. As Member States have increasingly experimented with new forms of funding and the delivery of health-care and social welfare services, health-care issues have not escaped scrutiny from the EU internal market and from competition and procurement rules.

**EU LAW SOCIAL POLICY GOAL**

- “The EU needs a social investment pact”, European Social Observatory (OSE) Opinion paper No. 5, May 2011, 25p. Three of the leading EU social scientists argue that important long-term EU social and economic policy goals must not fall victim to short-term policy considerations triggered by the banking crisis that hit the global economy in 2008. They encapsulate these long-term goals in the notion of a “social investment imperative” and warn for the dangerous mix of welfare chauvinism and fiscal austerity nationalism dividing Europe.

**HEALTHY AGEING**

- Promoting health in schools The paper emphasizes a concept of capacity building to find how the implementation of health promotion in schools can be supported. Findings have shown that schools need support from their environment not only in building resources (such as Human and Financial resources) but also in institutionalising health promotion (through networks and partnerships) into their core and management process.

**READERS’ DIGEST**

**HEALTH PERFORMANCE**

- “Hot Topic: Health Spending. Do countries get what they pay for when it comes to health care?” Conference Board of Canada. Canada’s health spending per capita is the fourth-highest of 17 countries assessed in the study on Health Spending rankings. But Canada ranks just 10th in overall health performance. Several countries spend less than Canada yet have healthier populations overall.

**INFORMATION HEALTH TECHNOLOGIES**

- What impact of IHT on healthcare systems in Germany and the UK?, Healthcare analysis. In differentiated organization of healthcare systems, due to different socio-cultural contexts, the implementation of IHT exercised a different impact on patients and health providers in both countries. Therefore, while a similar reasoning was followed according to which an introduction of IHT would help manage healthcare systems, the paper shows that existing patterns of healthcare systems were also reproduced during the implementation process.

**PATIENT PERSPECTIVE**

- Pay-for-performance in hospitals to measure Quality improvement. Health Affairs. The paper focuses on pay-for-performance (P4P) measures as a tool to assess the quality of care in hospitals. Examining the effects in 260 hospitals of a P4P demonstration project, the findings show that there is a need to tailor P4P programs to hospitals' specific situations as improvements in quality of care were observable mainly in hospitals that were the largest, well financed or operated in less competitive markets.

**PATIENT PERSPECTIVE**

- “Does the healthcare supply reform in France answers to the patient worries” (FR). IRDES. This study reveals that the users of the health-care system are primarily worried by two aspects: the doctor-patient relationship and in particular the
information exchange and the perceived quality of the clinical examination (duration of the consultation, currently 16 minutes on average, influencing the point of view in a relatively important way). The healthcare coordination is also an issue for the users: they put forward the role of the GP as “gatekeeper” in the health system, but they are not much concerned with the internal organization of the medical structure (pluridisciplinarity, team work) and to the age or sex of the doctor.

QUALITY MEASUREMENTS

- How to measure the quality of healthcare? The paper identifies five major recommendations to assess quality in healthcare, to help overcome the current deadlock between scientists and politicians regarding the capabilities of the current science of quality measurement. These include topics on validity and transparency, standard surveillance, performance change over time, tools to prioritize measures and an independent evaluating agency.

SOCIAL DETERMINANTS OF HEALTH

- Social determinants approaches to public health: from concept to practice, WHO, 2011

PHARMACEUTICAL SECTOR


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SPENDING FOR SENIORS TO DOUBLE OR MORE BY 2050

Spending on long-term care, which now accounts for 1.5% of GDP on average across the OECD, will rise accordingly. Sweden and the Netherlands today spend the most, at 3.5% and 3.6% respectively of GDP, while Portugal (0.1%), the Czech Republic (0.2%) and the Slovak Republic (0.2%) spend the least.

Source: OECD 2011

EVENTS

HUNGARIAN EU PRESIDENCY (SELECTION)

TRIO PRESIDENCIES

1/2010-6/2011: Spain, Belgium, Hungary
7/2011-12/2012: Poland, Denmark and Cyprus

HUNGARIAN EU PRESIDENCY (1-6/2011)

6-7 June: Informal EPSCO
24 June: European Council

OTHER EVENTS

The AIM pharmaceutical expert group met on 26 May. Following topics were discussed:

- The AIM contribution to the public consultation on the revision of the Transparency Directive
- The Process on corporate responsibility in the field of pharmaceuticals
- Feedback on Commission meeting on 22 March on Medical devices
- EUnetHTA stakeholder Forum

- Angelika Kiewel reported on a register in Germany of artificial hip and knee medical devices
- Laure Lechertier reported on the Mediator case in France
- Ilaria Passarani from BEUC informed on an EMA consultation on pack design and labelling for OTC products

The monthly AIM Flash is compiled by Ph. Swennen, R. Kessler and M. Machalska.
For more information on one of the topics mentioned above, please contact the AIM Secretariat.

How to use the hyperlinks in this document? Press the Ctrl button and click simultaneously on the link.