



# NEWSLETTER

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## **HOPE CONFERENCES AND EVENTS CO-ORGANISED BY HOPE**



## THE SELECTED HOPE ACTIVITY OF THE MONTH

### ***RARE DISEASES – CENTRE OF EXPERTISE AND NETWORKS OF REFERENCE***

HOPE was invited for the first time to the European Union Committee of Experts on Rare Diseases Workshop on Initiatives and Incentives in the Field of Centres of Expertise for Rare Diseases on 8 and 9 December 2010. HOPE has been working for several years on this issue; the invitation was recognition of its commitment.

This meeting took place in the context of the discussion on the Directive on cross-border healthcare, with concerns and worries being raised about the "new Comitology" of the Lisbon Treaty. A first session of the workshop was devoted to centres of expertise in Europe and the second to European reference networks. The audience was made up of Member States representatives, European organisation active in the field (EURORDIS and ORPHANET) as well as several leaders of European Commission co-financed projects in the field of rare disease.

On this occasion, Orphanet presented its report on *Designated centres of expertise for rare diseases in Europe*. This report is based on data extracted from the Orphanet database in December 2010 and gives a list of all centres of expertise considered as being national centres of expertise for a certain rare disease/group of rare diseases present in the Orphanet database, by country and by town.

The centres of expertise, which are flagged as "designated" centres in Orphanet, are those centres, which are considered at national or regional level to be a centre of expertise for a rare disease/group of rare diseases. This is a global term, which includes the concepts of centres of reference, centres of expertise, reference centres, expert centres and centres of excellence. They are officially designated as such by health authorities at national/regional level. However, there is no common definition of what a centre of expertise is at European level, nor amongst Member States, which have established such centres.

Even amongst countries with official centres of expertise, the definition of a rare disease varies between centres of expertise in Europe. The UK uses a prevalence of 1 in 50.000, Sweden and Denmark use 1 in 10.000 whereas France, Italy and Spain use the European Orphan Drug Regulation definition of 1 in 2.000. The number and geographical distribution of centres in each country also varies though not proportionally in function of the size of the population, reflecting differences in the organisation of the health care systems. Several countries have a national approach (Bulgaria, UK, Belgium, France, Greece, Norway and the Netherlands), whereas others, such as Finland, Italy, Spain, and Sweden have a more regional approach. The majority of countries have not yet started to identify their expert centres.

Centres of expertise differ from one country to another: in form (reflecting the heterogeneity of national health systems); in focus (some centres of expertise specialise in one rare disease, some in several rare diseases with similar needs, some on technologies shared across several rare diseases) ; in the process used to identify, select and designate them. Concerning the latest, some have a specific policy regarding rare diseases and have established/will establish centres of expertise in this framework (Belgium, Bulgaria, Czech Republic, Denmark, France, Italy, Portugal, Spain and Sweden). Some have established centres of expertise but not specifically for rare diseases (Croatia, Finland, Greece, Ireland and the UK). Some have no centres with these denominations, although they have centres with all characteristics of a centre of expertise (Austria, Cyprus, Estonia, Germany, Hungary, Latvia, Lithuania, Luxembourg, Netherlands, Poland, Romania, Serbia, Slovakia, Slovenia, Switzerland and Turkey).

Orphanet presented also the draft Preliminary analysis of pilot European Reference Networks (ERNs) for Rare Diseases, based on the experience of EC-funded pilot European Reference Networks and other EC-funded networks for rare diseases. The activities of pilot ERNs reflect some of the specific actions needed at European level in order to improve the situation for patients suffering from a specific disease/group of diseases across Europe. As a result, the activities and aims of ERNs are extremely heterogeneous. The geographical coverage of these networks is also heterogeneous due to the choice of partners identified for the pilot and the availability of expertise from country to country. Despite this variability, the actions of these pilot ERNs have a European added value in the field of rare diseases, as highlighted in the analysis, as their actions would not have been possible without European collaboration and networking. The pilot ERNs have thus explored various networking possibilities and the benefits of networking in the field of rare diseases.

However, the ERNs do not cover all of the criteria established by the High Level Group/Rare Disease Task Force that influenced the content of the Directive on cross-border care. Due to the variability of these networks' aims, it is very challenging to establish a common definition of ERN and to establish criteria for carefully selecting, creating or assessing ERN in a field where resources are limited. ORPHANET recommends that the experiences of the pilot ERN should be taken into account to assess the suitability of the criteria defined by the HLG/RDTF, and possibly revise these criteria.

Concerning financing, Andrej Rys, Director of Direction C "Public health" of DG SANCO, had previously declared during the autumn that "now we have the Joint Actions, but we should have secured funding procedures and measures with the next Health Programme 2014-2019." This will of course depend also on the final results of the discussion on the cross-border directive.

## EU INSTITUTIONS AND POLICIES



### ***HUNGARIAN PRESIDENCY OF THE COUNCIL OF THE EU***

The Hungarian Presidency of the European Union will start on 1st January 2011. Hungary is the last member of the Spanish-Belgian-Hungarian presidency trio. Therefore, its programme fits into the trio programme and the priorities are built on the results delivered by the Spanish and Belgian Presidencies.

According to the information material, during the first half of 2011 the presidency will concentrate on the reinforcement of the economy and on job creation to make growth sustainable and the recovery from the crisis irreversible. 2010 has been characterized by decision making and planning. 2011 will be the year of action: Hungarian presidency foresees the implementation of the decisions taken in 2010 and use the opportunities offered by the new policies introduced by the Lisbon Treaty. Besides measures with a long-term perspective, the Hungarian Presidency will do its utmost to ensure the adoption of the 2011 budget in the shortest time possible.

The main priorities of the presidency in the healthcare field are the following:

- “Investing in health care systems of the future” (Prior topic of the Informal Employment, Social Policy, Health and Consumer Affairs Council Meeting in April)
- EU Health Workforce
- Health Security
- EU preparedness plan
- Childhood vaccination
- Mental health (Conference in Berlin in March 2011)
- eHealth (10 - 13 May 2011, Budapest)

The Hungarian presidency will be followed by the Polish presidency in the second half of 2011. On health and consumer protection, Poland intends to emphasize the improvement of public health, with particular reference to the narrowing of differences in the health situation of EU countries and countries of the Eastern Partnership. A review of the health policies of the EU states will be a significant goal of the Presidency. It will also assign importance to the early detection, prevention and treatment of non-infectious respiratory diseases, with particular reference to adolescents. Regarding the social policy and employment, the Polish presidency will focus on ways of reconciling professional and private life, stimulating professional activation in view of the demographic challenges, promoting pro-active attitudes in the labour market and an active social integration policy, promoting diverse forms of cooperation between the government administration, local governments and NGOs for the fulfilment of social and employment policy goals.

**More information:** <http://www.eu2011.hu/>

## **EPSCO – COUNCIL CONCLUSIONS**

The Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) is composed of employment, social protection, consumer protection, health and equal opportunities Ministers, who met this year three times. The last meeting of the Ministers was held on 6 and 7 December 2010 and completed with several conclusions on the following issues.

### **HEALTH CARE SYSTEMS IN EUROPE**

The Ministers exchanged views on the joint report of the Economic Policy Committee and the Commission on health care systems in Europe and drew the following conclusions. The Member States' health security systems are currently facing different pressures, such as the financial crisis, the ageing population and the need to make expensive investments. Health should not be considered as a budgetary adjustment variable, and preventive health measures should not be regarded solely as expenditure, but also as an investment, which may reduce expenditure. The Commissioner in charge of Health and Consumer Policy, John Dalli, emphasised that sustainability was not about cutting costs, but about higher cost-efficiency. The Economic and Financial Council taking place the same day as the EPSCO Council adopted conclusions on the joint report on health care systems in Europe.

### **EUROPE'S HEALTH WORK FORCE FOR TOMORROW**

The Council adopted conclusions entitled "Investing in Europe's health work force for tomorrow: Scope for innovation and collaboration", inviting the Member States to strengthen collaboration in forecasting future health workforce needs and to raise awareness of the importance of attractive working environments in motivating the health workforce. The Member States and the Commission are called upon to develop an action plan to tackle the key challenges for the health workforce throughout the EU in the medium and long-term perspectives. The Commission should include training and education of the health workforce as a priority area and consider how to make the best use of EU tools for financing this.

### **CHRONIC DISEASES**

The Council also adopted conclusions on innovative approaches for chronic diseases in public health and healthcare systems, inviting the Member States to further develop patient centred policies in the field of chronic diseases. The EU countries and the Commission are called upon to start a reflection process with a view to optimising the response to the challenge of chronic diseases. This reflection should cover inter alia health promotion and prevention of chronic diseases, healthcare, research into chronic diseases and comparison of chronic diseases at European level. The outcomes of the reflection process should be summarised in a paper by 2012.

### **JOINT PROCUREMENT OF VACCINES AND ANTIVIRAL PRODUCTS**

EU health Ministers exchanged views on progress towards putting in place a mechanism for the joint procurement of vaccines and anti-viral products. This mechanism results from the lessons learnt from how the A/H1N1 flu pandemic was handled, which revealed the difficulties encountered by a number of countries in acquiring the said products.

A large majority of delegations agreed that framework contracts that Member States may enter into on a voluntary basis constitute the most suitable form for a joint procurement. It is expected that this would strengthen the Member States' negotiating position in discussion with the pharmaceutical industry and ensure equitable access to vaccines. The need to further clarify some outstanding issues, such as the question of product liability and the compatibility with competition rules, before taking any decisions has been highlighted.

A broad majority of Ministers also recognised the need for a common minimum coverage of pandemic vaccines and agreed that the vaccines for covering this common minimum should be delivered prior to all other additional orders and on an equitable basis. Ministers wished to target the common minimum coverage at strategic sectors such as healthcare workers, police officers and fire-fighters. The suggestions for such a common minimum cover rate varied between 2% and 20%, with many delegations stressing the need to take account of national specificities as well. Some delegation considered the definition of a common vaccination strategy as a precondition for setting up a common minimum cover rate.

#### **PHARMA-PACKAGE**

The Commissioner in charge of Health and Consumer Policy, John Dalli, expressed the Commission's willingness to modify its proposals concerning information to the general public on medicinal products for human use, which are subject to prescription in order to take into account the concerns of the Member States. The incoming Hungarian Presidency announced its willingness to address this file as a matter of priority as soon as the modified proposal has been presented.

#### **INNOVATION AND SOLIDARITY IN PHARMACEUTICALS**

The Council adopted conclusions on innovation and solidarity in pharmaceuticals, calling upon Member States to take initiatives to promote the rational and responsible use of valuable innovative medicinal products with a view to obtaining an optimal clinical outcome and an efficient management of expenditure. The European Commission and the EU countries should continue to work towards a stronger prioritisation in the allocation of resources for pharmaceutical research to increase the probability of valuable innovations. They should also give priority to revising the clinical trials directive with the aim of ensuring an improved regulatory framework for developing medicinal products. Furthermore, they should examine the possibilities of enabling an efficient cross-border exchange of clinical data, and take appropriate initiatives to establish interoperable registries, for instance on rare diseases. They should also examine how to facilitate availability to innovative medicinal products throughout the EU.

#### **2012 – YEAR OF ACTIVE AGEING**

Ministers adopted a general approach on a draft decision designating 2012 as the European Year of active ageing, pending the adoption of the European Parliament's opinion at first reading. The draft decision is aimed to strengthen intergenerational solidarity by increasing awareness of the contribution of older people to society and by spreading innovative measures, which could help to mobilise the full potential of the growing population in their late 50s and above. It seeks to stimulate debate and develop mutual learning between Member States in order to promote active ageing

policies, and it offers a framework for commitment and concrete action to enable Member States and stakeholders to develop policies through specific activities.

#### **NO AGREEMENT OF MATERNITY LEAVE DIRECTIVE**

On 6 December 2010, the EPSCO Council held a policy debate on the draft directive aimed at improving the protection of pregnant workers and workers who have recently given birth or are breastfeeding.

A very large majority of Ministers considered that the amendments adopted by the European Parliament at first reading, notably the requested extension of the minimum maternity leave to 20 weeks on full pay, did not constitute an appropriate basis for negotiations. They expressed concerns regarding the cost implications and emphasised that a directive should set minimum standards while respecting the principle of subsidiarity and the diversity of situations in the different Member States.

Many Ministers were reluctant to include paternity leave within the scope of the draft directive on maternity leave. Some delegations, however, considered that the draft directive should also cover fathers. Many Ministers were open to the idea of including a "*passerelle*" clause in the draft directive, allowing the Member States to take into account forms of leave other than maternity leave offered to the mother, which fulfilled certain conditions. Many Ministers stressed the need to carefully reflect on the draft directive, and some of them called for a further impact assessment. The Belgian Presidency concluded that the Commission's original proposal aiming to extend the minimum length of maternity leave from 14 to 18 weeks could be a more acceptable basis for a compromise than the European Parliament's amendments. It also stressed the need to examine this issue carefully, including with the social partners, in order to achieve a balanced outcome.

The Belgian Presidency announced that it would consider how best to continue dealing with the file over the coming weeks, in coordination with Hungary and Poland, the two forthcoming presidencies.

The European Parliament Rapporteur on maternity leave Edite Estrela (S&D, Portugal) has criticised the decision taken by EPSCO Council to reject 20-week maternity leave. Ministers went with the initial European Commission position of 18 weeks' leave as a basis for further negotiation. This decision shows that the Council "didn't fully understand Parliament's role within the provisions of the Lisbon Treaty," Estrela said. However, she thanked the Belgian Presidency of the EU Council of Ministers and the representatives of the incoming Hungarian Presidency for the commitment, determination and efforts shown in trying to find an agreement with the EP. Estrela reiterated her willingness, as the Parliament's Rapporteur, to work with the Council and the Hungarian Presidency to reach an agreement, which will meet the needs of European families and the European economy. Elisabeth Morin-Chartier (EPP, France) called on the European Council and the Commission to bring forward a new proposal placing an 18-week cap on maternity leave, so that an agreement that helps women can be reached. She said it was important that the text show imagination and innovation in bringing forward effective measures and finding a good work-life balance, for example, by making provision for more crèche facilities, and adapting working hours to the rhythm of family life for fathers as well as mothers. There had also to be complementary measures for easing the return to work after maternity leave. Marina Yannakoudakis (ECR, UK) takes the view that it is not for the EU to determine the length of parental leave that new mothers and fathers should take. This, she said,

was a matter for national governments and personal choice. The EP's plans would have reduced women's right to choose and would have made young women less employable.

#### **SOCIAL SERVICES OF GENERAL INTEREST**

The EPSCO Ministers adopted conclusions on a voluntary European quality framework for social services establishing quality standards which should be met by social services of general interest which sit between the economic and social and between the EU and Member States' areas of responsibility, said Belgian Secretary of State for Social affairs with responsibility for persons with handicap after the meeting.

*More information about the Council conclusions:*

<http://www.consilium.europa.eu/App/newsroom/loadbook.aspx?BID=79&LANG=1&cmsid=351>



#### **PUBLIC HEALTH – CROSS-BORDER CARE**

An agreement is in sight on the Directive, according to MEP Françoise Grossetête, the Rapporteur on the Directive.

An important step towards the adoption of the Directive seems to have been made during the trilogue meeting of the 15 December 2010. A trilogue gathers the presidency, the Commission and the European Parliament.

The Belgian Presidency found a balanced compromise to clarify the means of reimbursement and the definition of the treatments that patients will be able to benefit from when they decide to cross the border.

One issue was the reimbursement. The Council wanted to enlarge the list of cases for which the prior authorisation could be refused. The European Parliament Rapporteur wanted a clear and limited list of reasons, which is what the compromise is partially providing. Considering the legal basis article 168 (public health) and not only internal market (article 114), some of the ambitions of the Commission and the Parliament have been watered down. This is the case for eHealth and quality and safety norms. Concerning rare diseases the compromise respects regulation 883/2004 but will give a push to cooperation, in particular with the help of the Orphanet database.

The Council should adopt this compromise on the 21 December 2010. The Parliament will vote on it in January 2011.

## ***PUBLIC HEALTH – PHARMACEUTICALS – CLINICAL TRIALS***

On 5 November 2010, the European Medicines Agency (EMA) published a report on Clinical trials submitted in marketing authorisation applications to the EMA. It gives an overview of patient recruitment and the geographical location of investigator sites. The revisions to the pharmaceutical legislation, which came into force in 2005, increased emphasis on the ethical standards required of clinical trials conducted in third countries and included in marketing authorisation applications (MAAs) submitted in the EU. There is growing concern both among regulators and in public debate about how well these trials are conducted from an ethical and scientific/organisational standpoint, including good clinical practice (GCP) compliance and about the available framework for the supervision of these trials. Information is required in each MAA regarding the location of conduct and ethical standards applied in respect of clinical trials conducted in third countries.

This report was first published in 2009 with the data from MAAs submitted between 2005 and 2008. This second report is an update adding data from MAAs submitted in 2009. This report provides an overview of the distribution of the number of patients, investigator sites and pivotal clinical trials included in MAAs submitted to the EMA, on the number of sites subject to inspection and the geographic location of these inspections.

From this report, the following general points can be concluded:

- 61% of the patients in pivotal trials submitted in MAA to the EMA during the observation period from January 2005 to December 2009 were from third countries, comprising 25,9% from the ROW region (Africa, Middle East/Asia/Pacific, Australia/New Zealand, Central/South America, CIS, Eastern Europe-non EU), and 35,2% from North America;
- 7,8% of patients in pivotal trials submitted in MAA to the EMA during the observational period from January 2005 to December 2009 were included in trials in Middle East/Asia/Pacific;
- 9,2% of patients in pivotal trials submitted in MAA to the EMA during the observational period from January 2005 to December 2009 were included in trials in Central/South America;
- 11,2% of patients in the EU/EEU/EFTA region come from the EU-10 and EU-2 countries, which makes a significant contribution to the European figures.

The total number of patients per clinical trial is considerable higher in North America followed by ROW and EU/EEA/EFTA over the whole period 2005-2009. If we consider a cut off point of 125 patients per trial the most relevant countries are USA, Poland, Germany, Finland, China, Japan, Costa Rica, Panama, Brazil, Philippines, South Africa, India, Russia and Thailand. Around 25% (15 out of 60) of the countries in the ROW region have more than 80 patients (the average in the EU/EEA/EFTA region) enrolled per clinical trial.



## ***ENTREPRISE – PHARMACEUTICALS – TRANSPARENCY***

HOPE was invited on 15 December 2010 to a first meeting on the Review of Council Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems.

European Community legislation provides a harmonised framework for the authorisation of medicinal products. It is designed to ensure the highest level of safety for patients, while guaranteeing the free movement of medicines throughout the European Union. This common regulatory framework has made a major contribution to the development of a single European market for medicines and to the competitiveness of the pharmaceutical industry.

Concurrently, national policies play a major role in the provision and dispensation of medicines to patients after marketing authorisation. Member States are responsible for the definition of health policies and for the organisation and delivery of health services and medical care (Article 168(7) TFEU). This includes the power to regulate the prices of medicinal products and to determine the conditions of their reimbursement in the framework of national or regional health insurance systems. Pricing and reimbursement decisions are therefore subject to a variety of domestic rules and national policies to control pharmaceutical expenditure vary significantly within the EU.

Pricing and reimbursement measures are liable to create barriers to trade within the EU insofar as they affect the capacity of pharmaceutical companies to sell their products in national markets. In order to mitigate the potential impact of national rules on the internal market, Directive 89/105/EEC lays down a general framework, which creates procedural obligations for the Member States without affecting their power to organise their social security system.

The objective of the directive 89/105/EEC was then to avoid that pricing and reimbursement measures create obstacles to trade prohibited by the rules of the Treaty rules on free movement of goods (Article 34-36 TFEU). The directive is built on the principle of minimum interference in the organisation of national social security systems.

The possible review of the directive relates to several Commission initiatives which examined issues faced by the pharmaceutical sector and highlighted challenges linked to the pricing and reimbursement of medicines: the Pharmaceutical Forum (October 2008), the Commission Communication on the future of the pharmaceutical sector (December 2008), the Pharmaceutical Sector Inquiry (July 2009) and the pharmaceutical market monitoring exercise (2009).

Directive 89/105/EEC was adopted in 1989. The pharmaceutical market and national policies to control public expenditure on medicines have considerably evolved since then and continue to do so at a quick pace. Pricing and reimbursement measures are much more varied and complex than they were twenty years ago. The case-law of the European Court of Justice recognises the necessity of an extensive interpretation of the provisions of the directive in order to ensure that its core objectives

are not jeopardised by national systems and policies. However, many new forms of price control or reimbursement schemes are not clearly apprehended by the directive. This has created uncertainties regarding the exact legal scope of EU legislation and difficulties in the practical implementation of some of the procedural requirements. Scientific progress in the area of healthcare also raises new challenges, for instance with the emergence of personalised medicines.

The wide variety of pricing and reimbursement procedures, which can be observed across Member States, has an important impact on intra-Community trade, on the activities of pharmaceutical companies and on the availability and affordability of medicines for European citizens/patients. One of the main impacts of pricing and reimbursement regulation relates to the delayed entry of medicines on the market of individual Member States.

The Pharmaceutical Sector Enquiry has shown significant disparities in the time to market medicinal products throughout the EU. This situation is explained, in particular, by important differences in the processing of pricing and reimbursement applications. Some progress has been made but it remains slow and unequal between Member States, despite of increased cooperation in this area under the auspices of the Commission (Pharmaceutical Forum, Transparency Committee, Network of competent authorities responsible for pricing and reimbursement). The problem of delayed entry in the market affects both innovative and generic medicines. The Pharmaceutical sector enquiry showed that the competitive environment for generic products is particularly affected by national pricing and reimbursement systems.

Finally, Directive 89/105/EEC applies only to medicinal products. Nevertheless, medical devices can be subject to pricing regulation in the Member States and/or to decisions concerning their inclusion in the health insurance systems. Consequently, the relevance of the directive to the medical devices sector will be worth examining. The overall objective of this initiative is to ensure that the national measures on pricing and reimbursement of medicinal products do not hinder intra-Community trade and do not prevent, restrict or distort competition within the common market. According to the Commission, these objectives cannot be sufficiently achieved by Member States: the diversity of national policies makes it necessary to achieve a minimum level of procedural convergence at European level in order to create a level playing field for pharmaceutical companies and ensure timely access to medicines for all citizens. EU action is therefore justified and in line with the principle of subsidiarity.

Given the internal market objective of the directive, this proposal should be adopted based on Article 114 TFEU (ex Article 95 EC). This Directive has as its underlying principle the idea of minimum interference in the organization of national health systems. Article 168 (7) TFEU (ex Article 152(5) EC Treaty) acknowledges the Member States' responsibilities in the field of healthcare. The main aim of this initiative is to reinforce the internal market for pharmaceuticals, while at the same time respecting Member States' competences to organise their national health insurance system.

The underlying policy objective is to improve the functioning of the internal market for medicines. The aim of the review is therefore to look at the opportunity to update a directive dating back from 1989, taking into account the case-law developed by the European Court of Justice, the outcomes of the Pharmaceutical Sector Enquiry and of the pharmaceutical market monitoring, as well as developments in the market and in national pricing and reimbursement regulations. The opportunity to address pricing and reimbursement procedures for medical devices will also be examined.

The review will look at adequate regulatory and non-regulatory options, taking into account stakeholders' contributions and the Treaty obligation to preserve the competence of Member States' for the organisation of their health insurance systems. Broad policy options include:

- no regulatory/policy change;
- soft-law instruments such as the identification of best practices, the development of guidelines for the implementation of the existing directive or an interpretative Communication on the implementation of the directive;
- updating of the current directive to clarify its scope and improve the effectiveness of its provisions.

Given the responsibility of Member States for the organisation of national healthcare systems, the review will examine the procedural framework for pricing and reimbursement decisions, but it will not address the structure or substance of national health insurance schemes. The current directive is based on the principle of minimal interference in the organisation of national social security systems, so that recourse to soft-law instruments or the absence of policy change would fully respect the proportionality principle. Similarly, any proposal to update the current directive would not go beyond what is necessary to achieve the transparency of decision-making procedures and thereby avoid unjustified obstacles to the internal market.

### ***ENTREPRISE – PHARMACEUTICALS – ACCESS TO MEDICINE***

The second meeting of the Steering Group on access to medicines in Europe took place on 17 December 2010 in Bruges, chaired by Pedro Ortún, director at the Directorate General for Enterprise and Industry.

Considering the contribution that medicines provide to the health of individuals, the Commission considers that it is necessary to ensure that the pharmaceutical industry strategies are in line with the public health and societal needs and that all partners exercise their responsibilities. For this, the Commission has set up a process on corporate responsibility in the field of pharmaceuticals to initiate a momentum among the Member States, industry and other relevant stakeholders by considering in a balanced approach societal and industrial challenges.

Given the experiences of the G10 process and of the High Level Pharmaceutical Forum, the Process on corporate responsibility in the field of pharmaceuticals should facilitate discussions on ethics and transparency of the sector but also on non-regulatory conditions for better access to medicines after their marketing authorisation. The process will therefore comprise three independent platforms: transparency and ethics in the sector; access to medicines in developing countries with a focus on Africa; access to medicines in Europe, in the context of pricing and reimbursement.

During the 17 December meeting was the draft working methods for the later one were adopted. The outcomes of the platform will be based on the setting up and realisation of projects and the resulting recommendations. The work will concentrate on several issues, with the help of dedicated projects : Mechanism of coordinated access to orphan medicinal products; Capacity building on managed entry agreements for innovative medicines; Facilitating the supply in small markets; Promoting a good governance for non- prescription drugs; Market access for biosimilars. HOPE is engaged in capacity building on managed entry agreements for innovative medicines and facilitating

the supply in small markets. An additional activity was added: how to identify areas with the highest medical needs for a prioritisation of medicines development in the context of pricing and reimbursement decisions and how to characterise innovation?



### ***ENVIRONMENT – RESTRICTION OF HAZARDOUS SUBSTANCES (ROHS) RECAST UPDATE***

On 24 November 2010, the European Parliament voted in favour of the draft legislation agreed during the trilogue (meeting of Commission, Council of Ministers and Parliament) negotiations, meaning that the recast of the Restriction of Hazardous Substances (RoHS) Directive will not go to a second reading. The document will now go for formal approval by the Council before being published in the Official Journal, probably around the beginning of the second trimester 2011. RoHS has served as a blueprint for similar laws in fifteen other jurisdictions around the world. The new revision has not added any other substances to the “banned” list though it has simplified the process for doing so.

If publication progresses as planned, medical devices will fall within the scope of RoHS from around second trimester of 2014 and In Vitro Diagnostics (IVD) will follow two years later. Active Implantable Medical Devices (AIMD) will remain outside the scope for the foreseeable future. According to the industry, meeting the requirements of RoHS is not simple and may involve some redesigning of devices and changes to manufacturing processes. Producers should also remember to update their risk management files, as the risks associated with RoHS compliant products will be different. Producers who are not already working towards meeting the requirements of RoHS would therefore be well advised to investigate what is required and ensure they are well prepared in good time.



### ***SOCIAL AFFAIRS – WORKING TIME DIRECTIVE***

As part of its review of the EU working time Directive, the Commission has launched on 21 December the mandatory second stage of consultation with workers' and employers' representatives at EU level.

The second stage consultation paper asks social partners for their views on two alternative approaches based on either a narrower or a broader scope for the review. It seeks opinions on detailed options that cover key themes such as:

- on-call time;
- timing of minimum rest periods;
- tackling excessive working hours;
- better reconciliation of work and family life;
- clarifying areas whether the law appears unclear.

A wide consensus emerged from the replies of the EU-level workers' and employers' representatives to the first stage consultation. The clear message has been that changes to the current working time rules are urgently needed. There is also a high degree of consensus that EU working time rules should allow greater flexibility for workers' and employers' representatives to negotiate on the details of implementation at the appropriate level.

The Commission is also presenting a detailed Report on the implementation of the current Directive in the Member States. It sets out the current state-of-play, identifying the main areas of non-compliance or of legal uncertainty in the various countries. The first findings of independent studies on the economic and social impact of working time rules and of research on relevant changes in working patterns are also available. These findings mention issues like the detrimental effects that excessive working hours can have on health; the current spending constraints of Member States; and the issue of skills shortages as public and private employers find ways to reduce the impact of the working time rules.

The study also suggests that the Directive can act as a catalyst for efficiency gains and a better work-life balance. The Commission will be publishing these results to facilitate the social partners' replies to the consultation.

*More information:*

<http://ec.europa.eu/social/main.jsp?langId=en&catId=157&newsId=964&furtherNews=yes>

## ***SOCIAL AFFAIRS – SOCIAL SERVICES OF GENERAL INTEREST***

The Commission staff working document “Second Biennial Report on social services of general interest” is now available.

A key tool for monitoring the sector and fostering dialogue at EU level, this second Biennial Report on SSGI provides an update of the economic and employment data presented in the first Biennial Report published in July 2008 (Chapter 1). It also gives an overview of the various initiatives implemented across Europe to guarantee, improve and assess the quality of social services and focuses on the voluntary European Quality Framework developed within the Social Protection Committee, which in many ways represents the culmination of all these other initiatives (Chapter 2). Finally, Chapter 3 describes the latest developments in the debate on the application of the EU rules to SSGI

The role of SSGI is all the more crucial in times of economic recessions. As emphasised during the 2009 Czech Presidency Conference on social services, SSGI are an important source of job generation and a key tool for strengthening social cohesion. In the framework of the 2010 European Year for combating poverty and social exclusion, data show that social services play an important role in employment growth and poverty reduction. Thus developing the SSGI potentials, including where appropriate using resources from the European Structural Funds, can make a significant contribution to the achievement of Europe 2020 targets on employment and poverty reduction.

The wider context in which SSGI are provided is affected by a growing, increasingly complex demand due to structural changes in our societies, such as population ageing, changing gender roles and

more flexible labour markets. Moreover, SSGI in all Member States have come under serious pressures because of the economic and public budget crisis. The contracting economy has led to the growth of the need and demand for social services and, at the same time, has significantly constrained the financing basis in public budgets.

In a situation like this, increasing efficiency is crucial. Hence, the Commission seeks to underpin the efforts of Member States in the organisation and financing of high quality, cost-effective, accessible and affordable social services.

President Barroso, in his *"Political Guidelines for the next Commission"* of September 2009, recognised the need to *"give a boost to the overall development of the social and health services' sector, for instance by establishing a quality framework for public and social services"*. The Commission contributed to the development within the Social Protection Committee of the voluntary European Quality Framework for social services, which helps to create a common understanding on this issue across the Member States.

This initiative goes hand in hand with the Commission's commitment to help Member States in applying EU rules to SSGI. The correct application of these rules can in fact help public authorities to organise good quality social services in a cost-effective way. Building on its Communication on SSGI of April 2006 ("2006 Communication") and the Communication on Services of general interest of November 2007 ("2007 Communication"), the Commission has put in place a clarification strategy to provide guidance on the existing rules.

The latest developments – such as the work within the Social Protection Committee or the report presented to the President of the European Commission by former Commissioner Mario Monti – indicate that a number of issues still demand further reflection. The Commission is engaged in dialogue with stakeholders from all sectors to identify areas where the legal framework may be in need of further clarification and/or where amendments may be necessary. A stakeholder consultation on the application of State aid rules to Services of general economic interest will provide further input in this respect as will a similar exercise to be conducted on the EU public procurement rules.

## EUROPEAN COURT OF JUSTICE



### ***CROSS-BORDER HEALTHCARE***

The European court was asked by a Bulgarian court to give a preliminary ruling on whether the national health system of Bulgaria was obliged to pay for the medical treatment abroad of any Bulgarian who was unable to receive treatment in the country within the time normally necessary for the treatment, after taking into account the patient's current state of health and the probable outcome of the medical problem.

Georgi Elchinov was diagnosed with malignant cancer in his right eye. Bulgarian doctors recommended eye surgery, a procedure that could be carried out in Germany, but could effectively save his eye, unlike the procedure carried out in Bulgaria. He applied with the national health insurance fund to be allowed treatment abroad, but since the case was urgent and the answer took a long time, Elchinov left for Berlin, only to learn later that payment for the surgery had been denied. He underwent treatment in Germany and his eye was saved. Elchinov sued the fund in the Sofia Administrative Court and won. The fund then filed appeal proceedings before the Supreme Administrative Court, and eventually the ECJ was asked to give a preliminary ruling.

In its decision, the European court held that the refusal on the part of the health insurance fund was out of line, and maintained that the fund was obliged to pay for healthcare and treatment of Bulgarian citizens abroad if they could not receive such treatment in the country at all or on time, depending on the ailment. The European court established that excluding in all cases payment for hospital treatment given in another Member State without prior authorisation was unreasonable, especially in those situations where the patient is prevented from applying, or unable to wait, for such authorisation.

So, if a patient sought treatment abroad before having the agreement of the fund, the patient is still entitled to reimbursement in circumstances where the Member State could not provide timely or alternative cure. In coming to its decision, the court rejected the argument put forth by the insurance fund and the Bulgarian Government that the occurrence of such situations could undermine hospital planning and the financial balance of the social security system. The court ruled that Bulgarian law constituted an unjustified restriction on the freedom to provide and obtain services.

This legal ruling is significant, as the legislation of a Member State cannot exclude across the board reimbursement for hospital treatment given in another Member State to a patient without prior authorisation.

## **EU PROJECTS**

### ***RESEARCH – SIMPLIFICATION IN RESEARCH PROGRAMMES***

On 30 November 2010, under the patronage of the Belgian EU Presidency, the MEP Maria de Graça Carvalho (EPP) organised a workshop on “Simplifying the implementation of research programmes”.

This was in line with the report “Simplifying the Implementation of the Research Framework Programmes” adopted recently by the European Parliament. This debate focused on the new fortifications in EU research programmes and evaluation procedures and concluded with some guidelines for the next European Commission Research Framework Programme.

Among the recommendations of the Parliament’s report: coherence, flexibility, uniformity, trust, consistency, the “simplification” was the watchword during discussions. The industry, universities and research centres with support of political groups agreed on common recommendations on improving and facilitating procedures of the EU research programmes to make them more attractive, comprehensible and affordable for all.

In addition, in February 2010, the Université Catholique de Louvain lead a survey on concrete positive and negative aspects of the 7<sup>th</sup> Framework Programme (FP7) and, as a result, heavy administration procedures for preparation, evaluation, negotiation and reporting of projects, timing not adequate, lack of flexibility, lack of continuity were identified. On 12 October 2010, the Council invited the Commission to give around fifteen concrete proposals. A communication planned for February 2011 will give more information on this new programme.

*More information:*

[http://www.eppgroup.eu/Press/peve10/eve042\\_en.asp](http://www.eppgroup.eu/Press/peve10/eve042_en.asp)

### ***PUBLIC HEALTH – WORK PROGRAMME 2011***

The draft Commission Decision concerning the adoption of the 2011 public health work programme present a budget of € 47.060.000. Rather close to previous years, it still follows the three main objective of the programme: improving citizens' health security; promoting health, including the reduction of health inequalities; generating and disseminating health information and knowledge.

It shows however, important changes in the way money will be allocated. The winners are clearly the joint actions with € 17.040.000 (12 millions in 2010) against project grants € 4.650.000 (12 millions in 2010), a direct consequence of the Court of auditors’ report on the pitfalls of projects. Operating grants get € 4.000.000 and procurement € 17.753.028. There is € 800.000 for conferences: € 200.000 for Presidency and € 600.000 for other conferences. Direct grants are estimated to € 3.200.000; funding in 2011 can only be awarded to the following international organisations: Council of Europe, International Agency for Research on Cancer, Organisation for Economic Co-operation and Development, World Health Organization (WHO).

Joint actions enable the competent authorities of the Member States/other countries participating in the Health Programme and the European Commission to take forward work on jointly identified issues. Public bodies or non-governmental bodies based in a Member State or in other participating country, which participate in a given joint action, may participate in the joint action. However, they have to be expressly mandated to do so by the authorities of the Member State/other participating country concerned.

These joint actions are:

- Support to the implementation of national plans/strategies on rare diseases and related measures to implement Council Recommendation and Commission Communication on rare diseases; maximum EU co-funding € 3.000.000, co-funding percentage 60 %.
- Cross-border e-health instruments as supporting tools for medical information and research; maximum EU co-funding € 2.400.000, co-funding percentage 60 %.
- Complementary joint action on pilot HTA's on targeted health technologies; maximum EU co-funding € 6.600.000, co-funding percentage 70 %.
- Patient safety and quality of healthcare; maximum EU co-funding € 3.600.000, co-funding percentage 60 %.
- Assisting Member States in reaching the full potential of deceased and living donation; maximum EU co-funding € 1.440.000, co-funding percentage 60 %.

More generally, the work plan for 2011 focuses on five main areas: Health Information and advice; Diseases; Health determinants; Health systems; Legislation on products and substances.

On **health information and advice**, the work plan supports setting up efficient and user-friendly dissemination channels. These include in particular the setting up and running a knowledge management system.

Work on **diseases** in the 2011 work plan focuses on cancer and rare diseases. Concerning rare diseases, the programme will support the creation of pilot European reference networks on rare diseases and to the implementation of national plans/strategies on rare diseases to implement Council Recommendation and Commission Communication on Rare Diseases.

For **health determinants**, the work plan supports activities on a number of key health determinants: social determinants and health inequalities; nutrition and physical activity; alcohol and tobacco.

Concerning **health systems**, cross-border health care is one of the aspects the Europe 2020 strategy is considering. This entails ensuring high-quality, safe and efficient cross-border healthcare, which is the objective of the proposed Directive on the application of patients' rights in cross-border healthcare set out in Commission Communication COM(2008) 414 final of 2 July 2008. The use of new technology has a key role in making cross-border health care a success. This work plan supports work on patient safety, health technologies and their assessment as well as on health work force.

In this context, the support to the creation of pilot network of hospitals related to payment of care for cross-border patients is mentioned. The objective of this action is the setting up of a network that will investigate hospitals, which are receiving a significant number of patients from other Member States, with more than a third of members being hospitals located in cross-border regions. Hospitals will report and exchange information on any administrative issues related to payment of care for

cross-border patients, including issues related to determination of tariffs for care, potential loss of revenue for the hospitals, possible use of up-front payments and delays in reimbursement to the hospitals. The network will assess main causes of problems and propose possible solutions. The network will also set up a system to receive feedback from patients on their experience related to reimbursement of their own costs for cross-border care, based on informed consent. Finally, the network will compare DRG-based tariffs for a list of common types of elective surgery and propose conclusions on general cost levels between Member States and discrepancies between relative cost levels.

The joint action on e-Health aims at preparing the ground for the implementation of article 14 (on e-Health cooperation) of the proposed Directive of the European Parliament and of the Council on the application of patients' rights on cross-border healthcare in so far as the Directive is adopted by the Council and the European Parliament and its final content calls for such action. The Commission is currently identifying the unmet operational needs. Once completed, this exercise will propose a number of specific objectives to be covered by future actions. Two areas of unmet needs have been pointed out so far: e-Health instruments supporting research on diseases and treatments, and National contact points. With regard to the first need, this action should deliver a number of detailed recommendations, supported by good practises that will help start the implementation of this specific objective of the above Directive (health information and research) as far as the Directive is adopted by the Council and the European Parliament and the final content calls for such action. With regard to the second need, this action will prepare the roll-out of national contact points for cross-border healthcare. These national contact points will disseminate appropriate information on all essential aspects of cross-border healthcare to patients. The network will also disseminate relevant information to patients at EU level. This action will benefit patient mobility by increasing clarity on patients' rights when seeking cross-border treatment; patient safety by providing information on healthcare providers; and Member State co-operation on cross-border care.

The collaboration with OECD on health information aims to take forward work on the healthcare quality indicators project. This covers the development of the joint publishing of the "Health at the Glance - European edition" which addresses several aspects of health in the EU. This is also about the follow up on the health modelling: the effectiveness, efficiency and distributional impact of health interventions, which should result in a model to be employed to explore the relative roles of different factors accounting for alternative healthcare options and associated resource requirements. It concerns as well the follow up on the System of Health Accounts (SHA) revision, to extend collaboration among Eurostat/OECD/WHO Europe in data management, with the aim to achieve a highly integrated statistical system, which is able to generate fully comparable data. There will also be an analysis of the performance of the hospital sector: assessing the comparability of data on hospital procedures that is regularly collected by Eurostat and OECD, and coming up with recommendations to countries to improve data comparability. An evaluation of the Commission's cooperation with the OECD in the field of health in order to assess added value and the best focus for future work will also be conducted.

Setting up guidelines in support of e-Prescription interoperability will prepare the finalisation of "guidelines supporting the Member States in developing the interoperability of ePrescriptions". This is foreseen in the proposed Directive of the European Parliament and of the Council on the application of patients' rights on cross-border healthcare. It will draw on the expertise already established within the framework of the epSOS project, notably the work done on ePrescriptions.

This action has two objectives. The first one is a feasibility analysis of ePrescription interoperability guidelines in general, seeking to find out which aspects (e.g. Privacy and confidentiality, organisational frameworks, semantic and architectural/technical interoperability) should minimally be covered by the Guidelines; and at which level of specification can the Guidelines for these minimally covered aspects be established. Secondly, the outcome of the feasibility analysis will help inform the establishment of draft guidelines on selected aspects at their pre-assessed level of specification (e.g. broad, descriptive guidelines as opposed to the selection of one specific standard).

A support to the European system of health information and diffusion of innovation will provide a mechanism for pooling, presenting and updating good quality health information throughout Europe through the HEIDI European health wikipedia. The added value of this platform should come from the combination of four elements:

- involving the wider health community throughout Europe in providing and maintaining information;
- European added-value by providing a single central health reference for the EU;
- a technical platform which allows information to be constantly updated, rather than printed reports which inevitably go out of date;
- a quality assurance mechanism to ensure that the information is reliable, through validation of updates by experts in the relevant fields in Europe.

The membership of the Commission in the European Observatory on Health Policies and Health Systems is intended to support the core work of the Observatory and to strengthen the integration of European and cross-border dimensions into the work of the Observatory, with the aim of making best use of their particular expertise and capacity for the implementation of the European health strategy. Under their collaboration, the Commission and the Observatory will develop a tool for assessing the performance of European health systems. They will produce a book to assess the “state of the art” of health system performance comparison. The emphasis will be on performance information that sheds light on comparative system performance.

The item on research agenda for the EU on health economic evaluations is to propose a research agenda for the EU on health economic evaluations. The specific objectives are: a scanning exercise for existing health economic research (i.e. publications reporting on cost-effectiveness/utility and/or cost-benefit) in selected therapeutic fields leading to the identification of therapeutic fields where little health economic research is performed; an expert-based analysis of possible reasons for the observed scarcity of research in identified fields; and a proposal for a priority agenda on EU health economic research. This will take the form of a direct grant to WHO of € 200.000.

Finally, a feasibility study on health workforce will be produced for EU level collaboration on monitoring health workforce trends, forecasting health workforce needs and assisting the Member States in workforce planning. The objective of the study will be to examine the benefits and costs of sharing good practice and innovation at EU level in order to promote long-term workforce planning in the Member States. It should also assess and predict current and future changes in skill mix; to match workforce to patients' needs in an ageing society; and to assess what investment is needed in training to better utilise new technology.

## **OTHER NEWS**

### ***PUBLIC HEALTH – ROUNDTABLE DEBATE ON “THE DRAFT DIRECTIVE ON PATIENTS’ RIGHTS IN CROSS-BORDER HEALTHCARE”***

HOPE was invited to the panel discussion on the occasion of the roundtable debate on the “Draft Directive on Patients’ Rights in Cross-Border Healthcare” organised by the European Patient Forum (EPF) on 1 December 2010 in Brussels under the patronage of the Belgian EU Presidency.

According to John Dalli, Commissioner for Health and Consumers, the momentum achieved so far in the negotiations means that “time is of the essence” and flexibility is needed to reach agreement. However, Mr. Dalli reiterated that his guiding principle is “patients first”, so while the Belgian Presidency and the European Parliament can count on the European Commission’s support in finding acceptable compromise solutions.

In the course of the day, most of the participants at the debate contributed their views as stakeholders. In addition to the Health Commissioner, they included Members of the European Parliament, Commission officials, representatives of the Belgian Presidency and the Permanent Representations of Sweden, Denmark, Romania plus the Swiss negotiating team, as well as leaders of stakeholder organisations (nurses, doctors, community pharmacists, hospital, health managers, medical specialists, the pharmaceutical industry and medical devices industry).

Jo De Cock, Head of the Belgian National Institute Health & Disability Insurance (NIHDI) stressed that the Belgian Presidency’s approach to the Directive was not a simple application of the EU’s internal market rules, but a sector-specific approach based on high quality, equity and universality in healthcare. “The Directive will create a momentum beneficial to all patients, not just the one or two percent of patients that would need to travel abroad”, he said. He also emphasised that the debate is not just about general principles, but about practical issues that affect patients’ lives and which therefore require solutions to be found.

The Rapporteur on the draft Directive MEP Françoise Grossetête said that MEPs want to reassure the Council that the purpose of the Directive is not to promote health tourism or facilitate cross-border activity by healthcare providers – what is vitally important is that it offers patients the opportunity to access healthcare that is not available to them in their own countries. In this context, she regretted the “lack of ambition” shown by some Member States, which seem willing to accept a continuation of the current system of patients seeking recourse to the courts in defence of their rights.

Antonyia Parvanova, MEP addressed the wider topic of health inequalities. She stressed the importance of addressing the existing health inequalities across the European Union, and linked the Directive to the ongoing work by the Commission and the Parliament, including the health inequalities report now being discussed within the ENVI Committee. It is crucial to uphold the right of all patients to access good quality healthcare in their own countries, particularly in the context of the current economic climate. She finally highlighted that the Directive should be seen as a first step, which should later serve to promote a wider approach of public health initiatives at EU level.

## ***JUSTICE – ILLEGAL MIGRATION ACCESS TO HEALTHCARE***

Members of the European Parliament and NGO representatives have urged EU Member States to fight against inequalities of access to health care for children and pregnant women who fall into the category of irregular migrants. This appeal was launched during a public European Parliament hearing on 8 December 2010 in Brussels, as part of the World Human Rights Day.

Edite Estrela (S&D, Portugal), the Rapporteur on “Reducing health inequalities in the EU” stated that it is unacceptable that out of 16 European countries, nine of them were failing to respect the International Convention on Children’s Rights. These countries are Germany, Cyprus, Greece, the Netherlands, Poland, the Czech Republic, Slovenia, Sweden and the United Kingdom.

A new study by Médecins du Monde confirmed that these countries are not guaranteeing access to healthcare facilities for the children of irregular migrants or pregnant women among this community. Médecins du Monde (Mdm) indicates that:

- in the United Kingdom, women must pay all of the costs when they give birth in hospital;
- in Germany, neither these children nor pregnant women from this community were able to access the healthcare system because of the requirements for hospital administrations to report illegal immigrants (except in emergencies);
- in Poland, the children of illegal immigrants can only access health care at school and in Sweden, they can only access health care by paying the full cost.

In her comments on these results, Ludovica Banfi (the EU Agency for Fundamental Rights - AFR) noted that in 11 European countries “there are no specific mechanisms for the children of irregular migrants: they do not have any particular protection and are treated as adults without papers”. She added that, for example, pregnant women among this community in Austria and Greece, according to the law, only have access to health care in the event of complications when giving birth. Policies that restrict the fundamental rights of irregular migrants are aimed at turning these people into beggars, she concluded. Philippe Juvin (EPP, France), a doctor, underlined the necessity of “avoiding those in the care profession being turned into people responsible for regulating immigration policy”. Hélène Flautre (Greens/EFA, France) asserted that “these restrictive policies are themselves harmful, they put those without papers into intolerable situations and go against the idea of public health”. Finally, Dr Hans Wolff, an expert on public health at the University of Geneva, declared “it is necessary to ensure fair access to health care for all in Europe. If this system is not based on this principle, it will lead to the excessive use of emergency services and big problems in terms of costs”.

***More information:*** <http://huma-network.org/>

## ***PUBLIC HEALTH – 1ST DECEMBER – WORLD AIDS DAY***

Despite the development of effective therapies, which improve life expectancy for people diagnosed with HIV, it has been estimated that on average 30% of HIV infected Europeans are unaware of their infection and are diagnosed too late. The European Centre for Disease Prevention and Control (ECDC) commemorated World AIDS Day 2010 by organising a scientific seminar to spread awareness of the ongoing AIDS pandemic caused by HIV – which remains of major public health importance in the

European Union (EU) and the European Economic Area (EEA) as well. The focus was on the importance of the increased uptake and effectiveness of HIV testing, not only for the individual but also for the public health community.

To mark World AIDS Day, European Health Commissioner John Dalli addressed the issue of AIDS screening at a seminar in the European Parliament on 1 December 2010. On this occasion, the ECDC launched its evidence-based HIV testing guidance. These measures should help to inform the development, including monitoring and evaluation, of national HIV testing strategies and programmes in the countries involved. It outlines a strategic approach to develop effective national HIV testing interventions and to ensure access for all Europeans to HIV testing and counselling services. In order to normalise the stigma of this disease, leading HIV experts, EU policy makers and civil society agreed to invest in knowledge, treatment and prevention on HIV.

The Lisbon-based European Drugs Agency (EMCDDA) published guidelines for AIDS screening of injecting drug users, a group particularly affected by viral infections such as HIV, hepatitis and tuberculosis. Early detection is vital for early treatment and increasing life expectancy, as estimates show that about one third of people infected with HIV in Europe are unaware they have the illness, the European Commission reports.

To tackle AIDS on a global scale, European Development Commissioner Andris Piebalgs recently announced a 10% increase in contributions to the Global Fund to combat AIDS, tuberculosis and malaria, to which the EU is already the largest donor, providing 52% of resources. The increase will see the Commission contribute around 1,3 billion euro over the period 2002-2013. Despite the overall decrease in the number of new infections, the total number of people living with HIV worldwide continues to grow and now stands at 33,4 million. Sub-Saharan Africa remains the worst affected region, accounting for 71% of all new HIV infections in 2008.

### ***PUBLIC HEALTH – EPC POLICY DIALOGUE ON NEW TECHNOLOGY IN HEALTHCARE SYSTEMS***

On 15 December 2010, the European Policy Centre (EPC) organised a policy dialogue on “The role of new technology in overburdened health systems: breaking the bank or driving efficiency?” The EPC invited to the panel the representatives of European Commission (DG Information Society and Media), the industry sector (Johnson & Johnson) and NHS European Office, the UK member of HOPE. One of the most important tools related to the measurement of value of medical innovation is Health Technology Assessment (HTA). This tool helps to bridge increasing demand to innovative healthcare with budget constraints. However, for industry sector, other methods are able to combine cost savings and medical advancements. Some practical examples were presented, as the NHS Telehealth Direct – “*At home, not alone project*”. It is a 7-months project, which assists 80 patients with long-term care. In addition, a new national approach to innovation, QIPP (Quality, Innovation, Productivity, Prevention) aims to spread innovative best practices in the UK.

Besides these concrete proposals, new technologies involve many other consequences: improvement of the patient outcome. Indeed, all admitted that the role of patient is essential in innovative initiatives. Patients have to be well educated and informed on how to use the medical technology.

## ***EU HEALTH PRIZE FOR JOURNALISTS 2010***



In the second edition of the EU Health Prize for Journalists, 745 eligible articles were submitted by 438 journalists from all EU countries. The winners of the 2010 EU health prize for journalists were announced in Brussels on 30 November 2010.

Two Italian journalists, Gianluca Ferraris and Ilaria Molinari, writing for Panorama, Italy, won first prize for their joint article "Stealing Hope", which puts the spotlight on "healing clinics" that offer expensive, but unproven, therapies to vulnerable patients suffering from chronic diseases.

Second prize went to Czech journalist, Lucie Hásová Truhelková, for her article on organ donation, "Love Dwells in the Kidney".

Four Danish journalists from Berlingske Tidende, Kasper Krogh, Morten Crone, Line Holm Nielsen and Jesper Woldenhof, came third for their article "The Great Failure".

***More information and awarded articles:***

**[http://ec.europa.eu/health-eu/journalist\\_prize/2010/index\\_en.htm](http://ec.europa.eu/health-eu/journalist_prize/2010/index_en.htm)**

## PUBLICATIONS

### **HEALTH AT A GLANCE: EUROPE 2010 – OECD PUBLICATION**



On 7 December 2010, European Commission (DG Health and Consumers) jointly with OECD issued the report "Health at a Glance: Europe 2010". This report provides useful insight into the current situation of health in the EU. The report compiles data from the OECD, Eurostat and the WHO and presents key trends on health, health systems and health spending in the 27 EU Member States, plus the 3 European Free Trade Association countries (Iceland, Norway and Switzerland) and Turkey. It considers 31 European countries, including the 27 European Union Member States, three EFTA countries (Iceland, Norway and Switzerland), and Turkey and provides comparable information on important public health issues in Europe.

The first chapter, on Health Status highlights the variations across countries in life expectancy and healthy life expectancy, and also presents other indicators of causes of mortality and morbidity, including both communicable and non-communicable diseases.

The second chapter focuses on risk factors and non-medical determinants of health related to modifiable lifestyles and behaviours, such as smoking and alcohol drinking, nutrition habits, physical activity, overweight and obesity. It highlights that, while tobacco and alcohol consumption has fallen in many European countries, more than half of the total adult population across the European Union is now overweight or obese.

The third chapter on Health Care Resources, Services and Outcomes reviews some of the inputs, outputs and outcomes of health care systems, including the supply of doctors and nurses, different types of equipment used for diagnosis or treatment, and the provision of a range of services to prevent the transmission of communicable diseases or to treat acute conditions. It concludes with a review of care related to cancer, focusing on the coverage of screening programmes and survival rates for breast and cervical cancer.

The fourth chapter examines trends in health spending across European countries, both overall and for different types of health services and goods, including pharmaceuticals. It also looks at how these health services and goods are paid for and the different mix between public funding, private health insurance, and direct out-of-pocket payments by households.

The indicators have been selected based on the European Community Health Indicators (ECHI) shortlist, however, in some instances, the report deviates from the formal ECHI definitions because of issues related to data availability and comparability.

#### **More information:**

[http://ec.europa.eu/health/reports/docs/health\\_glance\\_en.pdf](http://ec.europa.eu/health/reports/docs/health_glance_en.pdf)

## **HEALTH CARE SYSTEMS: EFFICIENCY AND POLICY SETTINGS – OECD PUBLICATION**



The OECD has published the book “Health care systems: efficiency and policy settings”. The publication presents and discusses new comparative policy data gathered from 29 OECD countries on health care system performance and health policies, investigates the links between policy choices and health system efficiency and makes specific suggestions for improvements on a country-by-country basis. While population ageing and developments of costly health technologies are boosting costs, the containing of expenditure, especially as a consequence of the recent economic and financial crisis, represent the key policy challenge in most OECD countries.

This report demonstrates that exploiting efficiency gains would allow countries to continue improving the quality of care while holding costs constant. It groups countries into six newly defined types of health care systems, ranging from those that rely principally on private insurance and markets to those where governments take the lead, and identifies strengths and weaknesses of each country’s health care system and the policies that will boost efficiency.

Some of the main findings indicate that adoption of best practices could reduce costs by nearly 2% of GDP by 2017 across the OECD, as compared to a no-reform scenario. Savings could be above 3% of GDP in countries like Greece, Ireland and the United Kingdom; and if all countries were to become as efficient as the best performers, life expectancy at birth could be raised by more than two years on average across the OECD area.

### ***More information:***

[http://www.oecd.org/document/39/0,3746,en\\_2649\\_34587\\_46491431\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/39/0,3746,en_2649_34587_46491431_1_1_1_1,00.html)

[http://www.oecd.org/document/54/0,3343,en\\_21571361\\_44315115\\_46534006\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/54/0,3343,en_21571361_44315115_46534006_1_1_1_1,00.html)

## **IMPACT OF HEALTH TECHNOLOGY ASSESSMENT – WHO EURO OBSERVER**

The Euro Observer number 4, volume 12 of the WHO European Observatory on Health Systems and Policies, just released, presents an international comparison of the difference and similarities in the impact of Health Technology Assessment (HTA) in six countries.

With the rising costs of healthcare and the increasing number of new technologies, a growing number of countries are implementing HTA Agencies, having the scope of informing the decisions about reimbursement or acquisition of new technologies, based on clinical and economic evidence. However, different studies show that the impact of HTAs varies greatly across countries, even though they are assessing the same drug for the same indication.

This issue of Euro Observer presents the results of an analysis concerning the health technology appraisals across agencies in Canada, Australia, England, Scotland, Sweden and France. The aim of the analysis was to identify similarities and differences in the appraisal process, evidence requested, type of evidence used to reach the final recommendation and to identify differences and similarities in the recommendations across agencies.

While the first article presents the results of the analysis of all HTAs made by different agencies, the following articles focus on a subgroup of drugs with indications pertaining to diseases of the central nervous system (CNS), cancer and orphan drugs.

*More information:*

[http://www.euro.who.int/data/assets/pdf\\_file/0007/127798/EuroObserver\\_Vol12\\_No4\\_Winter-2010.pdf](http://www.euro.who.int/data/assets/pdf_file/0007/127798/EuroObserver_Vol12_No4_Winter-2010.pdf)

### ***ENHANCING THE WELL-BEING OF EUROPE'S CITIZENS – EPC WORKING PAPER***

The European Policy Centre has just published a working paper entitled “Improving European citizens, hard choice?”.

This Working Paper written by Fabian Zuleeg with Claire Dhéret and Benedetta Guerzoni also discusses the implications of different policy choices which are most likely to deliver a higher level of well-being to Europeans. These policy choices imply some trade-offs, say the authors. This paper is intended to serve as a basis for debate over how policy-makers can enhance citizens’ well-being in a sustainable manner and how the European Union could add real value.

*More information:*

[http://www.epc.eu/pub\\_details.php?cat\\_id=1&pub\\_id=1205](http://www.epc.eu/pub_details.php?cat_id=1&pub_id=1205)

### ***WHO EUROPEAN OBSERVATORY – NATIONAL LEAD INSTITUTIONS***

The European Observatory on Health System and Policy has just announced the launch of its network of National Lead Institutions (NLIs).

The Observatory, under a special agreement, collaborates with a selected number of national research and knowledge brokering organisations to co-produce the HiT (Health Systems Profiles) for their respective countries and to update them regularly. These National Lead Institutions (NLIs) have a strong track record in public health, health management and health systems analysis and produce independent and high level research.

Since it began developing the NLI network in 2009, the Observatory is entering a new phase of health systems country monitoring. Explicitly committed to a more regular updating of the HiTs, the network is in an ideal position to systematically report on ongoing reforms and policy changes in the countries.

At present the network is made up of the following institutions: GOEG, Gesundheit Österreich GmbH (Austria); KCE, Belgian Health Care Knowledge Centre (Belgium); THL, National Institute for Health and Welfare (Finland); URC Eco IDF, Université de Paris Val de Marne (France); Semmelweis University (Hungary); Myers-JDC-Brookdale Institute (Israel); CERGIS, Centre for Research on Health

and Social Care Management, Bocconi University (Italy ); Institute of Hygiene, Catholic University of Rome (Italy); NIVEL, Netherlands Institute for Health Services Research (the Netherlands); NOKC, Norwegian Knowledge Centre for the Health Services (Norway); UNL, Universidade Nova de Lisboa (Portugal); IVZ, Institute of Public Health of the Republic of Slovenia (Slovenia); SESPAS, Spanish Society of Public Health and Health Management (Spain); The King's Fund (UK).

***More information:***

**<http://www.euro.who.int/en/home/projects/observatory/publications/health-system-profiles-hits/national-lead-institutions>**

## HOPE CONFERENCES AND EVENTS CO-ORGANISED BY HOPE

*BETTER HEALTH - A SHARED CHALLENGE FOR HOSPITALS AND PRIMARY HEALTH CARE*

*20-21 June 2011 – Turku (FI)*



In 2011, HOPE Exchange Programme will be organised for the 30th time. Thousands of people from all over Europe - participants, host organisations, national and local co-ordinators - contributed to the success of this programme during three decades.

HOPE Exchange Programme, a 4-week training period, is targeting hospital and healthcare professionals with managerial responsibilities. They are working in hospitals and healthcare facilities, adequately experienced in their profession with a minimum of three years of experience and have proficiency in the language that is accepted by the host country.

During their stay, HOPE Exchange Programme participants are discovering a different healthcare institution, a different healthcare system as well as other ways of working. HOPE Exchange Programme 2011 starts on 23 May and ends on 21 June 2011.

Each year, a different topic is associated to the programme, which is closed by HOPE Agora, a conference and an evaluation meeting around the topic. "Better health - A shared challenge for hospitals and primary health care" will be the subject for 2011. The Finnish HOPE member will organise the 2011 Agora concluding the Programme, in Turku on June 20-21, 2011.

**TURKU ● ÅBO 2011**   
**EUROPEAN CAPITAL OF CULTURE**