NEWSLETTER

N° 91 – March 2012

CONTENT

Click on a title to go directly to the article

OTHER NEWS – EUROPE

HOPE CONFERENCES AND EVENTS CO-ORGANISED BY HOPE

CONFERENCE ON COMBATING ANTIMICROBIAL RESISTANCE

Various European officials and experts participated in a conference on the theme of antimicrobial resistance, which took place in Copenhagen on 14 and 15 March 2012.

Representatives from candidate and EEA countries and public interest bodies, as well as from the European Centre for Disease Prevention and Control (ECDC) and the European Food Safety Authority (EFSA) were also present at the event, which aimed to fuel debate within the EU council on the adoption of common measures to tackle antimicrobial resistance at EU level.

The conference centred on solutions to address the challenges and issues raised by the increase of antimicrobial resistance in both human and veterinary use, mainly through the sharing of best practices. Participants brought forward various solutions, putting emphasis on the importance of establishing better surveillance and data collection systems and on the necessity to put a halt to the overuse of antibiotics.

The fight against antimicrobial resistance is one of the key health priorities of the Danish Presidency. "*This is a serious threat to health services and there is an urgent need both for limitations on usage as well as better targeted use of antimicrobials. The response needs to be worldwide, as resistant bacteria do not respect borders. I wish the EU to lead the fight against overuse of antimicrobials and the subsequent development of resistant bacteria*", said Danish Health Minister Pia Olsen Dyhr.

More information :
http://eu2012.dk/en/NewsList/Marts/Uge-10/~/link.aspx?_id=B16A21E5D2AF427F904DD416A08689B6&_z=z

Public Health

INFORMATION TO PATIENTS – EUROPEAN COMMISSION PRESENTS THIRD PROPOSAL

On 10 February 2012, the European Commission presented its third legislative proposals for the Information to Patients component of the pharmaceutical package, which should establish rules governing information on prescription drugs and surveillance of possible side effects of such medicines.

The proposal follows European Commissioner for Health and Consumer Policy John Dalli's announcement in December 2011, that the amendments presented in October 2011 would be split in two parts relating to "Information to Patients" and "Pharmacovigilance" respectively. The split of the proposals results from worries expressed by Member States. It aims also to facilitate the discussion of the proposals by the co-legislators.

The latest proposals maintain Europe's ban on direct-to-consumer advertising and further restrict internet marketing by pharmaceutical companies.

The legislative package is composed of the following elements:

- an amended Commission proposal for a Directive regarding information to the general public on medicinal products subject to medical prescription;
- an amended Commission proposal for a Regulation regarding information to the general public on medicinal products subject to medical prescription;
- a Commission proposal for a Directive regarding pharmacovigilance;
- a Commission proposal for a Regulation regarding pharmacovigilance.

The proposals keeps on placing emphasis on the patient, based on the principle that the patient should request information before receiving it. They also determine the type of information to be provided and limit the channels through which such information may be communicated.

In addition, the legislative package suggests to render registered websites for objective and non-promotional information mandatory and to establish specific rules on the monitoring of those websites in order to incorporate the cross-border nature of internet-provided information and allow cooperation between Member States. Pharmaceutical companies may link their websites to EU databases and portals on medicinal products, e.g. the forthcoming EU medicines web-portal, the main point of access for information on medicines expected to be online in July 2012. The proposals

provide that the information must be controlled by the competent authorities and abolish the possibility for Member States to choose voluntary controls by self-regulation or co-regulation bodies. They however maintain derogations for Member States that cannot set up a prior control system for constitutional reasons related to the principles of freedom of expression and freedom of the press.

The four proposals will be now discussed by the European Parliament and the Council of Ministers.

More Information:
http://ec.europa.eu/health/human-use/information-to-patient/legislative-developments_en.htm

PATIENT SAFETY – EUROPEAN COMMISSION WORKING GROUP

Since 2006, the Commission Patient Safety and Quality of Care Working Group brings together representatives from all 27 EU countries, EFTA countries, international organisations, EU bodies and the key EU stakeholders, including HOPE. The Group assists in developing the EU patient safety and quality agenda.

Following the discussion that took place during the last meeting, (21 November 2011), 13 contributions have been made concerning the future of the work of the Working party.

The contributions suggest that the future work of the Group related with patient safety should be based on the conclusions of the implementation report of the Recommendation on patient safety, due by the Commission in June 2012. The Group should address gaps in the implementation, identified by the report.

The contributions suggest also that the Group could be used for:

- elaborating a proposal for terminology and for a common data set to be used for reporting and learning of incidents;
- exchanging information about practices on medication safety, hospital standardised mortality rate, evidence based patient safety solutions and cost-effectiveness of patient safety and quality improvement strategies;
- taking forward the issue of education and training of health professionals and other health workers on quality of care and patient safety with a focus on how to involve academia;
- elaborating an information tool for doctors to enable them access to updated information about therapeutic options;
- discussing what changes at health system level are necessary to ensure that high quality healthcare is provided to all patients; in this respect the Group could consider how quality and safety initiatives might be extended from secondary care to primary care;
- receiving information about other EU initiatives with potential impact on quality of care and patient safety, including regular update on the progress of patient safety and quality of care joint action.

There is a suggestion that a new area of work could be identifying mechanisms that would help empowering patients, as patient empowerment is a key element of quality improvement. The field of self-management in patients with chronic conditions might provide a useful paradigm to consider in

this respect. This new area would clearly enlarge the scope of interest of the Group, from patient safety only, to wider quality of care.

Further discussions are expected during the next meeting.

CHRONIC DISEASES – EUROPEAN COMMISSION LAUNCHES REFLEXION PROCESS

The European Commission and EU Member States have launched a reflection process to respond to the growing challenge of chronic diseases. This was called for in the Council conclusions on "Innovative approaches for chronic diseases in public health and healthcare systems" of December 2011. In addition, the UN High Level Meeting on non-communicable diseases in New York in 2011 confirmed that addressing chronic diseases has now become a global priority.

As part of this reflection process, the European Commission is inviting stakeholders, including patient organisations, health professionals and healthcare providers working on chronic diseases to share their views.

Responses are to be sent to the functional mailbox by 15 April 2012: sanco-chronic-disease-reflection@ec.europa.eu.

Questionnaire: http://ec.europa.eu/health/major_chronic_diseases/docs/eu_reflection_cd_questionnaire_032012_en.pdf

PATIENT MOBILITY – RECOGNITION OF PRESCRIPTIONS

The European Commission presented on 28 March 2012 its analysis of the answers to the consultation: "Measures for Improving the recognition of prescriptions issued in another Member State".

Article 11 of the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare addresses the recognition of prescriptions issued in another Member State.

In Article 11 of the Directive is stated that the Commission shall adopt the following measures.

- "Article 11 § 2 (a): measures enabling a health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by a member of a regulated health profession who is legally entitled to do so through developing a non-exhaustive list of elements to be included in the prescriptions and which must be clearly identifiable in all prescription formats, including elements to facilitate, if needed, contact between the prescribing party and the dispensing party in order to contribute to a complete understanding of the treatment, in due respect of data protection.

- Article 11 § 2 (c): measures to facilitate the correct identification of medicinal products or medical devices prescribed in one Member State and dispensed in another, including measures to address patient safety concerns in relation to their substitution in cross border healthcare where the legislation of the dispensing Member State permits such substitution. The Commission shall consider, inter alia, using the International Non-proprietary Name and the dosage of medicinal products.

- Article 11 § 2 (d): measures to facilitate the comprehensibility of the information to patients concerning the prescription and the instructions included on the use of the product, including an indication of active substance and dosage."

In Article 11 § 4 of the Directive it is stated that the Commission shall have regard to the proportionality of compliance costs as well a likely benefits from the above measures which the Commission plans to adopt by 25 October 2012. In keeping with this, the Commission is conducting an impact assessment to evaluate various policy options under consideration. The Commission seeks to understand stakeholder views in this respect.

The consultation lasted from 28 October until 8 January 2012 with the aim to see how the recognition of cross-border prescriptions could be improved. The results of the consultation will be used for the impact assessment on measures to improve the recognition of prescriptions issued in another member State. This impact assessment will be published later in 2012.

The responses are available on:
http://ec.europa.eu/health/cross_border_care/docs/cons_prescr_results_en.xls

The report is available on:
http://ec.europa.eu/health/cross_border_care/docs/cons_prescr_report_en.pdf

DIRECTIVE FOR PRICING AND REIMBURSEMENT OF MEDICINES

On 1 March 2012, the European Commission released its proposal to reform the 89/105/EEC "Transparency Directive" on the pricing and reimbursement of medicines. The proposal aims at enabling medicines to enter the market faster and reduce the duration of national decisions on the pricing and reimbursement of medicines. Despite the responsibility on pharmaceuticals given in 2009 to Directorate General Health, the proposal was designed and presented by Directorate General Industry and Entrepreneurship.

This proposal derives from the Commission's report on the pharmaceutical sector, which revealed long and cumbersome pricing and reimbursement decisions. Studies have shown that delays in pricing and reimbursement decisions can go up to 700 days for innovative medicines and up to 250

days for generics. Since the adoption of the "Transparency Directive" in 1989, national measures related to the pricing of medicinal products have increased in complexity, leading to complex pricing and reimbursement schemes.

The revision of the 1989 Directive aims at introducing the following main changes:

- guaranteeing shorter time limits for national, regional or local decisions on pricing and reimbursement;
- increasing the effectiveness of the directive by proposing strong enforcement measures, i.e. in case of non-compliance with the time limits, a Member State has to designate a body entrusted with the powers to take rapid measures such as: adopting interim measures with the aim of correcting the alleged infringement or preventing further damage to the interests concerned; awarding damages to the applicant; imposing a penalty payment, calculated by day of delay;
- introducing the obligation for Member States to regularly report on their decisions and the time involved;
- notifying national pricing and reimbursement draft measures to the Commission to facilitate compliance from the beginning;
- addressing the uncertainties relating to innovative pricing and reimbursement procedures**:** e.g. exclusion of tendering (covered by public procurement law) and of managed entry agreements (covered by contractual/administrative law) from the scope of application of the Directive.

The new directive reduces the time limits for pricing and reimbursement decisions from 180 days to 120 days for innovative medicines and from 180 days to 30 days for generic medicinal products when the price of the reference product has already been approved or it has already been included in the public health insurance system. In regards to the acknowledgement that Member States currently often exceed the time limits, the European Commission also proposes strong enforcement measures in case the decisions do not comply with the set time limits.

For medicinal products to be placed on the market, pharmaceutical companies have to obtain a marketing authorization from the European Commission or from competent national authorities, which is granted in accordance with harmonized rules aimed at ensuring the quality, safety and efficacy of medicines. Member States however have the competency to manage the consumption of medicines in their country, regulate their prices, or establish the conditions of their public funding. Once the marketing authorization is granted, they are also competent for deciding whether a medicine is eligible to reimbursement.

According to the Commission, these measures can lead to the creation of barriers to trade, by affecting the capacity of pharmaceutical companies to sell their products in domestic markets. To prevent national measures from creating barriers within the internal market, the Directive lays down a series of procedural requirements applicable to any national measure regulating the prices of medicines and their inclusion in the scope of health insurance systems.

More information:
http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/pricing-reimbursement/transparency/index_en.htm

PROFESSIONAL QUALIFICATION – LANGUAGE TESTING

The European Free Trade Association Court just published its judgment of 15 December 2011 on Case E-1/11 concerning interpretation of Directive 2005/36/EC.

The question referred has arisen in the context of appeal proceedings before the Appeal Board concerning the refusal of the Registration Authority to grant the Complainant automatic recognition of her Bulgarian qualifications as a specialised medical doctor.

The Complainant is a Bulgarian national, who is qualified as a medical doctor in Bulgaria with an additional specialisation in psychiatry and extensive experience as a psychiatrist in that EEA State. On 15 May 2009, the Complainant applied for an authorisation "as a medical doctor" in Norway and, in that regard, referred to written confirmation by the Bulgarian authorities that, on the basis of her education and professional experience as a medical doctor in Bulgaria, she was covered by Directive 2005/36/EC. By decision of 12 August 2009, the Registration Authority rejected the application. In its decision, the Registration Authority recognised that although, in principle, the Complainant had a right to an authorisation on the basis of acquired rights under Article 23 of Directive 2005/36/EC on the recognition of professional qualifications, in its assessment, the Complainant lacked the necessary aptitude under Article 48(3)(c) of the Norwegian Health Personnel Act.

In support of that conclusion, the Registration Authority noted that the Complainant had previously been refused approval of her practical training in Norway due to language and communication problems, insufficient theoretical skills and signs of poor insight in her own functioning. At the same time, the Registration Authority considered that there were grounds to grant the Complainant a one-year licence to work as a subordinate medical doctor in accordance with Article 49 of the Health Personnel Act.

On 11 September 2009, the Complainant brought an appeal against that decision and the matter was eventually transmitted to the Appeal Board for review on 22 June 2010.

THE QUESTION ASKED WAS THE FOLLOWING

Does Directive 2005/36/EC or other EEA law allow the authorities of Member States to apply national rules providing for a right to deny an authorisation as a medical doctor or only to grant a limited authorisation as a medical doctor to applicants with insufficient professional qualifications, to a migrant applicant from another Member State who formally fulfils requirements under Directive 2005/36/EC for a right to mutual recognition of professional qualifications (authorisation as a medical doctor without limitations), when the professional experience of the applicant in Norway has unveiled insufficient professional qualifications?

THE COURT GAVE THE FOLLOWING ADVISORY OPINION

In principle, Directive 2005/36/EC precludes the authorities of EEA States from applying national rules providing for a right to deny an authorisation as a medical doctor to a migrant applicant from another EEA State who fulfils the requirements under the Directive for a right to mutual recognition of professional qualifications.

However, an EEA State may make an authorisation conditional upon the applicant having a knowledge of languages necessary for practising the profession on its territory.

Moreover, an EEA State may suspend or withdraw an authorization to pursue the profession of medical doctor based on information concerning the personal aptitude of a migrant doctor relating to the professional qualification other than language skills, such as the ones in question, only if such requirements are objectively justified and proportionate to achieve the objective of protecting public health and if the same information would also entail a suspension or withdrawal of authorisation for a national doctor. If such grounds for suspension or withdrawal are available to the competent authorities at the time of assessment, the authorisation may be denied.

More information:
http://www.eftacourt.int/images/uploads/1_11_JUDGMENT_EN.pdf

NEW EUROPEAN-WIDE CLINICAL TRIAL TO TREAT STROKE AND CVA VICTIMS

On 19 March 2012, the European Union announced that it would subside a new clinical trial throughout Europe, with the objective of treating volunteer stroke or cardiovascular/ cerebrovascular accidents (CVA) victims with mild hypothermia. The phase III clinical trial will be deployed in 25 European Countries, with an EU contribution of almost 11 million Euros. It will be coordinated by a consortium formed by the Universitätsklinikum Erlangen and the European Stroke research Network for Hypothermia (EuroHYP).

Stroke is the second cause of death worldwide and the second cause of reduced life expectancy. Every day, 1000 Europeans die of heart failure and about twice that number survive but remain disabled.

"Cooling", or therapeutic hypothermia, is currently already effectively used as a treatment to reduce ischaemic brain injury following cardiac arrest in adult patients or at birth, by induction of a sort of brain hibernation that reduces the need for oxygen and prevents additional damage.

The objective of the trial is to treat 1.500 volunteer stroke victims with mild hypothermia, and if the expected benefits are confirmed, the procedure will then be deployed across Europe with the potential of benefiting hundreds of thousands of patients each year.

The results of the experiment will be shared with other countries that are not familiar with the technique and with some of the EU's neighbouring countries such as Turkey, Croatia and Norway, who will also take part in the trial.

"A project of this scale would not be possible without a pan-European approach - no one country or smaller group of member states has yet managed to organise a clinical trial of therapeutic cooling for stroke despite widespread acknowledgment that this is an important and promising therapy", said Dr Malcolm Maclead, Lecturer and Head of Experimental Neuroscience at the Centre for Clinical Brain Sciences at the University of Edinburgh, United Kingdom.

PATIENT SAFETY, SATISFACTION, AND QUALITY OF HOSPITAL CARE – RN4CAST

The study "Patient safety, satisfaction, and quality of hospital care: cross sectional surveys of nurses and patients in 12 countries in Europe and the United States" was released on 20 March 2012 in the latest issue of the British Medical Journal.

The study aimed to determine whether hospitals with a good organisation of care (such as improved nurse staffing and work environments) could affect patient care and nurse workforce stability in European countries. It found that nurses who reported better working conditions in hospitals and less likelihood of leaving also had patients who were more satisfied with their hospital stay and rated their hospitals more highly.

The research developed a cross sectional study of 1105 general acute hospitals; 488 in 12 European countries (Belgium, England, Finland, Germany, Greece, Ireland, Netherlands, Norway, Poland, Spain, Sweden, and Switzerland), and 617 in California, Pennsylvania, Florida, and New Jersey in the US. It included 61,168 professional bedside care nurses and more than 130.000 patients from participating hospitals.

The study found that nurses in Poland and Greece were three times more likely to give their hospitals a failing grade for safety than nurses in the US and Norway. The majority of nurses in every country expressed a lack of confidence that hospital management would resolve problems in patient care.

Specifically the researchers found that:

- high nurse burnout and job dissatisfaction were common among hospital nurses in Europe and the US;
- on average, only 60 percent of patients were satisfied with their hospital care;
- those nurses reporting high levels of burnout (notably in Greece and England) also reported an intention to leave their current positions;
- each additional patient added to a nurse's workload increased the odds of a nurse reporting poor or fair quality of care;
- patients were less satisfied with their hospital stay in those hospitals that had higher percentages of burnt out or dissatisfied nurses.

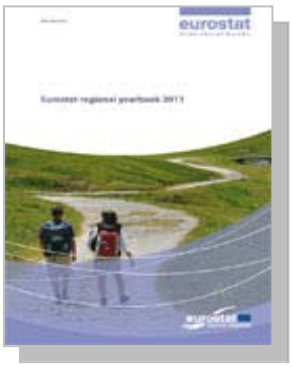
Policy implications for the findings suggest that despite the differences among the healthcare systems studied, particularly in terms of both organisation and financing, all countries encountered problems of "hospital quality, safety, and nurse burnout and dissatisfaction."

Many European nurses report they intend to leave their hospital positions, from 19 percent in the Netherlands to nearly half of all nurses (49 percent) in Finland and Greece, leading the researchers to ponder the potential for a worsening shortage of nurses. A significantly lower proportion of nurses in the US (14 percent) reported their intentions to leave their current positions, possibly due to increased efforts in the US to improve hospital nurse staffing levels. Having fewer patients per nurse has been linked to better outcomes for patients, including lower rates of death following everyday surgeries. Nearly 7 percent or 400 of the hospitals in the US have achieved "magnet status", so-called due to their ability to attract and retain nurses because of good work environments. No hospital in Europe has a similar "magnet" designation.

The study was developed by a consortium of investigators from 13 countries led by the University of Pennsylvania School of Nursing in the US and the Catholic University of Leuven, Belgium in Europe with a 3 million euro grant from the European Commission with additional funding from the National Institute of Nursing Research of the National Institutes of Health in the US.

Available at: http://www.bmj.com/content/344/bmj.e1717

EUROSTAT REGIONAL YEARBOOK 2011



The Eurostat regional yearbook 2011 has been published. It provides an overview of key statistics available for the regions of Europe on a wide set of very relevant social, economic and environmental issues, including health. Statistical information is an important tool for understanding and quantifying the impact of political decisions on the citizens in a specific territory or region. The aim of the publication is to cover as many subjects for which Eurostat collects regional data as possible.

The 2011 edition contains 16 chapters covering core subjects including one on health.

Considering that information on hospital discharges and causes of death are a prerequisite for monitoring the performance of health policy, the health chapter addresses this year some causes of death by cancer, the major form being combined neoplasms of the larynx, trachea, bronchus and lungs, and two gender-related forms, breast and prostate cancer. It also focuses on hospital discharges for in-patients suffering from those diseases.

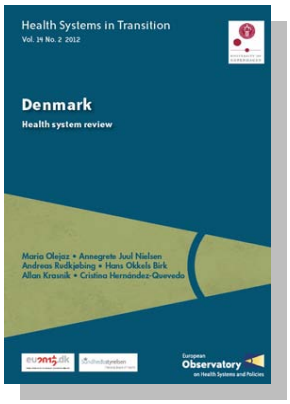
Causes of death data give information on diseases leading directly to death. They can be used as an indicator to plan health services. In the period 2006-2008 in the EU 27 the major cause of death was disease of the circulatory system, with the only exceptions of France and the Netherlands, where cancer took the lead. The form of cancer with highest death rates in all Member States, for all ages and both sexes, is combined malignant neoplasms of the larynx, trachea, bronchus and lung. The regions with the highest rates are Eszak-Alfold, Eszak-Magyarorszag and Del-Dunantul in Hungary. The regions with the lowest rates are Martinique, Guadeloupe and Guyane in France. The second largest cause of death by cancer in all ages and both sexes is breast cancer, together with malignant neoplasms of the colon. For women, the most-affected regions are Friesland, in the Netherlands, Trier in Germany and Bucureşti - Ilfov in Romania. The lowest rates were found in the French Reunion, Cantabria in Spain and Ionia Nisia in Greece. For men, the region with the highest rate is Ciudad Autonoma de Ceuta. Another gender-related form of cancer is malignant neoplasm of the prostate. The most affected regions are the French Martinique and Guadeloupe and the Finish Aland. The lowest rates are found in the Romanian regions of Sud-Vest Oltenia and Sud - Muntenia and the Spanish Ciudad Autonoma de Melilla.

Data on hospital discharges at national and regional levels are complementary means of estimating the frequency of treatment of some lethal diseases such as specific forms of malignant neoplasm. Regional data on hospital discharges of in-patients were not available until 2005 and not all countries are yet in a position to provide this data at sub national level. A comparison of the number of in-

patient discharges at the regional level indicates that regions in central Europe have the highest number of discharges per 100,000 inhabitants. Regarding the combined malignant neoplasms of the larynx, trachea, bronchus and lung, in principle, the area stretching from Germany in the west to Romania in the east and from Croatia in the south to Denmark in the north has higher rates of inpatients per 100,000 inhabitants than other areas of the EU. For breast cancer, again, the rates are highest in central Europe, followed by Finland and the Baltic States.

More information:
http://epp.eurostat.ec.europa.eu/portal/page/portal/publications/regional_yearbook

HIT DENMARK – WHO PUBLICATION



The WHO European Observatory on Health Systems and Policies has published the new profile of the Danish health system, part of the series "Health Systems in Transition" (HiTs).

The Health Systems in Transition (HiT) profiles are reports that provide a detailed description of a health system, reforms and policy initiatives under development in a specific country, providing relevant information to support policy-makers and analysts in the development of health systems in Europe and facilitating the exchange of experiences of reform strategies in different countries. They are based on a periodically revised template in order to facilitate comparisons between countries.

The new HiT on Denmark reflects recent health trends and structural changes in the Danish health system. Although this report reveals a system that generally provides high quality services within each sector, authors show that the fragmented structure of the Danish health system poses serious challenges in providing effectively coordinated care.

Traditionally characterised as a decentralised system, with responsibility for primary and secondary care located at local levels, several reforms from 2007 have strengthened coordination and centralised control in the Danish healthcare: the number of regions has lowered from 14 to 5 and the number of municipalities from 275 to 98.

Planning and regulation take place at both state and local levels. The five regions are responsible for hospitals as well as for self-employed health care professionals. The municipalities are responsible for disease prevention and health promotion.

More than 80% of health care expenditure is financed by the state through a combination of block grants and activity-based financing. Out-of-pocket payments play a major role in financing drugs, dental services and glasses, and a minor role for other services.

Most secondary and tertiary care takes place in general hospitals owned and operated by the regions. Outpatient clinics are often used for pre- or post-hospitalization diagnosis and treatments. The number of hospital beds has declined since the early 1990s in the acute, long-term and

psychiatric care sectors. Average length of stay has also declined through changes in treatment options, with an increase in outpatient treatment as well as a policy of deinstitutionalization in the psychiatric sector. Recent reforms include legislation on free choice of hospitals as well as waiting time guarantees, modernization of the hospital sector has included a restructuring of acute care, with centralization of units in so-called "joint acute wards". The government has also launched a major investment programme in new hospitals and improvements to existing ones.

The Danish Institute for Quality and Accreditation in Healthcare manages the Danish Healthcare Quality Programme (DDKM). DDKM is based on the principle of accreditation and standards and includes monitoring of quality of care in the primary and secondary sectors.

Doctors and other health professionals are employed in hospitals on a salaried basis. The number of physicians is experiencing a slight increase but recruitment problems persist, particularly in rural areas. General practitioners (GPs) act as gate-keepers and are fairly well distributed throughout the country. The number of nurses has increased in recent decades and during the past 5 – 10 years active recruitment of health workers from outside Denmark has taken place.

The use of information technology (IT) has received increasing attention within the health care sector and all primary care doctors now use electronic medical records.

A series of laws and initiatives have been introduced since the 1990s to strengthen patient rights, including national laws on patient choice as well as the establishment of an independent governmental institution responsible for complaints procedures.

Future concerns pertain to three key areas: prioritization of resources, solving the problem of a declining workforce and the organisation of the health system.

Available at:
http://www.euro.who.int/__data/assets/pdf_file/0004/160519/HIT_Denmark_080312.pdf

AMERICAN CHAMBER OF COMMERCE – INVESTMENT IN HEALTHCARE

The American Chamber of Commerce to the European Union (AmCham EU) invited HOPE to present its views during its February Plenary Meeting dedicated to investment in healthcare. The meeting took place on 28 February 2012 in Brussels.

The monthly plenary meetings bring together AmCham EU members and key decisionmakers. AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. According to AmCham aggregate US investment in Europe totaled €1,2 trillion in 2008 and currently supports 4,8 million direct jobs in Europe.

On 28 February 2012 AmCham released paper "Explaining AmCham EU's Position on Investment in Healthcare" aims to demonstrates why health matters, highlights promising areas for investment and asks for more sustainable solutions to maintain and increase Europe's competitiveness.

AmCham EU's background paper on investment in healthcare identifies five areas for investment such as prevention, e-health, medical innovation, integrated care and investment in citizens and patients. Health can only contribute to wealth when the right policies are in place. Such policies are required to meet the goals of the Europe 2020 strategy for smart, sustainable and inclusive growth.

AmCham EU recommends in particular:

- safeguarding innovation in the long run by implementing policies that overcome static thinking and unleash dynamic efficiency;
- providing smart regulations that are limited to their purpose;
- supporting innovative partnerships between the public and private sectors;
- taking a consumer approach to empower citizens to be innovators in their own health.

Robert Madelin, Director General for Directorate General Information Society, delivered a keynote speech clearly in line with the AmCham position.

MEASURING AND COMPARING QUALITY IN THE PUBLIC SECTOR

The Swedish Association of Local Authorities and Regions (SALAR) and the European Policy Centre (EPC) jointly organised a workshop entitled *Measuring and Comparing Quality in the Public Sector*, which took place in Brussels on 6 March 2012.

HOPE attended the event, which revolved around two presentations: one of the SALAR experience and one of the OECD's plans in regards to the measurement and comparison of quality in the public sector.

The Chair of the meeting and Chief Executive of the EPC, Mr. Hans Martens, highlighted the need for some European benchmarking in terms of the quality of public sector services in Europe. He put emphasis on the necessity to evaluate and look at the public sector in terms of the relationship between the quality of public sector services in terms of output and the costs of those services.

Håkan Sörman and Stefan Ackerby, from SALAR, presented what had been done in the past years in terms of benchmarking and ranking of public services in Sweden. The Swedish health sector was one of the key sectors to be was analysed and ranked by SALAR. According to the two representatives form SALAR, the open comparisons between various Swedish regions in terms of the quality of their health services was a success and represented an incentive for public authorities to improve the quality of their services.

More information:
http://english.skl.se/about_salar

BIOLOGICALS EXPERIENCE – HOW TO ENSURE BEST POSSIBLE PATIENTS' OUTCOMES

HOPE was invited with key stakeholders to a seminar on biosimilars that took place in Brussels on 7 March 2012.

This issue is particularly important for hospitals as many biologics are not sold in the retail setting but are administered at specialty practices or at hospitals. On their side, biosimilars manufacturers are currently faced with a choice: seek the minimum needed for regulatory approval and drive sales only through aggressive pricing and contracting; or take on the higher costs of addressing the biologics experience and building long-term confidence among the public in the quality, safety and efficacy of Biosimilars.

The purpose of the meeting was then to get an overview of the different issues around biosimilars. It focused primarily at patient outcome. It aimed for a better understanding why biologicals are different.

Patients often have a very different experience with biologicals than small-molecule chemical drugs. Since they require not only specific maintenance but also different administration, treatment with biologics can be challenging. In addition, the patients' outcome depends on the various healthcare providers that are involved in the treatment process: medical doctors, pharmacists, nurses, payers

but also the manufacturers. The specificities of treatment with biologics, the "Biologicals Experience", require a coordinated approach so that best possible patient outcome is ensured. This experience is a crucial factor for the success of both originator biologics and Biosimilars.

ECONOMICS AND HEALTH OUTCOMES IN HAEMOPHILIA

On 7 March 2012, HOPE attended a Round Table on the Economics and Health Outcomes of Haemophilia, which was organised by the European Haemophilia Consortium (EHC).

Several national haemophilia organisations, as well as other stakeholders such as representatives of the pharmaceutical industry were also present at the event.

The President of EHC, Mr. Brian O'Mahony, addressed the issue of the economics of haemophilia, mentioning the different costs associated to the disease, both direct and indirect, and highlighting the role of Health Technology Assessments (HTA). Mr. Daniel Arnberg, from the Swedish Haemophilia Society, illustrated this through a short presentation focusing on the case of Sweden, where a Health technology Assessment (HTA) is currently being undertaken on Prophylaxis and other haemophilia treatments. Among other things, the HTA is looking at the economic costs and the outcomes of the different products available for treating haemophilia. The question of data collection on haemophilia was also approached by Dr. Michael Makris from the University of Sheffield.

Finally, the pharmaceutical industry was able to give its perspective on the economics and health outcomes of Haemophilia.

More information:
http://www.ehc.eu/

INCREASED EUROPEAN COOPERATION ON PUBLIC HEALTH ISSUES

On 14 March 2012, EuroHealthNet and South-Eastern European Health Network (SEEHN) signed a Memorandum of Understanding to strengthen their cooperation in the field of public health, with a special focus on topics related to the prevention of non-transmissible diseases, mental health and combating inequalities in health.

Through this partnership for cooperation, the two Networks seek to reinforce public health services and capacities and improve equitable access to health care.

More information:
http://eurohealthnet.eu/policy/news-from-eurohealthnet

EUCOMED CONFERENCE VETTING SYSTEM – PILOT PHASE

On 21 March 2012, Eucomed (European medical technology industry association) launched a Conference Vetting System" (CVS), which will review and approve third-party educational conferences in accordance with the Eucomed Code of Ethical Business Practice.

The Code's purpose is to regulate interactions between Eucomed member companies and healthcare professionals, in order to ensure that industry's support of certain activities does not fuel inaccurate perceptions regarding the relationship between industry and clinicians, physicians, and nurses. These relationships should not raise questions regarding their bona fide nature and we should ensure that they cannot be construed as inappropriate value transfer and illegal financial ties between industry and clinicians. In that regard, the Code covers all types of interactions, such as research and consulting agreements, gifts as well as sponsoring of healthcare professionals to attend product trainings or third-party professional and educational conferences. In the latter case, because healthcare professionals are often sponsored by the medical technology companies to attend conferences It is critical that sponsoring is conducted in the most ethical, consistent and transparent manner.

In that framework, Eucomed has supported the creation of the EthicalMedTech platform dedicated to ethics and compliance projects in the European MedTech industry of which the Conference Vetting System is an integral part.

The Conference Vetting System is a centralised European system which will review the compliance of third-party educational conferences and congresses with the Eucomed Code. The system operates independently of Eucomed to ensure objectivity in conference assessments. It is the first system of its kind in the healthcare industry due to the binding nature of its assessment outcomes. The system assesses conferences in the geographical area covered by Eucomed's members and associate members (currently the European Union, Iceland, Liechtenstein, Norway, Switzerland, Russia, Turkey and the Middle East).

The system was launched on 21 March for a pilot phase expected to last 6 months, during which assessments will be recommendations only.

More information:
www.ethicalmedtech.eu

CHRONIC OBSTRUCTIVE PULMONARY DISEASE – CALL TO ACTION

21 March 2012 was the date of the official launch in the European Parliament of the European COPD Coalition (ECC) and the Call to Action on COPD (Chronic Obstructive Pulmonary Disease). Two representatives of the European Commission, one member of the European Parliament, ECC representatives and a patient suffering from COPD were the speakers of this meeting, attended by HOPE.

According to ECC, up to 10% of the European population suffers from COPD in Europe and most of them do not know they have it. An estimated 300,000 deaths in Europe are from COPD each year while thirty billion Euros are wasted through lost production. The World Health Organization (WHO) estimates that COPD, which is mainly caused by tobacco smoke exposure, will be the third cause of death worldwide by 2030.

Dr. Sylvia Hartl, medical Director of the Sozialmedizinisches Zentrum Baumgartner Höhe Ott-Wagner-Spital und Pflegezentrum, presented the findings and conclusions of the COPD Audit. This first European Audit on COPD made in some hospitals of 13 European countries showed that nearly 50 % of patients were either dead or back in hospitals within the 3 months of admission for a lung attack related to COPD. Early discharge programs are not always available, as well as rehabilitation or palliative care. Spirometry tests are done in less than 65% of cases although the study showed a great variability among countries.

Dr. Grigorij Kogan, Directorate General Research & Innovation explained that, although 250 million Euros were allocated for respiratory research projects, only 2 of the 50 projects financed (6 million Euros) were addressing COPD.

ECC Call to Action promotes 21 concrete measures to be put in place or supported by the European Union, in full cooperation with Member States, regulating bodies and stakeholders. The European COPD Coalition's Call to Action seeks political impetus to settle the right structure addressing all aspects of COPD: health promotion and prevention; healthcare; research and information. This framework should aim to improve the health and quality of life of European citizens, including persons at risk of, or affected by, COPD.

The reasons why COPD has drawn so little attention so far were, on the opinion of speakers in the event, because of the lobby from the tobacco industry and the fact that the illness appears very slowly and smokers minimize the impact.

More information:
http://www.copdcoalition.eu/what_we_do/call-to-action

EUROPEAN ALLIANCE ON PERSONALISED MEDICINE – CALL TO ACTION

On 27 March 2012, the European Alliance for Personalized Medicine (EAPM) launched its call to Action in the European Parliament. Personalised medicine is defined by the Alliance as products and services that leverage the science of genomics and proteomics (directly or indirectly) and capitalise on the trends towards wellness and consumerism to enable tailored approaches to prevention and care.

The EAPM, which is a multi-stakeholder platform, pointed out five main objectives of the Call:
1. ensuring a regulatory which allows early patient access to novel and efficacious personalised medicine;
2. increase research and development for personalised medicine;
3. improve the education and training of healthcare professionals;

4. acknowledging new approaches to reimbursement and HTA assessment, which are required for patient access to personalised medicine and its value to be recognized;
5. increase awareness and understanding of personalised medicine.

Paola Testori Coggi, Director General of DG SANCO, declared that the Commission will revise the regulatory system "to have it flexible enough" as now is "too complex" and "burden" for clinical trials.

Patricia Reilly for DG Research pointed out the progress achieved with cancer treatment so far. The Commission has already allocated 900 million Euros in research related to personalized medicine in the FP7.

Marian Harkin, member from the European Parliament explained that in Horizon 2020, the next Framework for Research and Innovation will provide research with 80 billion Euros and that "personalised medicine will remain among the priorities". She pointed out the importance of finding the right equilibrium between patient's protection and a more simple regulation for clinical trials.

HOPE, together with PriceWaterhouseCoopers, has recently published Personalised Medicine in European Hospitals. This report identifies key elements in the development of personalised medicine in European hospitals. This collaboration will help determine of the current state and the desired future state of personalised medicine practices within European hospitals, and will thoughtfully facilitate the creation of a culture of customised healthcare.

HOPE-PwC report on Personalised Medicine in European Hospitals:
http://www.hope.be/05eventsandpublications/personalised_medicine.html

PROVIDER-PAYMENT ASSESSMENT TOOL IN DEVELOPMENT – WHO EUROPE

WHO, along with the World Bank and the Joint Learning Network for Universal Coverage (JLN), is developing a diagnostic and assessment guide to support countries making reforms to mechanisms for paying health-service providers.

Health-systems financing is one of the key factors determining access to health services, the costs to patients and the quality and efficiency of service delivery. Many countries in the WHO European Region and globally seek ways to make health services available to all, as a key component of health-system reform.

Assessing and reforming provider-payment mechanisms can improve efficiency and quality in service delivery, which means increased value for money. In turn, efficiency gains can be used to extend population coverage or add new services to the benefit package. Improving efficiency helps health ministers make a stronger case for investing more in health.

The new tool will enable the assessment of provider-payment mechanisms in the wider context of health-system performance, and focus on avoiding unintended consequences from making reforms. Its development will take a year, and include field tests in selected countries.

The project to develop the tool is a JLN initiative, guided by a group of experts. Partners in the project include the Rockefeller Foundation, the Bill & Melinda Gates Foundation, the governments of Germany and the United Kingdom, the World Bank and the Results for Development Institute. The work of the expert group on provider payment is led by co-chairs from the World Bank, JLN and WHO. WHO/Europe hosted the first meeting of the expert group on 27–28 February 2012.

More information:
http://www.euro.who.int/en/what-we-do/health-topics/Health-systems/health-systems-financing/news/news/2012/12/provider-payment-assessment-tool-in-development

WHO/EUROPE TO ASSIST GREECE IN PHARMACEUTICAL HEALTH CARE PRICING

WHO/Europe has responded positively to a request from the Greek Ministry of Health and Social Solidarity to provide technical assistance in the field of pricing and reimbursement of pharmaceuticals and other public health areas based on a joint assessment.

This was announced by, at a conference about the future of health care in Greece held in Athens on 20 March 2012, organised by the Financial Times, under the auspices of the Greek National School of Public Health and in association with the Hellenic Association of Health Services Management.

During the conference, Dr. Hans Kluge, Director of the Division of Health Systems and Public Health of WHO/Europe shared regional experiences of increasing the efficiency of health care and public health, including in the pharmaceutical and hospital sectors. Highlighting the need to protect the poor and vulnerable, he urged conference participants not to forget the quality of care, and the need to involve patients and the community. Protecting the health workforce is of paramount importance, especially in the areas of nursing and midwifery.

More information:
http://www.euro.who.int/en/what-we-do/health-topics/Health-systems/health-systems-financing/news/news/2012/12/whoeurope-to-assist-greece-in-pharmaceutical-health-care-pricing

DUTCH COLLABORATING CENTRE WORKING ON NEW APPROACH TO PRIMARY CARE

On 20 February 2012, WHO/Europe agreed key research areas for the next two years with the Netherlands Institute for Health Services Research (NIVEL), a WHO collaborating centre for primary care.

Work will focus on achieving sustainable and measurable outcomes, based on the new conceptual approach of giving primary care a pivotal role in the health-service delivery system. NIVEL will draft research proposals on:

- the role of primary care in the health-care delivery system to address co- and multimorbidity;
- new ways to achieve people-centred care in the system.

The new approach also means that products and new developments in primary care must be aligned with work to strengthen the health-service delivery system. The collaborating centre will adapt its primary-care evaluation tool so that it can be used to evaluate multiple countries. Ministries of health and other stakeholders currently use the tool, in the form of a survey, to look at both the supply and demand of primary care, monitor progress on primary-care policies and set new priorities based on evidence. In addition, peer review of the tool is planned to occur by the end of 2012.

Further, NIVEL is developing a non-communicable disease module based on the tool to assess the effectiveness of interventions and activities in primary care and to map the situation in countries.

Finally, NIVEL will continue its work with other European collaborating centres for primary care:

- the International Centre for Primary Health Care and Family Medicine, Department of Family Medicine and Primary Health Care, Ghent University, Belgium; and
- the Andrija Stampar School of Public Health, Medical School, University of Zagreb, Croatia.

More information:
http://www.euro.who.int/en/what-we-do/health-topics/Health-systems/primary-health-care/news/news/2012/03/netherlands-collaborating-centre-working-on-new-approach-to-primary-care

INNOVATION IN HEALTHCARE WITHOUT BORDERS

16-17 April 2012 – Brussels (BE)

The European Commission is organising in collaboration with several European stakeholders a conference on innovation that aims to bring together the key stakeholders involved in the innovation process of the healthcare sector in view of Europe 2020 and the Innovation Union Plan.

The main objective of the conference is to act as an innovation in healthcare policy forum involving the key actors and policy-makers in order to:

- identify major challenges and build consensus to address them;
- develop initiatives and opportunities for Healthcare Innovation;
- provide continuity with previous events.

2012 Conference sessions will develop two tracks:

"Removing borders in the health supply chain" assessing priorities achieved to date and areas where additional efforts are needed

"Inequality and solidarity" exploring new challenges within EU and beyond.

Building on the events of May 2010 and March 2011, the 2012 conference is organised by the services of the European Commission (DG Research and Innovation, DG Enterprise and Industry, DG Health and Consumers, DG for Regional Policy), in consultation with other relevant DGs, major health associations and stakeholders.

Commissioner for Research and Innovation Máire Geoghegan-Quinn, Commissioner Antonio Tajani, responsible for Industry and Entrepreneurship, Commissioner for Health and Consumers John Dalli and Regional Policy Commissioner Johannes Hahn are invited to be among the speakers.

The programme of plenary and parallel sessions will allow a large space for debate and networking. It will be complemented by a small "fair" where associations and support structures will provide information to participants.

Programme and registration:
http://ec.europa.eu/research/health/events_en.html
Information on the 2010 and 2011 conferences, including outcome reports:
http://ec.europa.eu/research/health/innovation-in-healthcare-2011_en.html

AGING HEALTH WORKFORCE – AGING PATIENTS: MULTIPLE CHALLENGES FOR HOSPITALS IN EUROPE

11-13 June 2012 – Berlin (DE)

In 2012, HOPE Exchange Programme will be organised for the 31st time. This 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.

Each year a different topic is associated to the programme, which is closed by HOPE Agora, an evaluation meeting and conference. "Aging health workforce – aging patients: multiple challenges for hospitals in Europe" is the subject for 2012. HOPE German Member will organise the 31st edition of HOPE Agora in Berlin on June 11-13, 2012.

More information on HOPE Exchange Programme:
http://www.hope.be/04exchange/exchangefirstpage.html

Aging health workforce – aging patients: multiple challenges for hospitals in Europe

HOSPAGE

FROM 11 TO 13 JUNE 2012 IN BERLIN, GERMANY

The European symposium on "Aging health workforce – aging patients"

Featuring the AGORA of HOPE Exchange Programme 2012

More information and registration:
www.hospage.eu