

EXPERT CONTRIBUTION

**Reflecting a successful Belgian
Presidency from a health perspective**

As for the outcome of the Belgian Presidency in the pharmaceutical field, the Belgian Federal Agency for Medicines and Health Products (FAMHP) wants to draw attention to the achievement in December 2010 of a political agreement concerning the draft

Directive regarding the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source. This will pave the way for a first reading agreement in a highly complex political and technical dossier. Issues such as a regulation regarding the offer for sale of medicines via the internet, the introduction of safety features on medicines that present a risk of falsification, the increased control on all the operators who deal with medicines or active substances, the control in transit zones, the traceability of suspected counterfeit medicines via the possibility of recalls from patients etc., were concluded among the three institutions in the last months of 2010.

On the non-legislative agenda, the Ministerial Conference Innovation and Solidarity in Pharmaceuticals, held on 23-24 September in Brussels, should be mentioned. This Conference led to the adoption of conclusions of the Council on which unanimous agreement was reached on the political level on specific pathways in order to improve the response to the unsatisfied needs of patients. This included issues such as the strengthening of coordination and prioritisation in the allocation of resources for pharmaceutical research to increase the probability of valuable innovations that meet previously unsatisfied health needs, the exchange of information and experiences on exceptional procedures aiming to improve early access to medicines, the work on how information regarding relative effectiveness can be included as soon as possible in the development phase of a medicine.

Other realisations in the pharmaceutical field worth mentioning are the adoption of the Strategy 2015 at the level of the Heads of the Medicines Agencies (HMA).

As a result of the Belgian Presidency, much could be achieved to significantly improve patient safety and health care quality.

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IMPRINT

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CALENDAR

17 MARCH 2011**HEALTH CARE IN EUROPE:
TRANSFORMING POLICY, SYSTEMS
AND FUNDING, GENEVA/SWITZERLAND**

Under the motto: More for less: vision or illusion?, this one-day conference will address the question of whether current health care reforms are missing any opportunities to improve quality. Prominent speakers, including WHO Regional Director Zsuzsanna Jakab, OECD Deputy Secretary General Aart de Geus, and EMA Executive Director Thomas Linngren, will present new thinking in health care policies, and the impact of new technologies.

For more information please see:

<http://eu.economistconferences.com> ■

30-31 MARCH 2011**INNOVATION IN HEALTH CARE:
FROM RESEARCH TO MARKET,
BRUSSELS/BELGIUM**

This joint conference of DG Research and Innovation, Enterprise and Industry, and Health and Consumers will highlight the necessary policy developments for research and innovation in the health care sector at European and national levels. Participants, including Commissioners John Dalli, Maire Geoghegan-Quinn, and Antonio Tajani, seek to make specific recommendations to stakeholders.

For more information please see:

<http://ec.europa.eu/research/health> ■

7 APRIL 2011**WORLD HEALTH DAY**

The World Health Day 2011 is dedicated to the theme Antimicrobial resistance and its global spread. The World Health Organisation will launch a worldwide campaign to raise awareness of the increased number of drugs available and their jeopardized effectiveness for future generations. Special focus will be placed on HIV/AIDS, tuberculosis and malaria epidemics.

For more information please see:

<http://www.who.int/world-health-day> ■

PHARMACEUTICAL DIALOGUE 21

+ + + INFORMATION FROM THE PARALLEL TRADE INDUSTRY + + + FEBRUARY 2011 + + +

PHARMACEUTICAL PACKAGE & HEALTH CARE

Health continues to be high on the political agenda

The part on patient information is still required to complete the pharmaceutical package. However, even with the end of the package in sight, the topic of health will remain high on the political agenda. Health care expenditures are constantly rising and cost efficiency becomes more vital than ever to secure sound health care systems across Europe.

The plenary session in February brought a successful end to the report of Marisa Matias on counterfeit medicinal products. The agreement could be reached during the successful Belgian Presidency (also see expert opinion). However, the pharmaceutical package coming to an end represents just the beginning of essential reforms to European health care systems as many challenges remain. This is also reflected by the full health agenda of the Hungarian Presidency (see expert opinion in the previous edition). In particular, the issue on financial sustainability will continue to be a top priority. This fact was also demonstrated by the Hungarian Minister for National Resources, Miklós Ráthelyi, during the exchange with the European Parliament at the end of January: Ráthelyi conceived the idea of a joint meeting of EU-Finance and Health Ministers to tackle the matter of financial constraints and health care systems.

How to shape the future health systems in Europe? A question often asked, an answer often given: by cost efficiency. A more efficient management would enable us to steadily increase the quality of our health care, while meeting the demands of society. This also requires an open discussion about innovative solutions and products as well as a shift towards more long-term thinking on health care budgets.

The Alliance for cost-efficiency in healthcare (COSTEFF), of which VAD is a founding member and a driving force, will actively promote these issues of cost efficiency in 2011. The financial burden on patients and health care systems can be reduced by fully unlocking the potential of the industry and health care actors in order to be able to offer affordable medicines and homecare technologies. ■

EDITORIAL



Dear Readers,

The German Association of Pharmaceutical Parallel Distributors (VAD) has made great efforts to

communicate its expertise to European decision makers and be a dialogue partner during the preparation of the pharmaceutical package. In particular, our Pharmaceutical Dialogue accompanied the decision-making process throughout its journey. We thank our readers sincerely for the continuing interest.

The constant positive feedback on this piece of information challenged us to continue our efforts. Additionally, we want to go a step further and widen the issues in the Pharmaceutical Dialogue. Therefore, the dialogue will be edited by the VAD in cooperation with its European partner association, the Alliance for cost-efficiency in healthcare" (COSTEFF).

COSTEFF, founded in 2009, aims at raising the awareness of EU decision makers of the potential of cost effective innovative solutions emanating from the industry and the health care sector in general. Therein lies great potential; it just has to be picked up.

Sincerely,

Prof. Edwin Kohl
President of VAD & Chairman of COSTEFF

Combating the trend of rising health expenditures

Health expenditures in the European Union have been constantly rising over the last decades, and recent trends are not promising any good news for a ‘healthy’ financial recovery. Therefore, supporting financial sustainability will need to focus on public expenditure on health and public provision of health services and goods, representing the majority of overall spending and supplemented in just a small measure by private expenditures. Concrete measures have to arrest the progress of health expenditures which are growing faster than both GDP and population.

The driving factors of health spending for all European countries are demographic factors, rising income, technological changes, and systematic inefficiencies. These trends will continue to put pressure on European budgets, with alarming forecasts of public expenditure on health and long-term care almost doubling between 2005 and 2050 on average across EU countries, according to the OECD.



Source: EPC-Commission joint report on health systems, November 2010

Long-term sustainability of health expenditures at risk

The aging of the population, rising expectations for health care quality, as well as new and highly expensive technologies are not halting the growth in health spending. But in the end, our health care systems should aim to improve citizens' health, guarantee fair financing, and respond to patients' expectations, including quality, dignity, and confidentiality. Facing these opposing trends, efficiency and effectiveness of health care systems must be improved. Many Member States have implemented health care reforms in the past by successfully improving the way resources are used in the health care sector. However, continued fiscal consolidation measures will also cut financial resources available for health care. Tough choices lie ahead to secure the sustainability of our health care systems.

What options do we have?

Many EU countries recently implemented reforms in their health care systems in a fiscal and administrative manner. Cost efficiency is thereby one of the key elements of these reforms: The theme should read getting more value out of the money which is allocated to the health care sector. It is crucial to push innovative solutions. Just to mention a few: innovative channels of distribution of pharmaceuticals, biosimilars, as well as homecare. A better use of resources and available solutions can lead to improved health care services.

NEWS IN BRIEF

WHO STATUS REPORT ON ALCOHOL AND HEALTH IN EUROPE

The newly published WHO status report draws an alarming picture of Europe's alcohol behaviour and health consequences: The WHO European Region is the heaviest drinking region in the world.

The level of drinking varies among countries, leading to an average of 9.24 litres of pure alcohol consumption per person per year. The harmful use of alcohol is a significant burden on European health care systems.

However, alcohol-related harm can be successfully reduced by implementing the right alcohol strategies at policy level.

FIRST EUROPEAN GUIDELINES FOR SCREENING AND DIAGNOSIS QUALITY ASSURANCE IN COLORECTAL CANCER

Colorectal cancer is the most common newly diagnosed cancer in Europe. 150,000 Europeans die prematurely each year due to colorectal cancer, making it the second-most common cause of cancer deaths.

However, early detection followed by effective screening and high quality treatment could avoid many of these deaths.

Therefore, the European Commission published its first guidelines for quality assurance in colorectal cancer screening and diagnosis, which were requested in the Council conclusions of 2003 and built on the positive experiences gained from the European guidelines for breast and cervical cancer screening.

Toughest smoking ban enforced in Spain



While the European Commission is preparing its proposal on the revision of the Tobacco Products Directive 2001/37/EC – planned for the first quarter of 2012 – Spain already stepped forward: At the beginning of this year, Spain introduced Europe's toughest smoking ban for all enclosed public spaces like bars and restaurants and even some open-air ones, including children's play areas and outside hospitals. Additionally, it also prescribed high fines for infractions, ranging from 30 € for individuals to up to 600,000 € for establishments that break the law.

All EU member states have some kind of regulation in force, but the rules vary significantly from country to country. Therefore, the European Commission is currently considering the harmonisation of the presentation of warning labels and presence of substances in tobacco products, the improvement of consumer information, and the regulation of market access to tobacco products. Legislative trends of implementing stricter smoking ban rules are on the increase, while in some member states, e.g. Austria, Denmark, and Slovenia, more than one third of the population still smokes. The European Commission estimates the macroeconomic cost of tobacco-related diseases at 2.46 billion € per year. ■

New series: European health care systems in comparison

This new series will compare two health care systems simultaneously, highlighting national success stories, and compiling facts and figures in a qualitative way. European health care systems vary from country to country. They face some common challenges, but as much as the systems differ, as much the answers must differ. The Pharmaceutical Dialogue will compare different systems and present best practices in the following five editions. Let's get started: Belgium in comparison with its northern neighbour, the Netherlands.

Belgium has one of the highest health care expenditures (10.2% in 2008) in the EU. A little less but still above the EU-average is the situation in the Netherlands: Total expenditure on health as a percentage of GDP accounted for 9.9% in 2008.

Several health care reforms, including policies to control pharmaceutical expenditure, to strengthen primary care, and to improve lifestyles, have been successfully implemented in Belgium and the Netherlands. An article in Health Affairs (May/June 2008) even suggested that the Dutch health system may serve as a model for the US. The Dutch approach successfully combines mandatory universal health insurance with competition among private health insurers.

However, there are still challenges ahead for both countries: The main problem for the Netherlands is that health care seems to be relatively low in volume but high in price compared to other countries. In Belgium, it will be essential to manage the supply of professionals and strengthen primary care. Simplified administrative procedures will improve the quality of the system and help curb spending. ■

GLOSSARY

TOTAL EXPENDITURE ON HEALTH

The OECD defines 'total expenditure on health' as the sum of expenditure on medical, and paramedical activities, as well as nursing knowledge and technology aiming at among others promoting health and preventing disease, curing illness, providing health insurance, other funding arrangements, and health programmes.

GENERIC MEDICINE & BIOSIMILARS

A generic medicine is an equivalent of an original pharmaceutical product. It contains the same active substance, and is therefore interchangeable with the original product. A generic medicine is marketed in compliance with international patent law. Generic medicines are widely used in many EU countries in cost-effective treatment programmes, and are increasingly prescribed by doctors as effective alternatives to higher-priced original pharmaceuticals. It is important to distinguish generics from biosimilars: Biosimilars describe officially-approved subsequent versions of innovative biopharmaceutical products made by a different sponsor following patent.

IMPORTED PHARMACEUTICALS

Imported pharmaceuticals are bought from wholesalers (in particular EU countries) and then imported into a third EU country, e.g. Germany. Patients take advantage of the price differences between the country of origin and the target market for the same pharmaceutical. It is common to differentiate between parallel imports and re-imports depending on the location of manufacturing.