

# PHARMACEUTICAL DIALOGUE 28

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

## PHARMACEUTICAL & HEALTH CARE POLITICS

### Important consultations being finalised



The European Commission is actively opening one consultation process after the other concerning public health. While their contribution periods are coming to an end, COSTEFF and the VAD are working hard to contribute to all of these important policy areas.

The European association COSTEFF has already submitted its response on the concept paper concerning the implementation of measures for the performance of pharmacovigilance activities, and will continue to do so with the other consultations. On pharmacovigilance, COSTEFF points out the fact that the pharmacovigilance activities should also describe the scope and content of the implementation of measures for parallel distributors. This is especially true for parallel traded drugs which are centrally authorised according to regulation (EC) No 726/2004.

Parallel distributors want to contribute to the pharmacovigilance system to make the European medicinal product system safer and more transparent. As a meaningful contribution to the forthcoming European pharmacovigilance system, it could be seen as an obligation for parallel distributors to report on any serious adverse reactions to the national authorities. Parallel distributors cannot determine the risk-benefit balance of a drug. All adverse reactions should be collected, assessed and recorded in internal individual case safety reports which must be available on request to the national authorities at any time.

COSTEFF is currently preparing its contribution to the consultation on good distribution practice, which is due at the end of the year. Good distribution practice needs to take account for appropriate storage and distribution of medicinal products. It needs to consider the new requirements for wholesale distributors and brokers established by the new Directive 2011/62/EU. ■

## EDITORIAL



Dear Readers,

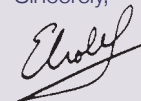
This edition of the Pharmaceutical Dialogue recognises the success of a pilot project carried out in Germany this year: In cooperation with the AOK

Nordost, one of Germany's biggest health care funds, 7x4 Pharma launched a trial on individualised blister packaging of medicines, bringing quality advantages into the daily health care of 550 patients, 21 health care installations, as well as 14 pharmacies. For many people requiring medicines over the long term, blister packaging is a godsend, allowing them to continue with their own medication for longer periods within the privacy of their own homes.

The project demonstrated once again that cost effectiveness and cost efficiency in health care is possible, while improving the quality of medicinal products and safety for patients.

In the face of the demographic challenge and existing systems of provision, it will be practically impossible to provide adequately for the medical requirements of an ageing population. Accordingly, there is an urgent need to develop creative and forward-looking approaches to solve this problem. The members of VAD and COSTEFF are constantly working to achieve these objectives.

Sincerely,



Prof. Edwin Kohl

President of VAD & Chairman of COSTEFF

## 7x4 Pharma – pilot project successful: cost-efficient and convenient for patients



In cooperation with health care installations, the AOK Nordost as well as several other health care funds and the BVDA (a national association of pharmacists) in Berlin/Germany, the 7x4 Pharma research project was successfully concluded, shown by the data of the University of Münster. The research results show that the individualised blister packaging of medicines for patients brings several advantages. Against the background of a continuously ageing society, individualised blister packaging provides a necessary contribution to quality and cost reduction.

7x4 Pharma's initiative is an innovative, service-oriented concept of automated individualised blister packaging of medicines for patients. It offers patients, pharmacists and other health care professionals an individually tailored service. Pharmacists will receive reliable and cost-effective support in providing individually packaged medicines to the chronically ill and, in particular, to elderly people. In this way, 7x4 Pharma would like to make a significant contribution to ensuring quality in the provision of medicines in the future.

7x4 Pharma was successful with its pilot project. Now it is time to set the course for necessary political legislation and an organizational framework within the health care funds. The project partners ask for binding legislative frameworks to provide for individualised blister packaging leading to higher quality and less cost.

### Blister packaging increases quality of life and saves money

The joint project between AOK Nordost, one of Germany's biggest health care funds, the Federal Association of German Pharmacists (BVDA) and 7x4 Pharma, which was carried out in 2009-2011, was a great success. The project included 550 patients, 21 health care installations, as well as 14 pharmacies. The research question asked whether there are direct or indirect economic effects of a switch from manual prepared to automated individualised blister packaging of medicines. And the question can definitely be answered with: Yes! The results of the study proved that automated individualised blister packaging reduces costs and increases medicinal safety.

### In a nutshell: an overall positive experience

Individualised blister packaging of medicines leads to fewer and shorter hospital stays. The study shows a reduction of 26.9 per cent in hospital stays; the duration of the stay decreased by 26.3 per cent. As a result: Costs could be reduced by 2,000 € per patient per year. With the use of the weekly blister for individual patients, direct savings are made possible because fewer medicines are wasted, less expensive generic drugs can be used, and only those tablets actually delivered are invoiced. In terms of indirect costs, the potential for savings lies in the safer and more effective therapy. Individualised blister packaging achieves its greatest potential with ambulatory treatment of chronically ill patients. However, blister packaging is more and more asked for by care homes as well. It contributes to avoiding the cost-intensive consequences of medicines being taken incorrectly, as evidenced by a rise in hospital admissions. ■

## NEWS IN BRIEF

### OECD: A SYSTEM OF HEALTH ACCOUNTS

The OECD, in cooperation with the WHO and the European Commission, recently published another work on health, "A System of Health Accounts".

This paper provides a systematic description of the financial flows related to the consumption of health care goods and services. As more and more countries increase their information demand, and at the same time implement health accounts, the data is getting more detailed and comparable.

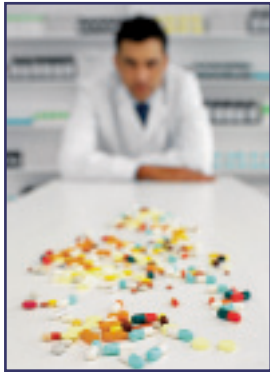
The aim is to create a single global framework for producing health expenditure accounts. Thereby, resource flows can be tracked from source to use. This new publication builds on the original OECD Manual, published in 2000, and the Guide to Producing National Health Accounts.

### PUBLIC CONSULTATION ON THE RECOGNITION OF PRESCRIPTIONS ISSUED IN ANOTHER MEMBER STATE

The European Commission launched a new public consultation on the measures for improving the recognition of prescriptions issued in another Member State. The objective is to consult stakeholders – including patients, health care professionals and the medical industry – on their view on the recognition of cross-border prescriptions.

The legal background is article 11 of the directive on patients' rights in cross-border health care, adopted in March 2011. Contributions can be made until 8th January 2012, by online questionnaire on the funding of many high quality actions.

## The European Commission's new Health and Consumer Programmes for 2014 – 2020

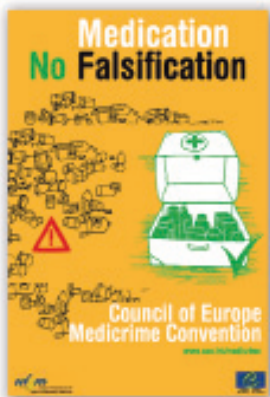


The Health for Growth Programme, running from 2014-2020 with a budget of EUR 446 million, will aim to foster a Europe of healthy, active, informed and empowered citizens. Keeping people healthy will at the same time contribute to economic growth.

The objectives of the new health programme are developing innovative and sustainable health systems, increasing access to better and safer health care for citizens, promoting health and preventing disease, as well as protecting citizens from cross-border health threats. Further actions will include co-operation on health technology assessment (HTA) and on rare diseases, as well as cancer prevention and control. In addition to the Consumer Programme, the two initiatives shall play a significant role in achieving the Europe 2020 goals.

The European Parliament and the Council will adopt the proposals by the end of 2013, to allow the programmes to start by 2014. The programmes are part of the EU Multiannual Financial Framework for 2014-2020.

## 12 countries join the Council of Europe Medicrime Convention



Twelve European and non-European countries join the Council of Europe Medicrime Convention, the first international treaty to fight counterfeit medical products. The treaty establishes as offences the manufacturing, supplying and trafficking of counterfeit medical products.

Austria, Cyprus, Finland, France, Germany, Iceland, Israel, Italy, Portugal, Russia, Switzerland and Ukraine paved the way for the implementation of the Convention which re-enforces national legislations on prevention, protection of patients, as well as prosecution of counterfeiters. In addition, the Convention will boost international cooperation between authorities. The participating countries will launch public awareness-raising campaigns on the dangers of counterfeit medical products, set international training programmes for officials and health professionals, and develop tools for the identification and follow-up of health damages.

Five countries, including three members of the Council of Europe, will have to ratify the Convention before it can come into force. ■

## GLOSSARY

### INDIVIDUALISED BLISTER PACKAGING OF MEDICINES

The technology developed by 7x4 Pharma for filling weekly blisters, the 7x4 Box, focuses on a range of medicines covering 400 solid forms for oral administration. This range concentrates on chronic illnesses and covers all of the relevant indications with the active substances and dosages commonly found on the market, as appropriate for patient treatment. In practice: The medicines delivered are taken out of their original packaging and packed into endless plastic strips (blister strips). The MDS (multi-dosing system) is a fully automated computer-controlled system which fills the weekly blisters in accordance with the individual patient's prescription. Constant checks and controls are applied.

### PHARMACOVIGILANCE

Pharmacovigilance is the process and science of monitoring the safety of medicines and taking action to reduce risks and increase benefits from medicines, according to DG Enterprise and Industry, European Commission.

### GOOD DISTRIBUTION PRACTICE

The European Medicines Agency describes good distribution practice as follows: "Good distribution practice (GDP) ensures that the level of quality determined by good manufacturing practice is maintained throughout the distribution network, so that authorised medicines are distributed to retail pharmacists and others selling medicines general public without any alteration of their properties. GDP should ensure among others that: the medicinal products that they distribute are authorised in accordance with EU legislation; and storage conditions are observed at all times, including during transportation."



Astrid Krag Kristensen has been the Minister for Health and Prevention since 3rd October 2011 and will represent Denmark on the Ministerial Council for the first six months of 2012. As yet it is unclear which focal points the socialist politician will bring to the European presidency. The 29-year old will very probably orient herself closely towards the party's programme. One of her first official acts was the financial regulation of artificial insemination. The new minister decided that the costs for artificial insemination in Denmark would be assumed by the state – as promised in the election programme. The payment of often up to 15,000 krone (€ 2,000) established by the previous government was very quickly revoked. The high costs had caused the number of artificial inseminations to decrease by about twenty per cent.

This must be seen as a sign that the financial burden on citizens will be relieved to a greater extent and that as a consequence, the costs of the public health care system may rise again. Solidarity is a principle that is strongly emphasised and frequently repeated in the public statements of Prime Minister Helle Thorning-Schmidt and the Minister of Health.

Astrid Krag Kristensen will certainly concentrate on European measures which are covered by article 152 of the European contract. Among these measures are the conditions concerning the trade in medicinal products and medical devices. During her visit to Brussels at the beginning of November – where she met with EU health commissioner, John Dalli and various members of the European Parliament – it did not become clear what her priorities would be during her tenure in the Danish presidency. The statement which she gave during her visit left everything open: "I am assuming that I will be able to contribute to bringing the health aspect to the foreground to a greater extent."

Nor did she give her views on the objectives stated by the previous government in May 2011. Her predecessor wanted to see the fight against antimicrobial resistance as the first priority for Denmark's presidency, and therefore proposed a joint monitoring programme to rationalise the consumption of antibiotics.

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**Dr. Hermann Drummer**, advisor for european politics

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**IMPRINT**

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**C A L E N D A R**

**5-6 DECEMBER 2011**

**2011 INTERNATIONAL HEALTH PROMOTION AWARDS, ROME/ITALY**

The International Health Promotion Awards 2011 will recognise community and workplace programmes that dramatically improve health. URAC and the Care Continuum Alliance, in charge of the award, will recognise, honour and share best practices. The award will announce six winners within two categories, the International Community Health Awards and the International Workplace Health Awards.

For more information please see:  
<http://www.aihpa.org/>

**8-9 DECEMBER 2011**

**2ND INTERNATIONAL CONFERENCE: SYNERGY IN PREVENTION AND HEALTH PROMOTION: INDIVIDUAL, COMMUNITY, AND ENVIRONMENTAL APPROACHES, LISBON/PORTUGAL**

The 2nd International Conference, organised by the European Society for Prevention Research (EUSPR), offers a platform for exploring environmental approaches to prevention, comparing them with individual and community level approaches. Effective strategies for prevention of most common risk behaviours must be based on a broad spectrum of interventions.

For more information please see:  
<http://www.euspr.org/>

**15 DECEMBER 2011**

**eHEALTH AND EQUITY IN THE GLOBAL HEALTH COMMUNITIES' WORKSHOP, BRUSSELS**

This workshop is organised by European Dynamics, S.A. as part of the initiative of the eHealth Unit, Directorate General Information Society and Media. In particular, it will discuss the types of disparities, health systems and their governance influenced by these eHealth solutions, policies and practices, as well as how to strengthen activities and programmes. Speakers will include representatives from the European Commission, the European Federation of Nurses Associations (EFN), the WHO and the European Centre for Disease Prevention and Control (ECDC).

For more information please see:  
<http://www.epractice.eu/>