VAD
German Association of Pharmaceutical Parallel Distributors

COST EFF
alliance for cost-efficiency in healthcare

PHARMACEUTICAL DIALOGUE 59

+ + + INFORMATION FROM THE PARALLEL TRADE INDUSTRY + + + OCTOBER 2017 + + +

PHARMACEUTICAL & HEALTH CARE POLITICS

"Back to Brussels": A full EU Agenda on health

Photo: eu

As the summer break is over, the European Institutions are back to work. Numerous challenges in healthcare are still on the agenda also after the summer break. The current political developments emphasise the ongoing struggle between the Member States and the pharmaceutical industry regarding the pricing of medicines. In the meantime, discussions regarding the future of EU´s health policies have activated patient groups and healthcare associations, which request more progressive health policies in order to tackle shortages and ensure access to medicines and the sustainability of the healthcare systems.

Access to medicines and pricing in the spotlight

The Member States continue to exert pressure aiming for more cooperation on pricing and reimbursement of medicines. The recently adopted Council Conclusions (on 16 June) encourage Member States to voluntarily share information on their pricing agreements with the pharmaceutical industry. The European Health ministers have agreed together with the Pharmaceutical Industry to install a High-Level Group to tackle the pricing issue. The WHO has also addressed the lack of transparency on pricing decisions and underlined the need for value-based pricing during the Fair Pricing Forum (in May).

IP incentives for the pharmaceutical industry on the way?

The European Commission has confirmed the importance of intellectual property (IP) for innovation. This topic will be intensely discussed since there are some Member States that are critical to further IP incentives. The Dutch Ministry of Health has commissioned its own IP study that will run in parallel with the Commission´s studies on pharmaceutical IP incentives and will be published by the end of 2017. The Commission´s studies are expected to be published in the first quarter of 2018.

Health focus for the Presidencies

The second half of the Estonian Presidency will bring some interesting initiatives on healthcare. A highlight of the Estonian Presidency will be the two-day conference regarding the implementation of the Falsified Medicines Directive (FMD), which will take place in November. After that, Bulgaria will take over for the first time, before Austria, in the second half of 2018. Health will be in focus for both of the upcoming Presidencies. ■

EDITORIAL

Dear Readers,

back from the holidays and the busy period is beginning. The political developments in healthcare demonstrate the Member State´s efforts to tackle shortages, increase the access to medicines and ensure the sustainability of their healthcare systems. The implementation of the Falsified Medicines Directive is expected to be amongst the key health topics of the Estonian Presidency **(see page 1)**.

Summer is not only a time for holidays but also a time still for work. Surrounded by the Austrian Alps, the Health Symposium of the European Forum Alpbach in August was dedicated to issues such as the access to innovative medicines. The outcomes of the Symposium will provide input for the preparation of the upcoming Austrian Presidency **(see page 3)**.

Finland can be seen as the best practice on how to apply the Public Service Obligation (PSO) through the mandatory reserve supplies system, which will be presented in this edition, in order to ensure the access to medicines in special circumstances when the availability is restricted **(see page 2)**.

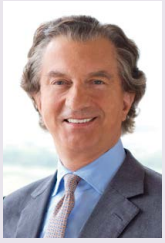
A recent judgment by the European Court of Justice provides an interesting look on how interests of public health and the free movement of medicinal products actually go hand in hand **(see page 3)**.

VAD is ready to continue its efforts in cooperating with all the relevant stakeholders in order to develop holistic strategies for better access to medicines and the free movement of medicines.

Sincerely,

Prof. Edwin Kohl

Chairman of COSTEFF and the VAD



Best practice Finland:
How to ensure access to medicines

Photo: istock/97

One of our Nordic EU Member States, Finland, appears to be a pioneer in tackling healthcare challenges. The Finnish citizens´ life expectancy is following the EU´s average statistics (EU28 80 years; Finland 78/84 years). Looking at the WHO statistics from 2015, excessive alcohol and tobacco consumption are the major health risk factors in Finland.

Mandatory reserve supplies system as an answer to Shortages

Even though, many EU Member States are currently faced with medicines´ shortages, Finland has adopted a mandatory reserve medical supplies system. The aim of this system is to ensure the availability of medicines in circumstances in which such availability is restricted or prevented as a result of suspension of deliveries, a serious crisis or other reasons. According to this system, Finland is obliged to keep a percentage of medicines as a reserve in order to avoid shortages.

Parallel Import for savings and competition

According to the OECD, healthcare in Finland is provided by a heavily regulated public system, which receives constant control. High inequalities in the access to healthcare, however, persist. Looking at data, Finland is not a significant parallel importing country. However, Finland adopted in 2016 a 134 million euros medicines savings package favouring the parallel import of medicines. An increase in the parallel import of pharmaceuticals could initiate price competition in the medicines reference price system and as a result enhance the access to high-quality affordable medicines.

PSO to ensure the availability of medicines

Other countries, including Estonia, have attempted to adopt the same system but due to the lack of commercial interest from the manufacturers´ side, so far, they have failed. The full implementation of the Public Service Obligation (PSO) or a similar system such as the mandatory reserve supplies system would be a reasonable solution in order to ensure the availability of medicines under any circumstances. Enforcing PSO or similar systems would end extreme measures such as export bans, which hinder the free movement of pharmaceuticals, hence the Internal Market. ■

IMPRINT

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NEWS IN BRIEF

Romanian medical system heavily supported by the pharma industry

The Romanian medical system and the big pharma have strong financial ties according to a recent revealing report by the Romanian Health Observatory. The total funding that was provided by the pharmaceutical and medical technology industries to hospitals, physicians, patient associations and medical organisations in 2016 reaches up to 47 million euros.

For most hospitals, the funding was provided in the form of medicines and other laboratory supplies. Doctors did not receive direct payment, but funds granted to foundations controlled by them.

This report comes at a critical time when Romania has imposed export bans on grounds of shortages, thus hindering the parallel distribution of pharmaceuticals and disrupting the harmonious function of the Internal Market.

Supplementary Protection Certificates in the centre of pharmaceutical innovation

The European Commission´s Deputy Director General, Mr. Martin Seychell, has underlined the need for more pharmaceutical incentives during a conference of the pharma industry.

The European Commission aims to launch a public consultation on supplementary protection certificates (SPC). The consultation will assist in the review of the SPC legislation and will be parallel to a study, commissioned by the EU, regarding the economic impact of SPCs and pharmaceutical incentives. Moreover, the launch of the Unitary Patent Court (UPC) has been delayed due to a constitutional challenge that arose by a German Federal Court.

The UPC´s health and life sciences sector was going to be located in the UK, but its future location remains uncertain pending the UK´s exit from the EU.

European Forum Alpbach:
Healthcare as a key pillar to Austrian EU Presidency

The traditional European Forum Alpbach in Tyrol, Austria, dedicated its Health Symposium to the upcoming Austrian Presidency and the current challenges in the healthcare sector. The participants shared the view that a European dialogue is further needed in order to tackle the challenges like financing healthcare systems and providing innovative medicines. Moreover, a successful national healthcare policy is only possible with systematic cooperation at EU level. Therefore, healthcare policies should be unattached to governmental terms of office.

The EU Commissioner for Health and Food Safety, Mr. Vytenis Andriukaitis, highlighted the need for further cooperation and coordination from the Member States´ side since the EU cannot negotiate on behalf of the Member States. Therefore, he urged Member States to enhance cooperation in pricing negotiations with the pharmaceutical industry. The outcomes of the Health dedicated Symposium will provide the basis for the preparation of the Austrian Presidency to the Council of the EU. ■

European Court of Justice:
Free movement of goods in line with public health interests

Photo: g.fessy/cjue

According to the European Court of Justice (CJEU), the free movement of medicinal products can be in line with national interests in public health. This conclusion can be drawn from a recent decision of the CJEU in the case ´Medisanus d.o.o. v Splošna Bolnišnica´ (8 June 2017). In this particular case, a Slovenian hospital ran a procurement to purchase blood products. The blood products, according to national regulations, had to be obtained from blood plasma donated in Slovenia.

The CJEU ruled that the national origin requirement was “inherently discriminatory” and prevented manufacturers from other Member States from participating in the procurement. Member States are entitled to be self-sufficient, when pursuing public health objectives. However, the CJEU ruled that the public health objective could also be fulfilled by products from other Member States according to the free movement of goods. Hence, the national origin requirement was also contrary to the Articles 34 and 36 TFEU, which prohibit quantitative restrictions between Member States. ■

GLOSSARY

Public Health and Self-sufficiency in health in CJEU judgment

In the recent European Court of Justice (CJEU) case ´Medisanus d.o.o. v Splošna Bolnišnica´, the Slovenian Government argued that the system for the collection of human blood was justified on grounds of public health.

The CJEU has consistently held that with regards to public health, ´the health and the life of humans rank foremost among the assets and interests protected by the treaties´.

The Member States are competent to determine the degree of protection to which they wish to afford to public health since they are entitled to be self-sufficient. EU self-sufficiency can be achieved through the pursuit of a national objective of self-sufficiency by each Member State.

In this particular case, the CJEU held that since the objective of an EU self-sufficiency is to protect public health, its scope must be interpreted broadly.

Supplementary Protection Certificate - an extension to patent rights

Supplementary protection certificate (SPC) is an intellectual property right that provides an extension to a patent right. SPCs aim to balance the loss of patent protection for pharmaceutical products that occurs due to the lengthy clinical trials of medicinal products.

An SPC can extend a patent right for a maximum of five years. A six-month additional extension is available, in accordance with Regulation (EC) No 1901/2006, if the SPC relates to a medicinal product for children for which data has been submitted according to a Paediatric Investigation Plan (PIP).

Currently, the EU´s ‘patent package’ that provides the basis for the creation of unitary patent protection in the EU does not explicitly provide for a ‘unitary SPC’. The European Commission is working on the articulation of unitary patent protection and SPC legislation.

EXPERT OPINION

Study proves positive effects of parallel distribution for Consumers

Study by Dr. Susan Méndez/Summary by Karsten Wurzer

National concerns over the sustainability of healthcare systems have generated a high level of regulatory pressure on pharmaceutical markets. A recent paper investigates and quantifies the impact of parallel distribution of pharmaceuticals in Denmark. The paper develops a structural model of demand and supply using data on price, sales and the characteristics of statins in Denmark and simulates outcomes in the event of a complete ban of parallel imports.

The paper emphasises the efforts carried out by the pharmaceutical industry in an attempt to limit parallel distribution by imposing supply restrictions in exporting countries or by challenging copyright rules. However, from a legal perspective, parallel distribution is protected through the EU rules that place the Internal Market as a priority over the potential losses that may occur due to the reduction of incentives for innovation.

From an economic perspective, there are two sets of key results: The first set focuses on price effects. On average, prices increase more in markets where the molecule has lost patent protection; wholesale prices for both generic and original products would increase due to the lack of competition from parallel import.

The second set of results reports the effects on market participants. This paper takes into consideration consumers‘ preferences. Prohibition of parallel imports leads consumers to substitute towards original products for which they have stronger preferences. In overall, a potential ban in parallel distribution would increase the prices of both original and generic products due to the lack of competition in the pharmaceutical market.

In conclusion, this paper reveals that banning parallel imports leads to (a) an increase of profits for original manufacturers and a decrease for generic firms, (b) a substantial increase in governmental healthcare and consumer expenditures and (c) a decrease in the welfare of Danish patients and firms. This paper demonstrates that the magnitude of savings generated by the parallel distribution of medicines appears to be much higher than the outcomes of previous studies. This paper comes as another proof that the parallel distribution of pharmaceuticals benefits the patients and the healthcare systems. ■

Dr. Susan J. Méndez, Research Fellow in the Health Economics research program at the Melbourne Institute of Applied Economic and Social Research.

The study is available here:
http://melbourneinstitute.unimelb.edu.au/downloads/working_paper_series/wp2016n08.pdf

CALENDAR

04 - 06 OCTOBER 2017
GASTEIN, AUSTRIA

European Health Forum Gastein

The discussions at the 20th European Health Forum Gastein (EHFG) will aim to take the healthcare debate to the political level–Health in All Politics. In a time of increasing populistic rhetorics across Europe, the EHFG is required to mediate between the different policy areas, guided by the European values of access to high quality care, equity and solidarity.

For further information please see:
ehfg.org/

10 OCTOBER 2017
GENEVA, SWISS

Health Care Summit 2017

The 2017 Health Care Summit aims to gather European and international policymakers as well as key industry stakeholders in healthcare in order to discuss on the political health agenda. The Health Care Summit will highlight the existing inequalities between developed and developing countries as they struggle to ensure access to healthcare. The stakeholders will discuss on the policy instruments and business models that must be implemented in order to ensure that innovation will lead to further access to healthcare.

For further information please see:
politico.eu/event/health-care-summit-2017/

08 - 09 NOVEMBER 2017
TALLIN, ESTONIA

Conference “Safer Europe without falsified medicines”

This two-day conference will be dedicated to the implementation of the Falsified Medicines Directive (FMD). The main focus will be on the legal aspects and the implementation of IT solutions at national and EU level. This conference will provide the opportunity to project-partners for mid-term discussions before the implementation of the FMD by all Member States and the adoption of IT detection systems for falsified medicines in the legal supply chain.

For further information please see:
eu2017.ee/political-meetings/conference-safer-europe-without-falsified-medicines