German Association
of Pharmaceutical
Parallel Distributors

alliance for
cost-efficiency
in healthcare

PHARMACEUTICAL DIALOGUE 61

+ + + INFORMATION FROM THE PARALLEL TRADE INDUSTRY + + + APRIL 2018 + + +

PHARMACEUTICAL & HEALTH CARE POLITICS

EU to step up against excessive pricing and lack of medicines

2018 is already underway, promising decisive developments in the EU´s health policies. In the meantime, the Member States are still struggling under the burden of excessive pricing of medicines which is imposed by some Big Pharma companies. The availability of medicines remains a key topic on the EU´s agenda and the European Commission warns that shortages of pharmaceuticals can have negative consequences for the health of patients.

European Commission urges Member States to apply the Public Service Obligation

The European Commission has reacted to the increased phenomena of artificial shortages caused by the malpractices of the manufacturers. The Commission has requested from Member States to discuss the implementation of Article 81 of Directive 2001/83/EC of the pharmaceutical legislation which introduces the Public Service Obligation (PSO), a principle that obliges manufacturers and wholesalers to provide a continuous supply of medicinal products on the market. The European Commission wishes to take stock of the measures implemented by the Member States with the aim of finding examples of best practices which could be shared with the rest of the Member States.

European Commission reacts against Pharma Industry´s abuse of dominant position

Manufacturers still enjoy strong negotiation position in the price-setting as EU pharmaceutical markets are separated. The recent “Aspen case” has triggered the European Commission´s interest in investigating further the anti-competitive practices followed by the pharmaceutical industry. Excessive pricing on life-saving medicines is a big issue for a number of Member States that see shortages in their stock or even the complete withdrawal of such products from the market. Such practices could ultimately affect the public health safety and for that reason Member States are more and more sensible to this topic.

EU focuses on the high prices of pharmaceuticals

The Member States are reacting against excessive pricing and the artificial shortages caused by the Big Pharma. 2018 has proved so far that it is the year when the European Commission and the Member States unite in order to build up pressure on the Pharmaceutical Industry to accept fair pricing of medicines and cease artificial shortages which threaten the access to medicines and ultimately patients´ lives. ■

EDITORIAL

Dear Readers,

With the beginning of 2018, the Bulgarian Presidency has taken over the Presidency to the Council of the EU for the first time. Parallel distribution of pharmaceuticals appears to be one of the most viable options for better access to medicines also in Bulgaria **(see Page 3)**.

Affordability and availability of medicines remain in the spotlight as Member States have been reacting to the excessive medicines´ prices and the artificial shortages caused by the Big Pharma. In the meantime, the European Commission has urged Member States to apply the Public Service Obligation in order to ensure availability of medicines across the supply chain **(see page 1)**.

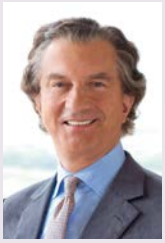
The UK´s pending exit from the EU has led to the creation of various scenarios regarding the free movement of pharmaceuticals and the availability of medicines through parallel import **(see page 2)**. Moreover, British community pharmacies react against the high medicines´ prices **(see page 3)**.

VAD is ready to contribute to the dialogue with the Member States and the upcoming Presidencies in order to ensure access to innovative and affordable medicines for all patients.

Sincerely,

Prof. Edwin Kohl

Chairman of COSTEFF
and the VAD



Post-Brexit scenarios for Parallel Distribution of medicines

Photo: istock/ miriam-doerr

The UK´s exit from the EU will bring many changes in healthcare and health policies which will affect all the stakeholders across the supply chain. UK has been so far one of the most important parallel importing countries in the EU with 9% parallel imports of pharmacy market sales at consumer prices in 2015. Parallel distribution has led to direct savings of 986.2 million euros for the National Healthcare System (NHS) in the period 2004-2009. The suggested indirect savings indicate that the prices of medicines in the UK are at least 3% cheaper than they would have been without the practice of parallel distribution.

Exhaustion of patent rights within the EU/EAA

Among the scenarios that are presented by the British Association of European Pharmaceutical Distributors regarding the impact of Brexit on the British market, the first one highlights the danger in case the UK loses the benefit of rights within the EU/EEA. If that were the case, the prices would rise as the only competition to the monopoly of the manufacturers would be lost. Since wholesalers and retail pharmacies would not have access to cheaper products through parallel distribution, the level of clawback would become unsustainable. The loss of parallel imports could ultimately lead to the loss of community pharmacists. Moreover, the prices of medicines could rise also for the EU citizens due to the change in parallel import law conditions.

International Exhaustion of Intellectual Property rights

An alternative scenario would be for the UK to adopt an international exhaustion for the Intellectual Property (IP) rights. This scenario could compromise the relationship within the EU regarding the parallel exports from UK into the EEA. Moreover, the need to align measures in order to secure patient safety and prevent counterfeit medicines would create regulatory issues which could make the exhaustion of rights with non-EEA countries difficult.

Protecting patients´ rights for access to life-saving medicines

The ultimate goal in the bilateral negotiations between the EU and the UK should be the patients´ interests and their right to have access to medicines. For this reason the existing benefits should remain as it appears to be the most viable option in order to ensure that the competition created by the parallel distribution of pharmaceuticals which leads to direct and indirect savings will not be compromised and that patients´ access to life-saving medicines is secured. ■

IMPRINT

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NEWS IN BRIEF

Vaccination and vaccine hesitancy at the centre of EU´s health policies

Recent communicable-disease outbreaks, such as measles, in various EU Member States have indicated the need for coordinated pan-European vaccination policies and the increase of vaccine uptake by the European Citizens. The European Commission has published a roadmap and a public Consultation requesting from Member States to strengthen their cooperation against vaccine preventable diseases. DG Health and Food Safety (DG SANTE) is reinforcing its support to national vaccination policies in order to increase coverage, through the preparation of a Joint Action on vaccination. The Joint Action will attempt to address vaccine hesitancy and enhance the cooperation of national immunisation advisory groups (NITAGs) with a view to increasing transparency and trust in the decision-making process regarding the introduction of new vaccines and the availability of vaccines.

Commission launches Health Technology Assessment proposal

The Commission has published a proposal for a Regulation on Health Technology Assessment (HTA) aiming to increase cooperation among EU Member States for assessing health technology. The Commission believes that more assessments will allow innovative, therapeutic tools reach patients faster. Moreover, the national authorities will be able to craft their healthcare policies on solid evidence and easier procedures for the pharmaceutical industry. This proposal will cover further innovative medicines and medical devices allowing the cooperation at EU level for joint clinical assessments. Member States will be able to use HTA tools not only for joint clinical assessments, but also for joint scientific consultations. The aim is to enhance the identification of emerging health technologies and lastly deepen voluntary cooperation between Member States.

Access to medicines for UK pharmacies in disarray

Photo: istock/ AmandaLewis

The fear of medicines´ shortages in the UK has forced pharmacists to pay heavy prices for generic medicines, while the British Department of Health is delaying the reimbursement of contractors. Community pharmacies are in danger of being emptied. Many reasons have been suggested in order to explain the increase in the prices, including the UK´s imminent exit from the EU. Supply issues are another reason, following the withdrawal of manufacturing licences by certain manufacturers that did not comply with the manufacturing practices as laid down by the European Medicines Agency (EMA).

The Healthcare Distribution Association (HDA), alongside the British Generic Manufacturers believe that certain wholesalers and independent pharmacist wholesalers are stockpiling excessive quantities of generic medicines, in order to create artificial shortages and release the medicines on the market once the prices rise due to the excessive demand. Certain proposed government regulations can act as the remedy for this situation requiring manufacturers, importers and wholesalers to provide more information regarding sales and purchases of generic medicines on a quarterly basis. ■

Bulgaria: Parallel Imports benefit Patients' Interests

Photo: istock/ Anton Donev

Amidst the Bulgarian Presidency to the Council of the European Union, the Bulgarian parallel distributors´ association has published an opinion, highlighting the benefits that parallel import of pharmaceuticals can bring to patients in Bulgaria.

First and foremost, parallel distribution allows low-income patients to purchase high quality medicines in reasonable prices. Moreover, parallel distribution acts as the competition to the monopoly created by the pharmaceutical industry, thus making the price effect beneficial for the consumers. The Ministry of Health however is encouraged to continue the checks and controls over the activities of wholesalers. More precisely, the competent authorities are encouraged to penalise illegal medicine trade as wholesalers are obliged to export only the surplus quantities. The Bulgarian parallel distributors endorse the fight against bad practices and encourage the Ministry of Health to follow the successful paradigm of many other Member States that have benefited from parallel imports of pharmaceuticals. ■

GLOSSARY

International Exhaustion of Intellectual Property rights explained

Before the UK joined the EU, English law permitted a degree of international exhaustion since parallel distribution was viewed as a positive influence for the market by creating competition, lowering prices and benefiting the consumer. The World Trade Organisation (WTO) Agreement on Trade Relating Aspects of International Property Rights (TRIPS) allows each Member State the freedom to address exhaustion of intellectual property (IP) rights.

The UK could adopt international exhaustion for some or all IP rights, thus allowing into the British market all products and services incorporating IP rights provided that the IP rights have been placed on a market by the IP owner or with his consent. In such a case the presence of significant intra brand competition from imports would still guarantee that UK consumers pay the lowest prices.

Joint Action Plan on Vaccine Hesitancy

The European Commission will increase its financial support regarding the national vaccination efforts in an attempt to increase coverage through the launch of a Joint Action on vaccination, which will be co-funded by the Health Programme (€3 million). The Joint Action will focus on vaccine hesitancy and will be coordinated by INSERM in France with 24 other countries acting as partners. The aim of the Joint Action Plan is to reinforce the interaction of Immunisation Information Systems (IIS) in order to increase vaccine coverage.

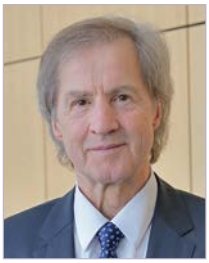
Moreover, it will assess the European reminder and recall systems and elaborate procedures in order to establish vaccine procurement as well as analyse the financing mechanisms for sustainable purchase. In addition to this, the Joint Action will create sustainable mechanisms for analysing barriers to low vaccine coverage. Future EU incentives on vaccination will focus on tackling vaccine hesitancy in social media, by using vaccines as the case study for combating fake news in the EU. The Joint Action will run for three years with the possibility of extension depending on its success.

EXPERT OPINION

25 year of European Internal Market

Mission (not yet) accomplished

by Jo Leinen



Citizen's support for the European project might not always be the strongest, since - as a wise man said – it is hard to fall in love with an internal market. However, citizens do appreciate the fundamental freedoms of the EU's internal market. In fact, free movement is the advantage of a united Europe that people often experience first-hand, through traveling, buying goods abroad, using a single currency or visiting a doctor who comes from a different EU country. 25 years since the "official" birth of the internal market on the 1st of January 1993 with the treaty of Maastrich it is still at the heart of European Integration. After 60 years of the existence of the European project starting with the Treaty of Rome in 1957, it is often the loss or restriction of obvious achievements, which brings back to memory the value of free movement.

After a quarter of a decade, the internal market has matured, but constraints are still visible. An EU internal market for medicines is not yet a reality. The development in this sector has not been linear, but characterised by setbacks due to lack of enforcement by the Commission and due to trends of national protectionism by the Member States. The Commission has attempted to abolish bureaucratic hurdles to an EU-wide trade of pharmaceuticals. Its 1998 Communication on the internal market in pharmaceuticals and the 2008 Communication on "Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector" argueing for a free market. It is stressed that an internal market for medicines should be completed despite the specific characteristics of the pharmaceutical sector. Member States should implement measures to remove obstacles that restrict EU-wide imports and exports. Ten years later, an internal market has still not become a reality.

Several Member States obviously fear shortages on their own pharmaceutical markets and want to prevent their lower-priced products from being exported to Member States with higher prices. Of course, in the sensitive health sector, a careful balance is needed between safeguarding a functioning European market with free movement of goods on the one hand and ensuring sufficient supply of important medicines to the consumers on the other. In theory, the EU's public service obligation from 2001 could strike exactly this balance, ensuring sufficient supply in a Member State while allowing for competition thereby offering attractive prices to consumers. Again, Member States have not been consequent in implementing the obligation while the Commission has been cautious in its enforcement. As the Commission is currently looking into the degree of implementation to draw consequences, the European Parliament should become more outspoken on this issue. The Parliament has been an advocate not only for citizens' rights but also for a functioning internal market without undue barriers. A clear follow up of the Commission's survey could be a suitable starting point for a new discussion on the free movement of medicines. After 25 years, completing the internal market is still at the heart of European Integration, but also a mission yet to be accomplished. ■

Jo Leinen is member of the European Parliament within the Group of the Progressive Alliance of Socialists and Democrats.

CALENDAR

24 - 30 APRIL 2018
GLOBAL LEVEL

World Immunization Week 2018

The goal of World Immunization Week 2018 is to exert pressure on greater action regarding immunization around the world, and focus on the role that everyone can play in this effort, from donors to individuals. The 2018 campaign will highlight the value of vaccines to certain donor countries and the significance of investing in immunisation programmes.

For further information please see:
who.int/campaigns/immunization-week/2018/campaign-essentials/en/

26 APRIL 2018
BONN, GERMANY

Parallel Distribution of Pharmaceuticals in Germany

This seminar will focus on the regulatory requirements of parallel import and distribution and will provide information on how to properly label and repackage medicines. Amongst the topics that will be discussed are the free movement of pharmaceuticals, the current challenges in the registration maintenance, e-submission, requirements for the pharmacovigilance system and implementation of the Falsified Medicines Directive. This seminar is aimed at specialists and executives involved in parallel imports /exports, approvals, repackaging and labelling.

For further information please see:
forum-institut.de/seminar/1804945-parallelhandel-von-arzneimitteln-in-deutschland

15 - 17 MAY 2018
BRUSSELS, BELGIUM

27TH ANNUAL EU PHARMACEUTICAL LAW FORUM 2018

This conference brings together senior legal professionals from private practice and in-house counsel in order to exchange views on topics such as the clinical trials regulation, key regulatory challenges, the benefits of the Unified Patent Court and Competition Law.

For further information please see:
lifesciences.knect365.com/pharmalaw/parallel-trade-2018/