VAD
German Association
of Pharmaceutical
Parallel Distributors

COST EFF
alliance for cost-efficiency in healthcare

PHARMACEUTICAL DIALOGUE 60

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

PHARMACEUTICAL & HEALTH CARE POLITICS

Medicines´ Shortages: a global phenomenon

Photo: eu

In the beginning of the phenomenon, some have quickly (and falsely) claimed that Parallel Distribution was responsible for the shortages of pharmaceuticals. But now it has become evident that there are other drivers for this phenomenon, which is a global issue. The United States of America, Canada and Australia have also noted shortages on life-saving medicines in the past decade.

Shortages around the World

A commentary in a Belgian pharmacy journal has claimed that the phenomenon reaches from "Afghanistan to Zimbabwe" encompassing 21 countries. The USA was concerned about prescription medicine shortages a decade ago. In 2011 medicines´ shortages in the USA were focused on five areas: oncology, anti-infectives, cardiovascular, central nervous system and pain management. On a global scale, there are many markets that have been identified as "fragile" to provide medicines on HIV/AIDS and tuberculosis.

Theories on causes of shortages

Many theories and explanations have been illustrated as causes of shortages. The increased global demand and the changes aiming to upgrade regulatory standards have been indicated as main reasons for shortages of generic medicines in the USA. Some theories claim that another cause is economic and can be attributed to the reimbursement policies, which discourage the low-cost generic treatments. Another theory places the blame on the expansion in the volume of products manufactured by the pharmaceutical industry without a corresponding expansion in the manufacturing capacity. Moreover, manufacturers appear to strategically deploy the production capacity in the commercially advanced markets.

Need for a responsible pharma industry in order to ensure access to medicines

The Council of the International Pharmaceutical Federation has called on all the stakeholders including authorities, manufacturers and wholesalers in order to ensure the medicines´ supply. However, the regulatory authorities cannot force manufacturers to report the reasons for shortages or the duration of these shortages. National authorities are ultimately responsible to ensure the access to essential medicines. ■

EDITORIAL

Dear Readers,

As the Institutions are getting ready for the Christmas break, the busy period is continuing and Bulgaria is preparing to take over the Presidency to the Council of the EU for the first time. Affordability as well as availability of healthcare are expected to be amongst the key health priorities of the Bulgarian Presidency **(see page 2)**.

Shortages are identified as a global, complex phenomenon which encompasses many countries and affects some of the richest ones such as USA, Canada and Australia. Pharmaceutical shortages due to manufacturing insufficiencies and strategic deployment of medicines to particular markets are identified as the lead causes of shortages **(see page 1)**.

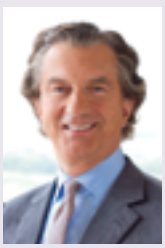
In the meantime healthcare experts in Europe are requesting more supply of medicines from the Big Pharma. A study reveals that after the EU enlargement, the medicines that were facing competition from parallel imports had lower prices than they would have had if they had never faced such competition **(see page 3)**.

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

Sincerely,

Prof. Edwin Kohl

Chairman of COSTEFF
and the VAD



Bulgarian Presidency: “United we stand strong” on healthcare

Photo: istock/andrzej63

Bulgaria, one of the youngest EU Member States, is preparing for its first-ever Presidency at the Council of the EU under the motto “United we stand strong”! This is a good opportunity to have a closer look at the healthcare system in Bulgaria. Looking at the WHO statistics of 2015, Bulgaria´s population is susceptible to non-communicable diseases, with heart attacks and strokes being the lead causes of death. Excessive alcohol and tobacco consumption have been identified as the main health risk factors.

Challenges of the Bulgarian healthcare system

Bulgaria still has one of the highest death rates across the EU with 15 deaths per 1,000 people. This makes it easy to understand, why Bulgaria has invested massively on healthcare during the recent years and has the highest rate of hospitals per capita in the European Union. The Bulgarian healthcare system is financed by health insurance taxes according to UNDP information from 2015. The health insurance payments were calculated at 8% of the monthly wage of the insured individuals. The lack of funding for hospitals has been identified as one of the biggest challenges of Bulgarian healthcare, a factor which leads to the lack of resources for medication as well the incapability of paying hospital debts and even bankruptcy and closure of the healthcare institutions. The World Bank had also voiced their concerns over the disproportionately high fees Bulgarian patients are charged for healthcare and medications – a share that was rumoured to be up to 43% in 2013.

Bulgarian Presidency to aim for affordability and availability of healthcare

Affordability of healthcare will be one of the key priorities for Bulgaria. Furthermore, the availability of healthcare and in this respect also of medication is high on the Bulgarian agenda. Bulgaria will create an expert panel to take place in Sofia during the Presidency, which aims to focus on the issue of shortages and provide concrete solutions.

Given the national interest in the access to affordable medicines, it would be an important initiative, if Bulgaria were to push the debate on the next level by identifying factors that are driving shortages such as supply quota. ■

IMPRINT

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NEWS IN BRIEF

Status quo of Parallel Import in Lithuania

According to the specialists of the State Medicines Control Agency of Lithuania, the conditions of parallel import to Lithuania can be characterised as being liberal. Even this system, however, is faced with challenges regarding the sustainable access of patients to medicines.

These challenges arise due to the existing agreements between the pharmaceutical marketing authorization holders and the pharmacy networks. The Agency has emphasized that the declared prices of parallel imported medicines are lower and this ensures a better access to medicines. They also state that parallel imported pharmaceuticals can improve the safety of medicines´ supply.

Brexit foreshadows EMA relocation and implications for access to medicines

The UK´s decision to exit the EU has led to a series of unprecedented developments. According to the Healthcare Distribution Association (HAD), there will be an increase in the risk of medicine shortages in the UK after Brexit. Manufacturers will need to adjust their forecasting and medicine distributors will not be able to import medicines from the rest of the European Economic Area (EEA) to accommodate the needs of British patients.

Another concern of healthcare specialists and patients was the relocation of the European Medicines’ Agency (EMA) from London. Accessibility for delegates and experts as well as staff retention was identified as being the key in order to ensure the Agency’s ability to function. The new host city Amsterdam promises continuity and connectivity as it has a flourishing economy, enjoys a high-skilled and multilingual workforce, while the Schiphol Airport has the highest number of flight connections with the rest of the EU countries.

EMA has already initiated a business continuity plan and has temporarily suspended a number of activities, including the benchmarking of medicines regulatory authorities as of 2018.

Experts call for more supply from the Big Pharma

Photo: kohlpharma GmbH

The scarcity of medicines´ supply has activated experts from the pharmaceutical supply chain who highlight the need to find political solutions in order to address the issue of shortages. The Pharmacists´ Association in Germany, ABDA, has called for an extensive reporting obligation to be introduced in the short-term in order to enable an emergency management. So far, manufacturers had to report potential supply disruptions only to hospital pharmacies.

However, pharmacists need to also be prepared and ensure that a minimum of pharmaceutical production in Europe is maintained or restored. According to proposals by other experts, the shortages can be avoided by introducing a "sustainable minimum storage". The experts suggest that the Federal Institute for Pharmaceuticals and Medical Devices can act as the central reporting point as it already has a list of potential medicines´ shortages based on voluntary reports from the industry. ■

Parallel Distribution and Price Competition after the EU Enlargements

Photo: kohlpharma GmbH

A study which uses 2003–2007 data from Sweden, examines whether the EU enlargement of 2004, when the Member States that joined the EU had low pharmaceutical prices, increased competition from parallel imports. An increase in the price difference or in the availability of pharmaceuticals for parallel distribution should increase price competition in the destination country.

The pharmaceuticals that were facing competition from parallel imports had on average 19–22% lower prices than they would have had if they had never faced such competition. The immediate effect of facing competition from parallel imports was reduced after the EU enlargement, while the gradual effect, rose.

These results can be attributed to the changes in consumer perceptions regarding parallel imports. In conclusion, the enlargement increased price differences between EU Member States causing those that were not subject to competition from parallel distribution to face it, while it increased competition for the countries that were already subject to it. ■

GLOSSARY

Definition and causes of shortages

So far there has not been an official definition of shortages including the period of time of the shortages. Many national authorities define shortages as "cannot be obtained", a terminology that remains unhelpful and vague. There are currently dozens of different definitions in the EU. The French agency (ANSM) and the EMA defines a medicine shortage as the incapacity of a pharmacy/hospital to provide a medicine to a patient within 72 hours. A shortage can result from either a halt in the medicine's production or a disruption in the supply chain.

Many theories have also unfurled explaining the lead causes of pharmaceuticals´ shortages. Some of these theories demonstrate that shortages are caused due to manufacturing insufficiencies. Moreover, manufacturers control the supply of medicines in the markets or have a preferential treatment over more commercially advanced Member States, hence under-supplying other markets.

EMA's Brexit Business Continuity Plan

The European Medicines Agency (EMA) which is currently hosted in London, UK, has published its Brexit Preparedness Business Continuity plan. This plan includes three categories of activities and the planning on every possible scenario. According to Category 3, EMA started to scale back some activities and freed a percentage of its human resources. Category 2 consists of activities, such as the proactive publication of clinical data and activities regarding the access to medicines, which will be maintained as long as possible. Category 1 includes the highest priority activities that are related to the assessment and safety monitoring of medicines.

The publication of this plan comes as a response to fears expressed by the pharmaceutical industry and healthcare associations regarding the potential disruption of the marketing authorisation of medicines and its implications for the access to innovative medicines.

EXPERT OPINION

Delivery bottlenecks
The onus is on manufacturers

Bottlenecks regarding the supply of medicines have repeatedly made headlines in recent years – and rightly so. More questionable are the responses. In 2015, Poland passed an Anti-Export Act, the intention of which was to impede or even prevent parallel trade. What was deliberately ignored in Warsaw was the fact that just three years earlier, Poland had intervened in the market with state subsidies for pharmaceuticals. Despite hostile reactions, other EU governments also decided to introduce restrictions on the free movement of medicines. In Slovakia, a corresponding act has been in place since October 2016.

Bottlenecks with medicines are also the subject of debate in Germany. This year, the Federal Institute for Drugs and Medical Devices (BfArM) listed two dozen drugs in short supply and also stated the main reasons for this: problems during manufacture and a lack of production capacity. The BfArM clearly sees no problem with parallel trade, nor does the German Government, which confirms the compliance of this with the rules of the EU internal market.

The topic has long since been discussed by politicians in Berlin and Brussels. With regard to manufacturers, those on the left in the Bundestag noted an "artificial shortage (of medicines) to increase profits". The act passed in March in Berlin to increase the supply of medicines considers the manufacturers to be responsible for providing information regarding sales volumes. Parallel trade has complied with this obligation for over a decade: retailers are required to submit reports to the EMA (Regulation [EC] 726/2004), thereby contributing to transparency and planning certainty.

In a widely acclaimed ruling, the European Court of Justice also reminded the manufacturers of their obligation (ECJ, C-468/06), by assessing the refusal to supply medicines to a parallel retailer as being discrimination in accordance with Article 82 (2) EC. The ECJ also emphasised the request of the retailer in question to increase production volumes by up to 20 per cent After all, the company making the complaint only wanted to acquire quantities of medicines that corresponded to the monthly average for purchases over the previous ten months. Which proves that the problem lies primarily with the manufacturing and transparency on the part of the manufacturers. ■

Harald Neuber, is a freelance journalist with a focus on health care issues who wrote and writes for several newspapers and magazines.

CALENDAR

OCTOBER 2017 - APRIL 2018
BRUSSELS, BELGIUM

European Health Parliament

The European Health Parliament is a platform which gathers young professionals, to work together in order to change the future of healthcare in Europe.

Under the motto "Make health great again", the third edition of the European Health Parliament will provide recommendations and solutions to key health areas including access to sustainable healthcare.

For further information please see:
healthparliament.eu/

22 - 23 JANUARY 2018
LONDON, UNITED KINGDOM

Social Media in the Pharmaceutical Industry

Social media is the perfect channel for the pharmaceutical industry and healthcare associations to educate, market and connect with patients and physicians.

This conference will include industry experts who will explain on ways to leverage social media platforms in order to develop effective digital strategies.

For further information please see:
ehealthnews.eu

06 - 07 FEBRUARY 2018
LONDON, UNITED KINGDOM

Parallel Trade Conference

This conference aims to explore the changes brought forth by the arrival of Brexit and the guidelines aiming to enforce the Falsified Medicines Directive (FMD) by 2019.

The conference will focus on the latest changes to regulation, implementation and IP practices of pharmaceuticals. The participants will also discuss ways in which currency fluctuations are likely to disrupt the supply of medicines to certain countries in the EU and beyond.

For further information please see:
pharmaphorum.com/events/parallel-trade-2018/