

PHARMACEUTICAL DIALOGUE 69

+ + + INFORMATION FROM THE PARALLEL TRADE INDUSTRY + + + MARCH 2020 + + +

PHARMACEUTICAL & HEALTH CARE POLITICS

The outbreak of the coronavirus and its impact on the global medical supply chain

China is the largest producer of active pharmaceutical ingredients in the world and the starting point in the global pharmaceutical supply chain for many medical products. In light of the recent coronavirus outbreak, officially known as COVID-19, medicines shortages may become an urgent challenge facing the European Union. It is crucial that European member states are not only prepared to handle the epidemic, but also to react to potential supply shortages, governed by the principle of solidarity.

Relocation of production outside Europe

The manufacturing of pharmaceutical raw ingredients has been increasingly relocated outside Europe. Up to 80% of all active ingredients for medicines are produced in China and India. Consequently, an incident such as the coronavirus outbreak could significantly affect the supply security of essential medicines in Europe. There are several factors for this: shutdown of production sites and establishment of quarantines for workers to prevent the spread of the virus; closure of the shipping infrastructure or additionally imposed import and export controls; or delays in inspections of manufacturing facilities by regulators from EU countries.

The imminent risk of failures of medicine supply and due to the coronavirus outbreak became reality: India, the world's largest producer of generic medicines, introduced export restrictions for certain ingredients and common medicines, fuelling fears of global shortages of essential medicines. This reflects the EU's over-reliance on active substances and pharmaceutical products from third countries and the vulnerability of the pharmaceutical supply chain.

Safeguarding the supply chain of medicines in the EU

With an increasing number of Member States imposing export bans as a response to the coronavirus outbreak, the virus becomes a direct threat to one of the foundations of the European Union, the Single Market. Export bans significantly interrupt the functioning of the medical supply chain, putting at risk European patients in need of essential medicines. As a response, the European Commission adopted guidelines calling on Member States to refrain from adopting any measures which could jeopardise the free movement of goods and to guarantee the supply chain of medicines and medical equipment.

In addition, the European Commission bets on one main driver for improving health-care and strengthening the pharmaceutical industry in Europe: an ambitious pharmaceutical strategy. The strategy aims to tackle EU-wide challenges related to availability, affordability and security of medicines' supply. While ensuring access to affordable medicines, the strategy focuses on enhancing European manufacturing capacity and the European pharmaceutical industry's role as world leader in innovation. ■

EDITORIAL

Dear Readers,

As the coronavirus outbreak from China continues to spread globally, the European Union is concerned about potential disruptions to medical supply and subsequent shortages of pharmaceuticals, underlining the EU's dependence on non-European countries. **(page 1)**

In light of increasing shortages of pharmaceuticals and medical products in Europe, the campaign #FillTheGap demonstrates that parallel trade of medicines constitutes an effective instrument to reduce these shortages. **(page 2)**

Pharmaceutical parallel trade has generated not only large direct savings, but also indirect savings, bringing more affordable medicines to European patients, according to a recently published study on the impact of the import of medicines on the competitive situation on the Polish market. **(page 3)**

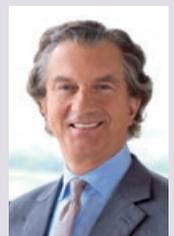
VAD is actively participating in the ongoing debates on the future of European health care. We remain committed bringing affordable high-quality medicine to European patients across the Union. I hope you join us in this effort. May you discover many informative insights as you read this 69th edition of our Pharmaceutical Dialogue.

Sincerely,



Prof. Edwin Kohl

Chairman of COSTEFF
and the VAD



#FillTheGap: Parallel trade as an effective tool to battle against medicine shortages in Europe

Shortages of pharmaceuticals are not a new phenomenon. However, in recent years, national medicine shortages and lack of access to medicines are on the rise in Europe, constituting an alarming, yet highly complex problem. The lack of medicines is not limited to life-saving medicines but also affects the most basic medical supplies and commonly used pharmaceuticals. The unavailability of medicines does not only lead to a loss of opportunity to focus on improving the quality of care and increased costs in health systems - considering that often more costly alternatives have to be referred to - but has also a significant impact on human health.

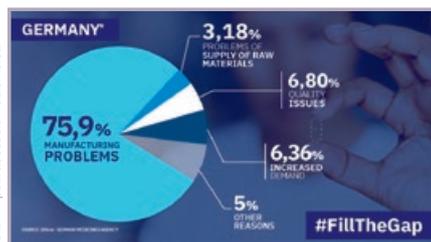


Foto: <https://acesstomedicine.eu/>

Shortages of medical products and pharmaceuticals can occur for many reasons. Due to the structure of the value chain, it may be argued that the most frequent causes for medicine shortages occur on the supply side, including, inter alia, recalls, loss of production, capacity constraints or manufacturing delays. Furthermore, consolidations of companies and the shift of production to the cheaper Asian region, especially to India and China, as well as intra-EU export restrictions on medicines significantly contribute to the existing problem of shortages in medicine stocks in Europe, therefore posing a risk to patients' health.

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#FillTheGap – improving access to healthcare

The campaign #FillTheGap, supported by Affordable Medicines Europe, the association representing Europe's licensed parallel distribution industry, and the Belgian Association of Parallel Importers and Exporters, aims to tackle the increasingly occurring challenge of medicine shortages in Europe by supporting an open European market for pharmaceuticals. Advocating the parallel distribution of pharmaceuticals, the campaign refers to three arguments: parallel trade has the infrastructure and resources to quickly help fill the gaps caused by medicine shortages; research has found that banning pharmaceutical parallel import negatively affects patients' welfare and care; and parallel trade generates enormous saving for EU countries and national healthcare systems.

But how exactly does parallel trade work? Parallel importers purchase medicines from pharmaceutical wholesalers in one EU member state and subsequently distribute them in another member state, where the same products are more expensive, while complying with the highest quality standards throughout the whole process. After re-labelling and re-packing medicines, parallel distributors sell the medical products to authorised wholesalers or directly to pharmacies in the recipient country. Parallel trade is based on one of the most fundamental freedoms of the European Union – the free movement of goods.

Parallel trade as part of the solution

The parallel distribution of pharmaceuticals benefits national health systems and ultimately patients by offering affordable medicines and increasing competition on the national pharmaceutical markets. What is more, parallel trade may constitute an effective tool to help fill the gap caused by medicine shortages: if a member state experiences a shortage of pharmaceuticals due to inefficient supply from manufacturers, parallel trade fills the gap by taking surplus from another EU member state and delivering it to the recipient country. Hence, it becomes clear that parallel trade is part of the solution to the problem, rather than the cause of it. Pharmaceutical parallel trade does not only generate enormous savings for national healthcare systems, but furthermore constitutes an effective tool to reduce medicine shortages by positively contributing to the availability and affordability of medicines in Europe. ■

NEWS IN BRIEF

The EAEPCC was renamed into Affordable Medicines Europe

On 21 January 2020, the European Association of Euro-Pharmaceutical Companies (EAEPCC) was renamed into Affordable Medicines Europe. According to Jörg Geller, President of Affordable Medicines Europe, the new name of the association "reflects better the industry's raison d'être: to make medicines more affordable for EU healthcare systems and patients. For the patient we effectively fight geo-blocking of medicines in a safe and regulated framework". This was further underlined by the simultaneous presentation of new studies on direct and indirect cost-savings generated by parallel trade in 2018 in Poland, Germany, Denmark and Sweden, amounting to a total of € 3.2 billion. The enormous savings reflect the essential contribution of parallel import to the affordability of medicines in Europe. ■

<https://affordablemedicines.eu/>



<https://acesstomedicine.eu/>



Impact of medicine shortages from the community pharmacists' perspective

The Pharmaceutical Group of the European Union (PGEU), an association of community pharmacists in Europe, published the results of a survey mapping the impact of medicine shortages across Europe from the community pharmacists' perspective. The results indicated large differences among European countries regarding legal solutions which may be offered in case of a shortages: generic substitution (79% of countries), sourcing the same medicine from alternative authorised sources (63%), and importing the medicine from a country where it is available (46%) are the solutions which can be provided in most of the European countries. ■

Parallel imported pharmaceuticals stimulate the price competition in the European pharmaceutical markets

In the last couple of years, health budgets in most of the EU member states were continuously increasing. A growingly large share in the national health budgets is represented by pharmaceutical expenditures and medical services. Parallel trade is an integral part of the medicine supply chain in the EU Single Market, resulting in enormous savings for national health systems and pharmacies. Currently published economic studies emphasize the significant impact of parallel trade on total savings for national health budgets in Germany, Sweden, Denmark and Poland. The total savings in these four markets amounted to € 3.2 billions in the year 2018 alone. The recently published study by the Polish Association of Importers of Parallel Medical Products (SIRPL) investigates the economic impact of parallel imports on the competition in the Polish pharmaceutical market in the period from 2010 to 2018.

Direct and indirect savings of parallel trade in pharmaceuticals in Poland

The study examines both direct and indirect savings. Direct savings reflect the price difference between the cheapest parallel imported pharmaceutical and the original manufacturer's price. Indirect savings are calculated by looking at the difference between the original manufacturer's calculated monopoly prices and the observed prices when there is competition resulting from parallel importers. The study shows that direct savings generated only in pharmacies and hospitals in 2018 amounted to € 42 million (Zł 181.7 million) and for the period from 2010 to 2018 to a combined € 189 million (Zł 814,6 million). The indirect savings from parallel imported pharmaceuticals amounted to € 57 million (Zł 244.3 million) in 2018 and € 467 million (Zł 2 billion) in the years from 2010 to 2018. Although the indirect savings accumulated in the hospital sector were much smaller in comparison to the indirect savings accumulated in the pharmacy sector, the study emphasizes that the competitive pressure was significant in both settings.

Fast growing parallel import market with some significant obstacles

The Polish market for parallel traded pharmaceuticals is fast growing, constituting the sixth largest market in Europe. The numbers of parallel imported packages sold in the market went from 9.2 million packages in 2010 to 33.7 million packages in 2018. Although the sales numbers are increasing, parallel imported pharmaceuticals are facing numerous regulatory obstacles. The price of parallel imported pharmaceuticals has to be 25% cheaper than the actual reference price of the originator's medicine price in order to enter the Polish reimbursement scheme. Although parallel imported pharmaceuticals are equivalent to the originator's products, which are offered by the producer at a higher price, they are effectively treated as generics instead. This treatment restricts the competitive pressure on the original manufacturers, thus significantly limiting the size of savings of the National Health Fund.

Positive effects for patients and the National Health fund

Despite the obstacles to parallel trade of medicines in Poland, the study clearly highlights the positive economic impact of pharmaceutical parallel import on the competitive pressure and its enormous savings effect for national healthcare sectors in general. In Poland, the total volume of direct and indirect savings amounted to €124 million in 2018 alone, benefitting hospital operators, the National Health Fund and patients. ■

Increasing parliamentary questions on medicine shortages in the EU

In recent weeks, parliamentary written questions on the topics of access to medicines and pharmaceutical shortages have significantly increased. This trend highlights the urgent need to establish measures and respond to growing medicine shortages at EU level. In an answer to a question on shortages of medicinal products in the European Union, EU Health Commissioner Stella Kyriakides underlined the launch of the Pharmaceutical Strategy to ensure Europe's supply of affordable medicines to meet patients' needs. Furthermore, the strategy aims to address the issue of dependency of the European pharmaceutical industry on the manufacturing capacities of, and the supply of active pharmaceutical ingredients from third countries.

Regarding a parliamentary question on parallel importing of medicines in Germany, Thierry Breton, EU Commissioner for Internal Market, stressed the compatibility of the German law on the supply of pharmaceuticals – which encourages parallel import of medicines in Germany - with the EU internal market rules. In this context, he clarified that member states may take restricting measures to address medicines shortages only if such measures are justifiable as appropriate, necessary and proportionate to the objectives pursued. ■



<https://affordablemedicines.eu/reports-and-studies/>

EXPERT OPINION

Challenges at EU-level: Shortages of supply of medicines in Europe

With Mr. Andreas Glück (Renew Europe), Member of the European Parliament and medical specialist for surgery



Foto: Andreas Glück

As a doctor and member of the Environment, Public Health and Food Safety Committee (ENVI) of the European Parliament, I am aware of the problem of supply shortages of medicinal products, both from a political perspective and from daily medical practice. There are several underlying reasons causing this untenable situation. Often, individual pharmaceutical active substances are produced by only one or two manufacturers. Hence, both a failure/halt of a production plant and a delay in delivery immediately

result in a supply shortage. Up to 80% of pharmaceuticals are manufactured outside the European Union, mainly in China and India. The reliance of the European pharmaceutical industry on production capacities in third countries appears to be particularly problematic with regard to the vulnerable transportation routes. Furthermore, as a result of epidemics or disaster, the demand of pharmaceuticals may unexpectedly increase. Therefore, the European Commission is currently monitoring the impacts of the outbreak of the coronavirus on the production and supply of medicines in the European Union.

Since public healthcare remains the competence of member states, the national authorities are responsible for dealing with supply shortages of medicines. However, today, all European member states are suffering from medicine shortages. This includes not only Eastern European countries, but since 2013 also Western European countries, such as France and Germany to an equal extent. Thus, facing challenges such as epidemics and the consequences of Brexit, it is indispensable that we, as European member states, jointly tackle these challenges and find concrete solutions at EU-level.

Measures in order to do so may include restoring manufacturing and production plants within Europe to decrease reliance on non-EU countries and strengthen the European pharmaceutical industry, thereby securing European control on the manufacturing process and enabling the use of shorter transportation routes. Establishing a joint medicine stock at EU-level to help tackle the problem is already a measure being discussed among members of the parliament in the ENVI Committee. Lastly, for the purposes of developing an early warning system in the case of shortages, the exchange and cooperation among member states is crucial. Therefore, the European Medicines Agency may play a decisive role in coordinating and bundling the exchange of information among the states. ■

IMPRINT

VAD e.V. German Association of Pharmaceutical Parallel Distributor

Prof. Edwin Kohl
President of VAD
Im Holzhau 8
D-66663 Merzig
Phone: +49-6867-920-1301
Fax: +49-6867-920-1303
Email: kontakt@vad-news.de

COSTEFF e.V. alliance for cost-efficiency in healthcare

Prof. Edwin Kohl
Chairman of COSTEFF
Jägerstraße 41 | D-10177 Berlin
Phone: +49-30-20 61 59 23
Fax: +49-30-20 61 59 24
Email: info@costeff.eu

CALENDAR

18 JUNE 2020
ANTWERP, BELGIUM

The 5th Conference on Digital Health

The third edition of the conference on digital health focuses on the development of a sustainable healthcare model for the future, enabled by technology and digital. The conference will deal with the transformation of healthcare financing by digital health, the use of technology and the implementation of digital health strategies in healthcare organisations. The event will bring together medical and non-medical professionals to discuss the future of the European healthcare system.

For further information, please see:

<https://www.the5thconference.com/digitalhealth20/>



4 – 5 MAY 2020
BRUSSELS, BELGIUM

EU Health Coalition's EU Health Summit - "Time for Action"

The second edition of the EU Health Summit after 2018 brings together participants together with the EU Health Coalition partners to develop implementing actions for policymakers and stakeholders in order to translate the 2018 summit's recommendations into concrete tasks and improve Europeans' health and health systems' sustainability. Combining workshops and the development of implementing actions, the overarching aim of the summit is the creation of a design of a concrete implementing plan for both stakeholders and policy makers in Europe.

For further information, please see:

<https://www.euhealthcoalition.eu/event/eu-health-summit-2020/>



24 – 26 MAY 2020
BERLIN, GERMANY

GIRP 61st Annual Meeting and Conference – "Leveraging innovation for the economy of wellbeing"

This year's annual conference organised by GIRP, the European Healthcare Distribution Association, aims to embrace the bigger picture to explore the future of care delivery and the force healthcare distributors are playing to leverage innovation for the economy of wellbeing. The event provides an opportunity for actors from the healthcare sector but also non-traditional healthcare partners to learn about innovative healthcare practices and new economic models which arise in the healthcare sector.

For further information, please see:

<https://amc.girp.eu/>

