VAD
German Association of Pharmaceutical Parallel Distributors

COST EFF
alliance for cost-efficiency in healthcare

# PHARMACEUTICAL DIALOGUE 68

+ + + INFORMATION FROM THE PARALLEL TRADE INDUSTRY + + + DECEMBER 2019 + + +

PHARMACEUTICAL & HEALTH CARE POLITICS

## Parallel trade of pharmaceuticals entails positive effects for consumers

An ever-recurring question regarding parallel trade of pharmaceuticals is whether parallel import is favourable from an economic point of view. A recent study carried out by the INNO AG shows that the calculated indirect savings in the year 2018 in relation to the entire German pharmaceutical import market amounted to €2.6 billion. These considerably positive economic effects emerging from parallel import of medicines are reconfirmed by a Danish study. The recently published study by the Danish Association of Parallel Importers of Pharmaceuticals investigates the economic impact of parallel imported pharmaceuticals and the associated savings in Denmark. The calculated savings included data form primary sector pharmaceuticals dispensed at pharmacies as well as from hospital sector pharmaceuticals. Both data sets include volume, prices and expenditures on medicines in Denmark in 2018.

### Direct and indirect savings of parallel trade in pharmaceuticals

The study shows that in 2018, the total savings resulting from parallel import of medicines amounted to €82 million (DKK 610 million), which represents 3% of the total expenditure on pharmaceuticals in Denmark. The study considers both direct and indirect savings. Direct savings reflect the price difference between the cheapest parallel imported pharmaceuticals and the original manufacture's price and amounted to €31.5 million of savings. Indirect savings are calculated by looking at the difference between the original manufactures' calculated monopoly prices and the observed prices when there is competition from parallel importers. Hence, it has to be noted that parallel trade of medicines encourages lower prices among the original manufactures. In 2018, indirect savings amounted to € 50.5 million in Denmark.

### Regulatory environment for parallel trade

According to the study, most savings occur in the primary care sector, where parallel importers hold a market share of 26%. The demonstrated relatively large savings in the primary care sector result predominantly from the more supportive and beneficial regulatory environment in this sector in comparison to the hospital sector. It can be concluded that the size of the savings amount depends on the regulatory conditions for parallel imports, i.e. conditions which allow and support parallel import of medicines. When it comes to the primary care sector in Denmark the regulatory framework gives parallel importers good market access and the opportunity to participate in tenders on equal conditions like the original manufactures. In contrast, the regulation in the hospital sector demands a commitment to ensure supplies of pharmaceuticals up front for a full year and at a specified price with financial consequences for suppliers in the event of failure to supply. This fact restricts the competitive pressure on the original manufacturers, thus limiting the size of savings. ■

EDITORIAL

Dear Readers,

Pharmaceutical parallel trade has positive economic impacts, resulting in direct and indirect savings which accrue to the healthcare service and patients, according to a recently published Danish study. **(page 1)**

The European Single Market is at the core of the EU's industrial policy. However, in line with the Commission's Vision for the European industry until 2030, it is inevitable to fully complete and deepen the Single Market to increase Europe's global competitiveness. **(page 2)**

Member states try to implement measures restricting pharmaceutical parallel trade to fight domestic medical shortages. A judgment of the Belgian Constitutional Court has demonstrated not only that this constitutes an infringement of the free movement of goods, but also that parallel trade does not cause these shortages. **(page 3)**

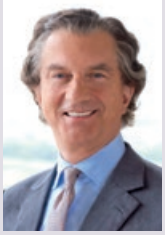
We congratulate VAD board member Mr Jörg Geller on his election as the new President of our european umbrella network the European Association of Euro-Pharmaceutical Companies (EAEPC). **(page 3)**

May you discover many informative insights as you read this 68th edition of our Pharmaceutical Dialogue.

Sincerely,

Prof. Edwin Kohl

Chairman of COSTEFF and the VAD



# A new vision for an EU industrial policy strategy

Foto: European Commission

In May 2019, member states agreed on a comprehensive long-term, forward-looking industrial policy strategy for the EU with a vision for 2030, calling on the Commission to present such strategy by the end of 2019. In this context, Commission President Ursula von der Leyen announced the establishment of a long-term strategy for Europe's industrial future within the context of her political guidelines for the 2019-2024 European Commission. Margarethe Vestager, Competition Commissioner and Executive Vice President, underlined the urgent need to develop an EU industrial strategy to further strengthen the European Single Market, since competition, "although vital for a thriving economy, was not sufficient".

### The European Single Market and pharmaceutical trade

The current fragmentation of the European Single Market, i.e. impunity of rule violations and existing barriers to cross-border trade, obstruct Europe to fully operate as a continental player. Therefore, the completion and full enforcement of the Single Market for goods and services constitutes a significant imperative for an ambitious European industrial strategy. In line with this, in its 'Vision for the European Industry until 2030', the Commission underlined that, in order to "ensure our global competitiveness, Europe must further strengthen the Single Market".

This particularly applies to the health sector and parallel trade of pharmaceuticals. The free movement of goods, on which this parallel trade is based, implies the protection of parallel imports as a tool for achieving and maintaining a Single Market and hence, the elimination of restrictions and unnecessary barriers to the free trade of pharmaceuticals between EU member states. Nevertheless, current practices of some member states and pharmaceuticals companies restricting parallel trade of pharmaceuticals by introducing export quotas or bans not only prevent benefits for the national health system but are also contrary to this principle of the Single Market.

Take the example of Belgium: an overturned Law on medicines as regards the unavailability of medicines would have introduced restrictions upon exported pharmaceutical products, thereby significantly limiting parallel trade with other EU member states. These restrictive measures, which were overturned by the Belgium Constitutional Court in October, would have potentially infringed the rules of the EU treaty on the free movement of goods. Similar measures of restricting or banning parallel trade of pharmaceuticals were also introduced in other member states, such as the UK, Romania and Greece –just to name a few.

### What's next?

As outlined in its future EU industry vision, the Commission pronounced a firm commitment to "strengthen the further integration of the market in all segments and ensure a level playing field through a uniform and effective enforcement of the Single Market rules". Eliminating existing trade barriers between member states, such as export bans of medicines and restrictions to parallel trade, will help the EU to improve its competitiveness and deepen the Single Market. This is necessary to further pass on benefits to end consumers: by expanding competition within the market, parallel trade lowers prices of pharmaceutical products, which ultimately benefits European patients and consumers. ■

## NEWS IN BRIEF

### The EAEPC elects Jörg Geller as new President

The European Association of Euro-Pharmaceutical Companies (EAEPC) elected Mr Jörg Geller, CEO of Kohlpharma GmbH, one of the EU's largest parallel importer, and member of the board of VAD, as its new President. EAEPC represents Europe's licensed parallel distributors of medicines sector in the EU. The association represents more than 120 companies, thereby covering 85% of the European market for parallel imports.

Upon his election, Mr. Geller said; "In the last four decades parallel distribution has become more and more a significant player in the fight for better affordability of and thereby access to medicines all over Europe. Recent studies indicate that parallel distribution in the Single Market, as the only price competition in the field of patent protected and prescription pharmaceuticals, is the key to save patients and healthcare systems money. By working in parallel we simply offer the better deal".

Mr. Geller then expressed his vision for the EAEPC moving forward; "Europe is facing both access and affordability problems like never before – in the coming years our sector will continuously show its value by importing into all Member States, proving savings and alleviating shortages for all Europeans". ■

**www.eaepc.org**

### Tackling inefficient spending in the healthcare sector

The European Federation of Pharmaceutical Industries and Associations (efpia) decided to have a closer look on (in)efficient health spending and presented its preliminary results at the 2019 ISPOR Europe Conference. According to Efpia, it is necessary to maximise patient outcomes which can be achieved through a certain investment in health, while at the same time continue to provide a high quality of care. This cannot be achieved through short-term cost containment measures, which, in contrast, will often have a negative impact on health outcomes. ■

# Medical shortages and parallel trade in Belgium – Court overturned export ban on pharmaceuticals

In April 2019, the Belgian Parliament has introduced new measures to modify the Law on medicines as regards the unavailability of medicines. The new act introduced a two-tier registration system for distributor of pharmaceuticals differentiating between domestic and exporting distributors, thereby introducing significant obstacles to export pharmaceutical products for the latter. Belgium has introduced this act in response to its medicine supply shortage with the intention to decrease the shortages by channelling more medicines to the domestic market.

### Infringement of the free movement of goods

However, the modified act significantly restricts parallel trade with other EU member states, raising the question whether it infringes the free movement of goods and services as enshrined in the legislation governing the European Single Market. In fact, at appeal from several wholesalers, the Belgian Constitutional Court decided in a recent judgment that an export ban for medicines is not suitable to prevent medical shortages and thereby, overturned the Belgian law preventing wholesalers and distributors from exporting medicines abroad. In its reasoning, the court focuses on the measure's compatibility with the EU rules guaranteeing the free movement of goods. In fact, in its judgment, the court states that the export ban did not seem to have achieved its intended effect of decreasing medical shortages and furthermore, that activities of exporters have no influence on the availability of certain pharmaceuticals in Belgium. Thereby, according to the Court, the challenged provision of the law amounts to a measure of equivalent effect as a quantitative restriction as prohibited by the Treaty of the European Union and the rules guaranteeing the free movement of goods.

Foto: European Parliament

### No link between export and shortages

Parallel trade of medicines is constantly exposed to accusations, both from individual representatives within the pharma industry and lobby associations. One of the accusations includes parallel importers' responsibility for existing medical shortages. However, in line with the arguments presented by the Belgian Constitutional Court, parallel trade does not cause medical shortages since wholesalers are already obliged by the Public Service Obligation to first serve the national market before exporting to other countries in order to meet the country's needs. The court now confirmed that there is no link between exports of pharmaceuticals and the occurrence of medicine shortages.

The judgment of the Belgian court will not suppress calls for action against increasingly occurring medical shortages in Europe. However, it underlines that the responsibility for causing shortages do not lie with parallel traders. Instead, it is inevitable to look for a solution at European level. Already in June, EU member states called on the Commission to investigate why Europe is experiencing these shortages and subsequently, take concrete actions. Dutch Medical Care Minister Bruno Bruins underlined the Commission's responsibility to place this issue high on its agenda and called for an EU-wide strategy to reduce future deficits both in the Netherlands, Europe and beyond. During talks in India on shortages of raw materials of medicines, he underlined that medical shortages is an international problem, given that failing production of raw materials due to pollution or production problems does not only affect the Netherlands and the rest of Europe, but also India and other parts of the world. ■

## GLOSSARY

### Vision for the European Industry until 2030

In its 'Vision for the European Industry until 2030', the European Commission sets out the future European industrial model to successfully connect economic progress with major environmental and societal challenges. The Commission sets forth key drivers and strategic imperatives to transform the European industry in 2030 into a global leader, further built its competitive advantage on cutting-edge technologies and foster investments. The vision builds on three main pillars: a fast and inclusive transformation of the European industry, global competitiveness, and social inclusiveness and values. ■

### Directorate-General for Health and Food Safety

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) develops and carries out the Commission's policies in this field. The Commissioner for the next term from 2019 until 2024 is Stella Kyriakides, a medical psychologist with experience in the field of social affairs, health and cancer prevention. From the next term onwards, DG SANTE takes on new responsibilities and portfolios, additionally dealing with issues on pharmaceuticals and medical devices, which was before allocated to the Directorate-General for Internal Market and Industry. ■

## IMPRINT

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EXPERT OPINION

# If there is a single market, then exhaustion should not apply

**With Mr. Karl Falkenberg, former Director General -European Commission and Senior Advisor of the European Policy Strategy Centre (EPSC)**

Foto: Karl Falkenberg

In November, a Round Table was held in Brussels on a specific topic of the internal market – trade in pharmaceuticals. At the beginning, the question culminated in whether the Commission lived up to its task – to be the guardian of the Treaties. Frequently, positions have been identified in the past that are more in line with national interests than the interests of a functioning European internal market.

**Mister Falkenberg, the discussion in the State Representation of the Saarland took place under the Chatham House Rules - nevertheless, you can tell us your impressions and assessments. The parallel traders complain that markets are becoming increasingly difficult and trade opportunities are constantly decreasing due to shrinking volumes of pharmaceuticals and hurdles in member states. Which impressions did you take away from the event?**

I thought that the event offered a valuable opportunity to discuss a number of issues raised in the context of the EU's Single market and pharmaceutical products. The basic issue is the apparent contradiction between the free circulation principle of the Single market and the exhaustion principle under intellectual property rights. The latter allows a patent holder to limit the sales of a product to individual markets, prohibiting the resale to other markets. This is an international rule, confirmed in the WTO's TRIPs agreement. The first question relates to the EU's internal market: if there is a single market, then exhaustion should not apply. The EU Court of Justice has repeatedly upheld this position, clearly favored by the EU Commission. The consequence is that there have been parallel trades developing in pharmaceuticals in the EU market, contrary to the situation in international markets. EU Member States take different views on these issues, some in favor, some concerned that free circulation may have an effect on pricing and hence on the viability of their respective national health systems.

**One MEP talked about the problem of transparency in the public health sector. Would an increase of transparency help with regards to the trade of pharmaceuticals?**

Transparency is definitely a good principle in this regard. Transparency with regard to the different rights involved and the way the Single Market regulates these issues. But also, transparency on the way national health system seek to influence pricing by setting the reimbursement conditions for pharmaceutical products. There also should be more transparency on the effects of parallel trade on the supply of medication in the individual national markets: does it fight shortages by supplying markets in particular need, or does it destabilize markets where lower prices are applied by shipping products to the higher priced markets.

**In your opinion, how do you resolve the conflict between the protection of the free movement of goods and the supply of medicines in the Member States?**

I think that there is a fundamental issue here: should one oblige producers to sell at different prices in different markets, to reflect the wealth of the respective health system, or should companies sell at a single market price and health systems take care of the social aspects of providing affordable medication not just to the wealthy, but also to the less favored populations. Transparency would also be useful in respect of understanding which system most efficiently addresses these questions.

**The lively and dedicated discussion was praised by all participants. Do you wish a continuation of this event format?**

I do believe that the different participants appreciated the opportunity to discuss the subject, but that there was consensus that the debate had only been a starting point and that two hours were definitely not sufficient to cover all relevant aspects. A follow-up, more structured and more thorough, would certainly be useful. Bringing together around a table relevant actors from the Commission, the Member States, the Parliament, industry and traders certainly could clarify issues better and help to define the most appropriate regulatory systems. ■

CALENDAR

03 – 04 DECEMBER 2019
BARCELONA, SPAIN

### EHTEL 2019 Symposium and 20th Anniversary – Imagine 2029: Our data, our health, our care

EHTEL's annual event will convene the European Digital Health Stakeholder Community in Barcelona. The symposium focuses on the most important challenges which face European health and care systems up to 2029 and discusses the role of data and digitalisation in health and care. Furthermore, the event tackles the question on how to prepare and maintain sustainable AI friendly eco-systems in digital health.

For further information, please see:
**https://ec.europa.eu/digital-single-market/en/news/imagine-2029-our-data-our-health-our-care-ehtel-2019-symposium**

04 DECEMBER 2019
BRUSSELS, BELGIUM

### POLITICO's Health Care Event – "Unlocking the Future of Health Care": Challenges and opportunities for transformation

This event organised by POLITICO brings together policymakers, medical professional and high-level experts for a discussion on the state of digitalisation of the healthcare sector in Europe and the outlook of the transformation of European health care in the next five years. The event offers the opportunity to look at potential obstacles to the digital health adoption in the European Union, discuss the European Commission's role and capacity of action within the context of the digitalisation of the healthcare sector, and explore digital health technologies.

For further information, please see:
**https://www.politico.eu/event/futureofhealth/**