VAD
German Association of Pharmaceutical Parallel Distributors

COST EFF
alliance for cost-efficiency in healthcare

PHARMACEUTICAL DIALOGUE 63

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

PHARMACEUTICAL & HEALTH CARE POLITICS

Study acknowledges positive effects of parallel distribution of pharmaceuticals for consumers

A study by Australian researcher Dr Susan J. Mendez of the University of Melbourne has proven the benefits of parallel distribution for patients and health care providers. Her study "Parallel Trade of Pharmaceuticals: The Danish market for statins" was published in the renowned Health Economics journal and presented in Brussels recently, at a round table in July 2018.

Restrictions not in the interest of patients

Her analysis focuses on Denmark, the market with the highest share of parallel trade in the EU. In her analysis, Prof. Mendez deals with statins, cholesterol-lowering medicines, that have long been the subject of parallel distribution in Europe.

Mendez conducts her studies on unintended detrimental effects a prohibition of parallel trade would have on the market. She elaborates especially why such restrictions are not in the interest of patients or health care providers.

Considering consumers' preferences

The Australian researcher finds that the prohibition of parallel imports induces consumers to use original products for which they have a stronger preference. A potential ban of parallel trade would therefore increase the prices of both original (2.5% increase) and generic products (3.5% increase), due to the reduced competition in the pharmaceutical market.

While the effect is positive for research-based pharmaceutical companies, it is negative for generic firms. The consumer surplus is also negatively affected, by limiting product choice and increasing expenditures. The study further finds that overall global welfare, the sum of consumer surplus and profits, would decrease following a prohibition. While other studies have only used consumer expenditures as a welfare measure, Mendez' comprehensive model also considers consumer preferences when estimating consumer surplus and is thus especially suited to display the benefits of parallel trade.

Banning parallel trade would decrease welfare

In her conclusions, Mendez notes that a ban of parallel distribution would lead to an increase of profits for the original producers and a decrease in profits for producers of generics. The ban would lead to significantly higher costs of government healthcare expenditures and additional costs for consumers. In the end, a ban would be detrimental to the welfare (and wellbeing) of Danish patients, and Danish firms. ■

EDITORIAL

Dear Readers,

Parallel trade or parallel distribution is a business often attacked and more often misunderstood. We therefore welcome the support of the academic community that proves in no uncertain terms that parallel trade really is beneficial to patients, states and overall welfare **(page 1)**.

Equally important is the political support for this successful model. However recently, the Commission has been seemingly reluctant in taking action, evidently for "political reasons". A robust approach by the Commission is yet indispensable, especially when dealing with the core values of the European Union, such as the freedom of movement of goods **(page 2)**.

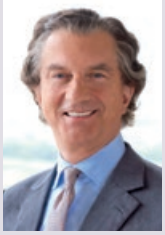
The political Brussels is already looking to the upcoming European elections in May 2019. These days, elections are all but predictable, but results aside: there already is speculation about structural changes within EU governance, especially with regard to DG SANTE **(page 3)**.

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. Enjoy reading this 63rd edition of our Pharmaceutical Dialogue.

Sincerely,

Prof. Edwin Kohl

Chairman of COSTEFF and the VAD



Industries looking for a more active Commission in the field of infringement procedures

Photo: eu

POLITICO has recently reported on the reluctance of the European Commission to take complaints regarding possible breaches of EU law of several economic sectors seriously. The report has followed the recent publishing of the annual infringement statistics of the Commission.

Massive decrease in infringement cases opened

In 2017, the Commission launched 716 infringement cases. At the end of 2017, 1 559 infringement procedures remained open. However, there is a massive decrease in opening cases compared to the Prodi Commission in 2003 with 2 709 cases opened and the Barroso I Commission in 2004 opening 2 993 cases. Even if the Commission is opening cases at roughly the same rate in the second half of the Juncker Commission as it did in the second half of the Barroso II Commission with around 700 – 1 000 cases a year, the factor that the number of Member States increased from 15 to 28 in the period has to be considered.

The Juncker Commission itself declared a political commitment to act more strategic in enforcing EU law. In its communication on "EU law: better results through better application", the Commission intends to "carefully weigh the various public and private interests involved". Since then, several sectors have experienced that the EU Commission is passing cases of EU law more frequently to national authorities.

A strong single market needs strong rules

While the Commission's action cannot be directly related to the number of cases opened, the EU's administration is at the same time proposing fewer directives and therefore creating fewer potential conflict zones with national governments. Even if the Commission is strategically acting as a political Commission, enforcing fundamental European values still must be at the core of action. For the preservation of a strong single market, strong rules and their enforcement are inevitable, in any member state.

Protection of fundamental freedoms as part of strategic action

Therefore, the European Commission will need to act, wherever there are developments against core principles such as the free movement of goods in Europe. This also applies for the pharmaceutical sector. There, the Commission is required to carefully monitor, determine risks, including possible infringements and where necessary act accordingly. The four fundamental freedoms – such as the free trade of goods within the Single Market – are the core pillars of the European Union and deserve protection, not in objection to strategic action of the European Commission, but as part of it. ■

NEWS IN BRIEF

Commission questionnaire on the implementation of the Public Service Obligation

With regards to the ongoing debate about shortages in medicines a working group of the Commission's health department DG SANTE has published the results of its questionnaire on the implementation of the Public Service Obligation (PSO) in the member states. The paper reaffirms that proportionate export restrictions could be legal according to Article 36 TFEU. However, it is immensely important to clearly define the meaning of proportionate in legal, abstract terms. The demarcation of what can be considered proportionate must not be too narrow. While parallel trade alleviates shortages everyday by importing lifesaving medicines, the benefits of parallel trade as a solution to reducing shortages were negligently not mentioned in the document at all. A demarcation would need to allow parallel trade, as part of the fundamental freedom of movement of goods. ■

HTA proposal remains controversial

The Commission proposal for an all-European joint process for Health Technology Assessment (HTA) continues to occupy the health community across Europe. After its initial publication in January 2018, the proposal came under harsh criticism from member states, most prominently from the German Bundestag that was unanimous in its criticism of the document. Meanwhile, the Committee on the Environment, Public Health and Food Safety (ENVI) has adopted its report. Then again, a representative of the Austrian Council Presidency has mentioned the possible introduction of a counter-proposal of the Council. The future of a European HTA process thus remains uncertain. ■

Deutscher Bundestag/Arndt Oehmichen

The future of DG SANTE: health topics affecting all EU citizens will require European attention

With the elections to the European Parliament and a new Commission approaching, the discussions on the future of the European institutions revives. A lingering question has occupied the health community in the European capital. Ever since the Commission's White Paper "The Future of Europe" named health as an example of "limited added value" in March 2017, a new debate emerged on the merits of the Commission's health department.

Member states call for subsidiarity

The Health and Food Safety Department (DG SANTE) has for a long time been a target of criticism. Technically, health policy is a domain of the member states. Ambitious regulatory endeavours by DG SANTE therefore often face harsh rebuttals from the member states. The ongoing debate to establish an all-European joint procedure for Health Technology Assessment (HTA) is a perfect example. The German Bundestag unanimously declared its opposition to the proposal and is now planning to file a subsidiarity appeal against the Commission.

Brexit and budget discussions

The question on the future of DG SANTE is gaining additional relevance in the context of Brexit: after the United Kingdom leaves the European Union, the next Commission will have one less member than the current one. It is conceivable that two departments will be combined in order to achieve this and in the eyes of many, DG SANTE, led currently by Lithuanian Commissioner Vytenis Andriukaitis, is a candidate for dissolution. Consequently, the NGO Global Health Advocates fears a "downgrade" of political ambitions regarding the health of EU citizens. Additionally, the Commission's proposal for the next multi-annual framework for the years 2021-2027 foresees the merger of the EU's health programme with the European Social Fund (ESF). The proposal assigns a budget of €413 million to this new "ESF+" over the seven-year period, down eight per cent on the current budget.

Health and wellbeing protected on an EU level

Regardless of the ongoing discussions on a reshuffle of departments in the upcoming Commission, topics with EU relevance need to be treated accordingly. They require EU action to be effective. Sufficient supply of pharmaceuticals, the protection against falsification and the safeguarding of access to medicines for any citizen are European topics. They affect the health and wellbeing of all Europeans and require European action. Taking the principle of subsidiarity seriously does not end at doing less more efficiently, it starts to function where action can add real value. Any future decision-maker will be required to consider the health and wellbeing for European citizens on a regional, national, but also a European level. ■

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

GLOSSARY

Infringement procedures

As the Guardian of the Treaties, the European Commission has the option of commencing infringement proceedings under Article 258 of the Treaty on the Functioning of the European Union, whenever it considers that a Member State has breached Community law. The purpose is to bring the general infringement to an end. The infringement procedure starts with a letter of formal notice, by which the Commission allows the Member State to present its views regarding the breach observed. If no reply to the letter of formal notice is received, or if the observations presented by the Member State in reply to that notice cannot be considered satisfactory, the Commission will move to the next stage of infringement procedure, which is the reasoned opinion; if necessary, the Commission will then refer the case to the Court of Justice. ■

Competition on the pharmaceutical market

The complex and heavily regulated market for medicines relies on several factors to maintain the competition that is necessary to achieve optimal outcomes for patients and health care systems. Once the patent for a product runs out it becomes legal for the producers of generics to enter the market. These generics producers, as the original producers, are free to set prices which will further be negotiated with national authorities. Parallel trade adds a competitive element to the market by way of making affordable imported medicines available to the market and thereby nurturing competition. ■

Making use of surplus resources

Parallel trade is the practice of making use of surplus resources on the medicines market. By exporting excess medication to other EU markets, parallel trade is contributing to the timely and affordable availability of medicines throughout the European Union. By way of the Public Service Obligation (PSO), wholesalers are obliged to meet domestic demands first. This ensures that exports do not come at the expense of domestic demands. ■

EXPERT OPINION

EXPERT OPINION: Medicines exports again political scapegoat

By Kasper Ernest, Secretary-General, European Association of Euro-Pharmaceutical Companies (EAEPC)

The Czech Minister of Health and his medicines agency is planning to introduce legislation that de facto bans export of all medicines from the Czech Republic. The direct inspiration for the proposal comes from Slovakia according to the authorities. This approach is absolutely disproportionate and overlooks the positive effects EU trade can have on the affordable and timely access to medicines for all European patients.

Shortages – a political hot potato

It is widely recognised, that the primary cause of shortages is to be found in manufacturing disruptions, commercial withdrawals, and the supply quotas imposed by manufacturers. By law (Directive 2001/83/EC art. 81), a marketing authorisation holder (MAH) has the obligation to supply the market, but according to the Czech authorities, this obligation is in practice impossible to uphold due to the power of MAH's. Instead, targeting exports answers the need for political action immediately. Ample experience from other countries provides evidence that this approach does not work. But politically hot potatoes are rarely handled appropriately.

Build on wrong assumptions

The Czech authorities seem to be of the perception, that the EU Commission have rubber-stamped the Slovak law because an infringement procedure was not launched. However, this is not the case. In fact, the EAEPC upon their complaint to the Commission, got a very clear response in the non-published pre-closure letter. The Commission states that the Slovak law "constitutes a measure having equivalent effect to quantitative restriction on exports of medicinal products according to Article 35 TFEU" and that "the Commission services would not consider the specific restrictive measure introduced by the Act on Medicinal Products as appropriate and necessary" (infringement of Article 36 TFEU).

The EAEPC was encouraged to go to the Slovak courts, as they are the first instance for upholding EU law. The appropriate measures to do so have been taken. For the Czech authorities to follow such a route is, hence, incomprehensible, and the EAEPC are working to see the idea transformed into a meaningful framework to handle shortages.

Industry commitment to restrict trade in medicines in shortage

The medicines trade industry in Europe is strongly committed to work towards a framework that sees the halt of exports when a medicine is truly in shortage in a Member State. This requires a two-step approach. First, we must have an EU-wide categorisation of shortages, so we can define when appropriate measures should be taken. Second, to take such measures, a strong toolbox must be available to national authorities. Such a toolbox includes investigations into the cause of a given shortage, fines on manufacturers failing to observe their obligations, appropriate restrictions to exports, etc. We must all work together to fight shortages.

Trade is a solution

EU trade is the only means to move medicines from Member States with excess supply to Member States with shortages within the week. At the same time trade gives rise to intra-brand competition consequently providing savings to health care systems and patients. Of the 13 medicines said to be in shortage by the Czech authorities, the medicines trade industry could have resolved several with appropriate imports. But the system and dialogue with the sector is lacking. The current stigma around trade in medicines benefits no one except the manufacturers. ■

CALENDAR

21 NOVEMBER 2018
BRUSSELS, BELGIUM

2nd Value Added Medicines Conference

Value Added Medicines contribute to addressing unmet patient needs. Moving from a one-size-fits-all to a much more tailored and patient specific approach, value added medicines are one of the key components of the customisation of healthcare. By answering patients' unmet needs, they represent a new horizon for those who are currently looking forward to a better quality of life with their treatment.

The Value Added Medicines Group engages with the healthcare community and policy makers to support greater access to medicines and to medicines innovation for all European patients. Recognising that healthcare systems are under considerable financial strain, we encourage greater collaboration between stakeholders. We recognise that patients, healthcare providers and payers have unmet needs and expect genuine value added improvement, more innovation and sustainable access models in the future.

For further information, please see:
https://www.medicines-foreurope.com/events/vam2018/

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For further information, please see:
https://ephconference.eu/