VAD
German Association of Pharmaceutical Parallel Distributors

COST EFF
alliance for cost-efficiency in healthcare

PHARMACEUTICAL DIALOGUE 66

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PHARMACEUTICAL & HEALTH CARE POLITICS

Pharmaceutical parallel trade in Europe – Ensuring access to high-quality and affordable medicines

In the European Union there have always been significant price differences between various countries for the same pharmaceutical product. Against this background, parallel pharmaceutical trading emerged in the late 1970s, with the primary intention of overcoming these drastic price differences for the benefits of patients and health care systems.

Functioning of the European parallel trade

Parallel importers purchase medicines from pharmaceutical wholesalers in member states with more competitive pricing systems and export them to countries in which the comparable compounds are more expensive. After being labelled in accordance with the national legislation of the country of destination, the parallel trader sells the products back to authorized wholesalers or directly to pharmacies in the recipient country. A distinction is made between parallel imports and reimports. Parallel imports are drugs that have been produced by multinational corporations outside the recipient country. If the medicine imported from the country of purchase was originally manufactured in the recipient country, it is considered as reimport.

A thorn in the side of the competitors

Due to its success, the parallel trade is constantly exposed to unsubstantiated accusations. In recent years, individual representatives of the pharmaceutical industry and powerful lobby associations, not only in high-price countries like Germany, have repeatedly attempted to blame parallel importers for existing medical shortages. It was also alleged that parallel trade would favour the spread of counterfeit medicines. Earlier this year, the current Commissioner for Health and Food Safety, Vytenis Andriukaitis, commented on these allegations and reaffirmed, in the view of the European Commission, pharmaceutical parallel imports cannot be held responsible for these public health challenges.

Substantial benefits for citizens across Europe

The European internal market is based on the principle of free competition, which leads to favourable consumer prices. In line with this principle, parallel trade is systematically expanding competition in the market for pharmaceutical products. Parallel imports and reimports compete with the manufacturers' reference medicines.

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EDITORIAL

Dear Readers,

The pharmaceutical parallel trade is a European success story that has been instrumental in making high-quality medicines affordable to patients across Europe. In order to meet patients' expectations for good health care in the future, restrictions on the freedoms of the European internal market must be overcome. **(page 1)**

This year's election to the European Parliament was eagerly awaited. The election results are likely to have significant impact on the European health sector. **(page 2)**

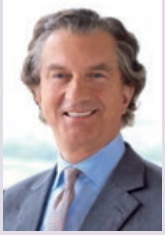
Pharmaceutical parallel trade is an effective way to achieve savings in national healthcare systems. In this context, it is enlightening to take a look at the indirect saving effects, which are particularly evident in Germany. **(page 3)**

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 66th edition of our Pharmaceutical Dialogue.

Sincerely,

Prof. Edwin Kohl

Chairman of COSTEFF and the VAD



They thus create the only price competition on the otherwise strictly regulated, somehow monopolistic market for patent protected pharmaceuticals - to the benefit of the respective health care systems, as well as consumers.

Due to an ageing population health care expenditure are bound to rise, which can be mitigated through parallel imports. National health insurances also record considerable savings due to the cost-effective offer of the established parallel trade (See page 3).

The remaining space for improvement

As we can see in the case of export restrictions

The European single market still needs to be deepened in some industries, as remaining barriers mean that some industry representatives, such as the parallel trade in the example of export restrictions, are still hindered from taking full advantage of the single market benefits. This means that parallel importers, in turn, are prevented to bring the benefits of the Single Market to European consumers. The lack of a genuine Single Market in pharmaceutical parallel imports creates a “missing link” between the EU’s Internal Market and consumers.

We therefore call on the Members of the European Parliament to renew its political determination to complete the Single Market, with a precise focus on effective coordination and alignment of EU and national policies. VAD fully supports the proper implementation and strong enforcement of EU Single Market legislation, while ensuring that parallel importers can trade cross-border without being subjected to national restrictions as well as achieving a homogenous functioning of all retail channels across the EU. ■

European elections 2019: Key findings and implications for the public health sector in Europe

Photo: European Parliament

The recent elections to the European Parliament have been instrumental in speaking of a “Year of Change” at EU level. High-ranking positions are being filled not only in the European Parliament but also in the other EU institutions. In particular, the new composition of the European Parliament and the Commission implicate potential radical changes in the political agenda of the EU.

New kingmakers and agenda setters

The Liberals and the Greens have emerged as clear winners of the European Parliament elections. With no more majority left for the grand coalition in the European Parliament, the two winning parties will play a crucial role in the appointment of the new Commission President. Consequently, it is safe to say that the political agenda of the Greens and the Liberals will gain enormous influence. It is expected that the new Liberal MEPs will push towards deepening the European single market by eliminating existing trade restrictions. In view of the Green Party manifesto, the influx of Green Members in the European Parliament will most likely increase pressure on pharmaceutical manufacturers. Especially, the Greens are in favour of extending the competence of the EU in health issues, since in their opinion DG SANTE has been too soft towards the pharmaceutical industry in the past. As a result, it seems likely that the Greens will push strongly for a Vice-Commissioner for Health, which has already been confirmed by the influential Green MEP, Bas Eickhout. Recently, the Secretary General of the European Commission, Martin Selmayr, emphasized that he was particularly convinced that the “green wave” would also have a strong impact on the program of the next President of the European Commission.

A European Parliament of new faces

A fundamental finding of the election analysis is the large number of newcomers in the European Parliament, considering that only one third of the previous MEPs have stood for re-election. This creates a notable vacuum in the ENVI committee, which deals with matters of public health. A large number of very dedicated parliamentarians, such as the Portuguese MEP, José Inácio Faria, the former vice-chair of the ENVI committee, Pavel Poc or the Slovenian EPP representative, Alojz Peterle, will need to be replaced in the upcoming weeks.

Health Technology Assessment in need of new leadership

The drafting of the legislative proposal of the Health Technology Assessment (HTA) is probably one of the most critical priorities in the forthcoming legislative period. This legislative file is considered to be a complex public health matter still to be negotiated. Also, in this context, the departure of some key players in parliament will be noticeable for the time being. Thus, successors to the lead rapporteur, Soledad Cabezon Ruiz and shadow rapporteurs, Françoise Grossetête and Gesine Meißner, must be found quickly in the upcoming weeks. Shadow Rapporteur Joelle Melin (ENF, France), Michèle Rivasi (Greens/EFA, France), Kateřina Konečná (GUE/NGL, Czech Republic) and Piernicola Pedicini (EFFD, Italy) were re-elected to the European Parliament and are expected to continue the work on the file. However, this could still be subject to change. Meanwhile, it is likely that the re-elected German MEP, Peter Liese, will take the lead in the ongoing legislative process for the EPP. ■

2,6 billion € for Germany- Indirect savings effects of pharmaceutical parallel imports

A remarkable German study from April of this year, conducted by the INNO AG and commissioned by the EAEPC, looks at the competitive effects of re-import and parallel imports on the German pharmaceutical market. Specifically, this secondary analysis investigated the indirect savings which can be achieved by pharmaceutical parallel imports. The general savings potential that lies behind the indirect savings effects shows the real potential of the parallel trade for the respective health care system.

Import clauses as savings instrument for European health systems

In 2004, in order to save money in the German health care system, an import quota for drugs has been introduced. This pharmaceutical import quota requires pharmacies to cover at least 5 percent of the drugs sold through parallel imports. In this context, only products that are at least 15 percent or 15 euros cheaper than the same reference product of the original manufacturer are credited. In the period 2011-2017, the market share of re- and parallel imports in the German pharmaceutical market of prescription medicines for all importers amounted to 8.9%. The total market share of imports preparations on all existing medical preparations is about 13.5%. Different mechanisms exist in other EU Member States, which also result in significant savings. Not only in Germany, "Big Pharma" is vehemently committed to deprive consumers of sustainable savings by lobbying hard against the import quota in Germany and the parallel trade in general, with changing but always doubtful or even false arguments.

Direct and indirect savings of pharmaceuticals parallel imports

In general, direct savings result from the price difference between original products and imported products and their market share. However, the latest secondary analysis focuses solely on the assessment of indirect savings. Indirect savings effects are on the other hand when the competition caused by the parallel trade leads to lower prices for the original pharmaceutical products. In the course of this, it is assumed that the market price of an original product would not change without competitive pressure. The renewed calculation of the indirect savings effects in 2018 in relation to the entire German import market results in indirect savings of around € 2.6 billion per year.

The savings potential of pharmaceutical parallel trade

It frequently occurs, that large pharmaceutical manufacturers claim that import quotas would not result in the desired savings in the health system and should therefore be abolished. According to other studies, the direct savings in 2017 were only € 264 million, and therefore much lower than the indirect savings. Only the indirect savings make it clear why manufacturers of original medicines for European markets are against compulsory importation quotas. In fact, these savings show how much the increasing competitive pressure created by parallel trade leads to lower pharmaceutical prices in general. Nevertheless, it is above all the EU Member States with lower purchasing power that are benefiting from this increase of competition, which ensures the affordability of high-quality medicines. ■

NEWS IN BRIEF

The European Commission launches the European Platform on Rare Disease Registration

The European Commission has created a new registration platform for rare diseases in order to merge the fragmented data in Europe on this topic. In general, a disease is considered "rare" if it affects less than five out of every 10,000 people. At present, there are currently about 30 million people in the EU who are diagnosed with a rare disease. In the past, the Directorate-General for Health and Food Safety has pointed out that in some Member States there are not enough patients to initiate meaningful studies necessary to treat the affected patients appropriately. With more than 6000 different rare diseases on the agenda, the platform is taking on this challenge. The optimized exchange and the simplified search for helpful information are the objectives that this platform aims to achieve. ■

New version of the Union Register of medicinal products

The European Union Register of medicinal products, which lists all medicinal products for human and veterinary use (over 1.300 medicines) authorized through the centralized procedure of the European Commission, has been in existence since 1995. Besides the designation of orphan pharmaceutical products, the register also covers the list of refused authorisations and reviews related to nationally authorised products. In May 2019, the Commission introduced the new version, which offers a whole range of additional features. These include, among other things, a new export and a filtering option. The aim of the updated version is the simplified navigation and optimized compatibility with mobile devices, which should ultimately lead to an improved user experience. ■

Europäische Kommission

Photo: European Commission

EXPERT OPINION

Safe medicines: A European success

By Jo Leinen, long serving and outgoing Member of the European Parliament (S&D Group)

Photo: MEP Jo Linen

Pharmaceutical Dialogue: Having served in the European Parliament for 20 years and not a bit tired, what is missing in Europe these days? Why does Europe not have a seat in the hearts of the people?

Leinen: There is a lack of energy and imagination to spread the idea of Europe and its advantages and make it more visible. The Commission has failed to do so, creating a vacuum that Member States use by often selling European achievements as their own.

Pharmaceutical Dialogue: Why are the major achievements, such as the Euro and the elimination of border controls, not perceived as the success of Europe?

Leinen: If these great achievements are not cultivated and communicated then people quickly forget where these accomplishments came from. This also applies to peace, freedom and prosperity. Communication must therefore become a permanent task that is not neglected.

Pharmaceutical Dialogue: The internal market has been questioned again and again. What would be the alternative?

Leinen: There is no real alternative. A fundamental questioning of the internal market simply implicates the return to nation-state solutions with all the negative side effects, such as the return of borders and tariffs. This in turn leads to burdens on the economy, reduction of wealth and investment. Ultimately, it would also be about job losses.

Pharmaceutical Dialogue: How can the single market be ensured in the future - ultimately as a competitive advantage in the globalized world?

Leinen: We must defend ourselves consistently against all tendencies of isolation and protectionism. Not only in Washington, but also in some European capitals, there seems to be the dream of building strong borders. I sincerely hope that the new European Parliament will vigorously resist these tendencies and work for a strong single market, thus securing our economic influence in the world.

Pharmaceutical Dialogue: Will free trade of medicines continue to be part of the internal market (under defined rules and framework conditions)?

Leinen: Medicines are goods that are freely traded in the European Union and fall under the rules of the internal market. Certainly, some additional rules have to be respected, but in principle the single market applies when it comes to trade of pharmaceuticals. I know that there are some Member States and economic interests that try to hinder or even prevent this free movement of medicines. In this context, too, I hope that Parliament will resist these attempts.

GLOSSARY

Health technology assessment (HTA)

The assessment measures the added value of a new health technology in comparison to existing technologies/current standard of care. HTA is defined as a multidisciplinary process that summarises information in a systematic, unbiased and robust manner about the medical, economic, organisational, social and ethical issues related to the use of a health technology. The goal of HTA is to support decision makers at national, regional or local level in their efforts to ensure that patients are treated with the best available treatment while keeping the health budgets under control/in balance. HTA also encourages economic stakeholders to focus their research on areas where they expect significant innovation ■

Legal Basis for Parallel Distribution

The legal basis for Parallel Trading follows from the principles of free movements of goods and exhaustion of intellectual property rights within the internal market. The EU's founding Treaty underlines that: "Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between member states."
Importers have as a rule to change the labelling - and in some cases the packaging - in order to meet all regulatory requirements of the national law in the reference market. The relabelled products and packages must meet all legal standards and are subject to thorough governmental supervision. The importer also ensures that all products are provided with patient information inserts in the local language. ■

IMPRINT

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