VAD
German Association of Pharmaceutical Parallel Distributors

COST EFF
alliance for cost-efficiency in healthcare

PHARMACEUTICAL DIALOGUE 57

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

PHARMACEUTICAL & HEALTH CARE POLITICS

What are the options for improving access to medicines?

Photo: eu

This question is high on the agenda of EU politics. In January, the Council of the European Union agreed in strengthening its ambitions together with the Commission to find suitable answers. Furthermore, the EU options on improving the access to medicines have been anchored in the Own Initiative Report of the European Parliament, following several months of debates. The report, which has been adopted in the Plenary in March, reflects the uneasy status quo on the pharmaceutical markets resulting from the growing dominance of Big Pharma.

Strengthen the Public Service Obligation

The European Parliament report calls, amongst others, on the European Commission and the Council of the European Union to analyse the causes of medicinal shortages, particularly referring to supply quotas. Policy remedies are expected to be enforced, such as the use of the Public Service Obligation (PSO), which obliges both manufacturers and distributors to safeguard the supplies in national markets. The report highlights that in many cases the PSO is not applied to manufacturers supplying the distributors. Furthermore, other business strategies deployed by some manufacturers are being criticised, such as the withdrawal of effective medicines from the market as well as the „pay for delay“ arrangements, which result in restrained access to medicines.

Choosing the right options to limit shortages

Pharmaceutical companies must make their medicines accessible to all the European citizens. The parallel distribution industry therefore fully supports the intention to examine the real reasons behind temporary under-supplies as called upon by the European Parliament report. As a responsible stakeholder of the pharmaceutical supply chain, the parallel distributors stand ready to contribute to the sustainability of Europe's healthcare systems by providing pharmaceuticals in competitive prices. ■

EDITORIAL

Dear Readers,

the need for increased competition in the pharmaceutical sector has clearly emerged and manifested itself over recent courses. The adoption of the Own Initiative Report on EU options on improving access to medicines by the European Parliament underlines this case.

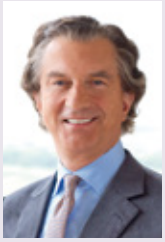
The report highlights concerns towards the increasing prices of medicines, a fact that exerts severe pressure on healthcare systems – a problem visible on both sides of the Atlantic (see page 3). In this regard, parallel distribution promotes competition within pharmaceutical markets in Europe, being a tool to decrease prices and facilitate enhanced access to medicines. However, parallel distribution can only function and be beneficial, if the principles of the Single Market are preserved ***(see page 2)***.

The VAD welcomes the adoption of the report, since it not only underlines the need to foster the sustainability of the European healthcare systems, but also calls for policy remedies such as the use of the Public Service Obligation, which is fully in line with the core aim of parallel distributors ***(see page 1)***. VAD is ready to contribute to a dialogue with all the relevant stakeholders in order to develop holistic strategies for better access to medicines and thereby serve Europe's citizens.

Sincerely,

Prof. Edwin Kohl

Chairman of COSTEFF and the VAD



2017
Building a true Single Market for Europe

Photo: vad

Boosting growth and investments into the real economy are amongst the top priorities set within the European Commission´s Work Programme for 2017. The European Single Market has been recognised in this respect as a basis for Europe‘s economic power and prosperity. The European Commission therefore intends to enforce a deeper and fairer Internal Market during the year of 2017.

Exploiting the potential of the Single Market

The parallel distribution of pharmaceuticals is an example of how the Single Market can be beneficial to the EU citizens. This practice brings competition to the highly monopolised and fragmented pharmaceutical markets and hence leads to lower prices and savings for the healthcare systems. Nonetheless, this practice has been jeopardised by export restrictions exercised in some Member States. The European Commission has deemed in recent cases that such restrictions are disproportionate and contrary to the free movement of goods.

Export ban is not the solution to structural problems

Within a wider enforcement package mostly targeted to the provision of cross-border services, the European Commission will particularly empower National Competition Authorities in order to be able to enforce rules that guarantee the existence of lawful competition in the market. Export restrictions are imposed due to claims that parallel distribution leads to shortages. However, both manufacturers and distributors of medicines are obliged to supply in the first place the national markets within the remit of the Public Service Obligation, which is often not fulfilled by manufacturers (see the glossary). The role of the National Competition Authorities, in this case, is to support National Health Authorities in the enforcement of the Public Service Obligation in order to balance the supply on the markets.

Being one of the few elements of the competition, parallel distribution plays a significant role in securing better access to medicines. Consequently, the Single Market rules are to be reinforced in every aspect, especially in the pharmaceutical sector. ■

IMPRINT

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NEWS IN BRIEF

EUROPEAN ASSOCIATIONS ISSUE RECOMMENDATIONS ADDRESSING SHORTAGES

The European associations representing manufacturers of medicinal products, parallel distributors, pharmaceutical wholesalers and pharmacists have announced a series of recommendations on the provision of information, designed to help tackle medicines shortages.

The European Association of Euro-Pharmaceutical Companies (EAEPC) is part of this industry initiative. The recommendations call for early detection and assessment of potential shortages, consistency of reporting. The recommendations aim to mitigate the impact of shortages on patients, provide patients and health professionals with up-to-date, meaningful information and improve the ability of health systems to diagnose and solve supply issues as they arise and collaborative governance processes.

EU TO SUPPORT RESEARCH IN AUTISM, DIABETES, CANCER AND PAIN

Under the second programme period of the Innovative Medicines Initiative (IMI), a 10th call for proposals has been launched aiming to support research in various aspects of autism, diabetes, cancer and pain. The total budget of the call, which has been running from December until March, amounts to €348 million.

IMI is a collaboration between the European Commission and the pharmaceutical industry aiming to support pharmaceutical research and development. The total budget in the current programme period (2014-2024) amounts to € 3.3 billion. The European Union provides half of the funding and the other half comes from the industry.
tions, across borders.

Discussing the benefits of parallel distribution in London

Photo: istock/narvikk

The UK capital hosted Europe's leading Conference on Parallel Distribution in the beginning of February. This year's edition particularly reiterated the positive effect of parallel distribution on the mitigation of prices. According to the representative of the privately owned pharmacy chain in Sweden, parallel distribution is the only competitor to the branded medicines sector. It leads to immediate competition and consequently price reductions in the country.

The much-contested topic of pharmaceutical shortages has been equally mentioned. Oliver Luksic, Head of Government Affairs at the European Association of Euro-Pharmaceutical Companies noted that research provided by academics has shown that most shortages are caused by production problems. The representative of the Danish medicines supplier further outlined the reality on the ground. Limited supplies from manufacturers to wholesalers equally result in shortages. The Danish supplier further referred to the fact that wholesalers normally procure from several Member States in order to safeguard the balance supplies throughout Europe. "Parallel distributors can even help sometimes when there are shortages", by evening those out, he added. The markets in Northern Europe have been gradually benefiting from the parallel distribution. As a responsible stakeholder within the pharmaceutical supply chain, parallel distributors can help to lower the prices, while simultaneously catering for balanced supplies. ■

Pharmaceutical pricing: savings needed more than ever

Similarly to Europe, the USA are also faced with pressure regarding the sustainability of its healthcare system. This is partly a result of increasing prices of pharmaceuticals. The new administration intends to make changes in the health insurance framework favouring amongst others the expansion of the access to prescription medicines. This will impose even greater pressure to the mitigation of pharmaceutical expenditures.

The new administration intends to reduce the costs through changes in bidding procedures by the U.S. government, which does not get involved in the negotiation or regulation of the price of pharmaceuticals so far, a practice that is very rare amongst the industry nations. As in Europe, the issue is of a complex nature and as such, any substantive moves will take time and will be mostlikely opposed by manufacturers. In Europe, the prices can be mitigated, for instance, by the parallel distribution, which is based on the Single Market rules and allows for significant savings for the health care systems through the convergence of prices to the lower level. As pharma expenditures are increasing, such practices are needed more than ever before. ■

GLOSSARY

MAIN DRIVERS OF SHORTAGES

While the phenomenon of shortages occurred in the recent decade, the overall volume of parallel distribution on the pharmaceutical market has been stable at 3% and even beginning to show a declining trend. A study, concluded in 2015, by the European Medicines Agency (EMA), outlines that the main reasons for shortages can be found in and result from a globalized supply chain as well as inconsistencies in the manufacturing chain. Furthermore, delayed payments on the side of health insurance authorities contribute to shortages. Although there are EU regulations addressing the tightening of supply volumes by manufacturers, these practices continue to exist and still contribute to shortages.

PUBLIC SERVICE OBLIGATION

The Public Service Obligation (PSO) denotes the equal obligation upon manufacturers and distributors to supply the national market with pharmaceuticals in the first place. This obligation is stipulated in Article 81 of Directive 2001/83/EC and was amended in 2004. However, not all Member States have implemented the PSO so far. Manufacturers have unlawfully benefited and often not supplied the markets sufficiently. More precisely, they have followed several strategies as market observers assume. One strategy aims to harm competition via parallel distribution by establishing quotas. Another one aims to exert pressure on national health insurance in countries who are partly not able to pay the bills due to economic and financial difficulties. And sufficient market supply is always a hostage for actual and future pricing bargains.Hence, the resulting imbalances cause availability problems, as summarized by a study orderedby the European Commission in 2012. A positive example of the PSO implementation is France, where obligations on pharmaceutical manufacturers have been enforced. The implementation and use of PSO will prevent shortages and will balance out the supplies.

EXPERT OPINION

A European approach to medicines´ shortages

The free movement of goods is one of the four fundamental freedoms of the European Union. Medicines, as one of the goods, are generally freely traded within the EU. However, the pharmaceutical industry has been implementing measures aiming to restrict parallel distribution.

The European Court of Justice (ECJ, C468 / 06 of 16/09/2008), however, has emphasised in consecutive rulings that general restrictions on parallel distribution are not allowed. The Court has previously held, that a pharmaceutical company in a dominant position has abused this position if it refused to carry out normal orders from wholesalers in order to prevent parallel exports. The ECJ has further noted, that in case there is a supply shortage on the national market, it is not relevant whether the company was in a dominant position. Additionally, the ECJ has ruled that the national authorities have the competence to protect public health in accordance to the obligations arising from Article 81 of Directive 2001/83 / EC.

The European legislation has reacted to shortages without overruling the fundamental freedom of trade. The ´Public Service Obligation´ obliges wholesalers to sufficiently supply the national market and then proceed to exports. However, the public service obligation is hardly applied in practice. In addition, there is a lack of information about the causes of supply shortages. It is unclear whether supply shortages can be attributed to wholesalers who export too many medicines or whether they are relevant to the price-pressure and the amount of production. The European Parliament has recently asked this question in order to achieve greater transparency (2016/2057 (INI) of 2 March 2017).

In this context, the EP calls on the EU Commission and the Council of the EU to analyse the reasons behind medicines´ shortages in the national markets. Towards this purpose, additional data are required and further studies may have to be commissioned. The objective should be to ensure that the Member States and the European Medicines Agency (EMA) are aware on which medicines are faced with shortages and what the reasons behind these shortages are. This will assist in maintaining a continuous and safe medicinal supply.

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CALENDAR

16 MAY 2017
BONN, GERMANY

SEMINAR ON PARALLEL DISTRIBUTION OF PHARMACEUTICALS

The seminar will provide the opportunity to discuss and share information on parallel distribution of pharmaceuticals as well as pharmacovigilance. The experts will inform the participants regarding the legal requirements, the procedures for the approval of medicines as well as instances when the approvals can be refused. Last but not least, the seminar will provide further insight on pharmacovigilance.

For further information please see:
forum-institut.de

10 - 12 MAY 2017
MALTA

EHEALTH WEEK 2017

This year's theme of the eHealth Week will be Data for Health: the key to personalised sustainable care. Data lies at the heart of service delivery and the development of effective health policy. Speakers and delegates will explore the changing ways in which personal health data is created, stored, shared and used. Advances in bioinformatics support a paradigm shift towards tailor-made prevention and treatment strategies for both individuals and population groups. Opportunities are growing for ICT to support patient-centred health services and involve patients in their own care, including the access to personal health data, sharing of data, and eHealth applications.

For further information please see:
ehealthweek.org

16 - 18 MAY 2017
BRUSSELS, BELGIUM

26TH ANNUAL EU PHARMACEUTICAL LAW FORUM

As one of the leading pharmaceutical law conferences in Europe, the Pharmaceutical Law Forum provides critical guidance on competition law, patent litigation, regulatory frameworks, compliance and licensing agreements. The forum will also cover debates and discussions on the Brexit and its impact on pharmaceutical law.

For further information please see:
lifesciences.knect365.com