VAD
German Association
of Pharmaceutical
Parallel Distributors

COST EFF
alliance for cost-efficiency in healthcare

PHARMACEUTICAL DIALOGUE 55

+ + + INFORMATION FROM THE PARALLEL TRADE INDUSTRY + + + OCTOBER 2016 + + +

PHARMACEUTICAL & HEALTH CARE POLITICS

European parliament:
"Access to medicines" in the spotlight

Photo: istock/LarsZahnerPhotography

The European Parliament is preparing to launch the Own initiative report on "EU options on improving access to medicines." Ahead of the presentation of the report in the Health committee (ENVI), the opinions on the dossier are being dealt with in the respective committees. The amendments to the draft opinion of the Petition committee (PETI) have particularly also addressed the shortages of pharmaceuticals.

Taking the helicopter perspective

Some of the proposed amendments in the PETI committee are urging to limit the parallel trade of pharmaceuticals as it leads to shortages. However, this picture is far from reality. Strong market position of "Big Pharma" poses a significant obstacle to access to medicine in general and the occurrence of shortages in particular. Further, the amendments also point out that the monopolistic position of manufacturers on the pharmaceutical markets results in high prices of medicines, and thus difficulties in access. However, manufacturers not only enjoy monopolistic positions in terms of price-setting, but they also abuse the dominant position in terms of the volumes that they source to the markets by imposing the supply quotas. These limitations result in shortages.

Creating an equal level playing field on pharma markets

The provisions of Article 81 of Directive 2001/83/EU particularly stipulate appropriate and continued supplies of medicines in order to cover the needs at the national market to be safeguarded by both, manufacturers and the distribution. The translation of this provision into practice is provided through the Public Service Obligation (PSO) (see glossary). Manufacturers limit the volumes by imposing supply quotas. By doing so, they thus unlawfully benefit from the incorrect implementation of ▶▶▶

EDITORIAL

Dear Readers,

Parallel traders of pharmaceuticals are a responsible stakeholder within the supply chain. At the EU-level, VAD and its umbrella organisation European Association of Euro-Pharmaceutical Companies (EAEPC) have been contributing for more than 10 years to the policy debates on how to improve the accessibility of medicines. Pharmaceutical shortages have been occurring both, within and outside the EU ***(see page 2)***. As regards the EU-level, balancing-out the pharma markets could significantly eliminate shortages.

Abuse of the dominant market position by manufacturers ***(Article 101 and 102 TFEU)*** is on the one hand reflected in high prices of medicines. The other side of the coin is linked to the fact that "Big Pharma" is tightening the volumes placed on the market. The obligation to supply the markets with sufficient volumes, as stipulated by the EU law, should be therefore adhered by manufacturers ***(see page 1)***.

With the view to address the reason of shortages, the parallel trade industry welcomes the initiative of the European Parliament to launch the report on improving access to medicines. We particularly call upon the European Parliament to address in the report the imbalances on the pharmaceutical markets regarding volumes and the implementation of the existing EU law in this regard.

Sincerely,

Prof. Edwin Kohl

Chairman of COSTEFF
and the VAD

the Directive and create imbalances on the market. It is up to the national authorities, particularly competition authorities, to use and enforce the PSO.

The European Parliament report will uphold a strong political message towards European Commission and Member States. In this vain, the necessity to use the existing EU legislation to create the balance on the pharmaceutical markets and avoid shortages is to be carried in this message. ■

Shortages: Not-only-EU difficulty

Photo: istock/Anton Donev

The Capital of Bulgaria, Sofia, hosted Ministers of health and other high level experts from Central and Eastern Europe (CEE-Region) at beginning of June. The purpose of this meeting was to find a common ground on how to improve patients' access to medicines in the region. The outcome of the meeting was market by the "Sofia Declaration on ensuring adequate access to pharmaceutical products at sustainable and affordable prices."

Beyond the Single Market

Amongst other things, the Declaration of Sofia stipulates "to jointly address key issues that our health systems are currently faced with, such as a lack of and difficulties with the availability of essential medicines." Besides the signatories form the CEE-Region from within EU, the declaration was also signed by the representatives of Serbia and Macedonia. These two countries are not part of the EU Single Market. The parallel trade of pharmaceuticals which is based on the EU free movement of goods, therefore, does not exist in these countries. Nonetheless, both Macedonia and Serbia are still subjected with shortages. Parallel trade of pharmaceuticals is, thus, not the reason of these shortages.

.. and within

The phenomenon of shortages appeared only in the recent decade in the EU, although the volume of re-exports shrank. Parallel exports are, therefore, not accountable for the situation even within the boundaries of the Single Market. To name only a few, pharmaceutical shortages may result from increased intervention of "Big Pharma" in the supply of pharmaceuticals. Globalized supply and manufacturing chain is causing significant problems in the availability of pharmaceuticals according to the European Medicines Agency (EMA). Manufacturing of active substances is for instance in hands of only one producer. The market entry of pharmaceuticals is postponed, or some products are even withdrawn from certain market not because the producer will not have any kickback, but even due to lower profitability than expected.

The case of Macedonia and Serbia clearly demonstrates that pharmaceutical shortages pose an issue beyond EU borders and the rule of the Single Market. The challenge for the years to come is to find policy initiative that will target their causes. ■

GLOSSARY

USE OF THE PUBLIC SERVICE OBLIGATION: PRACTICAL EXAMPLE

Imagine you are unable to obtain the medicine you need in Spain, although the same product is available in France. One of the reasons behind this may be the fact that France has accurately implemented the existing EU rules on supply of medicines. In contrast to Spain, France imposes the obligation upon manufacturers to supply sufficient volumes to the market.

As volumes of medicines sourced to the Spanish market are more tightly controlled (there is no buffer stock), the unavailability of your treatment is more likely to occur in Spain than in France. This would be not the case if Spain also implemented the EU rules on supply of medicines as stipulated in Article 81 of Directive 2001/83/EU.

ECJ RULING ON GREEK SUPPLY QUOTA

In the "Sot Lélos kai Sia" case, the European Court of Justice (ECJ) took a closer look at the supply quotas of pharmaceuticals that have been imposed by GlaxoSmithKline (GSK) upon wholesalers in Greece. The ECJ ruling stipulates that a manufacturer's refusal to supply wholesalers with a view to impede parallel trade constitutes an abuse of a dominant market position.

Noting that parallel trade is beneficial to end consumers, the ECJ ruled that the manufacturer violates European antitrust law if it seeks to prevent parallel exports by refusing to meet the orders of wholesalers. Thus, manufacturers are obliged to deliver to wholesalers the volumes according to the estimated demands of the market. On the top of that a certain surplus is to be provided as the demands are volatile. Manufacturers have been tightening quantities supplied to the market which in turn results in shortages.

Little innovation for plenty of money

A recent study conducted on the request of one of the German health insurance carriers, sheds more light on the actual "value for money" discussion of innovative medicines. The analysis assessed in total 23 new medicines, particularly oncology medicines, which were placed on the German market in 2013.

The findings are, however, not very encouraging. The study examined the therapeutic value, costs and alternatives already available on the market. The results show that only one innovative medicine could score in all three areas, and hence prove to be a valuable contribution for patients. Although the quality of the innovative medicines didn't much improve, the expenses of the health carrier have doubled in the comparable period in previous year. The numbers underpin the cause; the average package price of innovative medicines has risen from 670 to 1.418 Euro according to the analyses. ■

Pharmaceutical shortages: A case for global markets

Photo: istock/ nevarpp

Shortages of pharmaceuticals pose a challenge not only within the EU, but also at the global level. The International Society for Pharmaceutical Engineering (ISPE) has analysed the driving factors behind shortages worldwide and provided a guideline of best practice for the industry in this matter.

Besides the common factors that cause shortage such as non-availability of material or poor product quality, the Drug Shortages Prevention Plan also identifies further causes of shortages. These include for instance inadequately maintained facilities, lack of product and process robustness, or behavioural aspect that could result in an inadequate execution of company processes. The guideline recommends the manufacturers to build strong quality management systems and secure the business continuity planning. Throughout 2016, the ISPE will gather further best practice and solutions in conferences and training programs. ■

IMPRINT

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CALENDAR

24 OCTOBER 2016
BRUSSELS, BELGIUM

"TOWARDS AMPLIFIED AWARENESS OF EU RIGHTS TO CROSS-BORDER CARE"

This conference focuses on cross-border healthcare Directive and concerns around the performance of National Contact Points. It builds on the discussions that took place at the Informal Meeting of Ministers of Health held in Luxembourg in September 2015, as well as on the findings of the 2015 Commission report on the operation of the cross-border healthcare Directive.

For further information please see: **ec.europa.eu**

09–12 NOVEMBER 2016
VIENNA, AUSTRIA

9TH EUROPEAN PUBLIC HEALTH CONFERENCE

Under the theme "All for Health – Health for All," the aim of the conference is to contribute to the improvement of public health in Europe by offering a means for exchanging information and a platform for debate to researchers, policy makers, and practitioners in the field of public health and health services research.

For further information please see: **ephconference.eu**

16–17 NOVEMBER 2016
OSLO, NORWAY

EUROPEAN TELEMEDICINE CONFERENCE 2016

The conference will combine the efforts of several leading European healthcare organisations into two powerful days of health and innovation. Healthcare delivery organisations, governmental leaders, clinicians, researchers and university faculties will discuss the latest innovations in telemedicine.

For further information please see: **ehfg.org**

EXPERT OPINION

The current situation in Slovakia

The Slovak Republic has had a problem with specific medicine shortages for several years now. Even though this may be due to a number of different reasons, the Slovak Republic has long claimed that the sole cause is the re-exportation of medicines beyond the Slovak borders.

I am of the opinion that the root cause of these medicine shortages is rather complex, and begins with the regulated pricing mechanism of medicines; in Slovakia, the price of a medicine is the average of the three lowest prices of the same medicine in other EU Member States. Also there might be an insufficient checking mechanism on distributors' compliance with their legal duties. If these duties, such as a legal obligation to provide a medicine within 24 hours after the order, or notification obligations for large scale distributors regarding exports and imports were carried out, I assume that the problem with medicine shortages would rapidly reduce.

Proposed amendment of the act on medicines

The Slovak legal measure on medicines, which has been effective since 2012, includes a notification duty related to any medicines for those large-scale distributors who intend to export medicinal products for human use to other EU member states. Even the European Commission has been criticising this measure for more than a year now; the Commission is just about to bring a legal action against the Slovak Republic.

In response to, inter alia, this, the Slovak ministry of health has proposed an amendment of the act on medicines which is to replace the notification obligation for all medicine distributors, which was to be fulfilled before exports took place, by a new one - now it refers only to the distributors of the medicines that are funded by the national health insurance system, who will have to notify a designated Slovak institution (ŠÚKL) of any medicine exports from Slovakia within 7 days following the exports. This part of proposal would remove the shortcoming pointed out by the Commission. However, the Slovak Republic has taken the unnecessary steps further and far beyond this needed change.

Other proposed measures regarding the limitation of the re-exportation involve not only a more thorough checking mechanism and relevant stricter sanctions, but also serious entrepreneurial obstacles for the distributors. The amendment of the act thus sanctions all distributors with an aim to address only those who do not comply with their legal obligations. In the recent years, in Slovakia, there have been cases of distributors who circumvented legal obligations; e.g. they exported medicines that were in short supply without prior notification to the relevant authority. The list of the decisions, by which this authority refused to allow the exports of medicines, clearly shows that there are also distributors who respect the law and fulfil their obligations. In 2015, 135 decisions in relation to 14 distributors were published, in 2016, 1749 decisions in relation to 18 bodies. The decisions are issued on the basis of the notification of the distributors themselves. The proposal for the amendment of the act of medicines will also affect these complying distributors.

According to the proposal, only the producers and distributors authorised by a producer or medicine registration holder will be able to export the medicines abroad. What this would mean in practice is that only the importer of a particular medicine will be allowed to export it out of Slovakia. This would lead to a lowered competition on the distribution market. If this amendment of the act enters into force, it would have a negative impact on pharmacies themselves as well, which would in turn be entitled to re-sell the medicines only to the distributing companies that originally sold it to them, or other pharmacies. A similar measure in the Czech Republic did not lead to a decrease in medicine shortages.

I am of the opinion that a strict checking mechanism on the compliance with the legal obligations currently in place should take a priority over the interference with the entrepreneurial sector or free movement of goods. The government should, first of all, make sure that the distributors comply with the legal measures; it should interfere with the entrepreneurial sector only as a last resort and in the extent necessary. I think that the proposed amendment of the act goes further than is needed and adequate to reach the primary goal - ensure that there are sufficient numbers of medicines in Slovakia.

Repeated danger to the free movement

The Commission claims that the current system is dangerous to the free movement of goods; however, it is equally possible that the proposed amendments would in the end be deemed non-compliant with the EU law by the Commission. After the amendment of the act takes effect and informal meetings between the Commission and Slovakia take place, a lot of people currently employed in distributing companies may lose their jobs before another infringement regarding these presently proposed changes is carried out. The competition on the Slovak market will be eradicated and only then will the Commission, after two years of further communication, "force" Slovakia to make other amendments of the act on medicines arguing that they now endanger the common movement of goods. Thus, I will shortly ask the Commission in a written parliamentary question whether the new changes are to be compliant with the EU law.

The proposer of the amendment of the Slovak act indicates in his proposal that the measures will indeed solve the problem with shortage of medicines. However, even 4 years ago, the then minister for health, in implementing the pricing regulation, maintained the same view. Nevertheless, this has not become reality yet. ■

Author: **Richard Sulík**, Member of the European Parliament and Chairman of Slovak party Sloboda a Solidarita /Freedom and Solidarity)