VAD
German Association of Pharmaceutical Parallel Distributors

COST EFF
alliance for cost-efficiency in healthcare

# PHARMACEUTICAL DIALOGUE 51

+ + + INFORMATION FROM THE PARALLEL TRADE INDUSTRY + + + OCTOBER 2015 + + +

PHARMACEUTICAL & HEALTH CARE POLITICS

## Access to medicines: securing the supply for patients

Access to medicines has been subject to intense debates across the European institutions.

In view of the budgetary pressures on national health systems particularly triggered due to increasing costs related to the demographic changes, supply of safe and affordable pharmaceuticals has been of a broad and current interest both at the national and EU level. However, there is still a rocky road ahead to ensure the continuous supplies in Europe.

### Taking next steps in the fight against counterfeit medicines

The implementation of the Falsified Medicines Directive (2011/62/EU) that entered into force in January 2013 is due to proceed further, as the work on the technical guidelines for the implementation, Delegated Act, is entering the final stage. The European Commission has approved the draft proposal of the Delegated Act in mid-August. The long awaited publication of the Delegated Act is foreseen for beginning 2016, once the Commission´s proposal was formally endorsed by the European Parliament and Council in autumn.. The legislation foresees the introduction of safety features helping to verify the authenticity of products. Once the Delegated Act has been released, Member States have three years to transpose the guidelines into national legislation; the rules should be hence effective as of 2019.

### Internal market at risk

Free movement of goods is the cornerstone of the Single Market. However, some Member States introduced measures aiming to prevent the trade of pharmaceuticals, although there is no pwroven link between their availability and pharmaceutical shortages. For instance, export bans of pharmaceuticals were repetitively imposed by the Greek government in the past. Portugal, Bulgaria, Poland and Slovakia have introduced notification obligation of intended exports. The recent Bulgaria's Constitutional Court ruling prohibited the national regime by classifying it as restrictive and disproportionate in regards to the free trade. Further, the European Commission is investigating such dubious measures in several countries like Slovakia, Portugal, Czech Republic and Poland. These uncoordinated national decisions not only fail to address the root causes of possible pharmaceutical shortages; they even fragment the Internal Market. Therefore, these challenges must be worked on at the European level. ■

EDITORIAL

Dear Readers,

By exploiting the virtue of the Internal Market, parallel trade of pharmaceuticals has contributed to the reduction of pharmaceutical costs by introducing products to the national markets at competitive prices. As a result, European healthcare systems and patients have benefited from affordable medicines. Parallel trade is often falsely taken as a scapegoat for the undersupplies on the market.

The causes behind delayed deliveries of pharmaceuticals are more complex and subject to defaults in national policies (See p.1) or mismanagement at the side of the manufacturer (See p.2). In reality, parallel trade can help to fight shortages in individual Member States. The practice can balance the undersupplies at short notice by supplying the needed amount of pharmaceuticals to markets in which the given pharmaceutical is missing.

COSTEFF and VAD are glad to assume an active role in the debate on access to affordable medicines. In particular, we are optimistic to have an objective discussion on what can be defined as pharmaceutical shortage and on the real drivers behind shortages, before reasonable actions are undertaken.

Sincerely,

Prof. Edwin Kohl
Chairman of COSTEFF
and the VAD

# Pharmaceutical shortages: time for Europe to act!

While there are multiple reasons for undersupplies that need to be addressed, another key point with pharmaceutical shortages is in fact the lack of their definition. Debates revolving around this topic often take place in a misleading and non-objective manner. Time-delayed deliveries (waiting time of 24-48 hours) within certain regions are often but wrongly perceived as a shortage. The absence of precise definition within national or European legislation makes the debate on the roots and possible resolution of shortages even more complex.

### Resilience of distribution channels weakened due to "Big Pharma" undertaking

Manufacturers have in the recent decade assumed a more active role within the control of the distribution channels. Through the direct-to-pharmacy (DTP) distribution model, the industry takes away the added value of wholesalers by using them for logistical purposes only. The manufacturers are supplying the end-customers (pharmacies, hospitals) via limited number of exclusive wholesalers in the DTP. As these wholesalers don't own the stock, they are not able to compete among themselves by offering discounts and flexibly react to the demand. "Big Pharma" also restrict the quantities that they supply to wholesalers in each national market by imposing the so-called supply quota systems. In addition, severe cost cuts in national healthcare systems have led to payment defaults and made pharmaceutical companies tighten their payment and supply terms. Thus, the distribution channels became inflexible and less resilient which leads to the undersupplies. Last but not least, the increasingly globalised manufacturing chains that may cause postponements in production result in delayed supplies of pharmaceuticals to patients.

### Parallel trade is not responsible for shortages

It is often the case that parallel trade is misleadingly accused for pharmaceutical undersupplies. Parallel trade has been an integrated part of the pharmaceutical market for over 40 years and currently accounts for 3 % of the market. The volumes of parallel trade have been shrinking in recent years, while at the same time, shortages emerged. Thus, it is not accurate to make the parallel trade accountable for shortages, as shortages didn't occur in times when the volumes of import market were higher. On the contrary, parallel trade can help to eliminate shortages by filling the supply gap with imports at short notice. Not to mention that in many Member States, wholesalers are obliged by the Public Service Obligation to first serve the national market before exporting.

Parallel trade can also bring significant savings for national health care budgets by introducing pharmaceuticals at competitive prices. For the sake of the sustainability of health care systems, it is therefore indispensable to look into the real roots of undersupplies at the European and national level alike! ■

## NEWS IN BRIEF

### NEW EU LOGO FOR ONLINE PHARMACIES TO IMPROVE THE SAFETY OF PATIENTS

As of July 1, new EU safety logo has become operational. The logo which was introduced through the Falsified Medicines Directive (2011/62/EU) aims at protecting patients from counterfeit pharmaceuticals when buying online. The logo has to be located at each site of the homepage of the online pharmacy or reseller. When clicking on the logo, customers should be directed to the national regulatory authority website which lists all legally operating pharmacies and retailers of medicines in the respective Member State. Given the rising number of online pharmacies, the common logo is one of the instruments from the European Commission to eliminate the illegally traded products on the market.

### € 95 MILLION TO SUPPORT RESEARCH IN ALZHEIMER'S DISEASE AND DIABETES

Under the second programme period of the Innovative Medicines Initiative (IMI), a call for proposals has been launched over the summer. The total budget of the call amounts to € 95 million. Besides the research in various aspects of Alzheimer's disease and diabetes, also patient's involvement on the risk and benefit assessment of medicines will be funded.

IMI is a collaboration between the European Commission and the pharmaceutical industry aiming to improve development of better and safer medicines. Under the second programme period (2014-2024), the total budget of IMI 2 amounts to € 3.3 billion. Half of the funding is provided by the European Union and the other half comes from the industry.

# “The wrong prescription”

The Greek “reality on the ground” related to challenges in the supply of pharmaceuticals was illustrated in an article that was brought by a well-established German weekly newspaper “Die Zeit” over the summer (the wrong prescription“ – „Das falsche Rezept“ vom 13.08.2015). Despite the financial crises and the unstable situation in Greece, manufacturers claim to safeguard the continuous provision of pharmaceuticals to the country and state that the undersupply is caused due to exports.

As a matter of fact, the pharmaceutical companies supply often only against prepayments to the Greek wholesalers, whiles the customers of the wholesalers (primary Greek pharmacies) are only able to settle the invoices after weeks or months. The pharmacies depend on the support from national health care authorities that doesn’t have sufficient funds; so that they are not able to settle the wholesalers immediately. Hence, the wholesalers lack the funds to order from the manufacturer against prepayment. As a result, fewer products are delivered to Greece. The undersupply of pharmaceuticals is thus caused due to payment delays and not exports. Moreover, according to the Public Service Obligation, wholesalers have to first guarantee the deliveries at the national market. Only afterwards exports can be made. Therefore, the export bans of pharmaceuticals as introduced by the Greek government are not an adequate response to the situation. ■

## Germany’s securPharm: forerunner in implementing EU guidelines

The German stakeholder initiative, securPharm, has successfully entered the next stage by engaging into cooperation with European Medicines Verification Organisation (EMVO). On July 1, the link between the German repository system and a European Hub/EMVO marks the start of the European Medicines Verification System. In the light of the implementation of the Falsified Medicine Directive (FMD), the creation of the pan-European verification systems aims at securing the pharmaceutical supply chain against the risk of falsified medicines.

The securPharm project is the German concept for the implementation of the FMD. The initiative enables the verification of pharmaceuticals by introducing a unique code on each packaging that can be verified against a common manufacturer databank. Successfully proven under real-life conditions, securPharm should be fully operational at the beginning of 2019 correspondingly to the EU legislation. At a later stage, interoperability with similar systems from other Members States via the European Hub is planned. ■

## GLOSSARY

### PARALLEL TRADE OF PHARMACEUTICALS

Parallel trade of pharmaceuticals is a lawful form of trade within the EU’s internal market, based on the principle of the free movement of goods and exists due to the variation in pricing among Member States. It only concerns genuine standardised products (mostly under patent protection) which are in every respect marketed by the original distribution network. Through parallel trade, pharmaceuticals are imported from one Member State to another and then distributed ”parallel” to the distribution channel which is set up by the manufacturer. By bringing a greater choice of innovative genuine products at lower prices to the national markets, parallel trade has played an important role in driving down prices of originator pharmaceuticals and thus generates direct and indirect savings for the restrained health budgets.

### SAVINGS THROUGH PARALLEL TRADE BY THE NUMBERS

A study by the University of Southern Denmark (2011) calculates that the total direct savings realised due to the competition of parallel imports in Denmark, Germany, Sweden and the UK amounted to € 2.5 billion between 2004 and 2009. The direct saving realised by parallel imports in Germany amounted to € 192,5 Mio in 2013 and € 241,4 Mio in 2014 according to the latest Prognos study (2014). Parallel trade generates also indirect savings through increased competition on the pharmaceutical market. As parallel distributors offer a better price for the same products, pharmaceutical companies have to react by reducing their prices or at least limiting their price increases. Consequently, public health insurances pay less and can cut costs. It is estimated that these indirect savings amount to € 3 milliard in Germany.

EXPERT OPINION

# "The wrong prescription"- Greek lessons for the European pharmaceutical market

Are the wealthy Germans buying out the medicines from needy EU Member States, such as Greece, with the aim to cut their own costs? This line of argumentation is favoured by the research-based pharmaceutical industry with the aim to promote the export restrictions within the Member States. Such limitations are needed to prevent the citizens from undersupplies, according to the industry. The weekly newspaper, „Die Zeit", from 13.08.2015 has taken a closer look into the matter by means of an example from Greece.

The author begins its investigation in Greece, at the emergency department of the Evangelismos hospital. The conditions there are difficult. There is a lack of painkillers, pharmaceuticals against cancer and asthma. Some belive that Greek wholesalers are responsible for this kind of shortage of pharmaceuticals that they export the drugs to other european countries which were designated for Greece. But is this really the case? The journalist further continues the investigation in German pharmacies where he finds pharmaceuticals, particularly originating from the so-called parallel trade. For nearly 40 years now, certain companies stick to the following business model; they buy the pharmaceuticals in EU Member State that have lower price-level in comparison to Germany. Once these pharmaceuticals reach markets like Germany or others, they can be respectively offered there at lower rates. For these reasons, the pharmaceuticals became less expensive- not only for patients but also for the health insurance carrier.

Are these exports de facto resulting in shortages at the Greek market, or can the occurrence of shortages be explicated on a different basis? The Article confirms my own experience. The exports from Greece didn't increase during the crises; on the contrary, they dramatically declined. The „Zeit" article further investigates the actual and real causes behind the shortage.

A Greek wholesaler, who wishes to stay anonymous out of the fear that he wouldn't be delivered, draws a clear picture of the situation. The state is lacking the finances to refund the bills of pharmacies on time. Hence, the wholesalers are also lacking the finances as they supply the pharmacies. It is thus not surprising that the manufacturers refuse to deliver. Consequently, the author of the article confirms in his findings what I am repetitively told by our suppliers form Greece. "Yes, there is medication in Greece that is scarce. This is apparent in reports from doctors and patients. No, the re-importers are not to blame. Specifically, we should instead look at those who assign the blame. Firstly, the pharmaceutical companies who have earned well over the years in Greece and now only supply against prepayment to some extent. And secondly, the Greek government that has introduced an export ban to appear as if they are doing something without addressing the actual problem."

The article should be taken as an opportunity to demonstrate the necessity to protect the high value of the free movement of goods within EU. Should it be indispensable to safeguard the safe supply of pharmaceuticals to citizens and there are no less-restrictive measures available, Member States are exceptionally entitled to limit the free movement of goods. Yet, export restrictions have never fulfilled this prerequisite in practice. The „Zeit" author examined thoroughly the situation. Yes, shortages of pharmaceuticals occur. No, the undersupplies were not triggered by exports. By acting as guardian of the EU-Treaties and ensuring the freedom of the Internal Market, the European Commission is urged to take a closer look at the export bans and trade obstacles. ■

**Author:** Gabriele Nilsson Member of the board of directors - purchasing director kohlpharma GmbH

CALENDAR

12 - 13 OCTOBER 2015,
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**INTERNATIONAL CONFERENCE ON PHARMACEUTICAL PRICING AND REIMBURSEMENT POLICIES**

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For further information please see:
**euro.who.int**

14 - 17 OCTOBER 2015,
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