

# PHARMACEUTICAL DIALOGUE 56

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

## PHARMACEUTICAL & HEALTH CARE POLITICS

### Assessing the impact of Big Pharma on access to medicines



Photo: eu

The European Parliament work on the Own Initiative Report on EU options on improving access to medicines is slowly but surely reaching the final stage. Since the launch of the draft report, the topic has enjoyed much attention from within and outside the Parliament.

#### Shortages and the other “Big Pharma” issues

The draft report harbours strong reservations against the pharmaceutical industry in many regards. Evergreening of products, lack of transparency on the actual use of R&D funding, abusive pricesetting policies are taken up. There is yet another hot topic addressed within the report which has to do with the monopolistic behaviour of Big Pharma.

Pharmaceutical shortages have been increasingly an issue for the EU health systems. The triggers of undersupplies are of complex nature. Manufacturing inconsistencies, outsourcing of the production into third countries have been identified by EMA as the root causes of shortages (**see page 4**). Lastly, increased intervention of manufacturers in the supply chains and artificially imposed supply quotas by manufacturers has also significant impact on the situation.

#### All stakeholders of the supply chain are concerned

All stakeholders in the supply chain, especially manufacturers, need to be tackled in order to resolve the shortages situation. Parallel distributors are a responsible stakeholder within the supply chain and respectively one of the players on the pharmaceutical markets. It is therefore fair enough to analyse the impact of the practice on the current shortages situation along with all the other aspect such as supply quotas and manufacturing issues. After all, the comprehensive analyses should shed more light on the situation and propose targeted remedies. ■

## EDITORIAL

Dear Readers,

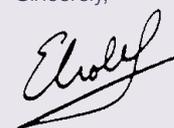
we all face some busy weeks before the year comes to an end and Malta takes over the EU Presidency. Particularly the European Parliament is occupied with assessing the role of the industry on the availability of medicines.

The parliamentary initiative on EU options on improving access to medicines is taking a critical stance on manufacturer’s dominant position on the pharmaceutical markets. This situation results in limited competition. In this respect, parallel trade is in fact a thorn in side of Big Pharma as the practice fosters price-competition by overcoming national borders.

In the light of the discussions on the parliamentary initiative, VAD is in favour of assessing the complex situation on the pharmaceutical markets. Not only the parallel trade but especially the practice of manufacturers is to be analysed with the view to tackle the roots of shortages (**see page 1**).

Finally, the analyses of EMA have proven that the drivers of undersupply are caused by manufacturers (**see page 4**). With this in mind, we welcome an initiative that will aim at restoring the much needed balance on the pharmaceutical markets!

Sincerely,



Prof. Edwin Kohl

Chairman of COSTEFF  
and the VAD



## Malta's EU Presidency: Looking into "big issues"



MALTA EU 2017

The smallest EU Member State will overtake the rotating presidency of the Council of the EU in the upcoming weeks. Maltese citizens enjoy one of the highest life expectancies in Europe (EU28 80 years; Malta 82 years). Looking at the WHO statistics from 2015, one

could say that the island seems to have a big problem though. The percentage of obese population (27%) is amongst the highest within the EU (EU28, 22%).

Malta seeks to refurbish the management of health care system by shifting the focus of hospital care towards the community. Equally important, the efficacy and effectiveness of hospital management (long surgery waiting lists, crowded departments and shortage of health professionals) needs to be improved.

### Presidency agenda eyes cross-border cooperation

Looking at the statistics, there is no wonder that Malta will address childhood obesity amongst the health-related priorities during the upcoming EU Presidency. Strengthening of cross-border health care will be equally in the spotlight. One of the aspects of cross-border health care is to make the access to treatments across the EU equitable.

### ... in pricing negotiations

Pricing of medicines is another big issue for the country, according to the Maltese Health Minister, Chris Fearne. National health services are primarily funded by general tax revenues and insurance contributions. As there are many limits to the state budget, expensive medicines pose a risk that might translate, into difficulties in patients' access. Cross-border cooperation to achieve transparent process during pricing negotiating with pharmaceutical companies will be, therefore, promoted by the Presidency.

Similar harsh economic realities can be observed also in other Member States. In addition, the rising trend of obesity across Europe will put yet more pressure on health expenditures. The European policy makers face thus a big issue; to moderate the health expenditures while enabling better access to treatments. The parallel trade is a welcomed policy option in this regard as it brings saving for the health care systems through increased price-competition on the markets. ■



## NEWS IN BRIEF

### HEALTHIER WITH EHEALTH

2016 has been a promising year for the cross-border cooperation on eHealth according to Clemens Martin Auer, Director General of the Austrian Ministry of Health in charge of the eHealth Network coordination.

In total 20 Member States have applied for funding with the view to support the creation of the eHealth National Contact Points. The "eHealth" adjustment to the already established contact points poses the necessary infrastructure that will facilitate the transmission of patient's data, such as patient summaries or electronic prescriptions, across borders.

### OECD: CREATING RESILIENCE SHOULD GET PRIORITY ON THE EU HEALTH POLICY AGENDA

EU countries are facing growing pressure to improve the resilience of health care systems in order to effectively meet the rising medical needs – this is one of the key findings of the OECD latest report "Health at a Glance 2016".

As the share of persons over 65 years is projected to increase from 20% in 2015 to 30% by 2060, demands for treatments and costs will continue to grow. The total pharmaceutical bill within the EU surpassed 200 billion EUR in 2014.

In the same year, a number of countries have seen increases of medicine spending for certain high-cost hepatitis C and oncological treatments. To this end, fiscally sustainable health systems are becoming an ever increasing necessity in Europe.

## IMPRINT

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Photo: istock/ OQ

## Discussing shortages in Bratislava

Within the framework of the Slovak EU Presidency, the capital of the Central European Member State hosted a conference on pharmaceutical shortages on November 18th. Three major topics were discussed: the parallel export, pharmaceutical shortages due to manufacturing insufficiencies and the access to innovative medicines. Representatives of EU as well as other European countries were invited to reflect on the matter.

Slovakia is on the verge of deploying yet another restrictive measure on pharmaceutical exports which will come into effect as of January 2017. With regard to the real market challenges such action turns out to be inadequate. Various international studies (including the recent EMA report from 2015) have outlined that shortages mainly result from manufacturing issues and production relocation into third countries. Pharmaceutical shortages constitute a growing problem at a global level, which makes it urgently necessary to adopt a common approach and to tackle the actual triggers. ■

## Parallel trade: Welcomed tool in fight against expensive medicines

A political group from within the German Parliament was this year dealing with challenges related to availability of medicines. In response to the written question of the parliamentary group of the Left, the Government particularly notes that undersupplies are caused mainly by inconsistencies in the manufacturing process. The reply further highlights the benefits brought by the EU-imports of pharmaceuticals for the health insurance authorities in Germany. These imported products have comparative price advantage to the product sourced by the manufacturer without compromising the quality. Last but not least, the imported products also create a certain pressure on the manufacturer to lower the overall price level. ■

## GLOSSARY

### EXPORT RESTRICTIONS IN SLOVAKIA

Slovakia will as of January 2017 introduce stricter rules on export restrictions.

The initiative comes as a reaction on the European Commission proceeding against the current law from 2013. This law enables the ban of exports and imposes upon the distributors an export notification of 30 days which was classified by the European Commission as disproportionate in regards to the EU Single Market.

The new rules stipulate that only the manufacturer can decide upon the export of medicines, which de facto transfers the competence of monitoring the market from the public authorities to the manufacturers. The monopoly in the pharmaceutical sector will be thus strengthened instead of fostering the EU Single Market and balancing out undersupplies.

### CONTRIBUTION OF PARALLEL TRADE TO FINANCIAL SUSTAINABILITY

Parallel trade has played, plays and will play an important role in driving down prices of originator pharmaceuticals. The current numbers underpin the cause.

The direct saving realised by parallel imports in Germany amounted to € 192.5 million in 2013 and € 222 million in 2014 according to the latest Prognos study (2014).

Parallel trade generates also indirect savings through increased competition on the pharmaceutical market. The indirect savings from imports of pharmaceuticals without original purchase amounted in Germany to € 18.5 million in 2013 and € 19.4 million in 2014 according to the latest Prognos study. The VAD estimates that the indirect savings triggered through the competition of the parallel trades amount to about € 3 billion in Europe to date.

## EXPERT OPINION

## Medicine shortages: EMA explains the causes



Supply shortages of vital medicines are not only annoying, but can, in the worst case; also have live-threatening effects on the affected patients. Therefore a dialogue at European level is of particular importance. It is hence highly welcome that the European Medicines Agency (EMA), based in London, addressed this issue in the course of a large-scale stakeholder meeting, which took place in October. The result was actually not surprising: the main driver of pharmaceutical shortages is the short market supply by manufacturers.

The twelve-page report of the respective authority does not refer to the parallel export of medicines – which is supposed to be one of the key triggers according to interested circles. This is in the first instance good news for parallel importers. Contrary to argumentation of manufacturers, which is also re-confirmed by EMA, it is only the industry itself that causes medicine shortages. The industry nonetheless managed to make the parallel trade into a bogeyman.

It sounds obvious that when medicines get exported, they will not be available on the home market. Some EU Member States, most notably Poland, followed this crude argumentation and enacted a ban on export, which does not stand up to legal scrutiny. Export bans also appear attractive in terms of the uneconomic argument that restricting the export into high-price countries will make it possible to obtain better prices on the home market. Whenever possible, the reimbursement price should also remain secret. However, time has proven the opposite. Intra-European trade leads to price competition for one and the same product. Consequently this translates into balanced price differences and lower price levels all over Europe. Prior to that producers' anxiety is quite understandable. But is it fair for the European contributors to fulfil the shareholder value dreams of companies with mainly American background?

Another important aspect gets often overlooked as well. Parallel traders do not exterminate goods. They just reallocate them. It is therefore unacceptable to make parallel trade responsible for shortages at pan-European level. In fact, it can possibly compensate shortages in case of an oversupply in other countries.

**Author: Jörg Geller**, executive manager of kohlpharma GmbH and member of board of the German parallel trade association (VAD) and the European Association of Euro-Pharmaceutical Companies (EAEP)

## CALENDAR

25 – 27 JANUARY 2017  
AMSTERDAM, NETHERLANDS

### 7TH ANNUAL PHARMACOVIGILANCE & RISK MANAGEMENT STRATEGIES FORUM

This two-day conference will serve as a platform for promoting expert dialogue on global drug safety issues and potential risks across a product's life-cycle. The forum is set to provide an overview of the most common mistakes at pharmacovigilance inspections and give useful guidance in creating a risk management plan. The list of speakers includes renowned representatives of the sector-relevant academic and corporate world.

For further information please see:  
**fleming.events**



07 – 08 FEBRUARY 2017  
BARCELONA, SPAIN

### WORLD AFFORDABLE MEDICINE CONGRESS

The World Affordable Medicine Congress is the largest and most acknowledged strategy and scientific forum on generic and biosimilar medicines. Since 2007 it brings two world class events together – World Generic Medicines Congress and Biosimilar Drug Development World. In the context of escalating healthcare costs and austerity measures this congress aims to promote the importance of adopting adequate business strategies for affordable medicines.

For further information please see:  
**healthnetworkcommunications.com**



06 – 07 FEBRUARY 2017  
LONDON, UK

### 11TH ANNUAL PARALLEL TRADE CONFERENCE

With Brexit and the new EU Falsified Medicine Directive, what does the future hold for parallel trade? This event will discuss short term versus long term concerns of pharma manufacturers, regulators, as well as parallel traders. The industry leaders will engage in an interactive debate and discuss how to keep abreast of the current trends and how to overcome all challenges.

For further information please see:  
**smi-online.co.uk**

