German Association
of Pharmaceutical
Parallel Distributors

alliance for
cost-efficiency
in healthcare

# PHARMACEUTICAL DIALOGUE 49

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

PHARMACEUTICAL & HEALTH CARE POLITICS

## Celebrating half a century of EU pharma legislation- more to come


50 years have passed since the Council Directive 65/65 on the approximation of the law relating to medicinal products was adopted. This first EU legislation on human medicines introduced clear rules on the authorisation and distribution of medicinal products and some founding rules that are in place until today. Around those principles a vast legislation has developed over the last decades in order to guarantee high standards of quality and safety for medicinal products.

Hand in hand with the enhancement of the legislation and based on the free movement of goods, also the pharmaceutical market developed rapidly. In this context, also the parallel trade has been an integrated part of the pharmaceutical market for more than 40 years now. According to the European Commission data, the EU was the world's biggest trader in medicinal and pharmaceutical products in 2013, with total trade amounting to € 156.9 billion (EU28) and value of exports reaching more than € 107.4 billion. With the rapid development of the pharmaceutical market, the EU is doing a great deal in the harmonisation of the provisions set within the national health care systems. In this context, there are still outstanding matters that need to be addressed at the EU agenda, particularly in order to provide for EU-wide level playing field in the pharmaceutical market.

### Challenges ahead for the pharmaceutical market

One of the core health legislations, which still need to be implemented at the national level, is the so called "pharmaceutical package." Notably, the Falsified Medicines Directive, which came into force in January 2013, aims at securing the supply chain of pharmaceuticals in Europe. It is anticipated, that the technical rules of implementation (Delegated Acts) will be published in 2015. Besides the pharmacovigilance package, the proposal for a new regulation supporting the pricing transparency at the pharmaceutical market has been subject to the legislative process since 2011. The dossier has been pending at the Member States level since the adoption at the European Parliament in 2013. As no foreseeable agreement could be reached in due course, the European Commission has pulled back the proposal within the new Work Programme. As the current proposal for the transparency rules has been scrapped, the European Commission is demanded to come up with a new legislative proposal that will be acceptable for both, the European Parliament and Council. Particularly, the transparency of the rebate contracts for pharmaceuticals between the insurance authorities and the industry has to be tackled in this regard. Also, the swift implementation of the "pharmaceutical package" is desirable. Another challenge is to eliminate the barriers at the nation level, such as the dual pricing model, that fragment the Single Market. ■

EDITORIAL

Dear Readers,

Given that the health care systems are subject to national regulations, the pharmaceutical market is also heterogeneous. Therefore, the EU has adopted a framework which aims at harmonizing the pharmaceutical sector in line with the subsidiarity principal.

Also 2015 will bring some challenges for the health care and pharmaceuticals. Against the background of financial constraints and tight budgets, financing of the health care will pose yet another challenge for the Member States. In this context, parallel trade can help to bring affordable pharmaceuticals into the market and hence provide for savings for the national healthcare systems.

Recent developments in the pharmaceutical sector demonstrate the efforts of the industry towards limiting parallel trade. One of the strategies used by pharmaceutical companies is the so-called "dual pricing" (or "free pricing") system (see p. 2) which undermines the free movement of goods within the Single Market.

The full integration of national economies and their markets, as well as the freedom to move goods and services without restrictions, contributes to Europe's prosperity. Therefore, COSTEFF and VAD strongly support an open and transparent pharmaceutical market.

Sincerely,

**Prof. Edwin Kohl**
Chairman of COSTEFF
and the VAD

# Dual Pricing:
# Another strategy against the Single Market


For many years, the pharmaceutical industry has been attempting to limit the parallel trade with pharmaceuticals and respectively the free movement of goods. Such practice can be demonstrated on the example of the "Dual pricing schemes" that have been amongst others also deployed in Spain. The so called "dual pricing", or "free pricing" system is a two-tier price model that is based on the applicability of different price levels depending on the final destination of the supplied pharmaceutical. Respectively, the pharmaceuticals that are to be supplied at the domestic market are sold at lower price levels in comparison to the products dedicated for exports.

### Lessons learned from the Spanish example

The above mentioned dual pricing has been practiced in Spain. In the 90´s, GlaxoSmithKline (GSK) imposed the wholesalers to comply with contractual conditions that fixed two different prices depending on the final destination of the product. In the GSK case (2001), the European Commission (EC) found that such practice produced restrictive measures on competition and thus violated the Article 101 TFEU (Prohibition of cartels and other agreements that could disrupt free competition on Single Market). Due to insufficient reasoning, the EC decision was later on annulled by the European Court of First Instance and by the European Court of Justice. Both courts ruled however that the GSK dual pricing policy was not legitimate.

At the time when the GSK case was subject to litigations, Pfizer and other manufacturers introduced already similar practices, the so-called free pricing, referring to the need to comply with the Spanish price-setting rules. Free pricing is based on rebates which are provided by the manufacturer to the wholesaler upon the confirmation that the product is supplied to the domestic market. As two different price levels apply, this practice is in fact the dual pricing and hence, subject to legal disputes.

### Spanish Supreme Court rules to annul the legality of dual pricing contracts

The Spanish Supreme Court recently addressed the question whether the dual pricing practice, even if the supply contracts between pharmaceutical manufacturers and wholesalers invoke the Spanish medicines law, are compatible with EU competition law.

The principles established by the Spanish Supreme Court are the following. Spanish regulations on the prices of medicines do not force Pfizer to implement its dual pricing system. Moreover, it does not matter if contractually agreed dual pricing schemes comply with Spanish regulations on the prices of pharmaceuticals, but whether such contracts are compatible with EU competition law. As the above described practice of pharmaceutical companies restricts parallel trade and hence the free movement of goods, this can be classified as an infringement of the EU rules (Article 101 TFEU). The Single Market can be restricted only on the grounds of justified reasons which are in this case not given. ▶▶▶

## NEWS IN BRIEF

### MAJOR EUROPEAN RESEARCH PROJECT ON PHARMACOVIGILANCE EVALUATION CONCLUDED

The recently concluded PROTECT project (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium) was a five-year public-private partnership which was initiated to enhance the monitoring of the safety of medicinal products. Notably, the consortium sought to develop tools and innovative methods that aim to strengthen the monitoring and evaluation of the benefit-risk profile of medicines marketed in Europe throughout their lifecycle.

The results may significantly influence practices in pharmacovigilance evaluation. Therefore, during 2015, European Medicines Agency (EMA) will analyze PROTECT's research outputs in order to identify priority results that are robust and which if implemented, have the greatest potential to positively impact public health. PROTECT has been co-funded by the European Union through the Innovative Medicines Initiative (IMI), Europe's largest public-private initiative aiming to speed up the development of better and safer medicines.

### EU TASK FORCE TO IMPLEMENT NEW STANDARDS FOR IDENTIFICATION OF MEDICINES

In February 2015, the European Medicines Agency (EMA) has established a task force for the implementation of international standards for the identification of medicinal products (IDMP) for human use in the EU. The IDMP standards developed by International Organization for Standardization (ISO) establish data elements, formats and terminologies for the unique identification of medicines and the exchange of information on medicines, including pharmaceutical dose forms, routes of administration, packaging and active substances.

These standards are expected to simplify the exchange of information between regulatory authorities across the world and they should also improve the safety monitoring of medicines. The implementation guides are currently under development at international level and expected to be available in 2016. Furthermore, the task force will agree an EU strategy and develop a road map and an EU implementation guide as key deliverables for 2015.

Although the Spanish Supreme Court does not have the competence to directly annul contracts, the judgement is significant to the extent that the common arguments used so far in Spain by pharmaceutical companies for the last years are not valid.

**Study: Dual pricing system poses limitation to free trade within the Single Market**

Besides the compatibility with the Spanish Law, the pharmaceutical companies justify the dual pricing strategy against the background that the form of competition brought by the parallel trade is undermining their incentive to innovate. The industry also claimed that it attempts to avoid shortages in the national healthcare system. However, the recently conducted Inno Study on "Analysis of the Impacts of Dual Pricing in Spain" did not find any evidence to substantiate these assumptions. The reoccurring arguments to justify the limitation of free trade such as ensuring availability of pharmaceuticals and optimized R&D investments lack empirical evidence. Moreover the system is posing a limitation to the free movement of goods within the Single Market. The dual/free pricing is used by pharmaceutical companies to fragment the European market into closed national markets by eliminating the possibility of exports to higher price markets. As a result, the pharmaceutical companies can maximize their profits by charging the highest possible price in each national market. Not only is such practice harmful to Europe's sustainable competitiveness and its innovativeness but also to European patients. ■

## Bulgaria:
# Restrictive export measures prohibited by Constitutional Court


January, the Bulgarian Constitutional Court came to the conclusion that measures such as quantitative restrictions of pharmaceutical exports and the notification regime (each export of pharmaceuticals is subject to a thirty-day notification obligation) are with no doubt restrictive in their nature and result in unreasonable delay of the exports. Furthermore, the respective law that serves as the background of these measures is targeted against the parallel distribution by identifying the parallel trade as one of the main reasons for the occurrence of shortages.

According to the ruling of the Constitutional Court, a clear definition of the main reasons behind the restrictive measures undertaken in Bulgaria is missing, given that there is no clear evidence between the occurrence of shortage and the parallel exports. Any restriction to the free movement of goods must be based on the proportionality principle which is in this case not given. The export notification obligation covers the entire market, regardless of whether or not shortages apply to the specific product. To this end, the export notification regime in Bulgaria is hindering the free trade within the Single Market. ■

## GLOSSARY

### DUAL PRICING SCHEME

Dual pricing is a practice of setting different prices for a given product depending on the market in which it is sold. This practice is based on an agreement between a pharmaceutical manufacturer and its wholesalers whereby lower prices are charged when the wholesaler is supplying the domestic market and higher prices are charged for exports into other Member States. Consequently, the parallel trade is hindered. The legality of such practices remains an open question and it has been subject to several litigations at the national and EU level. Last but not least, it has been also ruled as illegal by diverse courts.

### FREE PRICING SCHEME

Since the legality of the dual pricing system remains unclear and subject to several litigations, the industry has adopted other similar tactics, such as free pricing. Higher prices, or free prices, are normally imposed as a "default price". Particularly in Spain, the "regulated price" which is reimbursed by the national insurance company is subject to negotiation between the pharmaceutical manufacturer and the national authorities and is applied only when the products are supplied at the national market. Hence, if the wholesaler resells within the domestic market, the pharmaceutical company provides the wholesaler with a rebate that amounts to the difference between the free price and the regulated price. However, for exported products, there is no rebate and hence the free price applies. This system therefore is a de facto dual price pricing system; a lower price for the domestic market and a higher price for export.

EXPERT OPINION

# EU Single Market at risk due to restrictive national measures

The Single Market in the European Union seeks free trade with goods, capital, people and services. Any limitation of free trade within the single market is harmful to Europe's innovativeness and sustainable competitiveness and is only justified in very narrowly specified exceptions.

Parallel trade has had a major impact on the European pharmaceutical market and benefited consumers ever since the EU was formed. Pharmaceutical companies claim however that this form of competition reduces their income and hence their incentive to invest in research and development, i.e. they claim that competition makes them less competitive and less keen to invest in sustainable competitiveness. This argument is misleading and there is no empirical evidence to suggest otherwise. Furthermore, a series of studies have documented that consumers and tax payers benefit substantially from parallel trade.

However, the pharma industry continuously engages in attempts to limit free trade by employing a wide range of different instruments. In Spain, the pharmaceutical industry has implemented strategies that include restrictive and comprehensive contracts with wholesalers that regulate and dictate distribution of their medicinal products. Wholesalers must provide proof of sale within the Spanish market or be charged a higher "free price". Another strategy has been to supply the pharmaceuticals directly to pharmacies using wholesalers as providers of logistic services only. Wholesalers who do not own the products are – of course – not free to decide to whom to sell. These strategies serve one purpose only, to restrict the export of medicinal products.

Wholesalers can and should play an important role along the value chain but when they are constrained by restrictive contracts they can no longer respond to market conditions and cannot build up medicinal stocks to respond to changing demands. There is no justification for these onerous restrictions in Spain, which constitute a serious limitation of free trade.

Now is the time to take action at the national and EU level to counteract any restrictions to free trade that are incompatible with the single market goal and thus with sustainable competitiveness of European business and quality of life of its citizens.

**Prof. Dr. Heydebreck,** Managing board, inno AG

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CALENDAR

11 - 13 MAY 2015,
RIGA, LATVIA

**EHEALTH WEEK 2015**

Taking place during the Latvian Presidency of the Council of the European Union, eHealth Week 2015 comprises of two main events: the High Level eHealth Conference organised by the Latvian Ministry of Health and the Latvian Presidency of the Council of the European Union and WoHIT (World of Health IT Conference & Exhibition) organised by HIMSS Europe. Attracting over 2000 international delegates and 75 exhibitors, the event will welcome global decision makers from public and private healthcare sectors, clinicians, hospital and IT managers and VIP guests.

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

18 - 26 MAY 2015,
GENEVA, SWITZERLAND

**68TH WORLD HEALTH ASSEMBLY OF THE WORLD HEALTH ORGANIZATION**

The decision making body of the World Health Organization (WHO) meets annually in Geneva to determine the Organization's policies and appoint the Director-General, as well as to review and approve the program budget. Delegations from all WHO member states will attend and, in addition to procedural matters, discuss a specific health agenda that is prepared by the Executive Board.

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

29 JUNE - 1 JULY 2015,
LONDON, UK

**ORPHAN DRUGS & RARE DISEASES GLOBAL CONGRESS 2015 EUROPE**

The congress provides a unique platform for an intimate & interactive knowledge sharing and convergence of top tier government, pharmaceuticals, biopharmaceuticals, hospitals, non-profit organisations, orphan drugs developers as well as regional and local manufacturers to discuss the driving macroeconomic factors, policies and issues that will steer the development of orphan drugs globally.

For further information please see:
**paradigmglobalevents.com/**