German Association
of Pharmaceutical
Parallel Distributors

alliance for
cost-efficiency
in healthcare

PHARMACEUTICAL DIALOGUE 52

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

PHARMACEUTICAL & HEALTH CARE POLITICS

(Non-) Transparency of pharmaceutical pricing: time to act!

Particularly with the emergence of the innovative high-price pharmaceuticals on the market, the health insurance companies find it increasingly difficult to come up for their costs.

Access to medicines: a matter of affordability

The availability of medicines is closely linked to their price tag and thus their affordability for health carriers and patients. Given that the "Big Pharma" has a great influence upon the price-setting, the manufacturers have a significant impact on the accessibility to treatments. Once the price is set too high, the availability on the market is restrained. In the worst case, the situation results in undersupplies as the national authorities are not able to pay the bills.

Affordability of medicines: a matter of transparency

Improvements on the transparency of pricing and reimbursement of pharmaceuticals contain enormous potentials to increase the access to medicines. The current situation does not allow for instance the prescriber and the pharmacists to see which product is effectively the most cost-efficient. The rebate contracts negotiated between the industry and health carriers are also not disclosed. This situation results in higher prices due to inefficiencies and hindered competition. The parallel trade of pharmaceuticals have been mitigating these effects by supplying a great choice of pharmaceuticals at lower prices to the otherwise closed pharma markets. As such, the practice has been generating direct and indirect savings for the health authorities. Parallel trade is therefore a welcomed solution in the times of restrained health budgets.

The increased pricing transparency, and hence more competitiveness, across the pharma markets can be supported by the revision of the current EU transparency legislation. Following the failed attempt to update the Transparency Directive (89/105/EEC) and having in mind the current debate around access to medicines, an important step towards the price-optimisation of pharmaceuticals would be to re-launch the revision of the Directive in the near future. ■

EDITORIAL

Dear Readers,

With the beginning of 2016, the Netherlands will take over The Presidency of the Council of the European Union. The upcoming holder of the EU Presidency will target the affordability of medicines and the cost-efficiency potential of innovations within healthcare.

Sustainability of the health systems and access to affordable medicines will thus remain a pressing matter at the EU health agenda also in 2016. Equally important, the high-cost of innovative medicines will significantly contribute to the increase in pharmaceutical spending in the years to come. The "Big Pharma" is in a strong position when it comes to the pricing of pharmaceuticals (see p.1). In this view, the revision of the Transparency Directive should be picked up again with the aim to exploit the savings potential in the pharmaceutical pricing.

Parallel trade has been contributing to the efficiency of pharmaceutical spending for 40 years. Particularly in these times, the practice is a welcomed driver for more competition on the markets (see the Glossary). COSTEFF and VAD are therefore urging the European Commission to seize the opportunity and re-launch the revision of the transparency rules in due course.

Sincerely,

Prof. Edwin Kohl
Chairman of COSTEFF
and the VAD

The Dutch EU presidency: tackling the pricing of pharmaceuticals

The life expectancy at birth in the Netherlands stood at 81,2 years, two years higher than the EU28 average of 79,2 years in 2012 according to the European Commission data. In like manner, the health spending in the Netherlands (accounting for 11,8 % of GDP) lies well above the EU28 average. (EU28: 8,7 %)

Quality health care at affordable costs for all

A key feature of the Dutch system is that the premium for the health insurance may not be related to health status or age. This model was introduced with a major reform of the health care in 2006. The health insurance companies are hence obliged to offer a compulsory universal insurance package at fixed price for all, regardless of health status or age. The differences in the risk bared by the insurance companies due to the different risks presented by individual policy holders are compensated through a common risk equalisation pool. As health carriers receive higher compensation for high risk individuals, they are willing to accept them. In this way, core health insurance package is accessible to all citizens at affordable costs.

The next holder of the EU Presidency has one of the most comprehensive systems, not only in the EU, but also worldwide. Ever since the major reform in 2006, the Netherlands has maintained top positions within the most common ranking of European healthcare systems, the annual Euro health consumer index (EHCI).

Focusing on the "essentials"

The Dutch are no newcomers to the Presidency over the Council of the EU either. After overtaking the lead for the fourth time (1992, 1997, and 2004), the focus of the Presidency will be put on the "essentials". The Netherlands envisage amongst others an EU that stays competitive and keeps innovating. The Health Minister, Edith Schippers, has indicated that the Presidency will focus on European cooperation on drug prices and bringing innovative medicines to the EU market faster, and at affordable prices. With this in mind, a European agenda for the further improvement of market access rules for medicines will be developed. The Netherlands will kick-off the start of the next EU Presidency Trio (Netherlands, Slovakia, and Malta) in the first half of 2016. ■

NEWS IN BRIEF

"PRIME" SCHEME: ACCELERATING MARKET ACCESS OF "PRIORITY MEDICINES"

The European Medicines Agency (EMA) will support the pharmaceutical industry by offering an early and enhanced scientific and regulatory support to optimise the development and assessment phase of certain pharmaceuticals. Above all, also the entire authorisation procedure should be accelerated. The "PRIME" scheme will particularly focus on the development and market authorisation of pharmaceuticals for diseases that have currently no treatment options. It will also target medicines which may offer a major therapeutic advantage over existing treatments. The name of this project "PRIME" is derived from the classification of these medicines by EMA as "priority medicines."

ENHANCING THE EU HEALTH REPORTING AND MONITORING FRAMEWORK

The European Commission launched an improved key health data information tool in mid-November. The new European Core Health Indicators (ECHI) data tool brings a significant improvement to the previous "Heidi" data tool, by enabling the selection of more indicators in parallel. This facilitates the analyses and comparison of the health data in Europe. The new tool is covering by means of an interactive way several groups of health indicators including for instance demographic and socio-economic factors, health status or health determinants.

IMPRINT

VAD e.V.
German Association of
Pharmaceutical Parallel Distributor

Prof. Edwin Kohl
President of VAD
Im Holzhau 8
D-66663 Merzig
Phone: +49-6867-920-1301
Fax: +49-6867-920-1303

Email: kontakt@vad-news.de ■

COSTEFF e.V.
alliance for cost-efficiency
in healthcare

Prof. Edwin Kohl
Chairman of COSTEFF
Jägerstraße 41
D-10177 Berlin
Phone: +49-30-20 61 59 23
Fax: +49-30-20 61 59 24

Email: info@costeff.eu ■

Mandatory discounts subject to discussions in Austria

The debates around the increasing spending in health care and high-costs of medicines are revolving in many Member States. Austria has been no exception in this matter. Since the agreement on a yearly solidarity fee provided from the pharmaceutical industry towards the Austrian health insurances is due to expires by the end 2015, fierce discussions were held on the forthcoming agreement. Given this situation, the health ministry decided to come up with a draft law that would impose the mandatory discounts upon the industry.

While the pharmaceutical industry could raise profits due to high-priced medicines, the expenses of the insurance authorities in Austria increased dramatically. Additional sources of income for the health authorities seemed therefore reasonable. The industry was on the other hand arguing that the mandatory discounts would weaken Austria as a business location, claiming loss of investments and jobs. After turbulent debates, the situation has been resolved and an agreement on a solidarity fee for the period after 2015 came into place. The intended draft law on the mandatory discounts is therefore off the table. ■

Foto: istock/Markus Schieder

OECD: Increase in pharmaceutical spending due to "Big Pharma"

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 and exists due to the variation in pricing among Member States. Through parallel trade, pharmaceuticals are imported from one Member State to another and then distributed outside the distribution channel which is set up by the manufacturer. The practice has played, plays and will play an important role in driving down prices of originator pharmaceuticals.

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. 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. It is estimates that these indirect savings amount to 3 € milliard in Europe.

TRANSPARENCY DIRECTIVE

The current EU transparency rules date back to 1989. As the pharmaceutical markets have rapidly developed ever since, the need for a revision is given. The current rules do not tackle for instance the opaque framework agreements between governments and pharmaceutical manufacturers on the rebates. The 2012 proposal for the revision of the Transparency Directive (89/105/EEC) has been adopted by the European Parliament in February 2013. Since the Member States were unable to reach a common agreement on the proposal mainly due to the concerns over subsidiarity, the European Commission has decided to pull it back in the 2015 Work Programme.

EXPERT OPINION

Imports discipline the pricing policy and lead to indirect saving effects

The latest spending developments in regard to the supply of pharmaceuticals point to an upward trend, which happens in parallel to the above-average return on investment of pharmaceutical companies. Both developments are determined by the pricing policy of the manufacturers, which – in addition to their monopolistic profits obtained by patent protection, realize further profits through the international price differentiation.

Price differentiation describes the practice of offering the same product in different markets at different price levels. This enables the manufacturers to gain additional benefits besides achieving monopolistic profits. The import of pharmaceuticals disciplines the aforementioned pricing policy and leads not only to the known direct saving effects, but also to considerable indirect saving effects at similar volumes. In times of restrained budgets, demographic change and cost-intensive medical-technical progress, every contribution to a restriction of the current expenditure development is important.

Direct saving effects are achieved through the substitution of the expensive products through identical products that were however imported in parallel or re-imported. This is done by the pharmacists by dispensing to patients. Currently, direct saving effects amount to approximately 240 million € (potentially 343 million €) in 2014 based on the findings of the PROGNOS Institute.

By contrast, the knowledge about the functioning of indirect saving effect is less widespread. Whereas it is commonly assumed that it would be a reasonable strategy for manufacturers to prevent parallel trade by setting uniform prices, economic analyses of optimal pricing policies point to a different direction. It can be shown that it is profit-optimal for manufacturers to continue to differentiate prices under the condition of parallel trade. However, parallel trade narrows the manufacturers' profit maximizing price differentiations. Particularly in healthcare systems of countries that possess a high ability to pay, the import of pharmaceuticals leads manufacturers to lower the prices for patented pharmaceuticals. Several studies provided evidence of price cuts between 12-19 % in particular countries.

In order to achieve this effect, it is already sufficient that there exists the possibility of imports. This price-disciplining impact affects all channels of distribution of the manufacturers, for instance in negotiations regarding official reimbursement prices or within the procurement competition regarding unofficial reimbursement prices (e.g. discounts by manufacturers). Sample calculations show that indirect savings can account for a multiple of direct savings.

The development of the manufacturers' profit margins in the recent past shows that the pharmaceutical sector was able to safeguard or expand its economic position, also under the conditions of parallel trade. The recent increases in pharmaceutical spending point towards the same direction. At the same time, the disciplining impact of pharmaceutical imports signals that these increases in costs would have been significantly higher without such imports. ■

Author: Univ.-Prof. Dr. Martin Dietrich (PhD), Head of Chair in Business Administration and Health Services Management Research Faculty of Law and Economics, Saarland University, Germany

CALENDAR

27–29 JANUARY 2016, MUNICH/ GERMANY

6TH ANNUAL PHARMACOVIGILANCE & RISK MANAGEMENT STRATEGIES FORUM

Pharmacovigilance has radically changed over the last few years, the ever changing global and local regulatory demands have put a lot of stress on the pharmaceutical, biotech companies and all stakeholders involved. The event aims to give all stakeholders in Pharmacovigilance a better understanding on how to better manage drug safety across the all departments.

For further information please see:
pharma.flemingeurope.com

25-26 FEBRUARY 2016, LONDON/ UK

18TH INTERNATIONAL CONFERENCE ON EMERGENCY MEDICINE

The event aims to bring together leading academic scientists, researchers and research scholars to exchange and share their experiences and research results about all aspects of Emergency Medicine. It also provides the premier interdisciplinary forum for researchers, practitioners and educators to present and discuss the most recent innovations, trends, and concerns, practical challenges encountered and the solutions adopted in the field of Emergency Medicine.

For further information please see:
waset.org