German Association
of Pharmaceutical
Parallel Distributors

alliance for
cost-efficiency
in healthcare

PHARMACEUTICAL DIALOGUE 50

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

PHARMACEUTICAL & HEALTH CARE POLITICS

Transparency Directive:
In dire need of a new proposal

Since the Member States have been unable to reach a common position on the revision of the Transparency Directive, the European Commission has decided to pull back the proposal in the 2015 Work Programme. The 2012 proposal for the revision of the Transparency Directive (89/105/EEC) has been adopted by the European Parliament in February 2013. The proposal has been pending at the Member States level ever since.

A new approach is needed

With the growing complexity of the pharmaceutical markets, the revision of the Transparency Directive is indispensable. The context of the current legislation is outdated as it has never been revised since it entered into force in 1989. Provided that the health care systems frequently offer several potentials for cost savings along with the demographical development of an ageing population, pressure on the health expenditures is projected to increase. OECD estimates that health care costs are likely to jump from an average of 5.6% of the GDP in OECD countries to 9.6% in 2050. Improvements on the transparency of pricing and reimbursement of pharmaceuticals contain enormous potentials for cost savings without jeopardizing the safety of patients. The current situation does not allow for instance the prescriber and the pharmacists to see which product is effectively the most cost efficient.

New legislative proposal on transparency rules desired

Transparent pricing and reimbursement schemes are of great value for the entire pharmaceutical distribution chain, including the pharma industry, its distributors and parallel traders. Moreover, the measures can help Member States to manage the healthcare expenditures. Thus, a new legislative proposal by the European Commission that will address the non-transparency with regard to reimbursement prices is of a great importance if the EU wants to cope with future challenges for its health care. ■

EDITORIAL

Dear Readers,

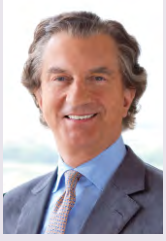
On July 1st, Luxembourg took over the presidency of the European Union from Latvia. Despite the fact that the country offers one of the most comprehensive health care coverages in the EU, Luxembourg is also facing several challenges related to demographic changes (see p. 2). The cost efficiency in regards to an ageing society and increasing health care spending has been a common denominator for the Member States across EU.

As advocates for more cost efficiency, COSTEFF and VAD is calling upon the European Commission to bring forward a new legislative proposal for the Transparency Directive that will amongst others tackle the question of price transparency as this topic was not touched upon in the former proposal that was withdrawn. Increased price transparency, i.e. disclosure of the secretly negotiated rebate contracts between the industry and national insurance authorities (see p.3), would certainly provide for cost savings of the restrained health budgets.

Therefore, COSTEFF and VAD are optimistic that European decision makers will support greater transparency of pharmaceutical pricing. The window of opportunity is open.

Sincerely,

Prof. Edwin Kohl
Chairman of COSTEFF
and the VAD



The Luxembourg EU presidency: a forerunner in provision of comprehensive healthcare

A brief look at the statistics of the Health at a Glance Report 2014 (conducted by the European Commission and OECD) shows that the life expectancy at birth in Luxembourg is among the highest in EU28: While life expectancy of women was 83.8 years in 2012 (EU28: 82.2 years), men had a life expectancy of 79.1 years in comparison to the 76.1 years of the EU average. Although the total spending on healthcare as a share of GDP is with 7% well below the EU28 average (EU28: 8, 7%), the country's per-capita healthcare expenditures are ranked among the top five in the EU. The shifting demographics resulting in an ageing population is posing a severe challenge for the upcoming decades for the country.

Ageing population: pressing matter for national and EU agenda alike

The current holder of the EU presidency has one of the most developed state-funded healthcare systems in Europe offering a general coverage of the population. The system is particular characterised by free choice of a provider by the patient and direct access to a specialist and covers majority of treatments. Due to the increasing life expectancy and low fertility rates, the health care systems need to shift however towards prevention and management of chronic diseases as well as more formal long-term care (assistance for elderly/dependant persons).

Thus, Luxembourg is seeking new possibilities to reduce the average expenditure per dependent person. Moreover, new therapeutic possibilities, increasing patient expectations and raising treatment cost have made the provisions of health care more complex. In response to these challenges, a health care reform was realised in 2010 with the view to foster long-term financial sustainability and improve the long-term care (rise in healthcare premiums, reduction in the remuneration of certain healthcare treatments, strengthening the "gate keeper" role of general practitioners by access to some specialised care). Luxembourg is also currently focusing on the digitalization of its healthcare system, since the inception of its comprehensive eHealth strategy in 2006.

Demographical challenges related to ageing population are posing an issue not only to Luxembourg. According to Eurostat's population projections for the period from 2011 to 2060, ageing is likely to affect all Member States of the EU. The proportion of 80 years or above in the EU28's population is projected to more than double between 2013 and 2080. As such, Luxembourg, as the last one form the current EU Presidency Trio, will particularly encourage a proper follow up of the reflection process on chronic diseases and of the reflection process on modern, responsive and sustainable health care systems. ■

NEWS IN BRIEF

PHARMACOVIGILANCE:
NEW MONITORING SERVICE TO BE INTRODUCED BY EMA

The European Medicines Agency (EMA) will take over the responsibility for monitoring a number of substances and selected medical literature to identify suspected adverse reactions with medicines authorised in the EU. The service will be initiated in the summer with the full roll out in September 2015.

By enhancing the quality and consistency of the reported data within EudraVigilance, the EU adverse drug reaction collection and management system, the service is targeted to improve the safety monitoring of pharmaceuticals.

The initiative is particularly of a great benefit for the industry which, for the active substances and literature covered by the EMA activities, will no longer be obliged to enter the information on suspected adverse reactions into EudraVigilance.

GERMANY:
FEDERAL COUNCIL CONFIRMS ROLE OF PARALLEL IMPORTS

The German Federal Council has recently confirmed the value of parallel imports by rejecting the request for examination of the import promotion (Importförderung) of pharmaceuticals.

The import promotion is established in the Social Security Code (Sozialgesetzbuch). The cost savings generated by imported prescription pharmaceuticals amount to 240 Million Euro, with the cost saving potential 340 Million Euros per year, in Germany according to the latest PROGNOS report.

Should the "Importförderung" be abandoned, pharmacies would have to examine whether a more cost-efficient, imported pharmaceutical, is available in each case in order to comply with the efficiency requirement. Hence, additional bureaucratic hurdles would be generated.

Pharmaceutical pricing:

Non-transparency as a driver behind "Big Pharma" profits

In accordance to the principle of subsidiarity, national authorities are free to set the prices of pharmaceuticals and to designate the treatments that they wish to reimburse under their own social security systems. However, the state price control only applies to reimbursable medicines whereas manufacturers are free of controls in the case of non-reimbursable products.

A common practice used by the national authorities is the comparison with pharmaceutical prices of other countries (i.e. external price referencing). The majority of Member States uses this approach to find a basis for their domestic price setting to different extend. The final price of new pharmaceuticals is also often subject to framework agreements between governments and pharmaceutical manufacturers. This negotiation process is rather opaque and results in non-transparent rebate contracts between the pharma industry and the national insurance authorities. The lack of transparency in the pricing and reimbursement of pharmaceuticals is providing for the profits of pharma industry, while the sustainability of health care system is jeopardised.

DTP and its effects

In order to have more control over the distribution channels, the manufacturers have in the recent decade assumed a more active role through the direct-to-pharmacy (DTP) distribution model. Traditionally, the pharmacies are being supplied by wholesalers. However, through the DTP, the manufacturer chooses to supply the products either through one exclusive or limited number of wholesalers. In some Member States, such as Czech Republic, Italy or UK, the proportion of sales to pharmacies directly by the manufacturer has significantly increased.

As the exclusive wholesalers don't own the stock, they are unable to swiftly react on the needs of the market, offer discounts and compete among themselves to become the main suppliers to pharmacies. Thus, the competition is being limited and the supply chain becomes less flexible. In times when shortages of pharmaceuticals occur in different Member States, it is questionable whether this highly controversial model is suitable. Given that the DTP model enables the manufacturer to control more tightly their supply chains, the overall resilience of the pharmaceutical distribution channels is weakened. It should be accessed whether DTP is more part of the problem than part of a solution. ■

GLOSSARY

EXTERNAL PRICE REFERENCING

WHO defines external price referencing (EPR) as: "The practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country".

Currently the price referencing is generally applied in all Member States besides UK, Sweden and Germany. External referencing varies greatly among the Member States. Most of them use EPR as the main criterion for price setting, but for Belgium and Italy it is merely a source of "supportive information". ERP is applied either to all marketed drugs (Luxembourg) or to specific categories of medicines such as publicly reimbursed medicines, prescription-only medicines or innovative medicines.

The number of reference countries included in the basket varies greatly from one country to another (1 for Luxembourg, to 31 for Hungary and Poland).

INTERNAL PRICE REFERENCING

Internal price referencing is defined by WHO as "the practice of using the price(s) of identical medicines […] or similar products […] with therapeutic equivalent treatment (not necessarily a medicine) in a country in order to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement of the product in a given country."

Although it is the opposite of EPR, it is often used to complement this process in order to cope with certain situations, for example, when a certain medicine does not exist in other countries and hence cannot to be referred to.

EXPERT OPINION

This is not a Fairy Tale

At first there was the bad news: frequent shortages of the medicine in pharmacies all around the country. The bad news do not impress the public opinion unless they are publicized in the media. This news was often repeated as it related to the health of people who obtained the medicine covered by public health insurance. The so-called journalistic investigation was taken up. The mysterious culprit of the shortage was quickly found: the parallel export.

As it is known, the parallel export is a mix of the greedy wholesalers and bureaucrats who don't want to stop this dirty business. The group of the members of parliament decided to fix this situation and initiated the changes in the law. Their goal was to limit the parallel export. The argument that the parallel export is a form of free circulation of goods consistent with the treaties did not find any acceptance during the parliamentary debate. It was not noticed that the parallel importation, beneficial to patients, would be impossible if not for the parallel export. Nobody paid heed to the experts who said that manufacturers may limit the supply of medicines and, ipso facto, affect the market situation.

In that way, the law which introduces complicated and rather restrictive parallel export permission principles was changed. The regulations of this law have not come into force yet.

Meanwhile, the results of another investigation led by the pharmaceutical surveillance were announced. It was revealed that the medicine which was missing in pharmacies, the same medicine that was the cause of the changes in the law, has been lying on the shelves of its manufacturer's warehouse. When asked about the possibility of a medicine's delivery, its employees lied and claimed that it was not there. The Police is examining whether such actions constituted a real threat to the patients' health at the request of the prosecutors' office.

All of this did not happen on a faraway planet, but in the European Union. What are the conclusions?

First of all, we need „more Europe", meaning the rules that will be common, European instead of just national. This will improve the quality of our life and weaken the protectionism.

Second of all, we need courageous and active "lamplighters" who will be able to lighten real problems with the same light from all the sides. Only then there will be a basis to make a reasonable decision.

Third of all, we need to remember that the bigger number of more detailed regulations does not have to change the reality. The rationality of ruling and the free market are doing better when there are fewer paragraphs. ■

Author: The team of Inspirat Consulting & Communication.

IMPRINT

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CALENDAR

15 - 17 SEPTEMBER 2015,
VIENNA, AUSTRIA

ANNUAL RISK MANAGEMENT AND PHARMACOVIGILANCE SUMMIT

The 2nd Annual Risk Management and Pharmacovigilance Summit, a sequel to last year's most popular pharmaceutical event in Europe specifically dedicated to pharmacoviglance, is giving all participants a great opportunity to gain fresh insights into the best practices in the pharmacovigilance field and learn from the leading experts within the pharmacovigilance and risk management area.

For further information please see:
pharmariskandcovigilance.com

30 SEPTEMBER - 2 OCTOBER 2015,
GASTEIN, AUSTRIA

EUROPEAN HEALTH FORUM GASTEIN

The leading health-related policy event in the European Union takes place annually in Gastein and provides a major platform for decision-makers in various fields of public-health and healthcare. The forum will reflect on the opportunities and risks for health in light of the outcome of the European elections, and will discuss how to maintain and improve the health of European citizens.

For further information please see:
ehfg.org

14 - 17 OCTOBER 2015,
MILAN, ITALY

EUROPEAN PUBLIC HEALTH CONFERENCE

The 8th European Public Health Conference aims 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 as well as public health training and education.

For further information please see:
ephconference.eu