

PHARMACEUTICAL DIALOGUE 58

+++ INFORMATION FROM THE PARALLEL TRADE INDUSTRY +++ JULI 2017 +++

PHARMACEUTICAL & HEALTH CARE POLITICS

Cyprus endorses parallel distribution as an ally of Competition



Photo: istock/Richmittis

In the beginning of April, the Auditor General of Cyprus published a report on the lack of competition in the procurement of medicines and the pharmaceutical pricing system in Cyprus. The Auditor General urged the Cypriot health ministry to adopt new measures, one of which is the parallel distribution of pharmaceuticals, in order to

tackle the lack of competition and the existence of monopolistic conditions in the pharmaceutical market. These phenomena have led to an increase in medicines' prices, damaging the public interest.

Cyprus joins Mediterranean coalition on access to medicines and pricing

Cyprus has recently signed the Valletta Declaration together with five other Mediterranean countries (Greece, Malta, Italy, Spain and Portugal). More countries are expected to join with Ireland and Romania being the first candidates. The first technical meeting is expected to take place in June and will be hosted by Cyprus. The Mediterranean coalition is an attempt to strengthen the voices of the Mediterranean countries for more access to medicines with fairer prices vis-à-vis the pharma industry.

Parallel Distribution as the solution to the problem

One viable solution would be to change the way the average wholesale price is currently set. The best solution however, would be to simplify the procedures for importing pharmaceuticals through parallel imports in order to increase competition. Cyprus follows the rhetoric of other countries such as Germany, Scandinavia and the UK in squeezing costs by supporting parallel distribution of medicines. In order to increase the positive results of parallel import of medicines to the country, parallel distributors are advised to submit lower bids in public competitions in order to give pharmacies better prices.

Striving for Sustainability of Healthcare systems

Other Member States are encouraged to follow the Cypriot example by endorsing parallel distribution in order to cut down the prices while providing access to high-quality medicines. The parallel distribution manifested itself, once again, as the Guardian of competition placing the interest of the consumers and the sustainability of the healthcare system at its core. ■

EDITORIAL

Dear Readers,

the need for Cyprus is following favourable policies to the parallel distribution of pharmaceuticals, aiming to support the consumers' needs and the sustainability of its healthcare system. Six Mediterranean countries have created a coalition aiming for more access to medicines in affordable prices (**see page 1**).

Estonia will succeed Malta in the rotating Presidency of the Council of the EU. The focal themes on healthcare revolve around eHealth and alcohol policy. Estonia will discuss the access to medicines intricate debate on an expert level and follow-up on the implementation of the Falsified Medicines Directive (**see page 2**).

But export bans are still threatening the harmonious function of the Internal Market (**see page 3**). In addition, the Commission has opened investigations against the pharmaceutical industry for abuse of its dominant position and price fixing of life-saving medicines. (**see page 3**).

The VAD welcomes Cyprus' audit report, which recognises the benefits of parallel distribution of pharmaceuticals for the patients and the healthcare systems. The VAD is ready to contribute to a dialogue with all the interested stakeholders in order to achieve a better access to medicines and tend to the European patients' needs.

Sincerely,



Prof. Edwin Kohl

Chairman of COSTEFF
and the VAD



Estonian Presidency: Digitalising healthcare



Photo: istock/KavalerkaVolha

One of the newest EU Member States will overtake the rotating presidency of the Council of the EU in July. Estonian citizens' life expectancy has increased by 6 points over the period 2000-2012 (EU28 80 years; Estonia 77 years). Looking at the WHO statistics from 2015, the population

is susceptible to non-communicable diseases such as heart diseases and diabetes.

Presidency agenda focused on cross-sector digitalisation and alcohol policy

Looking at the Estonian Commissioner's agenda it is no wonder that Estonia will address the digitalisation of healthcare during the upcoming presidency. The eHealth topic will include data ownership as well as cross-border sharing of patient-data. A Ministerial conference on eHealth will take place on 16-18 October. Estonia will also focus on reframing the alcohol policy and addressing taxation measures and labelling. There will be an informal meeting in Tallinn in July.

...on the access to medicines debate

Access to medicines is another big issue for the country since it is commercially less attractive for the big manufacturers and has experienced medicines' shortages. In an attempt to tackle the shortages, the country has introduced the "Restriction for medicinal products Act" enforced by the Estonian Medicines Agency, but it has not been implemented. The Presidency feels that the debate should move on to the expert level in order to reach viable solutions.

... on the Falsified Medicines Directive implementation

Estonia aims to organise a conference on the implementation of the Falsified Medicines Directive together with the Estonian pharmaceuticals association in Tallinn as a follow-up on the adoption of the Directive. The conference will provide the opportunity to the participants to share best practices and address the practical issues that can hinder the implementation of the Directive on the national level. ■

NEWS IN BRIEF

Parallel Distributors' voice on Social Media

The European Association of Euro-Pharmaceutical Companies (EAEPCC) has now joined the digital debate in healthcare by launching its Twitter account in April. The association will engage in the digital dialogue with stakeholders and the Institutions and provide quick information with added value also online.

The association will further update followers regarding the latest news on health policies as well as the parallel distribution of pharmaceuticals on the national and the European level. You can follow the EAEPCC under the address @EAEPCC_Brussels.

Brexit threatens access to medicines and healthcare

The activation of Article 50 by the United Kingdom on 29 March has triggered a series of unprecedented developments affecting also healthcare. The United Kingdom is an important hub for parallel distribution in Europe, being the second biggest net-import country with a share more than 15% by value in the recent years. If the UK manages to secure its position in the Single Market after Brexit, the country will continue to benefit from parallel distribution. Otherwise, the UK would need to set up import tariffs.

As a result, the prices of medicines could rise significantly for both UK and EU citizens due to the change in parallel import conditions and parallel distribution would decline. Medicines' availability could also be threatened if the UK leaves the regulatory system of the European Medicines Agency. British members of the European Parliament have urged both sides to assess the potential impact of Brexit on EU's health policies as well as citizens' lives.

IMPRINT

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Romania's export bans threaten the EU's Internal Market



Photo: istock/eyegabb

Since March 2017, the Romanian authorities have introduced new export bans on medicines included in the national programs of treatment. This is another false attempt to address the country's supply shortages. Such a practice constitutes an infringement of Regulation No 2679/98 on the free movement of goods. The European Commission has been notified regarding the situation. In any case, the parallel distributors can sue a state, which disrupts competition in the Internal Market. Currently,

there are close to 400 medicines in danger of limited supply from the market "due to the current pricing policy and the clawback tax" according to Mr. Vasile Barbu, president of Romania's National Association for Patients Protection. "Banning the parallel export would solve the problem only on short term," he concluded.

The Romanian Competition Council has warned against the practice of parallel export ban. The European Association of Euro-Pharmaceutical Companies has welcomed any dialogue with national and European authorities in order to find a better-balanced approach on shortages. ■

Pharma Industry in the spotlight for abuse of dominant position

The European Commission has launched a formal investigation on Aspen Pharma regarding allegations on excessive pricing in life-saving medicines and abuse of market dominance. Aspen has threatened to withdraw the medicines in question in some Member States and has done so in certain cases. European Commissioner for Competition, Ms. Margrethe Vestager, commented that it is alerting for the Commission when the price of a medicine increases by several hundred percent.

In 2016, the Italian Competition Authority fined Aspen Pharma for abuse of its dominant position. A number of NGOs have also notified the Commission during 2016 that Aspen pharma has been fixing unfair prices for certain medicines. Some of the products in question are also included on the list of notification in Spain that has been approved by the Commission. The case of Aspen demonstrates the pharma industry's common practice of causing artificial shortages of medicines as a tool for unfair pricing negotiations. In order to force the Member states to accept extremely high prices on life-saving medicines, the pharma industry, either threatens to remove the product completely from the market or reduces the supply drastically. These practices threaten the lives of the patients that are dependent on these medicines. Aspen Pharma has confirmed that the European Commission is currently investigating on its practices, but did not comment further regarding the allegations. ■

GLOSSARY

Regulation No 2679/98 on the free movement of goods

The "Strawberry Regulation" (Council Regulation (EC) No 2679/98 of 7 December 1998 on the functioning of the internal market in relation to the free movement of goods among the Member States) establishes an information and monitoring mechanism in order to eliminate the major obstacles to trade which inflict serious losses on individuals.

According to the Regulation "Member States should abstain from adopting measures or engaging in conduct liable to constitute an obstacle to trade and, on the other hand, take all necessary and proportionate measures with a view to facilitating the free movement of goods in their territory".

Pharmaceuticals, as one of these goods, are by principle freely traded within the EU through parallel distribution.

Digitalising healthcare with eHealth

The European Commission has been striving to increase the quality of healthcare services while following a patient-centred approach.

A revolutionary solution, heavily promoted by the Institutions and digital goliaths, is eHealth. eHealth can improve the prevention, diagnosis and treatment of diseases via tools and services using information and communication technologies (ICT).

With the use of the digital technology, the patients' health records as well as telemedicine services can become available between different countries. The aim is to provide life-saving data using the digital tools, increase healthcare quality and make eHealth tools user-friendly.

EXPERT OPINION

Focus on the Pharma Industry



The European Commission has initiated an official investigation into the manufacturer Aspen Pharma from South Africa (with subsidiaries in the EU) based on suspicions of excessive pricing for five cancer medicines. There are indications of sudden price increases of several hundred percent, mentioned Competition Commissioner Margrethe Vestager recently.

In order to make an impact, Aspen has threatened to remove the products from the market in some EU countries. In certain cases, the company even did so. Commissioner Vestager will now examine this practice closely: „When we get sick, we may depend on specific medicines to save or prolong our lives...But when the price of a medicine suddenly goes up by several hundred percent, this is something the Commission may look at. More specifically, in this case we will be assessing whether Aspen is breaking EU competition rules by charging excessive prices for a number of medicines.“

If the products actually disappear from the market, physicians would have less treatment options for often-fatal diseases. This can be extremely problematic.

Obviously, in the case of Aspen, the issue is not only the highly increased prices, but also the artificial shortages of medicines on national markets. In order to affect pricing, the industry either threatens to take the product off the market or reduces the supply drastically. A temporary national shortage of an important medicine is acceptable. However, increased exports to other countries have been repeatedly blamed as the causes of medicines' shortages. In the past, various Member States have imposed export restrictions or a temporary export ban.

The logical consequence of the „Aspen“ case would be that the Commission also investigates all export restrictions and ensures the free distribution of goods. Unfortunately, some national governments are still hindering competition and opting for export restrictions, although shortages are often not caused by increased exports but by monopolistic behaviors. The case of Aspen demonstrates that competition in the pharmaceutical market is necessary in order to keep medicines affordable, while protectionist measures only weaken competition in the long-term as well as the security of supply.

Mr. Haber, is Professor at the Danube University Krems, Austria, with an in-depth expertise on health economics.

CALENDAR

20 - 22 AUGUST 2017
ALPBACH, AUSTRIA

European Forum Alpbach

The Health Symposium will provide a global overview of the different health systems leading to regional topics of discussion such as the supply of the latest medicines, affordable access to innovative medicines as well as the communication between healthcare professionals and patients

For further information please see:
alpbach.org/en/event/health-symposium/



07 SEPTEMBER 2017
BRUSSELS, BELGIUM

European Public Health Alliance Annual Conference 2017 'Make Health your Business'

EPHA is organising its annual conference targeting policy makers and healthcare professionals. The conference will focus on different ways to use different levels of power and break through to real action on chronic diseases by making health everyone's business.

For further information please see:
epha.org/epha-2017/



16 - 18 OCTOBER 2017
TALLIN, ESTONIA

'Health in the Digital Society. Digital Society for Health'

This conference will focus on how digital technologies are changing the lives of the patients and healthcare. The conference will demonstrate already existing digital health solutions and technologies in an attempt to show that value-adding citizen-centric health services and systems are the reality and need to become available to all Europeans.

For further information please see:
sm.ee/en/ehealthtallinn-2017

