VAD
German Association of Pharmaceutical Parallel Distributors

COST EFF
alliance for cost-efficiency in healthcare

PHARMACEUTICAL DIALOGUE 62

+ + + INFORMATION FROM THE PARALLEL TRADE INDUSTRY + + + JULY 2018 + + +

PHARMACEUTICAL & HEALTH CARE POLITICS

Member States step up the fight against falsified medicines

Source: European Parliament

With less than half a year to go, 2019 will prove to be a significant time for the fight against falsified medicines as 2019 remains the final milestone for full implementation of the EU's Falsified Medicines Directive (FMD). The implementation of rules regarding the identification of individual medicine packs under the EU's FMD aims to discourage the existence of illicit and fake medicines in the supply chain. Combating fake medicines remains a key topic for the EU.

European Commission publishes study on penalties for falsified medicines

Directive 2011/62/EU amended Directive 2001/83/EC in order to include measures aimed at preventing the entry of falsified medicinal products into the legal supply chain. Article 118a of the Directive includes the requirement for Member States to introduce penalties related to the falsification of medicinal products, active substances and excipients. The European Commission has published a study in early 2018, which assesses the sanctions that have been put in place by the Member States.

Member States impose strict sanctions against falsified medicines

The study of the European Commission reveals that all Member States have sanctions in place. Most Member States apply criminal sanctions for the production and distribution of falsified medicines. In particular, in 21 Member States the manufacturing, distribution, brokering, import, export and sale at a distance of falsified medicines are sanctioned as criminal acts. In seven Member States, some of the activities attract civil penalties in the form of fines rather than criminal sanctions.

Commission assesses the implementation of the FMD

The Commission has also assessed that Member States have implemented the FMD in a satisfactory manner even though some Member States could include further administrative or civil sanctions. Within a presentation of the study in the European Parliament's ENVI committee, a Commission representative has also highlighted that in order to facilitate enforcement, it would be easier to introduce sanctions that penalise falsification per se without having to prove that products have caused harm to human health. The European Parliament has expressed its satisfaction on the progress that the Member States have made. ■

EDITORIAL

Dear Readers,

2019 marks the year when the Falsified Medicines Directive (FMD) will be fully implemented with sanctions being already in place for perpetrators. However, Member States still have a long way to go **(see Page 1)**. Austria is ready to take over the Presidency to the Council of the EU. Access to medicines and incentives remain high on the Presidency's agenda **(see Page 2)**.

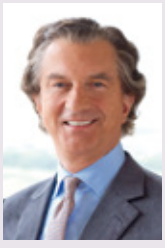
France is another example where the parallel-import of pharmaceuticals has proved to be of high importance in order to ensure access to life-saving medicines for patients **(see Page 3)**. Meanwhile, the Commission is looking into several antitrust cases in parallel trading, including in the pharmaceuticals sector **(see Page 3)**.

VAD participates actively in the successful implementation of the FMD in Germany in order to ensure that patients have access to high-quality medicines. VAD also continues the dialogue with the upcoming Presidency in order to promote the free movement of high quality pharmaceuticals in Europe.

Sincerely,

Prof. Edwin Kohl

Chairman of COSTEFF and the VAD



Austrian Presidency: A healthcare system that protects – at high costs

The EU's overall policy will be driven by the two predominant discussions on Brexit and the EU budget (Multiannual Financial Framework – MFF). Still, the Austrian presidency of the Council will be trying to revolve the debate around the core topic "A Europe that protects". This results in one pillar of the presidency being security and migration policy, another one stability in the EU neighbouring countries and last but not least competitiveness and digital issues. Recalling the national debate on skyrocketing medicine pricing that took place in Austria in 2017, it is not improbable to assume that a protective Austrian presidency would be open to consider this issue as well. The debate followed a joint event on the topic by the association of Austria's social insurers (Hauptverband der Sozialversicherungsträger, HV) and the Federal Ministry of Health, and drew harsh criticism from the pharmaceutical industry. A general focus is expected to be on subsidiarity, explicitly "doing less more efficiently". With a newly elected government, the full intentions remain unclear for the moment.

Federal health care system

According to Eurostat data, life expectancy in Austria in 2016 was at 81.8 years. A figure higher than the EU-28 average which remains at 81.0 years. Over the past 30 years, life expectancy has increased by more than eight years while infant mortality has decreased by more than 75 %. While on the one hand, life expectancy is increasing, on the other, fertility rate is falling. These demographics pose a huge threat to the Austrian healthcare system, already subject to overly complex regulation.

International Exhaustion of Intellectual Property rights

An alternative scenario would be for the UK to adopt an international exhaustion for the Intellectual Property (IP) rights. This scenario could compromise the relationship within the EU regarding the parallel exports from UK into the EEA. Moreover, the need to align measures in order to secure patient safety and prevent counterfeit medicines would create regulatory issues which could make the exhaustion of rights with non-EEA countries difficult.

A complex system ready for reform?

The Austrian Federal Ministry of Labour, Social Affairs, Health and Consumer Protection plays a central role in preparing laws, having the responsibility to craft both public health and health policy, playing the role both of the decision maker and the supervisory authority. The federal government lays down the legislative framework while the provinces are then in charge of defining legislation, enforcement and implementation. Federal, provincial and local authorities jointly provide public health services and administration.

All individuals not only receive publicly funded care, but also have the option to purchase supplementary private health insurance. The system is complex due to its multi-level governance structure while the numerous social health insurance carriers continue to operate in silo structure – a structure that drives healthcare costs to the top compared with other European countries. The government has thus agreed on reforming the healthcare system.

Priorities of the Austrian Presidency

The Austrian Presidency has set its priorities on continuing the discussions regarding the recent proposal on Health Technology Assessment (HTA) and the upcoming review of the Supplementary Protection Certificates (SPCs). In addition and following the initial ambition from the Estonian presidency, the digitisation of health care systems is expected to be of high priority. Built on the Bulgarian presidency, the Austrian presidency does also want to ensure the availability of life saving access to medicine for patients. ■

NEWS IN BRIEF

Supplementary Protection Certificates – Pandora's Box for the Big Pharma

The current IP rights discussion at EU level is undoubtedly one of the most challenging on the political agenda. The 2016 Council Conclusions have depicted the EU Health Ministers' concerns regarding the abuse of some IP-related incentives in certain clusters of pharmaceuticals. The Council of the European Union asked the European Commission to conduct a critical review of some additional forms of patent protection (namely the supplementary protection certificate, data protection and market exclusivity). Both DG GROW (internal market, industry, enterprise) and DG Santé (Health) of the Commission are conducting the review. The challenging nature of the review will demonstrate the access and innovation issues in medicines by investigating patent-based monopolies and exclusivities. The discussion will most likely signal to investors that the current pharmaceutical business model is no longer sustainable and hence create a nightmare for the monopolistic practices of the Big Pharma. ■

AI: a blessing in disguise with the potential to transform healthcare

Artificial Intelligence (AI) long seemed to be a double-edged sword. On the one hand, AI offers major innovation possibilities and enhancements from accelerating, cheapening and de-risking R&D to product design, deployment and market reaction to products. Current developments in the field of eHealth and mHealth allow the collection of patient data via applications and social media with remote patient monitoring. More precisely, electronic health records (EHRs) and genomics can be collected and diffused into predictive and prescriptive analysis. This allows the future forecasting of possible scenarios for the patients' health status. As a result, AI can lead to the full personalisation of healthcare. So far, the public opinion has been divided with differentiated opinions stemming from the age gap, the level of education and the technological differences between Member States. There are also many advocates that demand stricter data protection of patients' electronic information in order to avoid the misuse and manipulation of the health status of the European Citizens. Even though AI has a long way to go, it seems to be a blessing in disguise for personalised healthcare. ■

Possible Antitrust Probes for Parallel Imports

Photo: istock/Cecilie_Arcurs

In the past antitrust infringements in the pharmaceutical parallel import sector have attracted significant fines. The European Commission continues to conduct in-depth investigations into business practices that affect parallel trade. According to a recent article by the law firm Hogan Lovells, the Commission is currently looking into several parallel import cases, with possible formal antitrust investigations to follow. The targeted industries include diverse sectors such as e-commerce, consumer electronics and brewery products as well as at least one case from the pharmaceutical sector.

According to a leak referenced by Hogan Lovells, the company seems to be under scrutiny for the dual pricing of pharmaceuticals sold through national social security systems as well as the open market.

Pharmaceutical companies continue to be among the highest priorities of antitrust agencies around the world and in Europe. The European Commission maintains a dedicated info page for antitrust enforcement in the life science sector, and national authorities in the Netherlands and Belgium have named antitrust in pharma as priorities for the coming years. ■

France: Parallel-import as the Solution to Medicines' Shortages

Photo: kohlpharma

France has been experiencing difficulties regarding access to medicines for the past ten years. A recent dedicated reportage in French national TV, TF1 evening news identifies as the main cause for shortages the internationalisation of the production chain of pharmaceuticals. According to this reportage, the lack of raw materials as well as the lack of upgraded infrastructure can lead to manufacturing problems for the pharmaceutical industry.

In order to tackle the shortages, France parallel-imported medicines destined for the UK. The fear of shortages still remains however. Currently there is no legislation that sanctions the lack of proper supply of pharmaceuticals in the market. The healthcare community has expressed its concerns over the efficiency of the current legislation which does not guarantee the access to medicines and hence the safety of patients. ■

GLOSSARY

Article 118a of Directive 2011/62/EU

The European Parliament and the Council adopted Directive 2011/62/EU (the Falsified Medicines Directive) in 2011 in order to amend Directive 2001/83/EC and address the concerns regarding the falsified medicines in the legal supply chain. According to these provisions, Article 118a requires Member States to "lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to the Directive". Moreover, "these penalties must be effective, proportionate and dissuasive".

Article 118a also requires the Commission to submit a report to the European Parliament and the Council in order to provide "an overview of the transposition measures of the Member States as regards the Article". In any case, Member States should have notified the European Commission of the national provisions adopted by January 2013. ■

AI under the microscope

Artificial intelligence (AI) has been defined as the science and engineering of creating intelligent computer systems which are able to perform tasks in an independent manner without receiving direct instructions from humans. They use different sets of algorithms, which allow them to develop decision-making capabilities and opt for the best solution or response. On the other hand, it is commonly feared that AI could disrupt industries and lead to large-scale job losses. Yet, studies predominantly suggest that the benefits of technology outweigh the potential threats.

An overwhelming gold-rush mentality into pushing enthusiastic AI programmes can yet lead to resistance especially from doctors and patients. The most mature application of machine learning is the chance to enhance informed joint actions with customers, where applications can predict the next best channel, message and timing for engagement. ■

EXPERT OPINION

A new shot at a Transatlantic Agreement

by Nadja Hirsch

Ever since President Trump has launched his reckless attack on our liberal trade order, restrictions to the market in the shape of import tariffs on steel and aluminium have already been implemented, levies on German cars are on the table. Staunch allies of the United States such as the European Union and Canada are facing unjustified claims that their exports are threatening US national security.

Only due to the immense specialisation of our national economies, today's world economy manages to produce goods in a much more cost-efficient and resource-efficient way than ever before. Comparative advantages provide the foundation for economic prosperity, both within the European Union and on a global scale. With its current approach, the US is only sliding into a dangerous spiral of isolation. In a rare moment of truth, Larry Kudlow, Trump's top economic advisor, admitted that the tariffs imposed could indeed jeopardise his country's current high in economic growth.

Eventually, Mr Trump has to face reality and show willingness to negotiate compromises and to present sustainable solutions to the underlying challenges our global trading system is currently confronted with, first and foremost China's state-orchestrated overcapacities. Everything indicates that import tariffs on steel and aluminium are noncompliant with WTO rules. However, the countermeasures the Commission has come up with so far, namely tariffs on an array of US products such as whiskey or motorcycles, are no definite solution.

What we have to do is to fundamentally rebuild our trade relations with the Unites States in order to be able to return to a rule-based free trade system. It is imperative to resume comprehensive trade negotiations so both sides can resolve their issues as equals, leaving childish rhetoric and unnecessary accusations behind.

Open trade flows entail prosperity, progress and peace. National budgets are bolstered, jobs are created. Non-trade barriers need to be dismantled, while at the same time our high standards in human rights, occupational and food safety as well as environmental protection need to be maintained. We European Liberals continue to push for free trade agreements with our partners worldwide: digitalisation-proof and value-based. We call for a new Transatlantic Agreement - an accord much sought after in times of global insecurities and volatile economic cycles. A first step would be for the Commission to present detailed guidelines for trade talks in the near future: inclusive, transparent and ambitious.

The European Commission is now charged with the tricky task to step up to Trump's ideological protectionism while firmly opening the door to a "fresh start" in trade with the US. After all, cooperation beats retaliation by a landslide.

Nadja Hirsch is Member of European Parliament, Liberal Party

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

CALENDAR

26 - 27 SEPTEMBER 2018
LONDON, UNITED KINGDOM

The 9th Annual Biosimilars & Biobetters Conference

We are now entering a very exciting time, for over the next few years several originator patents are expiring, and we will see a new wave of biosimilars enter the market. After over a decade, the biosimilars industry is finally reaching a stage where key stakeholders understand and accept biosimilars. This is reflected in more tolerant legislation and an increased uptake of biosimilars across the globe. Will the originator dominate or will the biosimilar be a successful contender and spark a competitive environment? Have we done enough to convince the payer, prescriber and patient to switch? Biosimilars and Biobetters UK 2018 will deliver a stellar speaker line-up and bring together a global audience of biosimilar experts to discuss the latest developments and future of the rapidly evolving and expanding biosimilars market.

For further information please see:
www.smi-online.co.uk/pharmaceuticals/uk/biosimilars-and-biobetters

3 - 4 OKTOBER 2018
GASTEIN, AUSTRIA

European Health Forum Gastein

2018 is a big year for health. The World Health Organization and many key milestones for health such as the Tallinn Charter and Alma-Ata celebrate their anniversaries - and also the Universal Declaration of Human Rights and with it the very right to health itself. This year, the EHFG will focus on health within the Sustainable Development Goals of the United Nations Agenda 2030, and challenge participants and programme partners to explore how all can contribute to reaching the SDG targets, safeguarding health in Europe and beyond, and advancing sustainable development. Join the conversation at Gastein in 2018 to help make the case for health as a necessary key concern for European actors and institutions that impacts prosperity on all levels.

For further information please see:
https://www.ehfg.org/