VAD
German Association of Pharmaceutical Parallel Distributors

COST EFF
alliance for cost-efficiency in healthcare

PHARMACEUTICAL DIALOGUE 65

+ + + INFORMATION FROM THE PARALLEL TRADE INDUSTRY + + + APRIL 2019 + + +

PHARMACEUTICAL & HEALTH CARE POLITICS

European elections 2019: Health is developing into a main topic

So far, most major health issues have been part of the competence of EU Member States. It is not uncommon for individual states to vigorously reject attempts by the European Commission to assert more control. These circumstances often make it difficult to obtain results in the context of legislative processes. The disputes between national and European levels regarding the evaluation of the value of medicines is only one of many examples. For this reason, an increased number of citizens and politicians are in favour of the EU's expansion of power at public health level.

The latest Eurobarometer reflects a clear trend

Around 70 percent of voters want the EU to intervene more when it comes to their health care. This is one of the key findings of the Standard Eurobarometer 2018 and was supported by similar findings of the Special Eurobarometer, that provides in-depth thematic studies. However, the question remains what it means when respondents indicate by a large majority that they want the EU to do more? This does not necessarily mean that they want Member States to have less competence. Some experts interpret this result as a call for more cooperation between Member States and the Commission.

Will there be a Directorate General for Public Health in the future?

The departure of the United Kingdom will, in addition to reducing seats in the European Parliament, likely reduce a Commission post. In recent months, it has occasionally been suggested that the Directorate General for Health and Food Safety (DG SANTE) could be spared. The proponents of this proposal argue such a step could enable cross-departmental cooperation in order to promote overall effectiveness with regards to public health issues. However, some EU parliamentarians have already objected to this proposal. In addition, a coalition of 28 different health care organizations has teamed up to promote the appointment of a vice president for health in the future.

Health as the central issue of the upcoming European elections

The tension between the EU and the member states in terms of differentiated approaches and opinions in the healthcare sector will be a major issue in the coming EU election in 2019. Various candidates have already put health policy issues on their campaigning agenda. Manfred Weber, the leading candidate of the European People's Party, who will run for the Office of the Commission President campaigns for a double investment in cancer research by 2024. Other candidates have indicated that they will push topics like security of patient data or disease prevention in the centre of their campaign. ■

EDITORIAL

Dear Readers,

As we approach the EU elections, it becomes clear that the topic of health will be given high priority. Regarding the health sector, it seems that the upcoming election could become a landmark decision on the future of European health care. **(page 1)**

The completed falsified medicines directive is a milestone in the process of strengthening patient safety within the EU. In the public health sector, there is widespread hope that the total number of measures will soon bear fruit and effectively combat counterfeit medicines. This issue of the Pharmaceutical Dialogue takes stock of the directive and highlights the measures and their implications. **(page 2)**

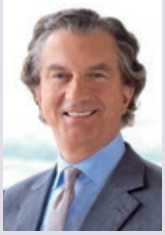
Medical shortages are generally a major challenge for the European health sector. A recent survey on pharmaceutical shortages in hospitals underpins this issue. **(page 3)**

VAD is actively participating in the ongoing debates on the future of European health care. We remain committed bringing affordable high-quality medicine to European patients across the Union. I hope you join us in this effort and wishing you many informative insights as you read this 65th edition of our Pharmaceutical Dialogue.

Sincerely,

Prof. Edwin Kohl

Chairman of COSTEFF and the VAD



New safety features for medicines sold in the EU are the cornerstone of the European Falsified Medicines Directive

Photo: imagrima/istock.com

Since February 9, new regulations have been introduced regarding the safety features (Supplementing Directive 2001/83/EC) of prescription medicines sold in the EU. This entry into force is the long-awaited final step of the EU's Falsified Medicines Directive (FMD). After years of preparation, the member states of the EU are now well-equipped to fully fight the distribution of counterfeit medicines.

The extend of falsified medicines in the EU

In general, there are hardly any precise estimates of the proportion of falsified medicines in the EU. However, there is a number of indicators that provide an idea of how relevant this issue has become for the public health sector and the pharmaceutical industry. According to a WHO (World Health Organization) estimate, 1 in 10 medicines in low and middle-income countries are falsified. Although the overall situation in the EU is much better.

Strengthening patient safety with a comprehensive package of measures

The Falsified Medicines Directive, which was adopted in 2011, contains a set of distinct safety measures. In addition to the safety features on prescription medicines, strict regulations regarding the importation of active ingredients have been initiated in recent years. Furthermore, improved record keeping for wholesalers and the EU logo as identification feature for online pharmacies have been adopted. The latest regulations contain a medicines authentication system and the introduction of mandatory safety features on the outer packaging of prescription medicines.

The implications of the new safety net for pharmaceutical importers

The pharmaceuticals authentication system is accompanied by an end-to-end verification of prescribed medicines sold in the EU. For pharmaceutical parallel traders in the EU, this system creates specific requirements. Due to this authentication system, European parallel traders will find themselves in a dual role in the future. In recent years, large parts of the medical import sector have been preparing for this dual role. On the one hand, importers have to control the drug packages that they import from within the EU and deactivate the distinguishing identification feature. On the other hand, importers themselves are supposed to equip re-labelled medical packages with an individual identifier. The data must then be uploaded to the EU hub connecting all national verification systems.

Future outlook of the public health industry

Most public health stakeholders are confident about the completed falsified medicines directive and the implementation of the specific measures that go along with it. Despite potential difficulties in the course of the initial phase, it is expected that the new system will soon prove itself to be effective. The majority of the public health sector agrees that the tremendous efforts and the large investments made are worthwhile in terms of expected results. The European Association of Euro-Pharmaceutical Companies that represents the interests of pharmaceutical importers in the EU welcomed the conclusion of the directive and notes that patient safety has become the current priority topic of the entire public health sector. ■

NEWS IN BRIEF

The European Commission announces the introduction of "ePrescriptions"

From now on, EU patients may be able to use digital prescriptions (ePrescriptions) issued by their physician when visiting a pharmacy in another EU country. The European Commission's initiative calls for the ePrescriptions to be electronically visible to the participating pharmacies in the host country via the new eHealth Digital Service Infrastructure without the patient having to submit a prescription.
Finnish patients can already access medicines in pharmacies in Estonia that were previously prescribed electronically by their doctor in Finland. The initiative applies to all ePrescriptions issued in Finland and to all Estonian pharmacies that have signed the relevant agreement. ■

Effective health and pharmaceutical policies require the expansion of competence for the EU Commission

Several health ministers from EU Member States are calling for more powers to be given to the Commission to ensure important changes and adjustments in the policy area of public health. In this regard, three essential parameters are essential to enable more effective public health action. Innovation for the manufacturing of effective medicines with therapeutic added value, full and equal access for all EU citizens to new treatment options and a sustainable healthcare system are the corresponding core topics that require increased attention in the upcoming years.

In various countries, innovation financing is linked to public funds. Therefore, the Greek Minister of Health, Andreas Ksanthos pointed out that there is the need to improve public scrutiny in the process of promoting innovation in the pharmaceutical industry. ■

[2] https://www.eaepc.org/images/pdf/evaluation.pdf

Medical Shortage in hospitals has increased significantly

Last year, The European Association of Hospital Pharmacists (EAHP) conducted a study on bottlenecks in medicines in European hospitals. The results show that medical shortages have worsened compared to the previous study conducted in 2014. For many health experts, the outcome of the study substantiates that medical shortages are a key issue for the European healthcare sector.

In particular, hospital pharmacists are concerned

The proportion of hospital pharmacists who indicate a deficiency as a problem in terms of optimal patient care has increased considerably. European hospital pharmacists emphasized the need for timely and accurate information shortages of medicines. Against the background of this result, the European Association of Hospital Pharmacists calls for comprehensive communication strategy on shortages. Targeting Member States will ensure that all supply chain actors receive adequate information on the medical shortages in their countries. In this regard, the EAHP stresses the need for all supply chain actors, the European Commission and national governments to improve the flow of information.

The problem relates to a variety of different active agents

Antimicrobials were the most commonly reported drug with bottlenecks at 77%. Problems have also been reported frequently with preventive medicines, vaccines (43%) and cancer medicines (39%). The combination medication Piperacillin/tazobactam, is the active ingredient most commonly associated with medical shortages. The shortage of this active ingredient was reported in 272 cases and in 18 different countries.

Understanding the causes of the issue

While 67% of the respondents reported their country has a system for reporting shortages in place, only 56 of those evaluated it to be effective. In addition to the ineffective information systems, however, it must be noted that the problems are quite different from country to country. Many respondents expressed their opinion, that manufacturers should be legally obliged to maintain stock levels and ensure sufficient supply of medicines, as it is the case in France. Other comments of feedback suggest severe problems when importing medicines from other countries, and the differences in price of the same medicine across Europe. The evaluation of the survey concludes that a deeper and more holistic analysis is needed as shortages are managed rather reactively instead of acting proactively.

EMA has also addressed the topic of supply shortages in the area of medicinal products very seriously. Already in 2012 a reflection paper stipulates that the trend to focus manufacturing to a few manufacturing sites supplying at a global level gives rise to shortages. This is being corroborated by the fact that shortages do occur in countries with little or no parallel trade, such as Switzerland and the United States.

EMA continues to state that industry's risk management tends to be reactive rather than proactive. Here the agency is of the opinion that sustained pressure is needed to bring about a change so that industry takes a proactive approach to quality risk management - also with regard to supply chain integrity.

Another study on the causes of medication shortages commissioned by EAEPC and performed by independent medical researcher Birgli in 2013 suggests that the pharmaceutical industry and medical supply chain are extremely complex and therefore exceptionally vulnerable for disruption, meaning small failures can have a big impact.

The four key-issues

– **Product withdrawal:** Pharmaceutical companies quickly withdraw pharmaceuticals from markets when they perceive that the current conditions are no longer sufficiently profitable.

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GLOSSARY

Supplementing Directive 2001/83/EC

The European Parliament and the Council adopted Directive 2011/62 (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 the supplementing Directive 2001/83/EC requires manufacturers to place "safety features consisting of a unique identifier and an anti-tampering device on the packaging of certain medicinal products for human use for the purposes of allowing their identification and authentication".
Directive 2001/83/EC also requires the wholesalers to verify "medicinal products at higher risk of falsification throughout the supply chain, to minimise the risk of falsified medicinal products circulating undetected for lengthy periods of time". ■

ePrescriptions and eDispensations

Patients travelling to other EU-countries can receive similar medication to that of their home countries through e-prescriptions and e-dispensations.
e-prescribing permits the electronic transmission of a prescription to a pharmacy while e-dispensing refers to the electronic access to a prescription and supply of the medicine to the patient. ■

IMPRINT

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– **Production problems:** With production facilities and processes having been streamlines over recent years, production has been concentrated on a smaller number of facilities making them more vulnerable for disruption; additionally a substantial amount of quality related recalls over recent years has led to shortages.

– **Quota-systems:** Originally introduced by manufacturers to limit parallel distribution, the quota systems have now become a cause of shortages. Manufacturers supply quotas are often not flexible enough to quickly react to fluctuation in demand.

– **Reimbursement problems:** The overall financial situation in some high debt countries has led to delays in national health system reimbursements to pharmacies, resulting in pharmacies being unable to settle accounts with wholesalers and wholesalers being unable to pay the producers. Additionally, in an attempt to reduce overall costs many wholesalers and pharmacies have eliminated buffer stocks leading to shortages if demand rises unexpectedly. ■

[1]https://www.ema.europa.eu/en/documents/other/reflection-paper-medicinal-product-supply-shortages-caused-manufacturing/good-manufacturing-practice-compliance-problems_en.pdf

EXPERT OPINION

Safe medicines: A European success

Tobias Gotthard, Member of the Federal Bavarian State parliament
Chairman of the Committee for Federal and European Affairs

Medicines safety affects us all. The topic: Counterfeit medicine has been the focus of attention in recent years and has thus unsettled patients across the European Union.

Since 9 February, new rules have been introduced regarding the safety features of prescription medicines sold in the EU. The new rules set the capstone for the implementation of the 2011 directive on counterfeit medicines.

The new regulation serves patients across the EU - the main aim of the Directive is to ensure the quality and safety of medicines sold in the EU. This is a measure that MEPs have always called for: Every pharmacy and hospital in the EU should recognize counterfeit medicines immediately. The development of the security system will provide our citizens with efficient protection against counterfeit and dangerous medicines.

From now on, the pharmaceutical industry will have to apply a 2D barcode and an anti-tampering device to the packaging of prescription medicines. In addition, pharmacies (including online pharmacies) and hospitals must verify the authenticity of all these medicines prior to handing them over to the patient. Medicinal products manufactured before 9 February 2019 which have no safety features may continue to be sold until their expiration date. However, under the new end-to-end verification system, the relevant stakeholders (in particular, pharmacies and hospitals) must verify the authenticity of the drugs throughout the supply chain.

The wholesalers are also legally obliged to verify certain medicines. This included all medicines that are returned to them by pharmacies, as well as all medicines that they do not purchase directly from the manufacturer. The pharmaceutical parallel traders look with confidence towards the actual implementation. Their motto is clear: we are prepared and ready to go.

It took a long time for the European Union to tackle the problem of counterfeiting. With this new and decisive step, European patients can be increasingly sure that there are no counterfeits in the supply chain. Now, it is a matter of swift and effective implementation of the directive.

Ultimately, this level of patient safety is another step towards strengthening Europe. Another important step. ■

CALENDAR

26 – 27 MARCH 2019
AMSTERDAM, NETHERLANDS

The 2019 Medicines for Europe Legal Affairs Conference

In its 15th edition, this conference will provide participants with the opportunity to exchange views and share ideas with leading industry executives and experts, counsel and European institution officials around the latest developments in intellectual property and legal affairs concerning generic, biosimilar and value added medicines within Europe and worldwide.

The conference will address international developments around IP and competition. The latest developments regarding Biosimilars and the SPC Manufacturing Waiver will also be core topics of the conference.

For further information, please see:
https://www.medicinesforeurope.com/events/lac19/

11 APRIL 2019
BONN, GERMANY

The FORUM Institute for Management: Parallel trade of medicines in Germany

A seminar that provides you with basic information about the regulatory requirements of parallel import and distribution - learn how to properly label and repackage your medicines.

This seminar is aimed at specialists and executives involved in parallel imports/sales, approvals, repackaging and labelling.

For further information, please see:
https://www.forum-institut.de/seminar/1904946-parallelhandel-von-arzneimitteln-in-deutschland