AFFORDABLE MEDICINES EUROPE
WORKING IN PARALLEL FOR A BETTER DEAL

VAD
German Association
of Pharmaceutical Parallel Distributors

PHARMACEUTICAL DIALOGUE 76

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INFORMATION FROM THE PARALLEL TRADE INDUSTRY

PHARMACEUTICAL & HEALTH CARE POLITICS

The upcoming Trio Presidency – expectations for EU health policy

When France, Czech Republic and Sweden take over the upcoming Trio Council presidency in January 2022, some new priorities alongside ongoing policy issues will be moved up the EU's agenda. With COVID-19 infections alarmingly on the rise across Europe and governments increasingly imposing tougher restrictions, it seems inevitable that the COVID-19 pandemic will – at least to some extent – shake up the political agenda of the incoming Trio Presidency. All three countries will have to deliver on addressing the economic and social consequences of the crisis, with an objective of strengthening European health systems.

Building a strong European health union

France, who takes over the presidency from Slovenia in less than a month, is keen on continuing to work on a European health union. The trilogues on the Commission's proposals on reinforcing the mandate of the European Medicines Agency and the European Centre for Disease Control and Prevention have been finalised and the Council will formally adopt the legislative texts at the beginning of 2022. The negotiations on the proposal for serious cross-border threats to health, however, are still ongoing, with several trilogues expected in the coming months.

France wants to take a further step and promote a "European public health policy that goes beyond health security," aiming to establish a committee of high-level experts to work on the broader health union.

Overhaul of the EU's pharmaceutical legislation

While France is similarly ambitious in accelerating the revision of the EU's general pharmaceutical legislation, which was announced in the Commission's pharmaceutical strategy, the Commission indicated that the publication of the package is expected for the end of 2022. This would leave it to Czech Republic and mainly Sweden to agree on a negotiating mandate on the revised legislation and enter trilogues with the European Parliament and the Commission. The last revision of the EU pharmaceutical legislation was tabled almost 20 years ago and thus, the review presents one of the most important EU healthcare reforms in decades.

A deepened Single Market for a competitive Europe

What is already apparent is that the development of the internal market will be among the priorities of the Trio Presidency. As the backbone of the EU's economy, ensuring the smooth functioning of a strong internal market is indispensable for guaranteeing greater access, availability and affordability of medicines. The Single Market was severely tested by export restrictions imposed by several member states following the outbreak of COVID-19, leading the Council to underline "the need to work together to strengthen the resilience of the Single Market to disruptions, including to key EU supply chains and economic sectors, such as pharmaceuticals [and] medical devices." ■

EDITORIAL

Dear Readers,

While the upcoming Trio Council presidency of France, Czech Republic and Sweden will mainly be occupied with the European health union and the revision of the EU's pharmaceutical legislation, a presidency safeguarding the Single Market is indispensable to ensure the affordability and availability of medicines in Europe. **(page 1)**

Equal access to medicines will in fact be a top priority for both the EU institutions and member states in the upcoming time, and cross-border movement of medicines cannot be overlooked when it comes to delivering on the accessibility of medicines. **(page 2)**

In a similar vein, the relocation of pharmaceutical production to Europe is high on the EU's agenda to decrease its dependency on pharmaceutical imports from third countries and tackle medicine shortages. **(page 3)**

The main goal of VAD and Affordable Medicines Europe is to ensure the availability of affordable medicines for European patients. To achieve this, we aim to contribute to ongoing debates in the field of health policies. May you discover many informative insights as you read this 76th edition of our Pharmaceutical Dialogue.

Sincerely,

Prof. Edwin Kohl
Chairman
of VAD

Jörg Geller
President of AFFORDABLE
MEDICINES EUROPE

How can we turn the Pharmaceutical Strategy into action and ensure equal access to medicines across the EU?

Photo: kohlpharma

Patients in the EU do not always enjoy the same level of access to medicines. As companies are not obliged to market a medicine in all EU countries, new therapies do not always reach the patients equally across Member States. This is more likely to happen in smaller and less wealthy markets where manufacturers might decide not to enter or withdraw from due to several factors, such as pricing and reimbursement policies and administrative procedures.

Ensuring equal access to medicines will be, therefore, a top priority for both the European Commission and Member States in the time ahead. Delivering on accessibility is also one of the key pillars of the EU Pharmaceutical Strategy and, under the upcoming revision of the pharmaceutical legislation scheduled for December 2022, the Commission is expected to put forward several initiatives to ensure patients in the EU benefit from the same level of access to medicines. These include a revised system of incentives and obligations taking into consideration the relationship with intellectual property rights, as well as improved access to generics and biosimilars.

Exploring new paths to secure access to health products

While designing incentives to boost innovation and promoting competition on off-patent medicines, fostering better possibility for cross-border movement of medicines could have a significant impact on accessibility of medicines while they are still on-patent.

To address the unavailability of medicinal products caused by non-launch or delayed launch in smaller markets, a viable and cost-effective solution is represented by parallel import. For centrally approved products (CAPs) it is possible to parallel distribute products approved by EMA in any Member State upon a notification procedure. Thus, in cases where manufacturing authorisations Holders (MAHs) refuse to launch a CAP in one or several Member States, parallel importers can step in to fill that gap and get access to those markets that the MAH chose not to enter.

Today this option is utilised in some Member States, like the Baltics, but guidance and best practice in this area could further improve the uptake, since the regulatory possibility to parallel distribute is not enough on its own. Precisely, for non-launched products prices will need to be set between the parallel importers and the national healthcare system, since there is typically no set price when the product is not launched by an MAH.

Hence, a better dialogue between the stakeholders involved should be encouraged on the example of the Baltic case, where a constructive relationship between authorities and parallel importers have contributed to ensuring the availability of products that otherwise would have not been launched. Likewise, in cases of market withdrawals, alternative supply routes for parallel trade products could be facilitated by adapting the current legal framework and utilised as a deterrent to avoid that MAHs withdraw old, lower priced products to move patients towards new more expensive drugs. Finally, it requires stronger obligations on MAH's to supply appropriate quantities in markets where the products are launched.

Policy-makers should not overlook the power of the internal market when seeking solutions to ensure equal access for all patients in Europe. ■

NEWS IN BRIEF

Affordable Medicines Europe discussed shortages and availability of medicines

On November 17th, Affordable Medicines Europe held a round-table lunch to give insight into shortages and the role of parallel trade in this. During the event, which took place in Brussels and was co-hosted by Cyrus Engerer MEP, Mr. Per Troein from IQVIA presented a White Paper on Shortages and Mr Kasper Ernest presented the new study on Trade Flow of imported medicines. Data showed that shortages were primarily found in manufacturing, and that parallel trade could not be attributed. Parallel exports primarily happen from high-income countries, which suffer less shortages. ■

EVENTS

Webinar series to zoom in on solution to the affordability of medicines

One of the main objectives of the upcoming revision of the EU's pharmaceutical legislation is to deliver on the affordability of medicines. As medicinal products take up an increasing share of health budgets in Member States, this new webinar series seek to zoom in on solutions to the affordability problem. Each of the three webinars foreseen will take a deep dive into an area that may contribute to increased affordability.

The series will consist of three webinars.

- January 11 with a first event hosted by Affordable Medicines Europe that will focus on competition in the pharma sector and will see the participation of Claudia Desogus, Adjunct Professor of the Universita' di Bologna, Søren Brenøe from Copenhagen Economics and Ilka Wölfle, Director of Deutsche Sozialversicherung Brussels.
- The second webinar, hosted by the European Public Health Alliance, will be held on January 18, and will zoom in on transparency on real costs.
- Finally, the last webinar, hosted by the European Association of Hospital Pharmacists on January 25, will tackle the issue of affordability from the procurement angle and analyse how procurement of pharmaceuticals can be improved to make medicines more affordable. ■

Relocation of the pharmaceutical industry to Europe as a strategy to re-establish the continent as the 'pharmacy of the world'?

Over the past decades, the pharmaceutical production – ranging from raw materials, fine chemicals, intermediates and APIs to finished dosage formulations - has been increasingly relocated outside Europe, especially to India and China. Once known as the 'pharmacy of the world', the EU suffered from its over-reliance on pharmaceutical products from non-EU countries during the COVID-19 pandemic. Revealed vulnerabilities in the supply chain and the lack of supply security of essential medicines in Europe placed the resettlement of pharmaceutical production back to Europe high on the EU's agenda.

Aiming for the EU's open strategic autonomy

The European Commission reacted to the EU's dependence on medicine imports in its pharmaceutical strategy, announcing measures to build up the EU's open strategic autonomy, "possibly including by diversifying production and supply chains […] as well as fostering production and investment in Europe."

As a response to the strategy, the European Parliament stressed in a resolution the need to promote the relocation of pharmaceutical production facilities back to the EU in order to regain the independence regarding its healthcare systems. To this end, members of the Parliament urged the Commission and member states to introduce financial incentives to preserve and enhance the EU's pharmaceutical industrial base.

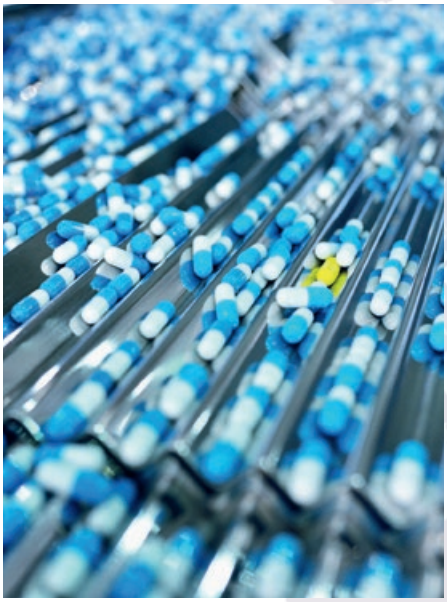

Photo: zorazhuang

A relocation of the pharmaceutical production to Europe is crucial not only to ensure a reliable and independent supply of medicines, but also to make sure that all of the EU's environmental and social standards will have to be adhered to, leading to better working conditions and stricter quality controls, in turn minimizing recalls.

Responsible pharmaceutical production within the EU

However, while the relocation of pharmaceutical production has gathered political attention, it is a long-standing development. Before taking immediate action, it is necessary to study the interdependencies and vulnerabilities in the global supply chain of critical medicines, intermediates, and APIs. Potential trade-offs in reshoring, such as increased production costs due to higher environmental standards, higher labour costs due to social regulation, and the lack of available skilled workers for new pharmaceutical factories in Europe, must be considered. Furthermore, an independent pharmaceutical supply chain runs deep - to be fully independent, a backward integration towards raw materials, fine chemicals and intermediates would be necessary. This takes time and in certain areas might be impossible altogether.

Responsible pharmaceutical production for certain classes of medicines within the EU should be a strategic target of the EU and its member states to ensure the needed autonomy and sovereignty in times of crisis. Combined with smart and resilient supply chains that spread risks across more than one supplier and country, this can be a solution. That being said, it should go hand in hand with stock keeping requirements, to guarantee that ingredients or medicines that cannot (yet) be produced in the EU are held on stock to cover a certain amount of time during emergencies. ■

NEWS IN BRIEF

Germany's coalition agreement: what's in it for health policy?

After almost two months of talks between the Social Democratic Party (SPD), the Green Party and Free Democratic Party (FDP) following the German federal elections at the end of September, Germany's coalition government took over power. Alongside leaders of the Greens and FDP, SPD the new chancellor Olaf Scholz presented the coalition agreement on 24 November. Having a functioning government in place in the EU's biggest economy comes at a right time at EU level, with negotiations on important dossiers and the French Council presidency coming up.

While differences over climate and finance policies between the three parties had to be ironed out in the final round of negotiations at the end of November, the incoming government relatively soon reached an agreement on health policy. For the upcoming government policy, the three parties intend to establish a "modern, cross-sectoral care and health policy", ensuring responsive health care and high-quality medicines as well as enabling innovation and digitalisation. By reducing bureaucratic obligations, enabling investments for production facilities and examining subsidies to ensure the security of supply, the three-party government aims to relocate the pharmaceutical production to Germany or the EU. On health financing, the coalition agreement sets out to strengthen the possibilities of health insurance funds to curb medicines prices and to apply the negotiated reimbursement price from the seventh month after market entry. Furthermore, a comprehensive digitalisation strategy intends to accelerate the implementation of an electronic patient file and enable telemedical services.

The first phase of the Structured Dialogue on security of medicines supply draws to an end.

September 29th marked the end of the stakeholder involvement in the Structured Dialogue on security of medicines supply that brought together relevant stakeholders operating in the pharmaceutical field to collect inputs on how to strengthen the resilience of pharmaceutical supply chains. The European Commission will now reflect on possible policy measures to ensure the security of supply and reinforce the EU's open strategic autonomy. ■

EXPERT OPINION

Mission (not yet) accomplished

By Thilo Bauroth

Photo: kohlpharma

Thilo Bauroth

The early years of parallel trading were characterised from the 1970s by the desire to create a common trading area. Since this period, the european internal market has emerged, accompanied by fundamental decisions which have defined the legal framework in which parallel trading operates. Better framework conditions arose in 1993, with the creation of the European Union's internal market. The single market ensured the free movement of goods, services, capital and individuals.

Parallel trading has developed into an important instrument of competition and thus cost reduction in the European Union. The objective is summarised once again in the Commission's 1998 Notice (KOM(1998) 588 final): "The purpose of completing the single market for medicines is not only to create an environment that fosters pharmaceutical innovation and corporate development, but also to improve the selection of medicines available to consumers with the required quality, safety and effectiveness at affordable prices."

It was clearly stated that parallel trading is an important driving force for market integration. This was a clear signal for the sector, for the Member States, for the pharmaceutical industry and even for the European Commission itself: parallel trading that uses price differences between different national markets inside the EU was considered to be a part of the completion of the single market.

A further, detailed principle of parallel trading is the principle of exhaustion under Community law, which characterises trademark and patent law. Initially, the importing of pharmaceuticals as part of parallel trading was very complicated. Numerous questions first had to be answered in favour of parallel trading from a legal point of view: Are statutory trademark regulations being breached if the drug is repackaged and, for example, how is a simplified licence granted?

Against this background, there were a multitude of decisions that supported parallel importing and made it more successful. The principle of free trade and the fundamental decisions improved the functioning of the single market. Naturally, this was not accepted by everybody and there were therefore constant attempts to hinder competition. In the early 2000s, numerous challenges still had to be overcome. The European Court of Justice was continually handling issues relating to protectionism in national markets. The Lelos ruling was key: In this, the European Court of Justice determined on 16th September 2008 that a manufacturer was abusing his dominant position in the market because it was not providing enough quantities so that export could be possible.

There were also constant complaints that there was a shortage of drugs, because parallel traders were apparently emptying national markets. A scarcity would always be at odds with the Public Service Obligation (PSO). Article 81 of European Directive 2001/83/EC gives Member States the option to demand that wholesalers first supply the domestic market adequately before providing goods for export. Again and again, parties with a vested interest accused parallel traders of being a gateway for counterfeit drugs. There was a lack of factual or legal evidence. On the contrary, due to it being a participant in the regular supply chain, parallel trading plays its part in ensuring a high level of security across the entire market with the implementation of the EU Falsified Medicines Directive.

Today, parallel trading is facing immense new challenges, but it will continue to be succesful. In the global battle against the Corona virus, it can offset potential supply shortages. Recently, we have seen border closures and export bans that are out of all proportion to the situation. In these cases, parallel trading can assist with ensuring the availability of medicines. As has already been the case in the past, parallel trading will make a contribution to ensuring savings, as well as offsetting incorrect allocations by the manufacturers. This benefits consumers in the form of quality medicines at good prices. The positive contribution of the parallel trading of medicines to the mitigation of healthcare costs is now firmly established. But its mission is not yet accomplished. Its position could be enhanced further if relaxations of the simplified licensing procedure are made in practice in special crisis situations, and also if price transparency is created by revising the Transparency Directive. ■

Thilo Bauroth has been in the pharmaceutical sector for around thirty years and has been working for kohlpharma in the parallel trade of pharmaceuticals since 1996. Since it was founded in 2000, he has served on the Board of the VAD (Verband der Arzneimittel-Importeure Deutschlands e.V. - The German Association of Pharmaceutical Importers). He is an expert in european developments in parallel trading. In particular, he is a keen observer of legal and regulatory developments in Brussels – as well as in the Member States.

IMPRINT

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