

PHARMACEUTICAL DIALOGUE

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INFORMATION FROM THE PARALLEL TRADE INDUSTRY

PHARMACEUTICAL & HEALTH CARE POLITICS

All eyes on the German election – what does it mean for EU (health) policy?

Following one of the most exciting federal elections in recent German history, the German Social-Democrats (SPD) secured a win in the election, achieving 25,7%. However, with the Union parties (CDU/CSU) coming in at 24,1%, followed by the Greens (14,8%) and the liberal FDP (11,5%), the results show that the leading parties need to reach a deal on a coalition to receive majority in parliament and both SPD's Olaf Scholz and CDU's Armin Laschet voiced their intentions to form a ruling coalition. With various party coalition options being possible, the following weeks will determine Germany's political future.

Germany's leading political role

Germany has repeatedly played a leading role in the health area politically, placing health policy high on the agenda at EU and global level. Under its recent Council Presidency, Germany highlighted the importance of developing 'strategic health sovereignty' and fostering European health cooperation. Similarly, Germany has stepped up as an important player on the global level, driving reform efforts of the World Health Organisation (WHO) and placing health on the agenda of the G20.

While all eyes are on Germany and much is expected from the future government both at EU and global level, European politics did not overwhelmingly feature in the election campaign of the different parties. However, with few major ideological

differences between the mainstream parties, no radical change is expected on Germany's pro-European political position.

German priorities as a driver for safeguarding European principles

In fact, when it comes to cooperation on health policy at EU level, the main political parties share a vision, supporting the creation of a European Health Union and calling for increased cooperation and coordination among member states. Furthermore, regardless the outcome of the coalition negotiations, increasing Europe's pharmaceutical independence and strengthening domestic medicine production as well as promoting the digitalisation of health care are going to be high on the agenda of all main parties.

Moreover, there are several key areas where the new German government should take a firm stance on principles essential for the functioning of the European Union. Representing the EU's biggest economy, the next government in Germany will be keen to safeguard the proper functioning of the EU's internal market and ensure the free movement of goods. Furthermore, in light of increasing healthcare costs and medicine shortages in Europe, promoting competition on the EU pharmaceutical market will be as crucial as the free movement of goods to ensure the availability of affordable pharmaceuticals in Europe. ■

EDITORIAL



Dear Readers,

All eyes were on the German election at the end of September. Regardless the outcome of the coalition negotiations, a government safeguarding the internal market and actively promoting competition is crucial to ensure the availability of affordable medicines in Europe. **(page 1)**

In fact, increased (price) competition on the pharmaceutical market through parallel trade significantly contributes to cost-effective health care for European patients, as new savings studies from German and Finland show. **(page 2)**

Moreover, a newly published study on trade flows of pharmaceuticals clearly underlines that the parallel trade of medicines is in fact not a one-way street but may be used as an effective instrument to fill the gaps caused by 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 75th edition of our Pharmaceutical Dialogue.

Sincerely,

Prof. Edwin Kohl
Chairman
of VAD

Jörg Geller
President of AFFORDABLE
MEDICINES EUROPE

Healthy competition is the road to affordable medicines



Photo: Kernick (istockphoto.com)

Ensuring patients' access to affordable medicines has become a growing challenge in most EU Member States. With the review of the pharmaceutical legislation foreseen to be presented in 2022, the European Commission has to deliver on its commitment to future-proof the European healthcare sector. This includes delivering on the increasing costs for medicines in order to ensure the sustainability of healthcare budgets.

The Commission has named several points where spurring competition is necessary. These relate to different limitations on the practical length of patent protection; e.g. enabling generics and biosimilars to be ready for launch as soon as patents expire; ensuring faster uptake of these; reducing patent-extensions via re-purposing of medicines etc. There is no doubt it will have a real effect on prices the sooner competition is allowed to enter the market.

The patent market takes up an ever-increasing share of the budget

However, fact is that on-patent products take up an increasing share of the medicines budgets in Member States. In 2011, the 1% highest specialised medicines consumed 32% of the European healthcare budgets – in 2018 this number had increased to 47% according to IQVIA. This worrying development cannot alone be addressed by what happens once products go off-patent. We are forced to look at how competition can be spurred while products are still on-patent.

The tools are in the competition toolbox – but will we use them?

Besides fighting anti-competitive behaviour from the pharmaceutical industry,

such as excessive pricing and pay-for-delay, we need to ensure healthy competition in the internal market for the on-patent medicines. Following a national investigation into the medicines market, the Swedish Competition Authority in August 2021 stated that parallel importers “are the only ones who can exert price pressure on the original manufacturers' medicines when under patent. If they [parallel imports] disappear then there will be no price pressure”. This is in line with statements from other competition authorities and independent studies into the competitive effects of parallel imports (PI).

PI in Poland (one of Europe's largest PI markets) resulted in € 721 million in savings from 2010-2018 for the healthcare payers and patients. For Denmark, Copenhagen Economics estimated the savings in 2018 at € 82 million, while in Sweden NERA and the Swedish authorities estimated savings at € 235 million. The largest savings are found in Germany where the German health insurers saved € 4.4 billion in 2020. As illustrated, PI is an indispensable asset for policymakers to foster healthy competition via the free flow of goods in the internal market. As a proven functioning tool to deliver on the affordability agenda – we should use it. All EU Member States can benefit from PI. And no - parallel exports do not lead to shortages. This is now regulated across Europe.

Transparency of prices

When looking at tools in the competition toolbox, one must not underestimate a fundamental prerequisite for well-functioning competition – transparency of prices. Unfortunately, in the EU, the price information asymmetry between buyer (healthcare payer) and seller is enormous. While public list prices are in many cases available, secret pricing agreements, managed entry agreements, secret discounts etc. obscure completely the picture. In reality, today, in getting a good price on a product, every Member State is on their own, hoping to make a better deal than their neighbours. The beneficiary of this information asymmetry at the end of the day is not the payer. We must do better in Europe. Therefore there is an urgent need for acting. ■

NEWS IN BRIEF

Revision of the Transparency Directive to ensure affordable medicines

While the current Transparency Directive aims to ensure transparent measures related to national price setting and the reimbursement of medicinal products with the objective to safeguard the proper functioning of the common market in medicinal products and encourage competition, it partly fails to deliver on these objectives. Instead, the current lack of transparency of medicines prices is significantly hindering the availability of affordable medicines in Europe. Factors such as secret price agreements, which by their 'voluntary' nature do not fall within the scope of the Transparency Directive, a lack of price transparency in public procurement as well as the exclusion of generic medicines from the scope of the Directive substantially impede competition in the European market, thus negatively affecting the affordability of medicines.



Photo: Alexandros Michailidis/istock.com

The practice of secret agreements between public authorities and pharmaceutical companies, including, inter alia, secret price discounts, clawbacks or rebate contracts, has constantly increased in some member states over the last years. These agreements, such as rebates offered, misleadingly seem to generate savings for the healthcare systems, while, in contrast, the lack of transparency potentially stabilises medicine prices at higher levels than the market would otherwise have dictated and in a spill-over effect translate into higher price levels in other member states. ■

Parallel trade flows reveal interesting dynamics in EU medicines market

A new study launched by Affordable Medicines Europe shows that 52 % of parallel exported products in 2020 originate in the 10 EU Member States with the highest GDP. This confirms the trend observed in a similar study based on 2018 numbers. The findings shed light on a market much more complex than medicines simply flowing from low-income southern and eastern countries to high-income northern and western countries. Rather trade flows in all directions, a testament to the fact that supply obligations work and that unexpected price patterns exist. Finally, it signifies that parallel trade can be used much more actively to alleviate shortages.

Supply obligations a main determinant for parallel trade

The public service obligation (PSO) for medicines established in EU law means that national patients must always be served first – before exports can take place. Therefore, parallel exports are based on excess stock in the individual markets. Hence, as a general rule, the market is driven by supply availability. Therefore, it is common that e.g. the price of a given product may be e.g. € 30 lower in Slovenia than Denmark, but due to a lack of excess stocks in Slovenia the product is not exported from there. Rather Danish imports may originate from Germany, even if the product is only e.g. € 15 lower – simply because in Germany excess stock is available. In conclusion, lowest vs. highest prices are far from the main determinant of parallel trade flows in medicines. Instead, availability of excess stocks is by far the most important driver.

Prices do not give a uniform picture

It is generally believed that low-income countries always have lower prices of medicines. However, this is not always the case. First, in the off-patent market there is no correlation between GDP-level and prices. Denmark, Sweden and the Netherlands, for example, have some of the lowest prices in the EU. Second, for the on-patent market, secret discounts and price agreements significantly blur the picture. Hence, list prices do not actually correspond to the actual price of the medicines

in many countries. In Germany, the use of secret agreements is increasing at a dramatic speed. Thus, officially prices may be high on paper, but in practice it is not the case for many expensive medicines.

Evidence on trade flows

The new study from Affordable Medicines Europe confirms also in the detail that trade is multi-directional. Looking at which countries are parallel exporting the most medicines, these are France, Germany and the UK (based on 2020 numbers, trade with UK ended only 3rd December 2020). These are all three high-income countries, and especially Germany is considered as having very high prices on average. This is also true for many products – this is why Germany is also still the largest parallel importer – but for many other products, German prices are below other countries. Poland is one of the larger parallel import markets in Europe, especially driven by imports in the off-patent branded medicines, generics, and OTC categories. Here Polish prices are, according to the Swedish Dental and Pharmaceutical Benefits Agency, around 50 % higher than in Denmark, Sweden, and the Netherlands.

Alleviating shortages with parallel imports

Based on the knowledge on parallel trade flows being multi-directional, it becomes clear that parallel trade may be an important tool in the fight against shortages. According to a study released by IQVIA, a shortage in one country is rarely equivalent to a shortage in another country and a very limited number of products have a general shortage issue across Europe. In fact, 95 % of shortages take place in only one Member State. For all these shortages, parallel imports represent a viable alternative, as excess stocks of the medicine are often available elsewhere. In practice, the flexible nature of parallel imports can be used to address shortages in a matter of days. The slow response time from manufacturers otherwise may be one of the main weaknesses in relation to shortages. Hence, parallel trade should be seriously considered as a main tool for alleviation of shortages. ■

GLOSSARY



Photo: KonjPharmia

Parallel trade as an instrument to fill the gaps

While the parallel trade of pharmaceuticals is ambiguously perceived as a one-way street where medicines are traded from lower income to higher income countries, it may be used as an effective instrument to fill the gaps caused by medicine shortages. If for example a member state experiences a shortage of pharmaceuticals due to intra-European pharmaceutical misallocation caused by inefficient supply from manufacturers, unforeseen regional supply requirements or hard to predict spikes in demand, pharmaceutical parallel trade can help, at least in part, to compensate such misallocations by exporting surplus supply from one EU member state and importing it to another one in need – regardless if the latter is a high or low income country.

A recent example occurred during the COVID-19 pandemic in Bulgaria, where in 2020 and 2021 parallel trade imported Augmentin, an antibiotic used to treat COVID-19. Due to parallel trade, the shortage of Augmentin was solved, providing patients in Bulgaria with their vital treatment. Similarly, when manufacturers in Romania withdrew Trileptal, used inter alia to treat patients suffering from epilepsy, from the market, parallel importers were able to step in and import the medicine to Romania.

These examples clearly underline two aspects: the flows of parallel trade of medicines are not unidirectional but occur in many directions and are similarly distributed across Europe. Moreover, parallel trade can be instrumental in quickly moving critical pharmaceuticals from one member state to another, if needed. ■

EXPERT OPINION

Promoting efficient tools to enhance patients' access to medicines

By **MEP Dolors Montserrat (Spain, EPP)**, Member of the Committee on the Environment, Public Health and Food Safety, Rapporteur on the Pharmaceutical Strategy for Europe



Photo: MEP Montserrat, European Parliament

While medicine shortages in Europe have been the focus of attention in recent years, the COVID-19 crisis has significantly exposed the growing threat of shortages and unequal access to pharmaceuticals. After more than one year and a half since the beginning of the health crisis, we identified some of the lessons learned for future pharmaceutical policy in Europe: promoting and accelerating the creation of a European Health Union, as well as strengthening the resilience of European health systems and ensuring the security of supply.

The Pharmaceutical Strategy for Europe addresses the latter in a series of measures. It comes at a time when it is more important than ever to ensure the access to affordable medicines and promote the competitiveness of the EU's pharmaceutical industry. The strategy constitutes a first step in overhauling the EU's general legislation on medicines in order to improve the security of pharmaceutical supply, solve unmet medical needs and increase market competition, while putting patients at the centre of EU health policies.

Putting patients at the centre of health policies – this undoubtedly implies guaranteeing the availability of affordable medicines to all European citizens. In this context, I believe that ensuring the proper functioning of the EU Single Market – one of the key principles of the European Union – and allowing effective competition in the pharmaceutical market is key to achieving this.

A functioning Single Market stimulates competition and trade, enhances efficiency, raises quality, and helps to set affordable prices to enhance access to drugs and its availability in all the Member States. In fact, in the complex and deeply regulated pharmaceutical market, fair competition constitutes one of the most effective tool to guarantee affordable medicines, motivating pharmaceutical companies to invest in innovative medical products and more affordable medicines' prices to the benefit of all the patients.

The European Health Union and the EU's Pharmaceutical Strategy constitute crucial first steps towards achieving availability, accessibility and affordability of medicines. However, to effectively tackle these long-standing problems, it is equally important to promote an efficient use of already existing tools in the area of healthcare. In line with the principle of free movement of goods, parallel trade is systematically expanding competition in the market for pharmaceutical products, providing opportunities for potential savings in health costs - to the benefit of health care systems and patients.

NEWS IN BRIEF

HERA: The EU is getting ready for future health emergencies

As part of the European Health Union, the European Commission on 16 September 2021 launched the European Health emergency preparedness and Response Authority (HERA). Filling a gap in the EU's health emergency response and preparedness, HERA will in the case of a pandemic or crisis ensure the development, production and distribution of medicines, vaccines and other medical countermeasures. The activities of HERA will be financed by a budget of €6 billion from the current multi-annual financial framework of the EU. ■

Commission President von der Leyen sets priorities in State of the Union speech

In her annual "State of the Union" speech, Commission President von der Leyen underlined the EU's progress in addressing the challenges posed by the ongoing pandemic. Furthermore, she highlighted the need to accelerate global vaccination and support measures to slow the spread of the virus. To strengthen the EU's crisis preparedness by building a European Health Union, von der Leyen proposed a new crisis preparedness and resilience mission for the entire EU, supported by investments of €50 billion by 2027. ■

The last year has proven us that only by working all together and showing solidarity, we can deliver on the availability of affordable medicines and put patients at the centre of health policies, not only in theory but also in practice. ■

IMPRINT

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