

PHARMACEUTICAL DIALOGUE **73**

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INFORMATION FROM THE PARALLEL TRADE INDUSTRY

PHARMACEUTICAL & HEALTH CARE POLITICS

Economic costs of COVID-19 putting pressure on national health systems

Healthcare costs in Europe over 2020 are a mixed bag. On the one hand, spending has stayed at 2019 levels or slightly decreased, as people postponed elective procedures or skipped preventive medical checks. However, Intensive Care Unit (ICU) beds being occupied by COVID-19 patients most likely eliminate the “savings” from skipped procedures. Therefore, the actual healthcare costs of 2020 may not be much lower than 2019 and long-term costs are still to be understood.

Healthcare systems facing hidden costs

There are also additional hidden and indirect costs that the healthcare system will have to bear. Due to the pandemic and across Europe, tens of thousands of elective procedures and outpatient appointments have been cancelled or postponed. This has relieved the immediate burden on healthcare and postponed costs, but not eliminated either. Healthcare systems will struggle to catch up with these procedures and make capacity available. Experts also predict that more care will be needed as patients have cancelled or postponed doctor visits, possibly leading to a more severe course of their illness. The activity of general practitioners in France, for instance, reportedly has dropped by 44 %, and that of outpatient medical specialists by 71 % between January and April 2020. It is still unknown what the implications for mental health will be. The lockdown is putting additional stress on individuals and families, implicat-

ing the need for additional care further down the road and once again leading to rising costs.

Mitigating rising healthcare costs

The EU is trying to mitigate this with the EU4Health program. With a total volume of € 5.1 billion, it is the largest health programme ever in monetary terms. The goal is to provide funding to EU countries and health organisations with the aim to boost the EU’s preparedness for major cross border health threats and strengthen health systems so that they can face epidemics and long-term challenges.

Today, the dilemma is clear: rising healthcare costs stand opposite of dramatic economic losses. In this environment, it becomes ever more important that all cost factors in healthcare are scrutinized. This is where parallel trade can make a difference. Through parallel trade, many patented medicines can be provided to patients at a significantly lower price than the same medicine sold by the patient holder. In Poland, for instance, parallel trade of pharmaceuticals and thus savings generated by it have steadily increased in the last years, amounting to € 124 million of savings in 2018. Nevertheless, regulatory barriers in the Polish market hinder a greater growth of savings from parallel trade, hence increasing national healthcare spending. In Poland, Germany, Sweden and Denmark alone, parallel trade generated savings of € 3.2 billion in 2018. ■

EDITORIAL



Dear Readers,

Rising healthcare costs and dramatic economic losses due to the COVID-19 crisis determine current debates on health policy. The pandemic revealed the importance of a strong and functioning cooperation and even interaction between EU and national officials responsible for policymaking in the field of health.

The special relationship between national level and European community is similarly reflected in the pharmaceutical parallel trade sector. For 21 years, VAD - as the national association of one of the biggest and most important markets for parallel trade of medicines – is a partner in dialogue at European level, engaging with policymakers and actively contributing to health debates.

For this reason, VAD is pleased to announce a cooperation with Affordable Medicines Europe (the European association of parallel importers) for the Pharmaceutical Dialogue. Founded in 1998 and under a new name since once year, Affordable Medicines Europe brings together the European pharmaceutical parallel trade industry.

Together, we will continue to bring you news from the pharmaceutical industry at EU-level. May you discover many informative insights as you read this 73rd edition of our Pharmaceutical Dialogue.

Sincerely,



Prof. Edwin Kohl
Chairman
of VAD



Jörg Geller
President of AFFORDABLE
MEDICINES EUROPE

European cooperation on pharmaceutical purchasing and pricing policy – an exception to the rule



Photo: Alexandros Michailidis/istock.com

In the global competition over access to the new developed COVID-19 vaccine, the European Commission has relied on a joint purchasing policy to secure enough COVID-19 vaccine doses for all European member states, inevitably leading to a joint pricing approach.

Joint EU purchasing and pricing policy in times of crisis

In the EU, decisions on the pricing and reimbursement of medicines fall under the competence of European member states. As a result, prices of medical products vary widely within the European Union. However, in the framework of the EU pharmaceutical strategy, the Commission proposed actions to develop cooperation on pricing, payment and procurement policies between European member states. Moreover, in the case of the newly developed COVID-19 vaccine, the European Commission presented an EU vaccines strategy to accelerate and secure the development, production and finally deployment of COVID-19 vaccines. European Commissioner for Health and Food Safety Stella Kyriakides underlined that “working together will increase our chances of securing access to a safe and effective vaccine at the scale we need and as quickly as possible.” In fact, the joint purchase strategy of the EU led to a stronger negotiation position than individual EU member states would have had and resulted in fair access to the vaccine for all citizens across the EU. By concluding Advance Purchase Agreements with

European pharmaceutical companies producing the vaccines, the Commission aimed to secure the manufacturing of COVID-19 vaccines and ensure sufficient supplies for all member states. The joint purchasing of vaccines in the EU inevitably led to a common pricing policy.

An exception to the rule rather than the rule itself

Although joint forces at EU level, showing European solidarity and ensuring a greater bargaining power, secured more COVID-19 vaccines for European citizens, a European purchasing and pricing policy generally does not have the same effect when applied to other pharmaceutical products. In fact, considering that pharmaceutical innovation is strongly driven by economic incentives, a joint EU pricing policy may undermine such incentives due to harmonised pricing decisions and hence, insufficient competition. Such a lack of competition within the EU can potentially lead to the fact that pharmaceutical companies delay the availability of their innovative medicines to European patients. Moreover, a joint purchasing policy could exacerbate shortages of medicines due to applied supply quotas. Shortages may be further aggravated by issues linked to a joint pricing policy, such as cost-cutting measures causing manufacturers of generic medicines to withdraw from the market.

Member states’ autonomy in pharmaceutical pricing decisions however is subject to EU transparency laws. The Transparency Directive aims to guarantee the transparency of medicines prices, prevent any distortions of the EU internal market caused by, inter alia, secret price agreements and foster competition in the EU pharmaceutical markets. While the directive lays down high-level controls such as time limits and an appeal mechanism, it does not address the merits of pricing decisions. Based on this, we encourage EU policy makers to focus first on transparency, which is an important and much-needed step, before attempting to overhaul the national competence of price setting – which is unlikely to happen. ■

NEWS IN BRIEF

Commission calls for preserving the internal market and free movement of goods

On 19 January, the European Commission presented several measures to combat the COVID-19 pandemic. In particular, the Commission urged European member states to maintain the single European market and the free movement of goods, stressing that export restrictions on medicines and medical products, as imposed by some member states at the beginning of the pandemic in March last year, significantly weakened the internal market. Furthermore, the Commission underlined the importance of maintaining the system of “Green Lanes” to keep transport flows moving and avoid any supply chain disruptions in the EU. ■

Commission implements EU authorisation mechanism for exports of COVID-19 vaccines

On 29 January, the European Commission introduced a transparency and authorisation mechanism for the export of COVID-19 vaccines outside the EU. With the mechanism, the Commission aims to ensure timely access to the vaccines for all European citizens and increase transparency of vaccine exports. The mechanism, which is in place until the end of March, requires pharmaceutical companies to notify the respective authorities of the Member States about its intention to export COVID-19 vaccines produced in the EU to third countries. ■

Commission launches structured dialogue initiative on security of medicines supply

At the end of February, the European Commission launched a structured dialogue on the security of medicines supply with actors in the pharmaceuticals manufacturing value chain, public authorities, research community, health professionals and patient organisations. The objective of the dialogue is to enhance the resilience of pharmaceutical supply chains and ensure the security of supply of affordable medicines in Europe. The structured dialogue initiative, which is part of the EU Pharmaceutical Strategy published by the Commission in November of last year, aims to achieve results by the end of this year. ■

European solidarity in action during the COVID-19 health crisis

Soon after the global outbreak of the COVID-19 crisis, the World Health Organisation (WHO) declared Europe the active centre of the pandemic with several member states being among the most affected countries in the world. While the crisis revealed a general lack of preparedness for such major cross border health threats and severe shortcomings in national health systems, it also showed new opportunities for cooperation and solidarity across Europe.

European solidarity in action

While the principle of solidarity is central to the EU's values and widely embedded within the legal framework of the EU, there was hardly any other time when solidarity in action counted more. With the outbreak of the COVID-19 crisis, the principle in theory had to be confronted with the reality of the EU's reaction to the health threat. While, in line with EU treaties, the primary responsibility for health protection and thus COVID-19 response measures lies with the member states, countries and regions across the EU increasingly showed solidarity in facing the pandemic.



Photo: apratt/istock.com

At the outbreak of the health crisis and in the time thereafter, European member states have supported each other in offering medical services and equipment and specialised personnel. With Italy being hit hard at the beginning of the pandemic, Germany, Poland and Romania, for instance, have sent teams of doctors to support the treatment of patients in the North and South of Italy. In the same vein,

medical masks, ventilators and other hospital equipment have been delivered to those countries and regions in need. Moreover, member states have come together in providing consular support and repatriating European citizens from countries outside of the EU.

A functioning EU Single Market as strong crisis response

In the context of the European Single Market, the corona pandemic, nevertheless, constituted a severe test for European solidarity. At the onset of the crisis, some EU member states initially reacted to the pandemic by restricting the free movement of medical products through export bans. While some export restrictions affected pharmaceuticals being essential and short for the treatment of COVID-19, several member states imposed bans on medical products neither related to the treatment of the virus, nor at risk of shortages in the exporting member state.

These protectionist national measures affect the global pharmaceutical supply chain and thus, may result in a lack of pharmaceutical supply and medicine shortages in the EU and worldwide. Export restrictions on medical products are not only detrimental to those member states hit hardest by the COVID-19 crisis, but also for the countries imposing them, since they are just as dependent on medical supplies and pharmaceuticals from other countries. The European Commission quickly condemned these measures, urging member states to "preserve the free circulation of all goods and guarantee the supply chain of essential products such as medicines and medical equipment".

Solidarity shown in the framework of the Single Market is crucial for a strong European response to the COVID-19 crisis. The sound functioning of the Single Market is not only inevitable for ensuring the supply and availability of medicines, but also for increasing the affordability of medical products. The Single Market and the free movements of goods guarantee the parallel trade of pharmaceuticals, which, in turn, generates significant savings for national health systems. ■

GLOSSARY



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Public health policy in the European Union

Pharmaceutical policy in the European Union is governed by a unique combination of the EU's horizontal objectives as well as the policies and objectives of member states' healthcare systems. In fact, according to Article 168 of the Treaty on the Functioning of the European Union, national governments are responsible for the organisation and delivery of health services and medical care, including pharmaceutical pricing and purchasing policies. The role of the European Union is therefore to complement national healthcare policies and help them achieving shared objectives, such as the protection of EU citizens' health, the modernisation of health infrastructure and the improvement of the efficiency of European health systems. ■

EU4Health: the EU's € 5.1 billion health programme

The EU's health programme "EU4Health" is a funding programme within the framework of the EU's next multiannual financial framework for 2021-2027. With a dedicated budget of €5.1 billion, the EU aims to address shortages exposed during the COVID-19 crisis, strengthen the resilience of national health systems and promote innovation in the health sector. In particular, the new programme will increase the EU's preparedness for future cross border health threats, support member states in developing quality health standards, improve accessibility, efficiency and resilience of health systems and promote the digital transformation of health systems. 20% of the dedicated budget are reserved for disease prevention and health promotion in an ageing population. EU4Health constitutes the fourth and largest of the EU Health Programmes since their adoption in 2003. ■

EXPERT PORTRAIT

Proven cost-containment instruments

With **Erwin Rüdchel**, Member of the German Bundestag (CDU) and Chairperson of the health committee

Photo: Erwin Rüdchel



We have been very fortunate to have had a degree of financial leeway in the healthcare system in recent years thanks to the economically strong years of the past. Nevertheless, it was of course always necessary to remember that financial resources are limited, with the situation being heightened by demographic changes and the rising costs resulting from technological advances.

The current coronavirus pandemic has now significantly exacerbated this situation, as costs have risen significantly due to the pandemic and, at the same time, revenues have decreased due to the economic slump. As a result, structural reforms that were at any rate already in the pipeline must now be tackled urgently in order to use the available funds efficiently. In my opinion, we primarily need hospital reform that includes better cross-sector care. In the pharmaceutical sector, we face the problem that costs for new drugs – especially for personalised medicines – can really explode and thereby ruin smaller health insurance companies. We have to urgently develop new financing models to accommodate this.

At the same time, however, we are already using several proven cost-containment instruments, especially in the pharmaceutical sector. These are, of course, primarily the German Pharmaceuticals Market Reorganisation Act (AMNOG) and the discount agreements, but we also save money in the healthcare sector as a result

of parallel imports, which allow us to benefit from differing international prices for the same products.

After the scandal over parallel imports a few years ago, it is important for me to stress that we must be able to trust that imported medicines are safe and effective. And we must also be able to trust that there will be no supply bottlenecks in the countries from which the pharmaceuticals are exported. That is an integral part of good European cooperation in the healthcare sector. The black sheep in the industry have done parallel imports – a process that I consider to be an important tool for controlling costs – a disservice by reigniting the discussion about their possible abolition.

That is why it is very important that there are serious and reliable companies that provide parallel imports. So far, the parallel traders have always proven to be trustworthy partners. ■



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NEWS IN BRIEF

Portuguese Council Presidency present priorities in the area of health

At the beginning of February, Portugal presented the priorities of its EU Council Presidency in the area of health. According to Portuguese Minister of Health Marta Temido, Portugal will focus on strengthening the EU's capacity to respond to public health crises and moving forward with building a European Health Union. Moreover, the Portuguese Presidency aims to increase sustainable and universal access to medicines and medical devices as well as to promote digital health.

In the framework of the EU vaccination strategy, Portugal will focus on the implementation of the EU export licensing scheme for COVID-19 vaccines, which has entered into force until end of March. In the context of the EU Pharmaceutical Strategy published by the European Commission in November 2020, the Portuguese Presidency will also address issues such as Europe's pharmaceutical production capacity and the availability of critical raw materials. The next EU summit takes place at the end of March. ■

Commission publishes action plan on European pillar of social rights

At the beginning of March, the European Commission published the European Pillar of Social Rights action plan, outlining concrete actions and measures to achieve a fair, inclusive and resilient socio-economic recovery from the COVID-19 crisis. In the area of health, the Commission aims to propose new tools to better measure barriers and gaps in access to healthcare as well as the European Health Data Space, aiming to ensure better healthcare, research and policy-making. ■

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