VAD
German Association
of Pharmaceutical
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COST EFF
alliance for cost-efficiency in healthcare

PHARMACEUTICAL DIALOGUE 70

+ + + INFORMATION FROM THE PARALLEL TRADE INDUSTRY + + + JUNI 2020 + + +

PHARMACEUTICAL & HEALTH CARE POLITICS

How COVID-19 challenged a core pillar of the EU – the European Single Market

While countries worldwide increasingly begin to lift lockdown measures due to decreasing numbers of COVID-19 cases, the crisis is far from over. The severe health threat is further compounded by the economic and societal fallout, which has hit hard on Europe. Measures taken by the European Union, its member states and European solidarity were - and still are - crucial for a strong and effective European response to the coronavirus crisis.

The Single Market as the EU's weapon

Nevertheless, some EU member states initially reacted to the COVID-19 crisis by restricting the free movement of medical products through export bans. Whereas these restrictions may apply to pharmaceuticals being essential and short for the treatment of the virus, aiming to safeguard national supply, some opted to expand the ban to medicines, which are neither related to the COVID-19 treatment, nor at risk of shortages in the exporting member state. Thus, the crisis highlights the challenge not only for national health systems, but also for one of the basic foundations of the EU, the Single Market.

Ensuring the smooth functioning of the Single Market will be indispensable for Europe's recovery and its economic well-being. On the consumer side, the benefits of the internal market are reflected in the form of reduced prices, higher quality and safety standards, greater choice and innovation. EU businesses benefit from increased commercial opportunities and easy access to a wide range of suppliers. Moreover, while the EU's internal market has already been deemed as its "hidden weapon in combatting COVID-19", it plays an equally crucial role for European patients. Equal access to and availability of affordable medicines – also through parallel trade - depend on the sound functioning of the internal market and is now, more than ever, even a question of European solidarity.

European solidarity in real life

As a response to disruptive barriers to the EU's internal market imposed by member states, the European Commission adopted a series of measures: the lifting of national export bans on medical supplies; the introduction of "green lanes" at border crossings for the continued movement of goods and essential services; and European wide public procurements for medical equipment.

Most governments complied with the Commission's calls to refrain from adopting measures jeopardising the free movement of goods, to avoid stockpiling and to lift export bans on pharmaceuticals. Such restrictions are not only detrimental to those member states hit hardest by the crisis, but also for those countries imposing them, since they are just as dependent on medical supplies from other countries. Ensuring the smooth functioning of the Single Market and enabling the parallel trade of pharmaceuticals – in times of crises more than ever - shows European solidarity in real life. ■

EDITORIAL

Dear Readers,

Countries worldwide increasingly ease lockdown measures after numbers of COVID-19 cases decrease, but the health crisis revealed important shortcomings to be addressed in the next years. With member states restricting the intra-community movement of pharmaceuticals through export bans, the functioning of the European Single Market is at risk. **(page 1)**

Moreover, the COVID-19 crisis resulted in increasing calls from policymakers and national governments to develop a new "EU Health Strategy", aiming to increase EU sovereignty on medical products and pharmaceuticals. **(page 2)**

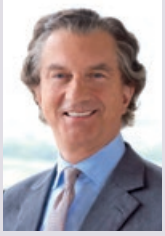
As Europe and the world are facing one of the most severe health crises in recent years, European solidarity becomes more important than ever. Export restrictions of medical products not only jeopardise the European Single Market, but also undermine the principle of European solidarity.

VAD remains committed to ensure the availability of affordable medicines in Europe. However, member states' adoption of export restrictions may significantly endanger the impact that parallel importers have on the security of medicine supply in Europe. We believe that in this moment of crisis, it is of utmost importance to work in solidarity and maintain the functioning of our internal market.

Sincerely,

Prof. Edwin Kohl

Chairman of COSTEFF
and the VAD



Increasing calls for greater EU health independence

Photo: dem10/istock.com

The COVID-19 pandemic brought to the forefront not only shortcomings in the health systems of many member states, but also severe challenges related to the supply and availability of (critical) medical products in the European Union. These challenges revealed the EU's over-reliance and dependency on active substances and pharmaceutical products from non-EU countries.

Public health as a shared competence

Public health policy in the EU is governed by a unique combination of the EU's horizontal objectives as well as the policies and objectives of member states' healthcare systems. National governments hold primary responsibility for the organisation and delivery of health services and medical care, whereas the European Union's role is 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.

The COVID-19 crisis has aggravated the performance of several countries, which were already experiencing challenges related to the resilience, accessibility and efficiency of their health systems. In the wake of the ongoing crisis, the European Commission proposed country-specific recommendations urging each member state to increase its efforts and take steps to enhance the resilience of its national health system and ensure the supply of medical products in May.

Greater EU health independence

In the framework of a joint COVID-19 recovery proposal, French President Emmanuel Macron and German Chancellor Angela Merkel called for a new European approach to health crises and greater EU health sovereignty. With a new EU "Health Strategy", the Franco-German couple aims to develop a strategically positioned European pharmaceutical industry. This industry will "in full respect of the Member States' responsibility for their healthcare systems, upgrade the European dimension of healthcare and reduce EU dependency". With the medical supply chain becoming increasingly global, the manufacturing of many medical products, especially generics, and active ingredients for European pharmaceutical companies has been relocated to China and India.

Therefore, the Franco-German initiative proposes, inter alia, to strengthen European capacity on research and development for vaccines and treatments; establish common strategic stocks of medicines and encourage production capacities for pharmaceuticals in the EU; coordinate European procurement policies regarding future vaccines and treatments; and set up an EU "Health Task force" to develop prevention and crisis management plans.

Stronger EU health policy with a larger budget

Together with an ambitious EU recovery instrument, the European Commission also proposed a stronger health policy with an increased budget. With a total of € 9.4 billion, the Commission's new "EU4Health Programme" suggests lines along which such a European health sovereignty may be established. In particular, the programme aims to improve the EU's crisis management capacity; make medicines, medical devices and other medical products available and affordable; and enhance national health systems and the health care workforce.

One of the main lessons learnt from the ongoing crisis is to build up European sovereignty, particularly in the health sector. Only then the EU and its member states are able to better respond to health crises and reduce the EU's dependency on foreign suppliers. ■

NEWS IN BRIEF

Commission publishes Roadmap on Pharmaceutical Strategy

On 2 June 2020, the European Commission published its roadmap on the EU pharmaceutical strategy. The strategy, which will be published at the end of the year, aims to improve and accelerate European patients' access to safe and affordable medicines and to strengthen innovation in the European pharmaceutical industry. According to the roadmap, the strategy will ensure greater access, availability and affordability of medicines, thereby contributing to the sound functioning of the internal market. Moreover, with the EU strategy, the Commission aims to enable innovation and foster the EU's pharmaceutical competitiveness on the global level, incorporating lessons learnt from the COVID-19 pandemic. ■

The European Consumer Organisation calls on the EU to step up action on medicines shortages

In a report on "Addressing medicines shortages during the COVID-19 pandemic and beyond", the European Consumer Organisation (BEUC) urges the EU to increase its efforts to ensure the availability of medicines to treat both COVID-19 and other diseases at any time. Therefore, BEUC calls on the EU, inter alia, to ensure effective communication among Member States about anticipated or actual pharmaceutical shortages; to include common terminology for medicines shortages and criteria for reporting by pharmaceutical companies in the EU legislation; to enable consumers to report on medicines shortages and their impact; to assess the impact of intra-EU parallel trade; and to explore means to enhance the EU's supply robustness. ■

Photo: sanjagrujic/istock.com

Parallel imported pharmaceuticals generate high indirect savings: the Swedish Case study

The COVID-19 pandemic had a strong impact on EU member states' budget and in the following years, a big share of it will be used for economic recovery. Now, more than ever, it is crucial to reduce pharmaceutical expenditures. Parallel imports of pharmaceuticals play a crucial role, providing European patients with more affordable medicines, respecting high standards of quality and safety. Economic studies, published shortly before the COVID-19 outbreak, demonstrate the significant impact of parallel trade on total savings for national health budgets in Germany, Sweden, Denmark and Poland. The total savings in these four markets amounted to € 3.2 billons in the year 2018 alone. A study published in 2019 by Nera Economic Consulting investigates the saving potential of parallel imported pharmaceuticals for the Swedish health care system.

The third biggest parallel import market

In Sweden, patients are charged for visiting general/specialist practices, hospitalisation and prescription medicines with payments capped to a yearly out-of-pocket expenditure of € 107 (SEK 1,100). The Dental and Pharmaceutical Benefits Agency (TLV) approves the national reimbursement price which is applicable to both originators' and parallel importers' products. The price of pharmaceutical products, which manufacturers and parallel importers set, will be inevitably linked to the reimbursement price of the Agency's benefit scheme. In 2017, the TLV generated between €50 and €70 million direct savings per year (SEK 500-700 million) by parallel traded pharmaceuticals. Direct savings reflect the price difference between the parallel imported pharmaceutical and the more expensive originator's product.

Parallel imports stimulate price competition

In 2018, sales of parallel imported medicines amounted to € 400 million, which is approximately 13 % of the total sales of pharmaceuticals in Sweden. The study showed that in the time frame of July 2015 to June 2018, there are product groups on the Swedish market for which the correlation between originators' prices and parallel trade market shares is positive. This finding can be explained by competitive pressure, indicating that even when the originator's price is increasing, parallel imports might prevent even larger increases by their market shares. Furthermore, the positive correlation may be explained by manufactures' preference not to affect the external reference price in other markets in order to avoid a greater loss of revenue in these countries.

Indirect savings through parallel traded pharmaceuticals in Sweden

However, the study clearly underlined that there are products on the Swedish market for which changes in originators' prices are very much aligned with the strength of market presence by parallel importers, leading to indirect savings. These savings reflect the difference between the original manufactures' calculated monopoly prices and the observed prices when there is competition resulting from parallel imports. The study found that indirect savings in Sweden represent 12.3% of the originators' revenues for those products with negative correlations facing parallel trade entry.

Since the study only considered medicines sold in pharmacies but not the medicines dispensed in hospitals, the indirect savings might be underestimated. Nevertheless, indirect savings in Sweden account for € 175.4million (SEK 1.8 billion) in 2018, leading to total savings of 17 % of the originators' revenue. ■

NEWS IN BRIEF

Commission urges Member States to strengthen resilience of national health sectors

On 20 May 2020, the European Commission adopted proposals for country-specific recommendations providing economic policy guidance to all EU Member States in the context of the COVID-19 crisis, calling on a coordinated response. In light of the most urgent health challenges brought about by the pandemic, the Commission's recommendations place a specific emphasis on investing in public health and strengthen national health systems.

The recommendations underline that the health crisis caused by the COVID-19 pandemic has revealed an urgent need to ensure and strengthen the resilience of the EU's national health systems. This particularly concerns the capacity of national health systems to efficiently tackle unforeseen crisis, such as the COVID-19 epidemic, and long-term structural changes to better prepare and equip for any potential future crises. Unmet needs for medical care for patients, insufficient capacity of the primary care sector und untapped potential for the usage of e-Health services are among the shortages identified by the Commission. Moreover, the Commission addresses long-term issues such as working conditions of doctors and nurses and shortages of health workers, as well as insufficient financing of certain areas with national health systems. ■

Photo: HRAUN/istock.com

EXPERT OPINION

Challenges of the COVID-19 crisis need to be tackled

With Mr. Peter Liese (EPP), Member of the European Parliament

Photo: Peter Liese

In the current situation, we all focus on maximizing European cooperation to provide a vaccine and/or drug against COVID-19 as soon as possible. In this process, Europe plays a key role in both research and development and in authorisation and production. We know: All vaccines approved and authorised in Europe are safe. This must and will also apply to a vaccine against the coronavirus. An attitude such as that of US President Donald Trump, proposing to inject people with disinfectant, is dangerous. We must proceed quickly, efficiently and, above all, seriously. Wherever a drug or vaccine is first developed, it must be distributed according to medical criteria. Moreover, a worldwide supply as rapid as possible is crucial. Therefore, international cooperation instead of individual national action is necessary.

In recent weeks, however, we witnessed shortcomings which we in Europe must take responsibility for. Increasingly shifting the production of active substances and medicines to Asia turned out to be a hasty and perhaps reckless step. At the same time, this has clearly underlined that bringing back and establishing production sites in the EU is crucial, especially in the event of supply shortages from China or India.

Therefore, I appreciate the results of the informal conference of European health ministers on 12 May 2020, where discussions focused on the topic of reliable and uninterrupted access to medicine in Europe. Pre-existing problems regarding the supply of key pharmaceuticals in Europe have become increasingly visible during the current COVID-19 pandemic. The intensified cooperation both between Member States and with the European Commission to ensure that access to affordable medicines is always guaranteed are to be welcomed.

We need to discuss the means of increasing and strengthen the medicine production in the EU, but we must also ensure that citizens and hospitals anytime have secured access to the medicines they need. Moreover, taking a closer look at the pharmaceutical market within the EU will also be a crucial part of a European dialogue on the supply of medicines. It is necessary that, in the future, we strike a better balance between the secure supply to national markets and the free movement of goods within the EU. As the European Parliament, we also bear the responsibility for ensuring that the focus is ultimately on the needs and interests of patients – on this, we must work more intensively in the future. ■

IMPRINT

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CALENDAR

30 JUNE – 3 JULY 2020
VIRTUAL CONFERENCE

DIA Europe 2020 – Healthcare Conference

The DIA Europe 2020 Annual Meeting brings together innovators from across the healthcare spectrum. Actors from the entire healthcare value chain, including regulators, HTAs, patient advocacy groups, and industry representatives come together to combine European insights with global perspectives on pharmaceutical development. Discussions focus, inter alia, on clinical development, regulatory science, data and data Standards, medical affairs and patient engagement.

For further information, please see:

https://www.diaglobal.org/en/flagship/dia-europe-2020

27 – 28 JULY 2020
BERLIN, GERMANY

International Forum on Epidemiology and Public Health

The forum on epidemiology and public health provides a platform for exchanging information and enhancing research on current public health challenges and developments. The conference will bring together researchers, public health professionals, healthcare providers, scientists, healthcare workers and academics.

For further information, please see:

http://globalhealthcareconferences.com/europe/

29 – 30 JULY 2020
VIRTUAL EVENT

Regulatory Science Forum 2020

The Regulatory Science Forum, organised by DIA, is a platform for sharing knowledge derived from regulatory science research and analyses conducted at the academic, industry and regulatory levels, promoting open dialogue between all stakeholders. In particular, the Forum will discuss areas, where more research on pharmaceutical policy, analysis and regulatory science is needed.

For further information, please see:

https://www.diaglobal.org/conference-listing/meetings/2020/05/regulatory-science-forum