

PHARMACEUTICAL DIALOGUE 71

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

PHARMACEUTICAL & HEALTH CARE POLITICS

Beyond COVID-19 – The future of EU health policy after the crisis

The COVID-19 health crisis has strongly impacted most countries around the world. It revealed severe under-performances in national health systems and alarmingly consumed government's health budgets.

In the EU, calls for the bloc's independence from imports of active substances and pharmaceuticals from non-EU countries increased, and voices to enhance national health systems' resilience and demanding a larger health budget were raised. In the crisis' direct aftermath, it became evident that EU health policy will face change by the lessons learned from the pandemic.

German Council Presidency and the EU healthcare agenda

Germany took over the Presidency of the Council of the EU at the beginning of July. The circumstances of the Presidency were quite different from original intentions: the EU's recovery from the pandemic and shortcomings in public health policies revealed by the crisis became the main political priorities for the second half of the year. During its presidency, Germany aims to discuss approaches for improving the pharmaceutical supply chains, including the retrieval of the pharmaceutical production in Europe; strengthen the EU's crisis management; further facilitate pan-European exchange of healthcare data and develop an EU-wide warning system for health emergencies.

EU's future role in the health sector

The underlying main question, which has increasingly been raised during the health crisis, however, concerns the EU's future role and competences in health policies. The European Parliament, on the one hand, called for stronger cooperation in the area of health and the creation of a European Health Union, including common EU-wide minimum standards for quality healthcare. The European Commission's original proposal of a stronger health policy with an increased budget amounting to a total of €9.4 billion, on the other hand, suggested lines along which health would be firmly established as a key priority in the aftermath of the crisis.

Health as a key priority?

However, at the end of July, after intensive negotiations of the EU's budget and recovery fund, EU leaders agreed to make large cuts to the EU's health programme, which was reduced from initially proposed €9.4 billion to €1.7 billion. The budget for the implementation of the EU's research programme 'Horizon Europe' has also, although less drastically, been reduced.

The significantly reduced financial envelope proposed for measures in the health sector jeopardises the ambitions raised during the crisis of incorporating the lessons learned from the pandemic into future health policy making. Despite healthcare primarily falling within the competences of EU member states, it is crucial, now more than ever, to invest in health to enable Europe to be better prepared for future health crisis. ■

EDITORIAL

Dear Readers,

Although the very first shock of the COVID-19 pandemic might be over, consequences of the health crisis continue to unveil. Now, the EU faces the urgent need to proactively incorporate the lessons learned from the COVID-19 pandemic into future health policy making. **(page 1)**

As the European Union continuously faces challenges related to access and availability of affordable medicines, it is crucial, now more than ever, to ensure a single market for the good functioning of pharmaceutical parallel trade. **(page 2)**

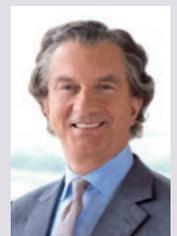
A recently published study analysed the origin of parallel imports of medicines across Europe. The results clearly object the widely spread accusation that pharmaceutical parallel exports originate from low-income countries but demonstrated instead that almost all countries in Europe export medicines. **(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. May you discover many informative insights as you read this 70th edition of our Pharmaceutical Dialogue.

Sincerely,



Prof. Edwin Kohl
Chairman of VAD



Pharmaceutical parallel trade – passing on the benefits to European patients

The current health crisis, one of the most severe health emergencies the world has faced, has significantly heightened debates in the political sphere on the access to and availability of affordable medicines in Europe, medicine shortages and the EU's dependency on pharmaceutical imports from third countries, mainly from Asia. The term of 'pharmaceutical parallel trade' has popped up occasionally within the context of these debates – but what exactly is parallel trade of pharmaceuticals, or how does it affect national health systems?

Parallel trade and the Single Market

According to the European Commission, parallel trade of medicines “involves importing the product into one Member State from another and then distributing it outside of the distribution network set up by the manufacturer or his/her authorised distributor”. Once re-labelled in compliance with national legislation of the recipient country, the imported products can be sold to authorised wholesalers, or directly to pharmacies in the recipient country. In economic terms, parallel trade is driven by differing price levels for pharmaceuticals within the EU, which are the result of different national regulations and/or different price policies of manufacturers for different national markets.

The commercial practice of parallel trade operates on the principle of the European Single Market, more specifically, on the free movement of goods between EU

member states. As such, the free movement of goods implies the protection of parallel imports as a tool for achieving and maintaining the Single Market and hence, the elimination of restrictions and unnecessary barriers – such as custom duties or export bans - to the free trade of pharmaceuticals between EU member states.

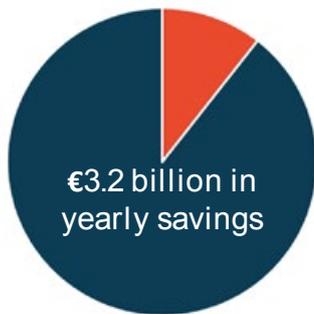
Ensuring the availability of affordable medicines

Parallel trade in medicines creates significant financial benefits in the form of direct and indirect savings. Direct savings result from the price differences between parallel imported medicines and more expensive original medicines, whereas indirect savings occur from price reductions caused by increased competition on the pharmaceutical market. In fact, several studies underlined that pharmaceutical parallel trade significantly contributes to cost-effective, high-quality health care for European patients. In 2018, savings potential in Poland, Germany, Sweden and Denmark alone amounted to 3.2 billion euros. Thus, it may be argued that parallel trade is the most efficient and strongest tool to make medicines more affordable.

In the context of the COVID-19 crisis, which has aggravated challenges related to the resilience of national health systems and shaken member states' health budgets, parallel trade can play an essential role in the reduction of health expenditures of governments.

A solution to medicine shortages

Not only in times of crisis parallel trade of medicines is exposed to wrong accusations. Often, its responsibility for the existence of shortages of medicines in Europe is claimed. However, in addition to the financial benefits explained above, parallel trade can help fill the gap caused by medicine shortages: if a member state experiences a shortage of pharmaceuticals due to inefficient supply from manufacturers, parallel trade fills the gap by taking surplus from another EU member state and delivering it to the recipient country. Hence, it becomes clear that parallel trade is part of the solution, not part of the problem. ■



Graphic: Affordable Medicines Europe

- Direct savings = €360 million
- Indirect savings = €2,883 million

German EU Presidency outlines main priorities in health sector

On 1 July 2020, Germany took over the Presidency of the Council of the EU and presented its main priorities for the upcoming six months. Drawing lessons from the COVID-19 crisis, the Presidency is focusing on improving the supply of pharmaceuticals, medical products and personal protective equipment in the healthcare sector. In this respect, the German Presidency aims to take measures to achieve greater autonomy in the EU regarding safeguarding the supply of medicines. Moreover, creating a European health data space, increased coordination of EU health policies and improving crisis management are among the German priorities. ■

European Commission supports initiative to facilitate international trade in healthcare products

Following a first discussion among trade ministers from European member states, the European Commission underlined its ambitions to establish an international initiative to facilitate trade in healthcare products with a group of partners from the World Trade Organization. A future agreement aims to address ongoing challenges on the access to affordable medicines and medical producers as well as on trade disruptions in times of crisis. The Commission outlined the framework of a potential agreement, which would abolish tariffs on pharmaceutical and medical goods and create a scheme of global cooperation in times of health crisis, covering topics such as import and export restrictions, public procurement and transparency. ■



Graphic: KohnPharma

Study on trade flows of parallel imported medicines: Parallel trade is not a one-way street

Parallel trade of medicines is constantly exposed to accusations, both from individual representatives within the pharma industry and lobby associations. One of the increasingly emerging accusations includes the functioning of parallel trade as a one-way street - with medicines being traded from lower to higher income countries. Against this background, a recently published study by Affordable Medicines Europe, representing Europe's licensed parallel distribution industry, clearly showed the contrary. The study analysed the origin of parallel imports of medicines across Europe with the aim to shed light on the trade flows of parallel imported pharmaceuticals, filling a gap in the ongoing debate on parallel trade in the EU.



Graphic: Affordable Medicines Europe

Origin of parallel imported medicines

The findings of the study are based on data from fourteen European countries, covering 85% of the total sales of parallel imports in Europe. Countries included in the study are Austria, Belgium, Bulgaria, Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Norway, Poland, Spain and Sweden. The data used within the study contains the original source country of the imports by country in percentage of value and their market share. In the framework of the study, the origin of parallel imports is understood as the location where the imports were originally marketed by the pharmaceutical manufacturer to then be transferred to another country by parallel trade.

The analysis of the data received showed that on average, 51.3% of parallel imported pharmaceuticals in Europe originate from high-income countries. The same trend can similarly be observed at national level: in nine out of fourteen countries, more than 50% of parallel imports have their origin in countries with high income per capita. Among the countries considered in the study, Spain has the highest proportion of its parallel imported medicine coming from high-income countries, amounting to 67.1% of its total parallel imports. Furthermore, the study revealed that France and the United Kingdom are the main sources of pharmaceuticals in the EU in terms of total volumes. Hence, the distribution of pharmaceuticals in Europe with regard to the direction of trade flows of parallel imported medicines is rather balanced.

Bringing the right products to the right place

A further analysis was conducted to study parallel exports of pharmaceuticals per capita. The results clearly revealed that countries considered as lower-priced exporting countries – including Hungary, Italy, Poland, Spain, Croatia and Portugal – export far below the European average. Instead, high-priced countries such as Norway, Austria, the Netherlands and Belgium are located above this export average. In particular, the study showed that Norway is the largest exporter of medicines per capita.

Thus, the study significantly objects the assumption and widely spread accusation that pharmaceutical parallel exports originate from low-income countries. In contrast, it clearly showed that almost all countries in the EU export medicines with low-income countries even exporting below the European average. The fact that medicine prices are decided at national level and are not homogenous across Europe furthermore supports the findings of the study that parallel trade of medicines is not interrelated with the income level of a country, but purely with the price of individual medicine concerned.

Agreement on EU's 2021-2027 budget falls short on support for health sector

On 21 July 2020, after intensive negotiations at the EU summit, the heads of state or government of EU member states agreed to a comprehensive package of €1 824.3 billion which combines the EU's multiannual financial framework (MFF) 2021-2027 as well as the EU's recovery fund to help rebuild the economy after the COVID-19 pandemic. The EU's recovery fund will consist of €390 billion in grants and additional €360 billion in loans.

However, in the course of the negotiations, cuts were made to the long-term EU budget, concerning the funding for proposed EU programmes and initiatives, including the new "EU4Health" initiative proposed by the European Commission. The financial envelope proposed for the new health programme, with which the EU aims to respond and tackle the health challenges of the COVID-19 crisis and strengthen health systems, was reduced from €9.4 billion to €1.7 billion. Moreover, the budget of the Horizon Europe programme, designed to foster innovation and research, has also been reduced to €80.9 billion, as compared to the initial proposal of €94.4 billion published by the European Commission.

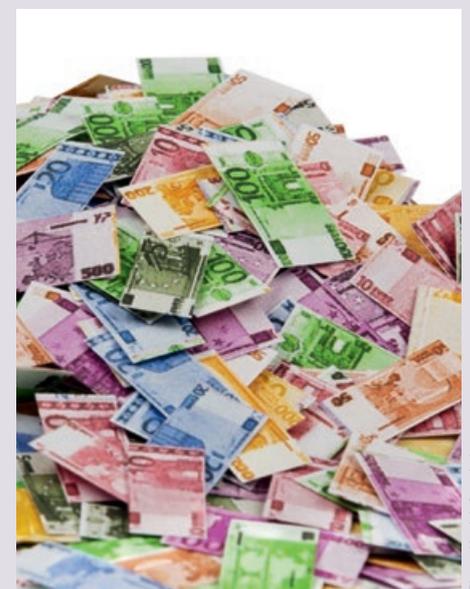


Photo: Kerrick (istockphoto.com)

EXPERT OPINION

**“What ever it takes“ –
defend single market at any time****With Jörg Geller, President of Affordable Medicines Europe, Brussels**

Photo: Kohlpfahma

The European Union is often accused of being a bureaucratic monster far removed from the needs of European citizens. Politicians and government representatives from member states pushing responsibility for critical topics or unfavorable developments away from their responsibility and blaming “those in Brussels”. But we should never forget that the European Union is not some third party or this far away unfriendly uncle rarely invited to family parties – the European Union is our family and it is the biggest and most successful peace project in the human history. We should

never forget the basic idea shortly named with “Peace and prosperity by Free trade”.

Nearly 70 years after the remarkable post-war initiative of Robert Schuman the “European Union” of 2020 involuntarily has proven that solidarity and the long time common understanding of this supranational institution is no longer self-evident but requires maintenance and hard work. As the Corona pandemic broke out, governments around the world resorted to national approaches in the fight against the uncontrolled spread of this new virus. This led us to lockdowns and border closings. Unfortunately, such approaches were counterproductive, and only exacerbated problems. Medicines could not reach the patient most in need, medical equipment was not available to nurses and doctors in the hardest hit areas, and ventilators were in desperate need in some communities, while others had warehouses full of ventilators collecting dust.

National approaches incl. closure of borders and stockpiling (in some cases even hoarding by Member States) was right from the beginning a too simple and naïve strategy. Of course, pandemics are always a question of uncertainties, time pressure and temporary and local quarantine measures. And without any doubt saving vulnerable people's life is the most important expression of humanity. But we are interdependent on each other, and we must therefore approach the challenge of this pandemic together.

Humanity and solidarity don't fall from the sky. We always have to keep in mind the alternative costs. In this case, the price was closed companies, grounded airplanes and lines of trucks on border crossings even around Europe. In consequence products from A to Z including food and medicines partially ran out of stock in shops and pharmacies in all countries.

We all remember news and pictures of empty storage racks and people buying in panic toilet paper, flour, canned food. The word “hoarding” became popular again. The general fear in this time of uncertainty of not getting enough fresh and constant supply even affected some national governments.

The aforementioned cross-border trade as guarantor for sufficient supply was suspended or even prohibited for several goods among those also medicines which were not but then became short in supply due to these restrictions.

Closed borders especially in the EU quickly showed us that the provision of goods is a question of specialisation and division of labour in production and international trade via open borders. In consequence the EU-Commission fought against illegitimate and improper unilateral measures and assured the free movement of goods in our European single market. The insistent plea of Commission President Ursula von der Leyen beginning of April addressing national governments to lift bans on exports and avoid stockpiling of medicines highlighted that the free movement of medicines is a question of solidarity.

For me it was also a milestone in the conservation of Schuman's memory. We all need more -not less- Europe. “What ever it takes” is a typical political statement to underline the importance of measures in crisis. And “what ever it takes” we have to defend and strengthen our single market at any time. Including the free movement of goods. ■

CALENDAR

26 OCTOBER 2020
DIGITAL EVENT**EU Health Summit - Time for action**

The EU Health Summit, organised by the EU Health Coalition, will focus on the underlying problems of healthcare systems exacerbated by the COVID-19 crisis. Bringing together actors of industry, research, patients organisations and politics, the event seeks to translate the lessons learned from the pandemic into a concrete political vision.

For further information, please see:

<https://www.euhealthcoalition.eu/event/eu-health-summit-2020/>

17 – 18 NOVEMBER 2020
DIGITAL EVENT**POLITICO Health Care Summit 2020**

The 5th edition of POLITICO's annual Health Care Summit will gather industry, policy-makers, patient representatives and regulators to discuss the European Commission's health mandate, consequences of the global COVID-19 pandemic and potential solutions to deal with the health challenges Europe is facing. Kasper Ernest, Secretary General of the European umbrella association of parallel trader “Affordable Medicines Europe”, will participate in the discussion on medicine shortages as a speaker.

For further information, please see:

<https://diievents.dii.eu/annual-health-care-summit/>



IMPRINT

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