

# PHARMACEUTICAL DIALOGUE 72

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

## PHARMACEUTICAL & HEALTH CARE POLITICS

### A pharmaceutical strategy for Europe – lessons learned from COVID-19?

Medicine shortages, rising prices of pharmaceuticals and unequal access to innovative therapies across Europe have increasingly become subject of discussion among health policymakers in Europe. At the same time, growing health needs of Europe's ageing population and a rising burden of diseases result in affordability constraints for health systems. The unprecedented COVID-19 crisis furthermore underlined severe shortcomings in national health systems and revealed the EU's significant dependency on active substances and medical products from non-EU countries.

#### Four pillars for a crisis-resilient pharmaceutical system

As a response, the EU launched a new pharmaceutical strategy to address the lessons learned from COVID-19, focusing on affordability, availability and sustainability of pharmaceuticals. In particular, the strategy will help to establish a future-proof and crisis-resilient EU pharmaceutical system, constituting the EU's "long-term vision for open strategic autonomy, and response to the challenges of today and the vulnerabilities exposed by COVID-19", underlines Stella Kyriakides, EU Commissioner for Health and Food Safety. The strategy will be based on four pillars. First, it aims to improve patients' access to safe and affordable medicines, while secondly enhancing competitiveness, innovation and sustainability of the EU's pharmaceutical industry. Thirdly, the strategy intends to enhance the EU's crisis preparedness and response mechanisms and, lastly, promote a high level of quality, efficacy and safety standards in Europe.

#### A functioning EU single market

The strategy covers the entire lifecycle of a medicine, from research to production, distribution, consumption and disposal. In this context, it underlines that "well-functioning international supply chains and a well performing single market for pharmaceuticals" are the foundation of the EU's efforts to ensure patients' access to affordable medicines. Therefore, the European Commission aims to revise the EU pharmaceutical legislation to address challenges impeding the competitive functioning of pharmaceutical markets. Moreover, the Commission announced to consider targeted policies on market competition to accelerate access to generic and biosimilar medical products. The strategy argues that generic and biosimilar medicines support the provision of affordable treatments, allowing potential savings in health costs due to increased price competition. With regard to debates on the affordability of medicines, the strategy recognises the traditional and constructive EU principle of subsidiarity that pricing and reimbursement policies fall within the competences of member states. Affordability – especially of patent protected Rx-pharmaceuticals for European patients – therefore continues to require an indispensable price competition via parallel trade within a functioning single market. ■

## EDITORIAL

Dear Readers,

The COVID-19 pandemic has shown vulnerabilities in the pharmaceutical supply chain, risking continuous supply and availability of (critical) medical products in the EU. As a response, the EU launched a new pharmaceutical strategy to improve and accelerate patients' access to safe and affordable medicines in Europe, aiming to address the lessons learned from COVID-19. **(page 1)**

In light of the recent acceleration in the spread of the COVID-19 virus, the impact of the crisis on global medical supply chains continues to increase, accelerating discussions on whether there is a need to restructure and rethink healthcare supply chains. **(page 2)**

This furthermore may pose a challenge in guaranteeing the supply and availability of medicines in the EU. Returning to a fully functioning Single Market is now, more than ever, essential for guaranteeing the supply of pharmaceuticals in Europe. **(page 3)**

VAD is committed – and playing an active part – to ensure the availability of affordable medicines for European patients. Therefore, we aim to actively contribute to ongoing debates and work in the field of European health policies. May you discover many informative insights as you read this 72<sup>nd</sup> edition of our Pharmaceutical Dialogue.

Sincerely,



Prof. Edwin Kohl  
Chairman of VAD



## Pharmaceutical supply for future generations

The COVID-19 pandemic has disrupted supply chains around the world and has tested the resilience and flexibility of a system we hoped is immune to crises. Governments were facing the challenge to provide a timely and affordable access to supplies such as medical equipment, diagnostic tests and medicines to their citizens. This was and is of course not an easy challenge to address since COVID-19 cases increased from 0 to 52 Million in a very short time period. It was impossible for global manufacturers to keep up with such a massive increase in demand especially in the first stage of the current pandemic.

### Increased global demand challenged manufacturers worldwide

In March 2020, the WHO estimated that the industry for critical medical products would have had to increase its production capacity by 40% to meet the increased global demand. During the first stage of the pandemic, governments worldwide started to implement export restrictions on medical products and stockpile not only essential medical equipment and medicines leading to further disruptions of the medical supply chains and medical shortages. To fight against a global pandemic such as the ongoing COVID-19 crisis, it is crucial to realize that we have to join forces and act together. Only then can we address one of the biggest future challenges: improve medical supply chains so they become more resilient and flexible.

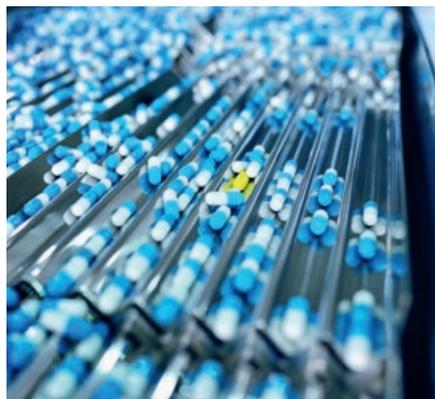


Photo: zorzhuang/istock.com

### How to prevent future disruption of the medical supply chain

Some governments including France, Japan and the US see the resettlement and the production of critical medical products in their own countries as the key element to make their health care system more resilient for future crises. Bruegel, one of Europe's leading think tanks, objects this approach of self-sufficiency. They argue that while localisation of production for some specific medical goods might be necessary to prepare for pandemics,

there are substantial advantages in keeping Europe's markets for medical goods open. Therefore, the strategy to make medical supply chains more resilient should be targeted and should avoid protecting parts of the market where there is no need for local production. Some industry representatives are following Bruegel's advice and even further argue that production of critical medical goods should be divided among several sites. With this approach, global demand can still be met even in the event of a breakdown of one of the production facilities.

### What are measures the European Union can take to secure the supply of pharmaceuticals of the next generation?

The European Commission is taking further steps in the fight against the COVID-19 pandemic and possible future health emergencies by putting forward a set of proposals to build a European health union. Firstly, an EU health crisis and pandemic preparedness plan will be developed. Recommendations for the adoption of plans at national levels, coupled with comprehensive and transparent frameworks for reporting and auditing will also be issued. Secondly, reinforcing mandates of key EU agencies, namely the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) will better protect EU citizens and address cross border health threats. With the reinforcement of its mandate, the EMA can facilitate a coordinated Union-level response to health crises by monitoring and mitigating the risk of shortages of critical medicines and medical devices and therefore help to secure supply for future generations. ■

## NEWS IN BRIEF

### Council and European Parliament triple funds for "EU4Health" programme

On 10 November, after ten weeks of negotiations, the German Presidency of the Council and the Parliament's budget negotiators agreed on the outline of an agreement on the next Multiannual Financial Framework (MFF 2021-2027). In their agreement, Council and Parliament agreed to triple the amount for the "EU4Health" programme which was agreed by the EU leaders at an EU summit in July. Hence, the health programme will now amount to €5.1 billion to be spent in the forthcoming seven years to address lessons learned by the COVID-19 crisis and make EU health systems more resilient. ■

### European Commission presents first steps towards an EU health union

On 11 November, the European Commission took the first measures towards creating a European Health Union. With its proposals, the Commission aims to strengthen the EU's health security framework and increase the role of EU health agencies in crisis preparedness and management to address cross-border health threats in a more coordinated way. The Commission's proposals in particular entail a stronger mandate for both the European Centre for Disease Control and Prevention and the European Medicines Agency as well as a new regulation on serious cross-border threats to health. Under the new regulation, the European Union would have the competence, inter alia, to adopt common measures at EU level to face future cross-border health threats and declare an EU-level public health emergency. ■



Photo: Alexandros Michailidis/istock.com

## NEWS IN BRIEF

## A strong and deepened EU single market as a guarantee for pharmaceutical supply

The COVID-19 crisis has underlined the necessity of protecting the health of citizens while at the same time guaranteeing the free movement of goods and ensuring the proper functioning of the European Single Market. In particular, the crisis endangered the supply of pharmaceuticals and medical products needed in the EU. Preserving the integrity of and moreover deepening the Single Market, nevertheless, is crucial for a strong economic recovery and guaranteeing the supply of pharmaceuticals in Europe.

### Distortions of the EU Single Market in times of crisis

At the onset of the crisis in March of this year, the COVID-19 virus prompted some EU member states to restrict the free movement of medical products through export bans. These export restrictions affected not only pharmaceuticals, which were essential and short for the treatment of COVID-19, but also medical products neither related to the treatment of the virus, nor at risk of shortages in the exporting member state.

Such protectionist government measures, affecting the global pharmaceutical supply chain, may result in inequitable supply and medicine shortages in the EU and worldwide. The European Commission made it clear that these measures infringe the free movement of goods and thereby significantly impede the functioning of the Single Market. Most EU member states subsequently complied with the Commission's appeal to lift export restrictions on pharmaceuticals and refrain from adopting any protectionist measures jeopardising the free movement of goods.



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### Single Market as key for guaranteeing pharmaceutical supply

The recent acceleration in the spread of the COVID-19 virus may again present a severe challenge for the proper functioning of the Single Market, endangering pharmaceutical supply. The COVID-19 crisis revealed the EU's dependency on active substances and pharmaceutical products from non-EU countries. It highlighted that no country is self-sufficient in the production of raw materials, active pharmaceutical ingredients or finished medical products needed to secure a well-functioning health-care system. Unilateral measures by national governments restricting the free movement of pharmaceuticals are detrimental to the availability of pharmaceuticals for European patients. It is therefore critical to return to a fully functioning Single Market in order to avoid any risk of shortages of medicines and ensure the supply of pharmaceuticals in Europe.

In September, the Council of the EU stressed the need to further deepen the Single Market, calling on EU member states to improve the implementation and enforcement of EU single market rules and remove unnecessary barriers to cross-border trade in the EU. In line with this, the European Parliament stressed the necessity of ensuring the sound functioning of the Single Market "to eliminate barriers to access to medicines, medical devices and protective equipment for all citizens, especially those living in Member States that, due to their small size or remote location, rely heavily on imports and do not have easy access to the supply chain."

The COVID-19 crisis has highlighted that equal access to, and availability of affordable medicines depend on the sound functioning of the EU Single Market. It is now, more than ever, critical to ensure a deepened and resilient Single Market based on the elimination of any trade barriers in order to guarantee pharmaceutical supply. ■

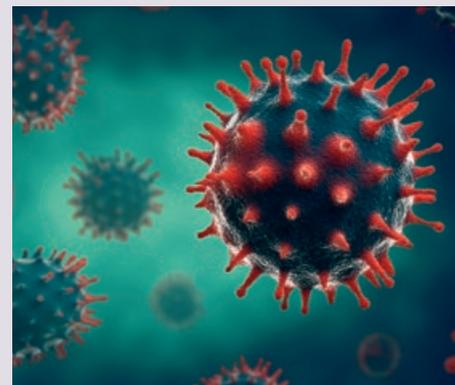


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### EU leaders call for a deepened Single Market for a strong recovery

In a special European Council summit at the beginning of October, EU leaders discussed the lasting impact the COVID-19 crisis will have on the European and global economy. In this context, the European Council issued conclusions underlining the urgent necessary to return to the normal functioning of the European Single Market as quick as possible. What is more, EU leaders called for action to include the lessons learned from the COVID-19 pandemic into future EU Single Market policymaking by addressing existing barriers to the Single Market and fragmentation across Europe.

In particular, the European Council underlines the need to strictly implement and enforce the Single Market rules as well as remove remaining unjustified barriers and refrain from creating new ones. In the area of health, EU leaders invite the European Commission to identify strategic dependencies of the EU, in particular in the health sector, and to propose measures to reduce these dependencies by diversifying and fostering production in Europe and ensuring strategic stockpiling of critical products. ■



Photo: Andreas Haas/istock.com

EXPERT PORTRAIT

## With a view to consumer protection

**With Manuela Ripa (Group of the Green/European Free Alliance),  
Member of the European Parliament**



Photo: xxxxxxxx

When Manuela Ripa became a Member of the European Parliament in July 2020, she brought with her ample of experience for this task. Between 2006 and 2009, she had already worked as an assistant in the European Parliament. Most recently, Ripa worked in the Saarland Representation to the EU. In addition to climate, environmental and biodiversity protection, consumer protection is one of her main topics. “Nevertheless, I always keep an eye on health policy,” says the Parliamentarian emphatically. She has previously worked as the personal advisor to the Federal Minister of Health, while also covering health policy issues during her time at the state representation. Her party, the Ecological Democratic Party (Ökologisch-Demokratische Partei, ÖDP), despite being temporarily a small party, sends a lawyer to Brussels and Strasbourg, who joins the political debate with verve. In order to emphasise her core issues, Ripa is part of the European Greens / EFA group and member of the following five committees:

• Committee on Industry, Research and Energy (ITRE),  
• Subcommittee on Security and Defence (SEDE),  
• Committee on International Trade (INTA),  
• Committee on the Environment, Public Health and Food Safety (ENVI),  
• Special Committee on Combating Cancer (BECA), the final report of which will be adopted in September 2021.

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All of these committees are important for Germany and especially for her home region. “There are many interests highly relevant also to Saarland for which I will take an active position”, underlines Ripa.

But her personal story and remarkable career clearly shows her general European DNA and the look for the big picture and the details inside the fundamental principles of the EU the same time. One concrete example arises in the area of healthcare.

Parallel trade in pharmaceutical is a policy area that – also with a view to consumer protection – is of great importance. “If we take the treaties seriously, barriers to the free movement of goods within the EU must be removed.” This goal can be achieved. “There will be shortages in the supply of medicines again and again, so we must look closely at the causes.” The lawyer is absolutely certain that the principle of the free movement of goods, which is fundamental to EU law, cannot be overridden too hastily.

Manuela Ripa will closely follow future developments in the area of pharmaceuticals, especially from the consumer perspective. COVID-19 has already triggered new discussions. Due to the pandemic, the EU will have to strengthen and actively support the relocation of pharmaceutical production back to Europe. However, further considerations are currently underway in all EU institutions. It could well be that the entire pharmaceutical production in 2021 – at EU level, but also globally – will be under continuing review. “I would like to help ensure that future initiatives do not involve any content that is unilaterally at the expense of parallel trade which has been repeatedly confirmed by courts to comply with EU law”.

IMPRINT

**VAD e.V. German Association of Pharmaceutical Parallel Distributor**

VAD / Verband der  
Arzneimittel-Importeure  
Deutschlands e.V.  
Im Holzhau 8  
66663 Merzig | Germany  
Chairman of the board:  
Prof. Edwin Kohl

**Contact and Chief editor:**  
Person responsible according to the German Press Law  
Karsten Wurzer  
Im Holzhau 8 | 66663 Merzig | Germany  
Telefon: 06867 920-1271  
E-Mail: kwurzer@vad-news.de  
[www.vad-news.de](http://www.vad-news.de)



CALENDAR

02 – 04 DECEMBER 2020  
DIGITAL EVENT

**Virtual Partnering: Infectious Diseases**

The current COVID-19 pandemic is a reminder on the necessity to continue to pursue our efforts to control infectious diseases, especially with intercontinental travel and increased mobility of people and animals. Inova in collaboration with Biotechnology Innovation Organization (BIO), are organizing a virtual partnering event on infectious diseases, focusing on the latest research from scientific congresses.

For further information, please see:

<https://www.efpia.eu/news-events/events/partner-event/virtual-partnering-infectious-diseases/>



14 – 15 JANUARY 2021  
ZURICH, SWITZERLAND

**International Conference on Public Health in the Digital Age**

The International Conference on Public Health in the Digital Age will gather leading academic scientists, researchers and research scholars to exchange their research results on and discuss the most recent innovations, trends, and concerns as well as practical challenges encountered and solutions adopted in the fields of digital public health.

For further information, please see:

<https://waset.org/public-health-in-the-digital-age-conference-in-january-2021-in-zurich>

