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IMPACT OF THE COVID-19 PANDEMIC ON THE MEDICINES SUPPLY CHAIN IN EUROPE

E. Gavazova*, D. Grekova

Department of Pharmaceutical Sciences, Faculty of Pharmacy, Medical University – Plovdiv, Bulgaria

ABSTRACT

Introduction

Medicines are products that are essential for human well-being. Access to affordable, effective, and safe medicinal products is a key condition for the functioning of health systems in all developed countries. The COVID-19 pandemic has brought new challenges to the pharmaceutical industry, the pharmaceutical profession, and healthcare. The pandemics highlighted the pre-existing problems and weaknesses of the medicine supply chain in Europe.

The aim of this study is to summarize and present the impact of the pandemic on the pharmaceutical sector and the objectives of the Pharmaceutical Strategy for Europe in anticipation of future international disruptions.

Results: At the beginning of the pandemic, EMA took steps to monitor drug shortages. The EC is taking steps to create a new European Health Union and Pharmaceutical Strategy for Europe - a regulatory framework that takes into account the lessons of the pandemic and supports research and technology that reaches patients to meet their therapeutic needs while tackling market failures.

Conclusion: Equal access of EU member states to qualitative, efficient and innovative medicines, and health services is a community priority. The COVID-19 pandemic has acted as a driving force and accelerator of the processes of transformation of healthcare and medicines supply in particular.

Key words: healthcare, pharmaceuticals, strategy, market, transportation, shortages, demand, procurement.

INTRODUCTION

Medicines are products that are essential for human well-being. The access to effective and safe medicinal products is a basic condition for the functioning of the healthcare systems of all developed countries. (1) The pharmaceutical supply chain is the means through which medicines are manufactured and delivered to patients. The pharmaceutical supply chain is a socio-technical system aimed to achieve improved health status through medicines provision. (2) The steps that are included in the Pharmaceutical supply chain are complex and vary from state to state. Petrova G. et. al. state that the pharmaceutical supply chain consists of all the activities related to the transportation of any medical product from the manufacturer to the patient. (3) The process should ensure that the needed medicines are accessible to the society and that the shortages are minimal. Economic efficiency shall be a priority in all the stages of the supply process.

Although the COVID-19 pandemic was not the first pandemic that humanity faced, it caused unprecedented disruptions and put a burden on all sectors including healthcare. The novel coronavirus which was named by the International Committee on the Taxonomy of Viruses,SARS-CoV-2 (4) spread fast from Wuhan(China) to all continents. Europe was not

***Correspondence to:** *EvelinaGavazova. Department of Pharmaceutical Sciences, Faculty of Pharmacy, Medical University – Plovdiv, Bulgaria, email: gavazova.evelina@gmail.com, GSM:0878556636*

an exception. The first reported case of COVID-19 in the European Union dates back to 24 January 2020. On 28 January, a cluster of four locally acquired cases, with indirect links to Wuhan, was reported from Germany. On 29 January, Finland reported an imported case from Wuhan. (5) The number of cases by 17.08.2021 raised to 60 008 184 including 1 212 033 death cases (6). Trying to prevent the spread of the infection, the European countries took a variety of restrictive measures, which have affected international trade ofn goods. Due to the closed borders, trade generally decreased, while exports and imports of medicinal products increased in the majority of EU Member States. (7)

The pandemic of COVID-19 led the pharmaceutical industry, the pharmaceutical profession, and healthcare to new challenges and highlighted the existing problems and weaknesses of medicines supply in Europe. The purpose of this study is to present the impact of the pandemic on the medicines supply process.

RESULTS

COVID-19 in Europe

Incident infection and mortality are the two main outcomes used to measure the impact of the pandemic, both of which can be expressed in different ways, including trends over time and cumulatively. In the early stages of the pandemics, Europe was seriously impacted by the fast spread of the infection and a high mortality rate. However, the European countries did not suffer equally and responded to the novel disease differently due to the individual demographic characteristics, population frequency, and healthcare systems. (8)

The European Commission is the main authority that took responsibility for the situation in the EU. The main areas of the response of the commission are summed up in **Table 1**.

Table 1. *Overview of the European commission's response to the pandemic*

Area of action	Responses
Public health	▪ On 11 November 2020, the European Health Union was established. ▪ Medical guidance by 7 independent epidemiologists and virologists for the management of the disease in the member states. ▪ Supporting the manufacturing and availability of personal protective equipment PPE and COVID-19 tests.
Research and innovation	▪ Securing safe and effective vaccines for Europe and the world. ▪ Anticipating the threats of new variants The Commission created the "HERA Incubator", a plan for EU-wide preparedness plan against COVID-19 variants
Crisis management and solidarity	▪ donations of protective equipment ▪ transport of medical teams from one country to another ▪ Through the EU Civil Protection Mechanism, the European Union is helping coordinate and finance the delivery of medical equipment and related items. ▪ COVAX: global vaccination ▪ rescue – a common reserve of medical equipment
Travel	▪ On 13 October 2020, EU Member States adopted a Council Recommendation on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic. ▪ Consular assistance for EU citizens abroad.
Jobs and economy	▪ Protecting small and medium-sized businesses ▪ Supporting the recovery of EU tourism ▪ Securing essential food supplies
Digital solutions	▪ Monitor the spread of the coronavirus ▪ Research and develop diagnostics, treatments, and vaccines ▪ Ensure that Europeans can stay connected and safe online

Although SARS-CoV-2 is the seventh coronavirus that infects humans (9) it brought many questions and boosted research in all areas. As there is not a specific treatment for COVID-19, experts used the available scientific evidence and the previous clinical experiences with SARS - CoV, MERS - CoV, and even HIV to consider the use of an array of potential therapies such as chloroquine and hydroxychloroquine, remdesivir, lopinavir/ritonavir, interferon beta, monoclonal antibodies, convalescent plasma, hyperimmune globulin, antibody-rich blood products either alone or combined with supportive care (e.g., oxygenation, ventilation, fluid management) under several regulatory approaches that healthcare authorities made available. Considering that these therapies are not approved by competent regulatory authorities to treat COVID-19, and that their safety and efficacy profile is under investigation, their use represented a critical responsibility. (10, 11)

Randomized clinical trials remain the main proof of the efficacy of any therapy.Several clinical trials brought hope in the fight against the pandemic. For example, a University of Oxford randomized clinical trial demonstrated the beneficial use of dexamethasone, a generic drug, in improving survival rates in COVID-19 patients with respiratory complications. (12)

The World Health Organization launched The SOLIDARITY PLUS trial which is the largest global collaboration among the WHO Member States. Two thousand researchers in 600 hospitals from 52 countries take part in the trial. (13)

The COVID-19 crisis dramatically showed how innovative trial designs to evaluate multiple interventions simultaneously can produce rapid and reliable answers (14). The pandemic switched the design of clinical trials from competitive, fragmented conduction of small monocentric trials to collaborative work and progress by shared approaches to data measurement and collection which is fundamental for more effective drug development and assessment. (15)

Increased Demand and Medicines Shortages

During the first days of the pandemic, countries around the world restricted transport within and between them as they struggled to stop the spread of the novel disease. The reduced transportation affected the manufacturing, supply, and distribution of medicines. Although the supply situation has improved since May 2020, the constraints in the global medicines supply chain remain. (16) The possible reasons for supply disruptions are shown in **Figure 1**.

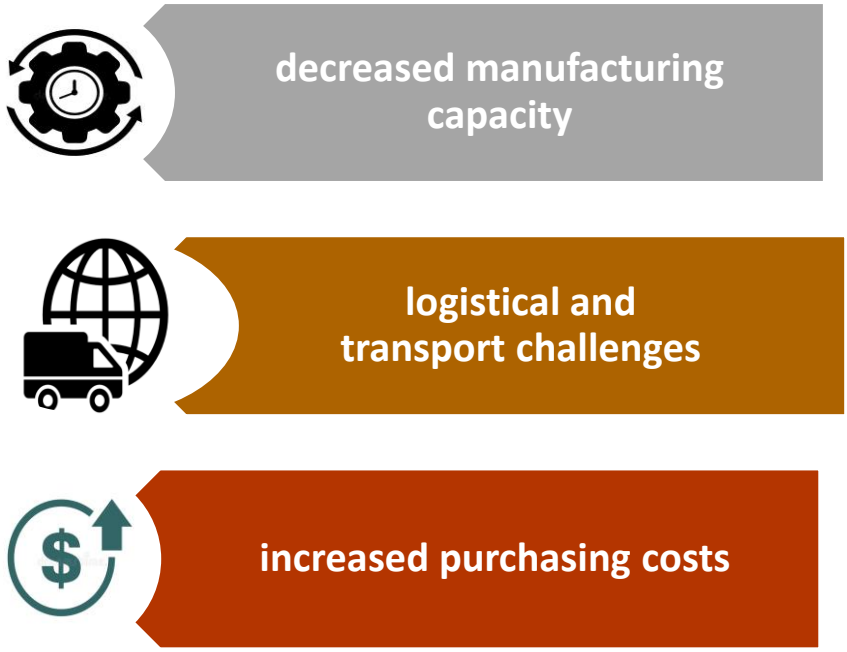

Figure 1. Possible reasons for medicine shortages during the COVID-19 pandemic identified by EMA.

WHO is working with governments, industry, and the Pandemic Supply Chain Network to boost the effective management of the supply chains. The increased demand for personal protective equipment due to the pandemic was also addressed. To meet the rising global demand, WHO estimated that the industry must increase manufacturing by 40 percent and ensure resource allocation for the critically affected countries. (17).

The demand for some medicines used in patients with COVID-19 in intensive care units (ICUs) also increased. This contributed to shortages. Several studies have identified drug shortages as a public health issue of high significance (18, 19). The definition of drug shortage given by the American Society of Hospital Pharmacies (ASHP) is "a supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent" (20)The FDA defined it as "a situation in which the total supply of all clinically interchangeable versions of a drug is inadequate to meet current or projected demand at the user level" (21) Factors that affect drug shortages vary from difficulties in acquiring raw materials and manufacturing problems to regulatory issues, business decisions, etc.(22-24) Shortages of medicinal products are an anticipated public health issue in the context of crisis like the pandemic. In the reflection paper developed by EMA regarding the experience of the regulatory authorities during the early months of the COVID-19 pandemic. The document is aimed to provide guidance on medicines' demand forecasting, which is an effective strategy in shortage management. (10)

The enhanced fast-track supply issues monitoring system placed in the EU enabled regulators to: detect and monitor supply disruption, predict future issues early. The system focused on particular medicines identified by the national competent authorities including anesthetics, antibiotics, resuscitation medicines, and muscle relaxants as their availability was crucial to COVID-19 patients in ICUs.

The system for shortage reporting was established by the EU Executive Steering Group on Shortages of Medicines Caused by Major Events in April 2020. Each pharmaceutical company is responsible for reporting on ongoing or anticipated shortages of medicines used to treat COVID-19 patients.

Nevertheless, pharmaceutical companies are obliged to report shortages to the national competent authorities concerned in parallel.

Pharmaceutical procurement

Pharmaceutical procurement is a complex process that involves many steps, agencies, ministries, and manufacturers. (25) The increased demand for personal protective equipment, essential medicines, ventilators, and diagnostic tests,challenged even high-income countries. (26) (27) Moreover, countries with existing inequities and developing healthcare systems struggled to provide service and ensure safe pharmaceutical procurement. (28) Among all government functions procurement is the most vulnerable to corruption especially during times of emergency. (29) As enormous amounts of additional funding are directed to rapidly resolve a critical problem like the pandemic, time and resource limitations lead to decision mistakes. For instance, a senior procurement official at the National Health Service NHS in London was accused of illegal trade with personal protective equipment (30), and the government procured 3.5 million tests that could not be used (31).In another case, the United States Federal Government paid a direct award of US$ 55 million for N95 face masks to a company that had no experience in supplying medical supplies and no recorded employees. (32)

The corruption in procurement leads to wasted resources which could lead to insufficient health coverage.An estimated US$ 16 trillion has already been spent by governments globally on their responses to COVID-19. (33)

On the other hand, the pandemic provoked a positive shift from national procurement to joint procurement for COVID-19 vaccines and therapeutics (as for remdesivir) in the EU countries. Member states exchanged information, negotiated drug prices jointly, and even bought pharmaceutical products together. The joint procurement procedures aim to ensure that the participating countries have an uninterrupted

supply and increase the bargaining power of the public counterpart in price negotiations. (34)

The new Pharmaceutical strategy for Europe

After public consultations with stakeholders between July and September 2020, the European Commission adopted a new "Pharmaceutical strategy for Europe," on 25 November 2020. This strategy was built on the lessons learned from the pandemic and aims to ensure the quality and safety of medicines while boosting innovations. (35) The strategy is based on four main pillars **Figure 2.**

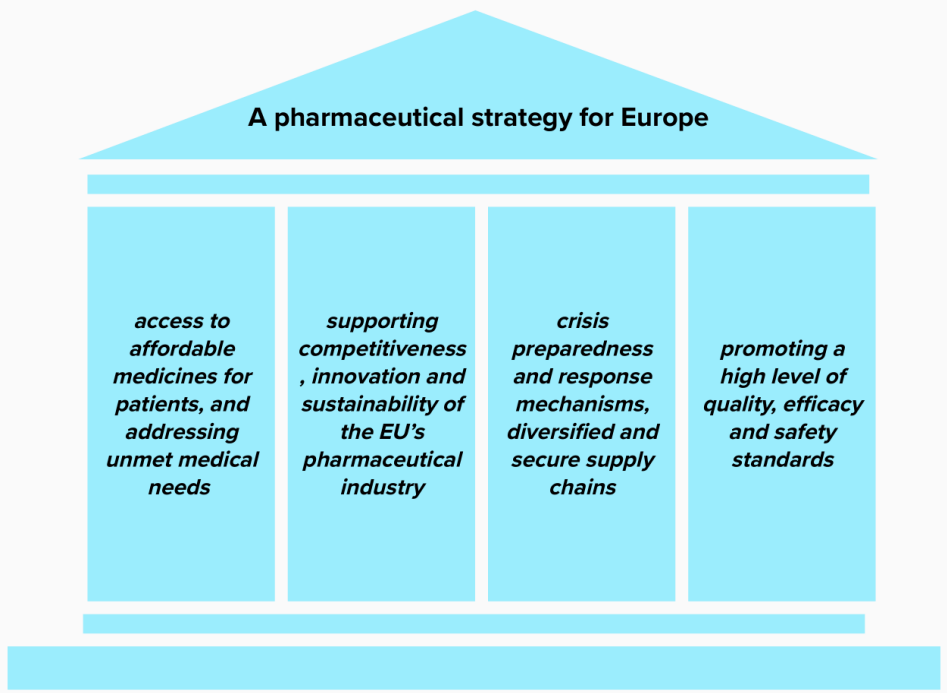

Figure 2. The four pillars of the European pharmaceutical strategy from November 2020.

With the development of the strategy, more than 12 million people were infected with COVID-19 in Europe. (36) The hospital expenditures raised by 20-30%. (37) Despite that the progress in the treatment and management of the infection is notable, the pandemic continues to put stress on the healthcare systems and economics. The crisis underlined the need for establishment of more efficient preparedness and response mechanisms. The COVID-19 pandemic was not the only issue that emphasized the need for a better pharmaceutical strategy that shall ensure a resilient pharmaceutical system in the EU. The aging of the European population and the unmet medical needs of oncology patients and those suffering from rare diseases are being the focus of the new strategy. (38, 39) The PRIME program launched in 2016 by the European Medicines Agency addressed the unmet medical needs of the society and aimed at improving accessibility.(40) However, issues such as antimicrobial resistance which is reported to be responsible for 33 000 deaths every year, contribute to the complex functioning of the pharmaceutical system nowadays. (41) The EU is also becoming increasingly dependent on third countries for importing medicines and their active ingredients, which in the case of emergencies and transportation limitations leads to shortages of essential medicines. The COVID-19 crisis underlined the need for a clear overview of innovative and sustainable manufacturing capacities in the EU, including possibilities for flexible production and conversion of production, as well as identification of potential alternatives. (42) The first actions aligned with the Pharmaceutical strategy for Europe are assessment and revision of the legislation concerning pediatric medicinal products and orphan medicines. (43-45) Another initiative is The Structure dialogue initiative, that is a two-phased process gathering the actors in the pharmaceuticals manufacturing value chain, public authorities, research community, health

professionals and patient organisations, to discuss the issues in the pharmaceutical supply. Based on the evidence gathered through the two phases concrete measures will be taken to ensure diversified and secure supply chains. (46)

CONCLUSION

Equal access of the EU member states to safe, efficient and innovative medicines, and health services is a community priority. The COVID-19 pandemic has acted as a driving force and accelerator of the processes of transformation of healthcare and medicines supply in particular. All processes involved in the Pharmaceutical supply chain were influenced by the crisis. Response mechanisms were placed by the authorities in an attempt to mitigate shortages and manage other disruptions. The increased funding that the pandemic requires, lead to insufficient procurement and corruption. The European pharmaceutical strategy is the next step in the development of an efficient pharmaceutical supply chain and healthcare services of high quality and affordability.

Since new waves of the COVID-19 pandemic featuring new variants of the virus are anticipated, a further investigation of the impact of the pandemic on the Pharmaceutical supply chain in the European countries would provide a better understanding of the weaknesses and risks associated with such events.

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