

THE ROLE OF THE EUROPEAN HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY AND THE IMPACT OF THE JOINT PROCUREMENT AGREEMENT ON THE ACCESS OF MEDICAL COUNTERMEASURES SUCH AS VEKLURY (REMDESIVIR) IN BULGARIA

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Abstract: In 2014, the European Commission launched the Joint Procurement Agreement (JPA), which allows the EU to take additional measures to improve public health, as well as to combat serious cross-border health threats. The JPA aims to increase access to safe, effective and affordable medicinal products to the participating countries in the Joint Procurement Agreement. The study examines certain medicinal products and vaccines that have been provided to Member States thanks to the JPA mechanism. The aim is to track the overall effect: from access to relevant medicines to the improvement of public health. Materials and methods: Analysis of data from national and European sources, including data on the accessibility of medicinal products in countries of the European Union that participate in the Joint Procurement Agreement and the information regarding availability of the medicinal product Veklury (INN Remdesivir). Results: Data analysis showed that access to relevant medicines led to improvements in patient health, including reductions in disability and mortality and reductions in healthcare costs. Conclusion: The results of the study show that the Directorate General HERA of the European Commission plays an important role in improving public health in the European Union. Through the Joint Procurement Agreement, HERA facilitates Member States' access to safe, effective and affordable medicines, vaccines and medical devices. The HERA Invest funding initiative to promote research and development of medical countermeasures and technologies will also help address priority cross-border health threats. During global pandemics and the need for rapid reactions on the part of the Union – the JPA remains the first choice of Member States in their fight against future epidemics/ pandemics.

Keywords: HERA, JPA, medicinal products, Veklury

1. INTRODUCTION

In recent decades, the world has become more and more global. The member states of the European Union (EU) are more and more connected and upgrade the levels of cooperation with each other, and the levels of cooperation are not limited only to the fundamental ones for the EU – free movement of people, capital and services, also include security systems, common payment systems (currency), education, but also cooperation in the field of healthcare. Uniform approaches in the field of health care are for now summarized by a common approach in joint pan-European public procurement for the purchase of medicinal products and medical devices, common European institutions such as: the European Medicines Agency (EMA), the European Health Crisis Response Authority (HERA), the European Center for Disease Prevention and Control (ECDC) and others, to the concept of cross-border healthcare and greater connectivity of Member States' (MS) health systems. This connectivity between the health systems of the Member States lays the foundations of the future European Health Union. On the other hand, higher levels of globalization, which are defined by growing cross-border flows of people, goods, and capital, have sped up the spread of viruses throughout the world and raised the possibility of major public health emergencies. From a global perspective, no nation is immune to viruses, and biosecurity is becoming more interdependent. This calls for more international cooperation as a way to secure global public health.

The European Commission has launched the European Health Emergency Preparedness and Response Authority (HERA) in response to the COVID-19 pandemic and has highlighted the importance of preparedness and response planning in the healthcare sector. By coordinating European, national, and regional preparedness and response strategies, HERA attempts to avoid, identify, and quickly address health emergencies (“HERA, the EU's new Health Emergency Preparedness and Response Authority”, 2022). Additionally, it spurs improved coordination and quick action to create, accumulate, and acquire the equipment required to handle the emergency. The onset of the COVID-19 pandemic exposed vulnerabilities in the European Union's preparedness and capacity to respond, along with

insufficient funding. The initial response from the European Union was mostly on separate basis (“2021 State of the Union Address by President von der Leyen”, 2021). It was initially frequently difficult for the 27 members of the European Union to work together and respond in unison, and it required time for nations to settle and begin operating in an organized way. The European Commission's new Directorate-General, known as HERA or the European Health Emergency Preparedness and Response Authority, was established on September 16, 2021 (“COMMISSION DECISION of 16.9.2021 establishing the Health Emergency Preparedness and Response Authority”, 2021). The Directorate-General was established in response to the COVID-19 pandemic in order to prevent, detect, and quickly respond to future health emergencies for which the European Union must be ready. HERA's budget constitutes more than €6 billion from the EU's long-term budget - the multiannual financial framework for the period 2021-2027. HERA is anticipated to improve the coordination of health security in the EU during the phase of preparation, hasten the time it takes to respond to crises, and boost the EU's overall framework for public health emergency preparedness.

The availability of critical medicinal products is becoming a major challenge for the European and global pharmaceutical markets. Even EU countries with a high gross domestic product, which have traditionally well-developed health care systems based on social solidarity and justice, face difficulties in providing vital medicinal products in the context of a pandemic or other health crisis. To achieve this, national governments are taking proactive approaches to implement cutting-edge new policies. New initiatives aim to increase pricing transparency and boost collaboration, for instance through unified pan-European public procurement for medicines and medical devices (Vogler et al., 2021).

This article will explore the role of HERA and the Joint Procurement Agreement in improving global pandemic preparedness in the European Union as well as examine the accessibility of medical countermeasures such as Veklury for treatment of COVID-19 in Bulgaria (“HERA anticipates threats and potential health crises, through intelligence gathering and building the necessary response capacities”, 2021).

2. MATERIALS AND METHODS

The article examines various national and European sources of information. The information regarding availability of the medicinal product Veklury (INN Remdesivir), via data from sources of information such as the Ministry of Health and the National Assembly of the Republic of Bulgaria have been analyzed.

3. RESULTS AND DISCUSSION

An innovative tool for multi-country procurement of medical countermeasures against international health hazards is the Joint Procurement Agreement (JPA). The European Commission launched the JPA in 2014 to promote public health and address significant cross-border health hazards. The JPA allows 36 participating countries (EU member states, Norway, Lichtenstein, Island, Albania, Serbia, Bosnia, Montenegro, North Macedonia and Kosovo) increased access to safe, effective, and affordable medicines, vaccines, and medical devices. In order to assure equitable and cost-effective access to medical supplies for participating states during acute health crises, the JPA was designed as a tool to solve obstacles by increasing buying power (“Public health: Joint purchasing of vaccines and medicines becomes a reality in the EU”, 2014).

The JPA has been especially helpful during the COVID-19 epidemic, ensuring that participating EU member states have equal and affordable access to medical supplies (Mcevoy & Ferri, 2020; “Guidance on using the public procurement framework in the emergency situation related to the COVID-19 crisis”, 2020)

The principles of Joint Procurement for medicinal products are:

1. Fairness: The procurement process must be fair and transparent, and all suppliers must be treated equally.
2. Integrity: The procurement process must be free from corruption and fraud.
3. Transparency: All information related to the procurement process must be made public, including the tender documents, the evaluation criteria, and the award decision.
4. Efficiency: The procurement process must be efficient and cost-effective.
5. Sustainability: The procurement process must take into account environmental and social sustainability considerations.

If the incentives for long-term collaboration are in place, the JPA has the potential to boost collaboration and efficiency in the EU's health system (COVID-19 Procurement Actions, 2020)

The Joint Procurement Agreement (JPA) differs from traditional procurement methods in several ways, as outlined below:

- Centralization: The preparation of RFPs, the choice of vendors, and contract negotiations are all centralized by the JPA. As a result, the procurement process can be made simpler and more effective (Georgopoulos, 2022).

- Multi-country procurement: The JPA is a cutting-edge tool for multi-country medical countermeasure procurement against international health hazards. This makes medicines, vaccinations, and medical equipment accessible to participating EU member states at reasonable prices (Azzopardi-Muscat, Schröder-Bäck & Brand, 2016)
- Equitable access: In times of severe health crises, the JPA seeks to ensure that participating EU member states have equal and affordable access to medical supplies. This ensures that all participating countries have access to the necessary medical supplies, regardless of their size or economic status (Mcevoy & Ferri, 2020).
- Improved security of supply: The JPA aims to improve security of supply for all EU member states. This ensures that participating countries have access to the necessary medical supplies in times of crisis (Georgopoulos, 2022)
- Professional networks: The JPA aims to create professional networks among participating countries. This allows for the sharing of best practices and expertise, which can lead to improved health outcomes (Azzopardi-Muscat, Schröder-Bäck & Brand, 2016).

A collaborative framework agreement for the supply of Paxlovid, an oral medication for COVID-19 patients at risk of developing severe disease, was signed on November 23rd by the European Commission's Health Preparedness and Response Authority (HERA) and Pfizer. The agreement permitted up to 3,427,517 five-day Paxlovid treatment courses to be purchased by the thirteen EU and EEA Member States and EU candidate nations ("Commission secures almost 3.5 million COVID-19 treatments through joint procurement contract", 2022)

On 28th of July 2022, The European Commission's Health Emergency Preparedness and Response Authority (HERA) has signed a framework contract with GSK for the joint procurement of Adjupanrix, a pandemic influenza vaccine. Twelve Member States and other joint procurement countries are participating in the agreement, under which they can purchase up to 85,000,000 vaccine doses, if necessary, in the event of an influenza pandemic. The deal ensures a future supply of 85 million doses of GSK's pandemic influenza vaccine, Adjupanrix, to 12 European countries ("HERA signs Joint Procurement contract for Pandemic Influenza Vaccine", 2022)

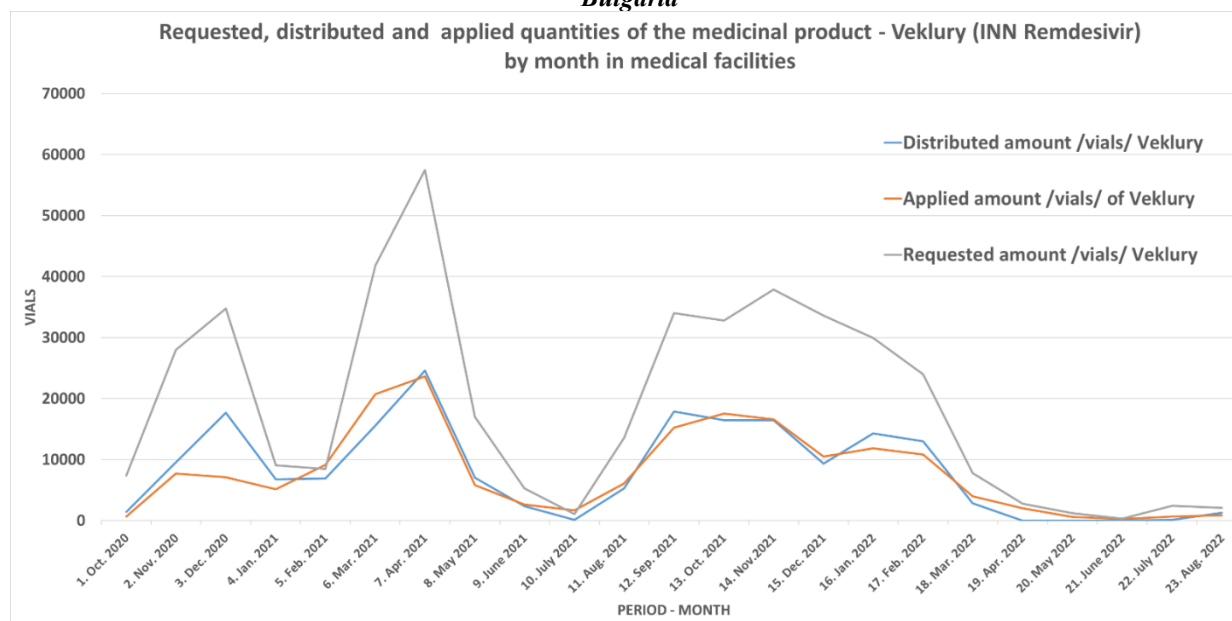
The pooling of Member States' efforts in providing medical countermeasures, including medicinal products, in response to the COVID-19 pandemic has been an undisputed success. Veklury (INN Remdesivir) is the first medicinal product approved in the summer of 2020. by the European Commission, after a positive opinion from the European Medicines Agency (EMA) for specific treatment of coronavirus infection. Veklury is approved to treat Coronavirus (COVID-19), per the approved Summary of Product Characteristics ("Summary of Product characteristics of Veklury", 2022). It is used in adults and adolescents (over 12 years old and weighing at least 40 kg) with pneumonia who need supplementary oxygen (low or increasing oxygen flow or other non-invasive ventilation at the start of treatment). Adults who do not require additional oxygen but are more likely to develop severe COVID-19 can also use the medication. The European Commission successfully carried out a joint public procurement for the purchase of the medication Veklury in the second half of 2020. A total of 36 countries participated in the Joint Public Procurement Agreement, including all EU countries, Norway and Iceland (the two European Economic Area countries), the United Kingdom, as well as six candidate and potential candidate countries. Based on the good collaboration in the agreement, the 36 participating countries were able to deliver the medicinal product to their citizens in emergency conditions. Until now, the medicinal product Veklury (INN Remdesivir) is provided on the territory of Bulgaria based on the EU Framework Agreement for the joint award of public procurement in actions for medical countermeasures, ratified by the National Assembly of the Republic of Bulgaria ("Health Minister Angelov: All patients for whose treatment the medicine Remdesivir is needed are covered", 2020; "Official letter from the Health Minister of Bulgaria to the Parliament of the Republic of Bulgaria", 2020).

Until now, our country has been included in two such consecutive framework agreements. According to the already expired Framework Agreement No. SANTE/2020/C3/048, Bulgaria (Ministry of Health) has concluded four bilateral agreements to ensure the quantities, which are as follows: [17, 18] ("The Ministry of Health has secured sufficient quantities of medicinal products applicable to patients with COVID-19", 2021;

1. Contract RD-06-317/22.10.2020 for a minimum quantity of 2,593 vials;
2. Contract RD-06-321/30.10.2020 – for a minimum quantity of 30,000 vials (59,280 vials purchased in total);
3. Contract RD-06-46/31.03.2021 – for a minimum quantity of 36,000 vials (58,487 vials purchased in total);
4. Contract RD-06-200/04.10.2021 – for a minimum quantity of 30,000 vials (a total of 87,000 vials purchased).

The second, currently effective framework agreement Framework Agreement No. HERA/2022/NP/Q001, to which the Republic of Bulgaria is a party, was concluded on 18.07.2022 ("Commission signs new Joint Procurement contract for COVID-19 therapeutic", 2022).

Figure 1: Requested, distributed and applied quantities of the medicinal product – Veklury in hospitals in Bulgaria



On the graph presented above (Figure 1), the synchronous movement of the lines of the monthly requested, distributed and applied in Bulgaria vials of the medicinal product Veklury are shown. It is noteworthy that the amounts of Remdesivir claimed by the medical facilities for hospital care are twice as much as those distributed, which is an indicator of the wide use of the medicinal product in the country. During the period from October 2020 to August 2022 (since the conclusion of the first contract with the holder of the marketing authorization) 188,509 thousand vials of the medicinal product Veklury (INN Remdesivir) have been used, which have provided therapy to about 19,000 patients. For the same period, the requests for the medicinal product from the medical facilities for hospital care were for over 425,000 vials.

4. CONCLUSION

The specifics of the price regulation and the untimely market launch simultaneously in all of the member countries of the European Union make it difficult for patients to access medicinal products and medical countermeasures. A proactive approach is needed in terms of revising the pharmaceutical legislation at EU level regarding simultaneous marketing in all EU countries in order to guarantee that all EU residents have equal access to medications (“Reform of the EU pharmaceutical legislation”, 2023). The considered example with Bulgaria and the timely delivery of the medicinal product Veklury already in 2020 is indicative of the advantage that the Joint Procurement Agreement has over the standard procedures through which every medicinal product in the European Union passes. The JPA is a complementary mechanism to those already existing in the standard EU regulatory pathways, but it should be borne in mind that during global pandemics and the need for rapid reactions on the part of the Union – the JPA remains the first choice of Member States in their fight against future epidemics / pandemics.

REFERENCES

- “HERA, the EU's new Health Emergency Preparedness and Response Authority” (2022), European Commission, [https://www.europarl.europa.eu/thinktank/en/document/EPRS_BRI\(2022\)698941](https://www.europarl.europa.eu/thinktank/en/document/EPRS_BRI(2022)698941)
- “2021 State of the Union Address by President von der Leyen” (2021), European Commission, https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_21_4701
- “COMMISSION DECISION of 16.9.2021 establishing the Health Emergency Preparedness and Response Authority” (2021), European Commission
- Vogler S, Haasis MA, van den Ham R, Humbert T, Garner S, Suleman F., (2021) European collaborations on medicine and vaccine procurement. Bull World Health Organ, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8477421/>

- “HERA anticipates threats and potential health crises, through intelligence gathering and building the necessary response capacities” (2022), European Commission, https://commission.europa.eu/about-european-commission/departments-and-executive-agencies/health-emergency-preparedness-and-response-authority_en
- “Public health: Joint purchasing of vaccines and medicines becomes a reality in the EU” (2014), European Commission, https://ec.europa.eu/commission/presscorner/detail/en/IP_14_418
- Mcevoy E. & Ferri D. (2020) The Role of the Joint Procurement Agreement during the COVID-19 Pandemic: Assessing Its Usefulness and Discussing Its Potential to Support a European Health Union”, European Journal of Risk Regulation, https://www.researchgate.net/publication/346411343_The_Role_of_the_Joint_Procurement_Agreement_during_the_COVID-19_Pandemic_Assessing_Its_Usefulness_and_Discussing_Its_Potential_to_Support_a_European_Health_Union
- “Guidance on using the public procurement framework in the emergency situation related to the COVID-19 crisis” (2020) OJ C1081/1. On the Guidance, see R Baratta, “EU Soft Law Instruments as a Tool to Tackle the COVID-19 Crisis: Looking at the ‘Guidance’ on Public Procurement through the Prism of Solidarity” (2020) 5(1) European Papers, European Forum 365–73
- COVID-19 Procurement Actions, (2020) MedTech Europe, <https://www.medtecheurope.org/resource-library/covid-19-procurement-actions/>
- Georgopoulos A. (2022) The EU’s Joint Procurement Agreement in Light of COVID-19: Learning the Correct Lessons from the Pandemic and Identifying Actions for Improvement, University of Nottingham - School of Law; <file:///d:/Downloads/SSRN-id3981564.pdf>
- Azzopardi- Muscat. N., Schröder-Bäck P. & Brand H. (2016) “The European Union Joint Procurement Agreement for cross-border health threats: what is the potential for this new mechanism of health system collaboration?”. Health Economics, Policy and Law, https://www.researchgate.net/publication/305268978_The_European_Union_Joint_Procurement_Agreement_for_cross-border_health_threats_what_is_the_potential_for_this_new_mechanism_of_health_system_collaboration
- “Commission secures almost 3.5 million COVID-19 treatments through joint procurement contract” (2022), European Commission https://ec.europa.eu/commission/presscorner/detail/en/ip_22_6491
- “HERA signs Joint Procurement contract for Pandemic Influenza Vaccine” (2022), European Commission, https://cyprus.representation.ec.europa.eu/news/european-health-union-hera-signs-joint-procurement-contract-pandemic-influenza-vaccine-2022-07-28_en
- “Summary of Product characteristics of Veklury” (2022), European Medicines Agency, <https://www.ema.europa.eu/en/medicines/human/EPAR/veklury>
- “Health Minister Angelov: All patients for whose treatment the medicine Remdesivir is needed are covered” (2020), Ministry of health, <https://www.mh.government.bg/bg/novini/aktualno/ministr-angelov-vsichki-pacienti-zachieto-lecheni/>
- “Official letter from the Health Minister of Bulgaria to the Parliament of the Republic of Bulgaria” (2020), Ministry of Health, <file:///d:/Downloads/412151054-06-1008.pdf>
- “The Ministry of Health has secured sufficient quantities of medicinal products applicable to patients with COVID-19” (2021), Ministry of Health, <https://www.mh.government.bg/bg/novini/aktualno/ministerstvoto-na-zdraveopazvaneto-e-osigurilo-dos/>
- “The government has approved contracting to provide Remdesivir”, Ministry of health, (2020), <https://www.mh.government.bg/bg/novini/ministerski-savet/pravitelstvoto-odobri-sklyuchvaneto-na-dogovori-za/>
- “Commission signs new Joint Procurement contract for COVID-19 therapeutic” (2022), Gilead Sciences 2022 https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1845
- “Reform of the EU pharmaceutical legislation”, 2023, European Commission, https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en