

POLICY BRIEF

Centralized vaccine procurement in the post-COVID-19 European Union

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Abstract

Introduction:

The COVID-19 pandemic has confronted healthcare systems worldwide with societal, psychological, and economic burdens. The widespread use of the developed COVID-19 vaccines has been generally pursued to stop the spread, decrease mortality rates, and lift the economic burden of healthcare systems. However, it became apparent that the demand for vaccines outnumbers the supply provided by pharmaceutical manufacturers. This policy brief explores the use of centralized procurement globally to formulate recommendations on how the European Union (EU) and its member states can benefit from such an approach.

Policy Options:

Globally, different models with varying levels of collaboration on procurement are implemented. The collaboration can be limited to information sharing or extend towards centralized procurement of medical goods. However, during the COVID-19 pandemic, countries collaborated at an unprecedented scale, pooling together resources and expertise to ensure access to scarce vaccine supplies. The resulting centralized approach witnessed in the United States (US), EU, African Union (AU), or through COVAX highlighted the benefits of centralized procurement in the state of crisis.

Recommendations:

- An independent institution for pandemic preparedness and response:
 - focuses on transparent and timely access to vaccines
 - supports strengthening of national capacities and healthcare systems through periodic monitoring and evaluation.
- A centralized procurement system for all EU member states under the independent institution.
- The development of comprehensive and efficient emergency preparedness plans.

Keywords: COVID-19, Vaccination, Centralized procurement, HERA, EU, Emergency response

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Introduction

In March 2020, the World Health Organization (WHO) declared the COVID-19 outbreak a pandemic. Globally, the virus has cost more than five million lives, and infection rates have been continuously in flux since the first cases of the virus were reported (1,2). The contagiousness of the disease has confronted healthcare systems worldwide with the question of how to stop its spread most effectively (3). In the early stages of the pandemic, it quickly became apparent that the containment of the virus was nearly impossible without taking drastic measures. Countries implemented mitigation and suppression strategies to slow down disease spread, such as social distancing and lockdowns (4-6). Such strategies contributed to the overarching goal of flattening the curve, in which the number of cases is spread over a longer period of time to not overwhelm healthcare systems' capacity and resources (2). However, it cannot be neglected that despite their effectiveness, such measures carried extensive economic costs and wideranging social and psychological costs. Additionally, since their effectiveness depended heavily on individual adherence, standing alone, they were inadequate to contain the virus (7).

Therefore, the development of vaccines for COVID-19 was anticipated with great interest as an effective strategy to end the pandemic and alleviate the above-mentioned burdens from nations and inhabitants (4). The health benefits of vaccinating against COVID-19 include the reduction in mortality and morbidity for those most at risk. Additionally, it reduces further cases and often averts severe disease cases. The economic benefits of vaccination include a reduction in treatment costs. fewer absenteeism rates in the workforce, and hopefully the expedition of a return to normal social and economic functioning (8). A recent study states that COVID-19 vaccination for individuals above 60 years has already averted 469,000 deaths globally, highlighting the importance of vaccination in the ongoing pandemic (9,10). The European Commission (EC) has declared COVID-19 vaccines as the best way out of the pandemic, presupposing high vaccination rates (11). Therefore, high availability of safe and effective vaccines in an equitable and timely manner is crucial (3,10).

Context

The existence of vaccines does not mean that countries have the infrastructure and resources to effectively distribute them, nor that individuals will accept them. In the EU, access and availability failed to meet demand when vaccination campaigns started in March 2021. Thus, despite the availability of the needed technology, the EU was - and remains - unable to distribute enough vaccines in an equitable way across its Member States (MS) (12). The EU took a approach in securing common and facilitating distribution. Presented in June 2020, the objectives of the Vaccines Strategy were to 'accelerate the development, manufacturing and deployment of vaccines against COVID-19' (11). However, actions taken to meet the objectives have been widely criticized and were subject to much scrutiny (12,13). Some of the flawed aspects of the strategy included, as stated by EC president von der Leyen, being too optimistic regarding the ability to mass-produce vaccines, acting too late in granting authorization, and not preparing MS equally to distribute vaccines (12,14). Moreover, lack of transparency, lengthy negotiation processes which ended only after a possible threat of monopolizing by the US, and suboptimal vaccine rollout with no regard to national capacities led to inequitable and less than timely access



(12,14). The delay in procurement also led various groups to negotiate with manufacturers on their own (14).

Acknowledging the weaknesses of the vaccine strategy, the EC launched the European Health Emergency Preparedness and Response Authority (HERA) in September 2021 (11). It is a key pillar of the new European Health Union, aiming to fill gaps in the EU's health emergency response capabilities. and preparedness HERA combines the power of the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), and it has already been challenged for having various flaws. For example, HERA is not an independent agency, and key European institutions such as the European Parliament are not involved. Furthermore, according to the treaties (TEU and TFEU), the EU only holds limited competency to actually translate HERA's vision into action.

The pandemic has demonstrated that the strategies tackle health current to emergencies at the European level are insufficient. Even though the development of HERA could be a first step in the right direction, the accelerated momentum of the pandemic must be utilized to work towards a comprehensive strategy. Therefore, the aim of this policy brief is to develop a new strategy for vaccine procurement in the EU, built upon and informed by previous strategies throughout the world.

Policy Options

In November 2020, the EC adopted the 'Pharmaceutical Strategy for Europe'. The initiative aims to ensure access to affordable medicines, enhance the crisis preparedness and response mechanisms, and diversify and

secure supply chains whilst promoting a strong united EU voice in the world (15). Yet, witnessed during the pandemic, as inefficiencies in the supply chain, procurement capacity constraints, and limited financial resources can hinder access to lifesaving medicines. To be well-prepared for the possible occurrence of similar scenarios as the COVID-19 pandemic, we argue that a new, revised procurement strategy, which ensures equitable and timely access to vaccines for all, is needed. We consider centralized procurement, by aggregating demand, increasing bargaining power, and improving procurement management, as a useful tool to comprehensively address flaws in previous strategies. The WHO defines it as the combination of 'several buyers into a single entity that purchases (...) on behalf of those buyers' (13). Figure 1 illustrates factors influencing the feasibility of a centralized procurement approach.

Based on the characteristics of different procurement models (as displayed in Table 1), governments and organizations choose the best option for them. Examples include informed buying, where only information on prices and suppliers is shared, or coordinated informed buying. where members additionally conduct joint market research. In the group contracting model, members enter joint negotiations with selected suppliers; however, the procurement can be done individually, in contrast to the central contracting and procurement scheme. Some strategy choices are discussed below, focusing firstly on general procurement mechanisms and secondly on COVID-19 specific procurement approaches, which provide the basis for the development of our conclusive recommendations.



	Information S	haring Models	Pooled Procurement Models			
	Informed Buying	Coordinated Informed Buying	Group Contracting	Central Contracting and Procurement		
Characteristics	Information sharing on prices and suppliers Procurement conducted individually	Information sharing on prices and suppliers Procurement conducted individually Joint market research	Joint Price Negotiations Joint Selection of Suppliers Procurement conducted individually	Joint Tenders and Contract awarding through a representative organization Central procurement unit pools the resources and conducts the purchase on behalf of MS		
Strengths	 Least costly, less complex t Reduced administrative and Reduction of risks associate 	Least costly, less complex than joint procurement Reduced administrative and horizon scanning costs Reduction of risks associated with the choice of supplier		 Savings due to bulk purchasing Lower prices More efficient supply chain Improved accountability, transparency, and costefficiency 		
Weaknesses	 Lack of economies of scale factor May not contribute to lower price purchase 		 Complexity – requires a reliable governance system High setup cost 			
Opportunities	 Development of standardize medicine development asse May contribute to further po Improved international collar 	ed methods for manufacturers and assments olitical integration aboration	 Improved harmonization of the drug registration process Improved reliability and accountability of suppliers Pooled resources and expertise Greater involvement of local manufacturers Creation of a single market Promotion of international trade 			
Threats	 Unwillingness of MS to sha Limited impact of the reference 	re the information ence pricing	 Differing needs among member states Lack of involvement of bigger MS Lack of political will and commitment 			

Table 1: SWOT Analysis of Possible Collaboration



Procurement Pre-COVID 19

Prior to the pandemic, collaboration on procurement was utilized by international organizations such as the PAHO Revolving Fund and UNICEF (16–19). Within Europe, such activities before the pandemic were often justified by insufficient individual markets of the participating countries (20); this is particularly true for the procurement of small-volume products, such as orphan drugs and innovative medicine. Appendix A provides an overview of European collaborations in place before the pandemic. However, such pre-existing structures were not equipped to deal with a large-scale health crisis like COVID-19.

Centralized Procurement EU

However, during the pandemic, due to the scarce supplies, and state of emergency, many countries decided to cooperate on an unprecedented scale. Governments were entering into Advance Purchase Agreements (APAs) with vaccine companies to secure access to vaccine doses. Meaning they were committing to purchasing products that were yet to enter the market. Most of these agreements were between private manufacturers and intergovernmental organizations (i.e., EU, COVAX, African Union).

The EU negotiated APAs with vaccine manufacturers as part of their vaccination strategy (21). This followed an unusual approach as vaccines' safety, quality, and efficacy were previously assessed at the EU level by the EMA, while price negotiations and subsequent reimbursement decisions were commonly taken at the national level (22).The legal basis for pooling competencies at the EU level was the Council regulation EU 2016/369 (23), which set up the emergency support instrument under the principle of solidarity to respond to the pandemic.

Figure 1 illustrates some of the general factors influencing centralized procurement embedded into the broader context of pandemic preparedness. It underlines the complex interplay of various factors.



Figure 1: Fusion of Centralised Procurement Feasibility and Pandemic Preparedness Model; Adapted from ECDC, 2009



Centralized Procurement Africa

In Africa, by February 2020, the Africa Joint Strategy for Continental COVID-19 Outbreak was adopted. Managing the coordinated continental-level response required the leadership of the African CDC, which birthed two main operational units; the Africa Task Force for Coronavirus and Africa CDC's Incident Management System (24). To pool resources, strengthen the supply chain, and improve coordinated actions against COVID-19, an African Coronavirus Fund was established, which has aided the AU to procure and distribute essential medical equipment and supplies, thereby strengthening mobilization and response rates (24).

Procurement US

To coordinate the acceleration of development, procurement, and distribution of pandemic countermeasures, the United States government started Operation Warp Speed (OWS) (25). This collaboration between the Department of Defense and the Department of Health and Human Services consisted of services like the Center for Disease Control and Prevention, the National Institutes of Health, and the Biomedical Advanced Research and Development Authority (BARDA), which served as the basis for the development for its European counterpart HERA. Whilst the focus of OWS included therapeutics and diagnostics, most financial resources were spent on developing vaccines (25). BARDA's approximately 18 billion US dollar investment in various manufacturers made OWS the greatest global effort to develop COVID-19 vaccines (26). The vaccine tracking system by the CDC allowed states to place weekly orders, however, states had no say in which vaccines were delivered (27).

Centralized Procurement COVAX

Globally, in April 2020, COVID-19 Vaccines Global Access (COVAX) was set up to ensure equitable access to COVID-19 tests, treatments, and vaccines (28). COVAX has two modalities of participation. Firstly, lowand middle-income countries participate through the Advance Market Commitment (AMC) instrument (29). After confirming participation, supported by WHO and partners, countries develop national deployment and vaccination plans before signing indemnity and liability agreements. Participants can request additional technical assistance and cold chain support. Secondly, self-funded participants indicate the share of the population to be covered (10%-50%), whereupon COVAX negotiates and enters agreements with manufacturers on their behalf (30). Countries then receive vaccines through optional or committed purchase arrangements, both requiring up-front payment. Participating countries sequentially receive enough doses to cover 20% of the population. Once all reach the 20% threshold, further doses are allocated according to vulnerability and risk criteria.

A comprehensive overview of key mechanisms for the different procurement approaches can be found in Table 2, whereas their SWOT analysis is presented in Table 3.

Analysis

The described policy options show a general tendency in international organizations and states to explore more centralized approaches to tackle emergency health crises. This trend in pooling further powers at the EU level becomes apparent in the recent call to establish a European Health Union. The pandemic has shown the need for timely and coordinated responses in the procurement of



vaccines for the general population. Table 3 highlights that the benefits of centralized procurement outweigh its shortcomings. Equitable and timely access to vaccines in a transparent manner seems to be its core strength derived from the procurement policies. The lack of procurement legislation and limited financial resources seem to be recurring themes in the policies of PAHO, UNICEF, and COVAX, which hinder their effective use. Additionally, the complexity of setting up such systems, currently one of the main challenges and contributions to a lackluster COVID-19 response, could be overcome by utilizing the already high level of harmonization of the EU and involved institutions such as EMA and the ECDC and potentially HERA. Questions as to the extent to which MS will give up autonomy over vaccine purchases might need to be clarified. To counter discordance, it should be considered to apply centralized procurement only in a health crisis through the emergency support instrument of the EU. We argue that the opportunities of centralized procurement presented in Table 3 can be harnessed by the EU, while the threats can be overcome through already existing structures in the EU.

The application of APAs under a centralized procurement scheme in the EU demonstrated some pitfalls that must be addressed. Extended price negotiations with vaccine manufacturers led to a delay in vaccine procurement. Consequently, MS stopped relying on EU efforts to procure vaccines. The observed delays ultimately resulted in a shortfall in the number of vaccines available to EU residents. However, the EU was able to negotiate a price lower than the U.S., possibly attributing to a lengthier negotiation process (31). The formulated policy options built upon the pharmaceutical strategy for Europe, which addresses crisis preparedness and securing supply chains in pharmaceutical products. The examples of centralized procurement given in section 3 shall guide the implementation of the EU procurement system.

Stakeholders

Improving EU vaccine procurement requires the involvement and alignment of various stakeholders. The EC, Parliament, Council of Ministers, individual MS. and pharmaceutical industry hold high interest and power. The EU institutions would most likely favor a centralized procurement system as this can increase their negotiation power. pharmaceutical On the other hand. companies are less inclined to support a centralized procurement system as it potentially limits their influence on pricing. Another challenge is aligning MS interests to agree on how this new procurement system should look. The integration of stakeholders with high interest but low power, for example, the ECDC, WHO, EMA, and more, must also be regarded.

Considering the above analysis, the following recommendations were developed, aiming to produce comprehensive guidance on how to procure vaccines in a crisis through a pooling mechanism whilst aligning the majority of stakeholder interests. In anticipation of a future crisis, we want to generate fruitful cooperation and collaboration at all levels and across borders and act as an undivided EU.



	EU	UNICEF's	РАНО	Operation Warp	COVAX AMC	COVAX	AU COVID-19
		Supply Division	Revolving Fund	Speed		Facility	Response Fund
Model	Central	Central	Group	N/A	Central		Central
	contracting and	contracting and	contracting		contracting and		contracting and
	procurement	procurement			procurement		procurement
Ownership	EU member	UNICEF	PAHO member	US Government	Gavi, The	Gavi, The	Africa CDC
	states		states		Coalition for	Coalition for	
					Epidemic	Epidemic	
					Preparedness	Preparedness	
					Innovations,	Innovations,	
			XX . 11 1	XX 1 11 1	WHO	WHO	D
Financing	Emergency	Mainly donor	National budgets	National budget	Mainly donor	National	Donor funding
mechanism	Support	funding, a few	(price of the	and additional	funding	governments	
	Instruments	countries pay in	vaccines $+3,5\%$	funds allocated			
	National	full for the	recapitalization	through BARDA			
	Budgets	vaccine purchases	ree)				
		+ administrative					
Droguromont	Controlized	Controlized	Loft to the states	Controlized	Controlized	Controlized	Controlized
activities	Centralized	Centralized	Left to the states	Centralizeu	Centralizeu	Centralized	Centralizeu
Timeframe	COVID-19	Permanent	Permanent	15 05 2020 -	COVID-19	COVID-19	COVID-19
1 men ame	nandemic	rennanent	I ermanent	24 02 2021 then	Pandemic	Pandemic	Pandemic
	pandenne			responsibilities	1 andenne	1 andenne	1 andenne
				transferred to the			
				White House			
				COVID-19			
				Response Team			
Range of	COVID-19	Routine	Vaccines,	COVID-19	COVID-19	COVID-19	COVID-19
products or	vaccines	vaccination	syringes, and	therapeutics,	vaccines	vaccines	vaccines
services involved			related supplies	diagnostics, and			
				vaccines			
Purchasing	Direct	Multi-year tender	Annual tender	Direct	Direct	Direct	Direct
mechanism	procurement:			procurement:	procurement:	procurement:	procurement:
	Advance			Other transaction	Advance Market	Optional/	Advance
	purchase			Agreement	Commitment	Committed	purchase
	agreement					Purchase	agreement
						Arrangements	

Table 2: Policy option characteristics



Table 3: SWOT Overview of Procurement Policies

	Strengths	Weaknesses	Opportunities	Threats
EU	Higher negotiation power compared to single member states (lower pharmaceutical prices)	Transparency of the negotiated conditions	Exploration of more centralized and multi- national efforts to purchase and distribute medicinal products	APAs cause the possibility of purchasing ineffective or unsafe vaccines, or vice versa
	Ensures access to promising vaccines in a timely manner for all MS			Risk of a pharmaceutical contractor not adhering to predetermined conditions
	Risk-sharing between the pharmaceutical manufacturers and the EU			
UNICEF	Provides equitable and efficient access to vaccines	Initial capitalization and management of funds	Lower unit prices, eventually generating cost savings	Reporting and evaluation according to harmonized external standards rather than national ones
	Resource pooling ensures equal access for MS	National procurement legislation	Greater stability in vaccine supplies	Reliance on external bodies (a risk that country capacities will not be developed accordingly,
	Guided by an experienced partner			creating a long-term dependence on external bodies)
РАНО	Global recognition of PAHO	Limited financial resources	Partnerships for resource mobilization	MS unable to meet the annual requirements for the Revolving Funds
	High level of accountability Promoting equity and encouragement of collaboration between local agencies	Very bureaucratic and rigid in processes		Financial and operational stability of the MS
US	Guarantee of enough vaccines for the citizens of the US	Other countries were also able to close deals with the vaccine manufacturers and had more vaccine doses per capita than the US	Ordering system for vaccinations can be seen as an example of a system for the EU	States have no say in which vaccines will be delivered, causing relegation of the vaccines
COVAX AMC & FACILITY	Expertise of partners (translating into broad manufacturer portfolios and strong	Insufficient funding	Promotion of health equity and the benefits of multilateralism	Vaccine hoarding in high-income countries
	bargaining power)	Severe demand-supply gap		Few countries offer vaccine donations (if so, they often arrive last-minute and in small numbers)
		Lack of transparency in concluded contracts		Slow process, leading participants to enter into bilateral agreements undermining COVAX efforts
African Union	Aid in the procurement and distribution of essential COVID-19 medical equipment and supplies	Vaccine shortage Low vaccination rates	Legal, operational, and institutional autonomy of the Africa CDC from the African Union Commission	Delays in accessing COVID-19 vaccines
	Reinforcement of AU MS response to the COVID-19 challenge		Sustained close collaboration at the national, regional, and continental levels	
			Encouraging vaccine manufacturing on the African continent	



Recommendations

The discussed policy options demonstrated the necessity of establishing a designated institution charged with the ownership and control of a centralized crisis response, which presents an entirely independent body (hereinafter referred to as the institution) as opposed to the recently developed HERA under the EC. This allows the institution to act detached from other key EU players. Its mandate must ensure not only transparent negotiations and timely access to vaccines but also establish continuous efforts and support to strengthen national capacities and systems through healthcare periodic monitoring and evaluation. This guarantees that when vaccinations are procured, MS are equipped to utilize them efficiently according to national needs. The institution shall function as the overarching and coordinating emergency response body and, more specifically, should build on the approach of centralized procurement taken by the EU in COVID-19 pandemic, the of which advantages have been discussed above.

Since health is a MS competence, this strategy requires ensuring that MS interests are aligned, to then be transferred to the supranational level. It is apparent that such an endeavor requires will and political commitment. Therefore, the momentum created by the COVID-19 pandemic must be utilized to bring together European institutions, MS, and relevant stakeholders, to initiate negotiations that will facilitate the streamlining of interests. Such congregations create room for copious deliberation, helping all parties to agree on the institution's exact scope and modus operandi. Similarly to HERA. the institution must aim to collaborate closely with the ECDC and EMA, incorporating their advice in the development of the pandemic response. Regular meetings with representatives of all three institutions,

pre- and during a pandemic, allow for monitoring of disease threats and medicinal products. A sufficient amount of resources must be invested to set up a resilient technical infrastructure that allows for continuous data sharing. This data exchange provides an base for the institution's evidence negotiations with vaccine manufacturers. Widely criticized in the COVID-19 was the lack of transparency. Hence, content of negotiation processes should be made available to citizens in an easily accessible, comprehensive manner, on a designated part of the institution's website. Since public money is spent, we need to be aware of agreements made at the supranational level.

The existence of comprehensive and efficient emergency preparedness plans which enable MS to effectively respond to and manage future pandemics must be ensured, as this allows strategies, such as the abovementioned centralized procurement, to function smoothly. To sustain emergency preparedness across the EU, adequate resources need to be dedicated toward interdisciplinary proactive pandemic preparedness and response planning, following the cycle depicted in Figure 1. participating Common standards for countries shall be developed, adhered to by participating MS, transferring competencies to the EU, where insufficient national capacities to respond to a pandemic are present. There is an urgent need to evaluate MS infrastructure and pandemic response to identify shortcomings. Once identified, the institution can direct resources and support towards MS in greatest need.

As the name entails, a pandemic affects the whole world. COVID-19 has distinctly demonstrated how interconnected the globe is, where European public health is highly influenced by global public health.



Therefore, it should not be neglected that the EU must internally strengthen the centralized approach and further foster international partnerships to promote timely and swift emergency responses, comprehensive information, and evidence sharing, all helping to mitigate international public health emergencies.

Conclusion

In conclusion, vaccine procurement policies in the EU hold great potential for improvement. During COVID-19, the lack of transparency in lengthy negotiation processes, and lack of unity and solidarity were considered problematic. By setting up a centralized procurement mechanism under a novel independent body for emergency and pandemic response, the procurement of vaccines in a future health crisis will run smoothly. Embedding this in elaborate emergency preparedness planning, the EU will be able to react timely and in MS and citizens' best interest.

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Appendices

Appendix A

Table 1: European collaborations in the procurement of health technologies

	Start date	Countries involved	Scope	Aspects of procurement covered
Central Eastern European and South Eastern European Countries Initiative	November 2016	Romania, Bulgaria, Croatia, Latvia, Poland, Serbia, Slovakia, Slovenia, Republic of Moldova, FYR Macedonia	Pharmaceuticals	Price negotiation
Southern European initiative	June 2016	Greece, Bulgaria, Spain, Cyprus, Malta, Italy, Portugal	Innovative medicines	Information sharing on prices and markets, collaboration on R&D
Declaration of Sofia	June 2016	Bulgaria, Croatia, Estonia, Hungary, Latvia, FYR Macedonia, Romania, Serbia, Slovakia, Slovenia	Pharmaceuticals	Information sharing on prices and markets, with potential for joint purchasing in the future
Nordic Pharmaceuticals Forum	June 2015	Denmark, Iceland, Norway, Sweden	Pharmaceuticals	Horizon scanning, information sharing on prices and markets
Romanian and Bulgarian Initiative	June 2015	Romania, Bulgaria	Innovative medicines	Joint negotiations in purchasing to get lower prices for pharmaceuticals and cross-border exchange of medicines in short supply to ensure continuity of access
BeNeLuxA	April 2015	Belgium, Netherlands, Luxembourg, Austria	Pharmaceuticals And medical devices	HTA, horizon scanning, information sharing on prices and markets, joint negotiation for purchasing to ensure affordability
Baltic Partnership Agreement	May 2012	Latvia, Lithuania, Estonia	Innovative medicines	Centralized joint purchasing (tenders, negotiation, payment, and distribution) to reduce expenditure and ensure continuity of access

Adapted from (32)



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