



### Work Package 6 – Task 6.1.3



Deliverable D.6.3: Report on financial mechanisms for vaccine procurement, based on a survey among EU/EEA and EU-JAV consortium Member States.

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Grant Agreement No.:	801495
<b>J</b>	
Start Date:	01/08/2018
End Date:	31/07/2021
Lha Date.	51/07/2021
Project title	European Joint Action on Vaccination — EU-JAV
	Wpc
WP number	WP6
Deliverable www.her	D6.3
Deliverable number	
Title	Report on financial mechanisms for vaccine procurement
	based on a survey among EU/EEA and EU-JAV consortium
	Member States.
<b>B 11 1 N</b>	
Responsible partner No.	9
Organisation	Istituto Superiore di Sanità, Italy
Name	Antonietta Filia MD PhD, Maria Cristina Rota MD
E-mail address	antonietta.filia@iss.it, mariacristina.rota@iss.it
Nature	
P roport	v
R-Teport	^
O-other (describe)	
Dissemination Level	
<b>PU</b> -public	
	60
<b>CO</b> -only for consortium	
members	
Delivery Month Planned	M36
Actual Delivery Date	20/07/2021
(dd/mm/yyyy)	50/07/2021





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### Working Group

The activities of Task 6.1.3 were conducted by:

Antonietta Filia (WP6 Leader), Maria Cristina Rota, Department of Infectious Diseases, Istituto Superiore di Sanità, Rome, Italy.

in collaboration with:

<u>Rosa Prato, Domenico Martinelli</u>, Department of Medical and Surgical Sciences, University of Foggia, Italy.

<u>Carlo Signorelli, Anna Odone, Vincenza Gianfredi, Daria Bucci, Roberto Croci,</u> University Vita-Salute San Raffaele, Milan, Italy.

### Acknowledgments

We would like to thank Oleg Benes (WHO Regional Office for Europe) for helpful comments and discussions while drafting the questionnaire, Truus de Graaf (RIVM, Netherlands) and Pertti Sormunen (THL, Finland) for piloting the survey, and Vaccines Europe for useful discussions. We are also grateful to all participants in the survey and all EU-JAV members who contributed to the discussion.





### Acronyms

COVID-19	COronaVIrus Disease-2019
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Agreement
EU	European Union
EU-JAV	European Joint Action on Vaccination
GAVI	Global Alliance for Vaccines and Immunizations
JPA	Joint Procurement Agreement to procure medical countermeasures
MS	Member State
NIP	National immunization Programmes
NITAG	National Immunisation Technical Advisory Group
NRA	National Regulatory Authorities
РАНО	Pan-American Health Organization
SARS-CoV-2	Severe Acute Respiratory Syndrome CoronaVirus 2
UN	United Nations
UNICEF	United Nations Children's Fund
VPD	Vaccine-Preventable Diseases
WHO	World Health Organization
WP	Work Package





### **Executive Summary**

The present report is the second deliverable of Task 6.1 (Work Package 6: Vaccine Supply and Preparedness) of the EU Joint Action on Vaccinations (EU-JAV), which has the following objectives:

- Review previous experience about vaccine shortages and responses of EU countries (and non-EU consortium member countries);

- Analyze and evaluate local financing mechanisms for purchase and stock of vaccines.

- Develop guidelines on procedures to estimate vaccine needs and procurement in EU-MS in the short and long-term;

It refers to the objective « Analyze and evaluate local financing mechanisms for purchase and stock of vaccines. The methodology used to produce this deliverable consisted in:

- Workshop with participating EU JAV consortium member states and main stakeholders.
- Consultation of the literature on vaccine procurement and advantages and disadvantages of self-procurement versus centralized/joint procurement.
- Survey among EU/EEA and EU-JAV consortium Member States (MS), to collect information on the local financial mechanisms for vaccine procurement used in their respective countries, and to explore MS opinions on key barriers and enablers of success of joint procurement initiatives.

It is important to note that the activities related to this deliverable were carried out prior to the availability of COVID-19 vaccines and therefore these are not included in our results. However some considerations on procurement of COVID-19 vaccines are discussed.

The workshop was held in October 2019, in Rome (Italy), at the first General Assembly Meeting of the EU-JAV.The aim was to present the main results of the first deliverable («Report on previous experiences with vaccine shortages in EU countries and non-EU consortium member countries), and responses at national and European levels»), obtain feedback from partners and stakeholders, and discuss future activities. The discussion was focused mainly around the feasibility of centralized procurement of vaccines and whether it is a possible solution for mitigating vaccines shortages. A decision was made to evaluate advantages and disadvantages of centralized versus self-procurement of vaccines and to conduct a survey among MS to





explore local financial mechanisms for vaccine procurement, experiences with and opinions on joint procurement.

Both self procurement (which can occur at the national or subnational levels), and joint procurement methods have advantages and disadvantages. However, the available literature on this topic is scarce and often limited to low and middle income countries, and this reduces the generalizability to the EU/EEA context. There is limited data on the impact of current vaccine procurement methods on the performance and sustainibility of vaccination programmes.

In order to collect information on the financial mechanisms used for vaccine procurement, participation in joint procurement initiatives (and other forms of cross-border collaboration) and Member State opinions on joint procurement of vaccines, we conducted a survey from August to October 2020, among persons in charge of the national or subnational immunisation programme(s) or of vaccine supply/procurement in EU/EEA and EU-JAV consortium Member States. Twenty-eight countries were invited to participate, including all 20 EU-JAV partners (which consist in 18 EU/EEA countries, Bosnia-Herzegovina and Serbia), and eight EU/EEA countries not participating in the EU-JAV. Fourteen of 28 invited countries responded to the survey, all EU/EEA.

Survey results highlight that vaccines included in the national vaccination schedules are entirely funded by the national or subnational government in the majority of countries. Other reported sources of funding include health insurance contributions either directly funded by the central government or with reimbursement of costs. It also highlights that not all vaccines included in national vaccination programmes are completely state funded. Most countries allocate specific funds to vaccines and use annual budget planning, while midterm or longterm planning is seldom used by countries. Budget planning is centralised in most countries. Decision-making to finance introduction of a vaccine is based, among other things (epidemiology of the disease and cost-effectiveness evaluations), on NITAG recommendations. However, lack of information on the size of the population to be vaccinated (e.g., size of highrisk populations) and estimating the exact coverage levels to be achieved, were reported by some countries as main difficulties in forecasting and budget planning. These issues will be addressed in the next deliverable of WP6, whose aim is to develop guidelines for procedures to estimate vaccine needs and procurement in EU-MS in the short and long-term.





Regarding the current framework for vaccine tenders, most countries reported using price criteria, with only three countries using quality criteria. There is some evidence that while price-based tenders can bring a reduction in prices, at least in the short term, they may contribute to vaccine supply issues, discourage the provision of value-added services and be a disincentive for future R&D. They also have not been shown to increase vaccination coverage.

Survey results suggest that overall, the current financial mechanisms for vaccine procurement used in the surveyed countries seem to function well and that in general, these countries are satisfied with their procurement process. Survey respondents identified as main strengths of current procurement systems, transparency, homogeneous and adequate prices and equal access to vaccines. The main reported weaknesses are the high level of bureaucracy and long and complex tendering procedures. One country highlighted the need to conduct more longterm agreements, another the difficulties with subnatiobnal budgeting. In three countries, there is no national centralized process for vaccine purchasing; one of these countries highlighted that this means no discount for high volumes of doses purchased.

Regarding joint procurement, prior to the EU Joint Procurement for COVID-19 vaccines (in which all EU countries participated), several countries had participated or were participating in other more limited joint procurement initiatives with other European countries. The general perception of these countries is that JP has several advantages but also disadvantages. However, most participants agreed about the usefulness of JP of vaccines in improving MS preparedness in the event of serious cross-border health threats caused by vaccine preventable diseases. Some countries seem to be unfavorable to JP because of its potential to seriously affect the vaccine market and to disturb a healthy market. Indeed short term versus long-term impact of joint procurement, for example on the sustainability of the suppliers, should be analysed and considered.

Besides joint procurement, half of responding countries reported participating in other forms of cross-border collaboration to support decision making during national procurement, such as sharing vaccine price information, conducting joint market research, sharing information and discussing tender processes and supplier insight. According to respondents, possible advantages of these collaboration models include increased transparency on prices, increased negotiating power, decreased prices and administrative costs. A concept analysis for a regional





EU data warehouse for sharing data/information of supply and demand is ongoing in the framework of the EU-JAV Work Package 6.

The common procurement of COVID-19 vaccines, led by the European Commission, with the participation of all EU Member States, is a very recent and important example of a common approach taken to procuring vaccines in EU during a cross border health threat, as well as the financing mechanism used. Advanced purchase agreements were used and these have been a crucial element contributing to the European response to fight the COVID-19 pandemic. Thanks to the common EU Vaccines Strategy, the Commission was able to build a diversified portfolio of several vaccines, based on different technologies, from several suppliers, at a fair price, and has ensured access to COVID-19 vaccines for all Member States. The strategy also enabled the support and speeding up of development and manufacturing at scale of COVID-19 vaccines and allowed the exportation of doses to over 100 countries worldwide. In order to strengthen the EU preparedness and response in future health emergencies, in November 2020, the Commission, among other initiatives, set out the main elements of the future Health Emergency Response Authority (HERA), to be proposed by the end of 2021. HERA is part of the European Health Union and will provide a dedicated structure to support the development, manufacturing and deployment of medical countermeasures (including vaccines) during a health crisis of natural or deliberate origin.

This report has several limitations. The main limitation is that the report is based on a questionnaire survey conducted during the COVID-19 pandemic, when many health professionals were heavily involved in outbreak control activities, and therefore only 14 of 28 (50%) invited countries responded to the questionnaire. Some responses were delayed and sometimes incomplete. Another limitation is that much of the published literature on vaccine procurement is limited to low- and middle-income countries and therefore some aspects may not be generalizable to most EU/EEA countries.

The main conclusions we can draw from this survey are several. In EU/EEA, vaccines included in the national vaccination schedules are entirely funded by the national or subnational government in the majority of countries and none of the participant countries use private donor funding. Most countries use annual budget planning cycles (mostly centralised), while mid-term or long-term planning is seldom used by countries. Longer term planning is recommended because it allows a more comprehensive view of future vaccine demand.





Overall, countries are satisfied with their procurement process; however, most countries reported using price criteria, which may be a disincentive for manufacturers to participate in tenders and invest in R&D. One of the requirements of a healthy market is that a range of suppliers be available; in order to achieve this requirement, price should not be the only criterion considered in vaccine tenders. The majority of participants reported being favourable to joint procurement of vaccines during serious cross-border health threats caused by vaccine preventable diseases. Other forms of cross-border collaboration (such as sharing vaccine price and other market information), and lending of vaccines in case of vaccine shortages have been used in EU, and should be encouraged. Availability of a regional EU data warehouse of supply and demand coud be a step in this direction. A concept for such a data warehouse is being developed in the framework of the EU-JAV Work Package 6.





### 1. Introduction

Vaccination is one of most significant public health achievements and one of the best investments in public health. European national immunisation programmes (NIPs) have generally performed well in achieving high immunisation levels for childhood vaccines. However, there are numerous challenges faced by NIP in most countries, including a high number of newly recommended vaccines, higher prices of newer vaccines, disparities in immunization levels within countries, low levels of immunization for some hard to reach groups and for subjects with chronic illness, shortages in vaccine supply and the increasing investments required to license and produce new vaccines. In recent years, some parts of Europe have experienced outbreaks of vaccine preventable diseases due to declining vaccine coverage driven at least partly by anti-vaccine campaigns (1).

In 2018, the EU Commission issued a Council Recommendation on strengthened cooperation and coordination between EU countries, industry and other relevant stakeholders, against Vaccine Preventable Diseases. The recommendation included, among others, a reference to strengthening vaccine supply, procurement and stock management (2). In this context, Work Package (WP) 6 "Vaccine supply and Preparedness" of the European Joint Action for Vaccines (EU-JAV, https://eu-jav.com) aims to define common basic principles for vaccine demand and develop a concept for how a data-warehouse for an EU-wide central repository for all consortium members (EU and non-EU) on vaccine supply and demand data can be designed (3). Task 6.1 of the WP has the following objectives:

- Review previous experience about vaccine shortages and responses of EU countries (and non-EU consortium member countries)

- Analyze and evaluate local financing mechanisms for purchase and stock of vaccines

- Develop guidelines on procedures to estimate vaccine needs and procurement in EU-MS in the short and long-term.

Our recent «Report on previous experiences with vaccine shortages in EU countries (and non-EU consortium member countries), and responses at national and European levels», the first deliverable of Task 6.1 of this Work Package, highlighted that many countries in EU/EEA have reported vaccines shortages in recent years. Nineteen of 21 participating countries experienced shortages (including stockouts) in the study period from 2016 to 2019. Vaccine shortages are





a serious public health issue as they can lead to missed opportunities for vaccination and a greater risk of occurrence of deadly vaccine-preventable disease (4). The causes of vaccine shortages were found to be multifactorial, including supply, demand and information factors, and varied by vaccine and country. One of the conclusions of the report was that procurement and tender mechanisms should be improved and take into consideration, among others, multisource suppliers, other factors besides price, and the length of contract. An efficient and reliable vaccine procurement system, the process by which vaccines are acquired, either domestically or internationally, using specific procedures and/or mechanisms, is in fact essential for avoiding shortages and optimizing immunization programme performance. The procurement of vaccines is a complex process that requires specialized knowledge to ensure that high-quality products are acquired, at affordable prices, at the right quantity, and in a timely manner (5-6).

The present report is the second deliverable of Task 6.1 and refers to the objective « Analyze and evaluate local financing mechanisms for purchase and stock of vaccines ». It describes the local financial mechanisms and methods for vaccine procurement used in EU/EEA and other EU-JAV countries, advantages and disadvantages of centralized/joint procurement strategies, and opinions of MS. The methodology used to produce this deliverable consisted in:

- Workshop with participating EU JAV consortium member states and main stakeholders.
- Consultation of the literature on vaccine procurement and advantages and disadvantages of self-procurement versus centralized procurement.
- Survey among EU/EEA and EU-JAV consortium Member States, to collect information on the local financial mechanisms for vaccine procurement used in their respective countries, and to explore their opinions on joint procurement initiatives.

It is important to note that the activities related to this deliverable were carried out prior to the availability of COVID-19 vaccines and therefore these are not included in our results. Some considerations on procurement of COVID-19 vaccines are given in the Discussion. Also, in this report the terms joint procurement and centralized procurement will be used interchangeably.





### 2. Work Package 6 Workshop

During the First General Assembly Meeting of the EU-JAV, which took place in Rome on 2-3 October 2019, workshops were held for each of the EU-JAV work packages. The aim of Work Package 6 (Vaccine Supply and Preparedness) workshop was to present the main results of the first WP deliverables and planned future activities, obtain feedback from partners and stakeholders, and discuss future activities.

During the workshop, results of a survey conducted for Task 6.1.1 were presented. The survey aimed to review previous experiences with vaccine shortages in EU countries and non-EU consortium member countries, and responses at national and European levels (4). Stakeholders' points of views were also collected. Survey results highlighted that vaccine shortages are a relevant problem in Europe, and helped to better characterize the magnitude and impact of the problem, and to identify critical points around vaccine supply. Some initial considerations and recommendations were made. In summary:

- more research is needed especially in economics and marketing areas and how the different causes of shortages intertwine with each other;
- there is a need for all countries to have an immunization supply chain plan;
- national institutions and vaccine suppliers should better anticipate the demands together;
- coordinated actions, tender mechanisms and procurements should be improved;
- shortages of biological products deserve the same consideration as vaccine shortages.

The workplan for the second deliverable (Financial mechanisms for centralised procurement) of Task 6.1 was presented and discussed. The discussion was focused mainly on whether centralized procurement was feasible (for all vaccines or selected vaccines), whether it is a possible solution for mitigating vaccines shortages, the steps and barriers involved, and on previous experiences with joint procurement. Partners suggested that it would be useful to not focus solely on centralised procurement, which may not be a feasible mechanism, but also on other procurement methods. Concerns were raised also by industry (Vaccines Europe) about joint procurement. It was highlighted that there is a risk that centralized procurement may create a monopoly situation. It may be hard for a supplier to maintain capacity for a given product if losing a tender in a joint procurement and, in practice, this may create a monopoly situation. Several participants commented on the importance of a healthy market. There are





few vaccine manufacturers and a healthy market is important for manufacturers to maintain capacity and preparedness. Finally, another comment that was made is that a starting point when it comes to joint procurement is to assure that there is a centralised national tender. This is not the case for all Member States. It was concluded that it would be useful to widen the scope of our report and to consider not only centralised procurement, which may not be a feasible mechanism, but also other procurement methods. It was therefore decided to evaluate advantages and disadvantages of centralized versus self-procurement methods and to conduct a survey among MS to explore local financial mechanisms for vaccine procurement, including joint procurement initiatives.

### 3. Vaccine procurement: key concepts from the literature.

The literature was consulted to clarify key concepts and definitions about vaccine procurement and to explore advantages and disadvantages of joint versus self-procurement strategies.

### a. Relevant definitions of procurement and purchase mechanisms

The procurement of vaccines is a complex process that requires specialized knowledge to ensure that high-quality products are acquired, at affordable prices, at the right quantity, and in a timely manner (6). It involves a continuous interplay between public health professionals, national policymakers, international organizations and regulators, and manufacturers (7).

Governments have several options for vaccine procurement; each government must decide the best procurement mechanism for its country, which is also dependent on the country's level of income, and based on various factors such as vaccine amount and type purchased, cost/quantity factors, restrictions on the use of funds, capability of national regulatory authorities for vaccine quality assessment, and procurement staff's experience and skills (8-9).

The World Health Organization (WHO) identifies two main strategies (or methods) of vaccine procurement:

 Direct (or self) procurement. In self-procurement, countries are autonomous in their decisions and do not have to comply with WHO prequalification requisites. The acquisition is achieved via three different main purchase mechanisms, which depend on





the country size, needs/shortages, and bargaining power: competitive bidding, request for quotation and sole-source procurement (8).

- a. <u>Competitive bidding</u> is a "procurement process in which clearly stated product specifications and contract requirements are issued to multiple suppliers to solicit pricing and performance responses".
- b. <u>Request for quotations</u> is a process where "offers (quotations) are requested from several prospective suppliers without employing formal sealed bidding procedures".
- c. <u>Single source (or sole source)</u> refers to "purchasing from a single manufacturer without competition among potential suppliers".
- Pooled (joint) procurement. Cross-country collaboration can take place at various levels, ranging from informed buying to central contracting and procurement, as detailed below (6,8):
  - a. Level 1 (<u>information sharing and individual informed buying</u>). Procurement is conducted individually by each country, but information about suppliers and products/prices is shared. Benchmarks and best practices are identified.
  - b. Level 2 (<u>coordinated informed buying</u>). Procurement is conducted individually by each country. Market research is jointly performed. Supplier performance and prices are monitored via shared information, which may also involve the national political level.
  - c. Level 3 (group contracting). Procurement is conducted individually by each country but countries jointly negotiate prices, select suppliers and agree fom whom to buy. In this context, the legal framework, procedures and policies need to be completely harmonized. Group contracting is a useful example of economy of scale.
  - d. Level 4 (<u>central contracting and procurement</u>). In centralized (or joint) procurement, participating countries combine into a single entity that purchases vaccines on their behalf. Tendering, awarding contracts and delivery are coordinated by a single representative organization, which can also implement supplementary technical and functional roles. Central procurement is traditionally performed within supranational entities (e.g. European Commission, PAHO).





# b. Vaccine procurement: advantages and disadvantages of self- procurement and joint procurement methods.

Both self procurement (which can occur at the national or subnational levels), and joint procurement methods have advantages and disadvantages, as summarized in Table 1 (10-16). It is important to note that the available literature on this topic is scarce and often limited to low and middle income countries. Some of the factors described below may therefore not apply to the EU/EEA context. It is nevertheless important and informative to understand the experiences of other countries that have engaged in joint procurement initiatives.

The main advantage of self procurement is the possibility to tailor decision-making according to the country's national immunisation plan. On the contrary, joint procurement requires negotiated agreements between countries which are potentially difficult because of countryspecific differences. The disadvantages of self procurement include a variable level of transparency, price heterogeneity, and lower bargaining power. Also, national/subnational contracts may lead to varying contract conditions between regions counties/countries.

Advantages of joint procurement are increased transparency and accountability, and greater quality assurance as suppliers who do not perform well may not be selected for the next procurement cycle.

JP may allow saving costs thanks to economies of scale, reduction of bureaucracy, and, in theory, lead to a more cost-effective organization by avoiding duplications of costs. Each member-state in a joint procurement agreement increases its individual contractual power, and this is particularly true for smaller countries. As higher volumes of required vaccines are associated with price reduction, smaller countries might manage to obtain the same (or even a higher) contractual power than bigger ones. Moreover, a larger prospective market share might encourage suppliers to develop new products and deploy more R&D investments. The incentives are especially conspicuous when both large volume and long-term contracts are guaranteed. Pooled agreements are also instrumental in safeguarding equity and ethics, especially in a public health emergency, as it became clear in the current COVID-19 pandemic.





### Table 1. Advantages and disadvantages of self and joint procurement methods (globally).

S	elf-procurement	Joint procurement			
Pros	Cons	Pros	Cons		
	Variable level of transparency	Increased transparency			
	Price heterogeneity	Lower unit purchase prices (at least in the short term)			
	Possible cost duplication	Potential cost reduction (administrative, ancillary services, staff, etc.)			
	Potential increased bureaucracy (but efficient national procedures might be less bureaucratic than aligning many aspects of vaccine tendering for specific national procurement and distribution structures).	Reduction in administrative burden for individual countries			
		Improved quality assurance (as suppliers who do not perform well may not be selected for the next procurement cycle)			
Tailored decision-making	Higher risk of corruption (less likely to be an issue in the EU/EEA context compared to other parts of the world)	Centralization of decision-making (reducing risk of local lobbying activities)	Reduction of involvement of local staff responsible for procurement		
	Lower bargaining power	Potential higher bargaining power (especially for smaller countries)			
	Fragmentation of procurement rules	Harmonized public procurement rules	Modification of national legislative framework		
Autonomous decision-making	Potential risk of corruption*		Need for negotiated agreements. Potentially difficult multilateral agreements (country-specific differences, language and level of development)		
		Higher R&D investments, knowledge sharing			
National/subnational call for tender suited to NIP		International call for tender	Potential reduction of local manufacturers' power (may not be applicable to EU/EEA context, where mainly four companies are supplying most of the vaccines).		
More flexibility in procurement and payment schedules	National/subnational contracts that lead to varying contract conditions between regions/counties/ countries	Centralized agreements (same contract conditions through contractors)	Less flexibility in procurement and payment schedules		
	Low volume of vaccines required may lead to producers being less interested in submitting bids, and therefore potentially to vaccine shortages.	Higher volume of vaccines required means a larger prospective market share for suppliers, which may incentivate them to submit bids, and also to develop new products and deploy more R&D investments.			
			Challenges in logistics (supply, storage, lots) of a high volume of vaccines		
	Higher risk of collusion if only a few local competitors are selected as potential providers (may not be applicable to EU context)	Potential reduction of collusion risk given the high number of competitors (may not be applicable to EU context)			
		Creation of networks of professional experts			

Joint procurement requires a shared political will to sign and enact international agreements, overcoming national laws. This calls for the harmonization of national public procurement laws





among candidate states, requiring more transparency and elimination of the potential barriers and differences that might make group procurement difficult. However, harmonization is not an easy process because it should consider each country's needs.

Another potential disadvantage is that joint procurement can make payment schedules less flexible. Also, the request to pay using the same international currency is a potential limit. In Europe, and EU-JAV, even though most countries use Euro as currency, some do not (e.g. Denmark, Norway, Romania, and Sweden).

In joint procurement, member states should have a third-party independently manage the scheme. This entity should mediate among different, and possibly conflicting, member states' interests in a credible, impartial fashion. Whether such an organization should be one created ad hoc for the task or be part of an existing agency is a matter for research.

Due to the complexity of the system, a one-fits-all approach to vaccine procurement appears to be unfeasible. Indeed, both procurement methods have pros and cons, and careful considerations are necessary in choosing the best option. Some key features of successful joint procurement programmes have been identified in the literature; these include ownership, equity, transparency, stable central financing, standardisation, flexibility and gradual development (16). Security of supply, favourable prices, reduction of operational costs and administrative burden and creation of professional expert networks have been identified as desirable outcomes. Security of supply is an important outcome for all countries, while price savings, reduction in administrative burden and creation of professional networks may be especially of interest to smaller countries (16).

#### c. Examples of joint procurement initiatives in Europe.

A number of initiatives have been set up in Europe in the last decade to increase collaboration between countries on the procurement of medicines (6). Some of these have involved vaccines, as described below.

#### EU Joint Procurement Agreement for medical countermeasures

Prior to the COVID-19 pandemic, joint vaccine procurement initiatives in Europe were limited to a few countries and a joint procurement initiative involving all EU/EEA Member States had never occurred (17). In 2014, the EU Joint Procurement Agreement for medical





countermeasures (JPA) was established by the European Commission and introduced as an innovative mechanism for the procurement of pandemic vaccines and medical countermeasures (18-20). This initiative was started after the outbreak in 2009 of H1N1 pandemic influenza which highlighted weaknesses in the access and purchasing power of EU countries to obtain vaccines and medications during a health crisis. The joint mechanism for procurement of medical countermeasures, including vaccines, set common rules for practical organisation of joint procurement procedures to support fair and equitable access to, and distribution of, pandemic influenza vaccines for the future. The aim was to improve EU countries' preparedness to mitigate serious cross-border threats to health, secure more equitable access to specific medical countermeasures and an improved security of supply, together with more balanced prices for the participating countries (18).

According to the JPA, a joint procurement procedure can start if at least four Member States plus the Commission vote in favour and participate in the procurement process. The Financial Regulation and the Rules of Application provide a procedural framework for organising procurement procedures under the JPA. As of April 2020, the JPA has been signed by 37 countries, including all EU and EEA countries, the UK, Albania, Montenegro, North Macedonia, Serbia and Bosnia and Herzegovina, as well as Kosovo (19).

#### Other joint procurement initiatives for vaccines in the EU.

Other joint procurement initiatives for vaccines in the EU, described in the literature, include the Joint procurement of vaccines under the Baltic Partnership Agreement and the Romanian and Bulgarian Initiative (17).

The Baltic Partnership Agreement started at the end of 2014 and was the first joint procurement focused on vaccines. The first open procedure (for the BCG vaccine) was announced in 2015 but was unsuccessful (no tender was submitted). The procurement technical specifications only allowed vaccines with valid marketing authorization in all three Baltic States (Estonia, Latvia and Lithuania). However, there was only one producer with a suitable registered product and he declared serious production problems within the tender submission timescale. The tender had to be drawn up for joint procurement through competing wholesalers as the manufacturer was not interested in participating in the joint procurement process directly for such a small market and small amount, despite the three countries pooling their leverage to jointly negotiate prices with suppliers. For example, the necessity of producing





uniform packaging in the three languages was not considered to be cost-effective by the manufacturer. The next procedure involved joint procurement by Estonia and Latvia of rotavirus vaccine in 2016 (Lithuania does not have rotavirus vaccine in its immunization schedule). Another procedure regarded a collaboration between Latvia and Lithuania for the procurement of pneumococcal vaccine. The problems encountered in these initial procedures are useful to illustrate the challenges that need to be overcome in order to increase leverage for reducing prices and ensuring availability. Besides joint procurement procedures, an important component of the Partnership Agreements is the lending of centrally procured medicines, including vaccines, which enables countries to prevent and alleviate shortages. Since 2012, there have been several lending processes, which have helped countries to solve serious shortage problems (17).

The Romanian and Bulgarian Initiative started in June 2015, hoping to use joint negotiations to get lower prices in purchasing pharmaceuticals, but also involves cross-border exchanges of medicines in short supply in either country, to ensure continuity of access (17)

### d. Financial mechanisms for vaccine procurement

Vaccination programmes need an adequate level of resources in order to function properly. These should cover not only vaccine funding, but also program management, monitoring, and comunication. The main sources of funding for vaccine procurement and distribution are broadly (21, 22):

<u>Domestic revenue</u>: General government domestic revenue is used by all countries to finance immunizations. In some countries, funds raised from payroll taxes (mandatory insurance contributions) and pooled in national / social insurance schemes also provide a potential source to fund vaccination

<u>External funding</u>: Many developing countries with low to medium national gross domestic product per capita obtain funding from nongovernmental organizations and donors (e.g. Global Alliance for Vaccines and Immunizations - GAVI).

<u>Alternative/innovative financing</u>: Innovative financing mechanisms have been proposed to overcome challenges in immunization financing, from resource generation to program performance, mainly for funding vaccines in low and middle income countries. These refer to mechanisms that either source funds from outside the traditional means of general taxation





or donor assistance, or create systems or incentives that improve program performance (22, 23). Most innovative financing mechanisms imply collaboration between multiple stakeholders. They either source new funds or make existing funds go further (performance improvement). Few of the innovative mechanisms have been implemented sustainably and there is limited evidence that they contribute to additional resources (21).

A 2018 report on the organization and delivery of immunization services in the European Union notes that funding mechanisms for vaccination vary across the EU and across vaccination types, including out-of-pocket, publicly funded, official health insurance and employer funding, either in full or in part (24). The ability to fund vaccination programmes (including capacity, identification of and response to inequalities in uptake, monitoring and investment, as well as unit vaccination costs) can be frustrated by financial crises. According to recent data, immunization funding represents only a small proportion of total healthcare spending in Europe (25,26). Also, vaccination programmes remain highly vulnerable to budget cuts since benefits are not immediately and completely identifiable. In some high-income countries, vaccine hesitancy has been identified as a greater issue in reaching optimal vaccination coverage than is the availability of funding. Some countries, such as those in Southern Europe with fewer resources available, may be more sensitive to changes in funding than others (24).

# e. Impact of vaccine procurement methods on performance and sustainability of vaccination programmes.

Various procurement agencies have assessed the market dynamics and performance of procurement for medicines in general, and identified various determinants of a healthy market (6), defined as one in which high quality products can be readily procured at competitive and affordable prices from a range of suppliers. To ensure a healthy market and adequate supplies, and avoid creation of a monopolistic situation, multiple suppliers are necessary (6).

Furthermore, a 2012 WHO report, based on a literature review and a survey among WHO European MS, identified procurement practices for medicines that were likely to lead to more competitive prices and increased access to patients. Among these was procurement by a centralized body to negotiate prices. Various gaps and barriers to be addressed were also identified (6).





However, there is limited data on the impact of current vaccine procurement methods on the performance and sustainability of vaccination programs. The published literature indicates that vaccine shortages occur frequently, mainly in middle income countries but also in high income countries icluding EU countries, USA, Japan, New Zealand, Canada, and Australia (4, 27-34). These can lead to missed vaccinations and higher occurrence of vaccine preventable diseases. Multiple causes have been identified for vaccine shortages, and reasons are often multifactorial (4,27, 28, 34). None of the referenced articles describing vaccine shortages assessed whether these were linked to the procurement method used.

A recent joint publication by European Observatory on Health Systems and Policies, EC and WHO on the organization and delivery of vaccination services in the European Union examines the health system related factors influencing vaccine uptake and highlights the importance of developing a systems approach to national vaccination programmes. However, the role of procurement methods and stockouts are not discussed (24).

Our previous survey on vaccine shortages investigated the level at which vaccine procurement is performed in participating countries and found that vaccine procurement in EU/EEA and other EU/JAV countries is almost entirely performed by the public sector at national level (4). It also noted that a higher number of shortages were reported by the one country that procured vaccine exclusively at subnational level and by the one country that procured vaccines exclusively through the private sector. Although it was not possible to establish a correlation between procurement level and number of shortages, these findings suggest that future research could better investigate the relationship between procurement mechanism and resilience to shortages.

Vaccination coverage (VC) is one of the important measures of success for a national immunization program. A recent study reviewed the academic and policy literature and performed interviews with stakeholders involved in vaccine procurement, to document the relationship between procurement method dynamics and VC against vaccine-preventable diseases in four European countries: Germany, Italy, Spain and Romania, for measles-containing vaccines, hexavalent and influenza vaccines (35). The authors identified five main vaccine procurement methods which they categorized into a spectrum from methods focusing primarily on price (price-based) to methods based mainly on value (value-based). In detail, the authors indicate available data suggesting that the use of price-based tenders has resulted





in a reduction in prices, at least in the short term but that, at least in the case study countries, this was associated with worsening vaccination coverage. Because VC depend on multiple factors, the association does not imply causation; however according to the authors, the vaccine case studies across countries did show that lowering prices were not able to increase vaccination coverage. With regard to the relationship between price and supply sustainability, the authors note that price-based tenders do not necessarily encourage long-term sustainability in supply and the vaccine market and that, due to the complex and lengthy production process for vaccines, tenders with single winners could contribute to the exacerbation of supply issues. The authors also examined the relationship between price and competition/vaccine choice, encouraging value-added services, and incentives to invest in R&D. They concluded that price-based tenders can contribute to a reduction in choice of vaccines available for patients and physicians and suggest that lower profitability for R&Dbased producers have contributed to market consolidation and a decrease of companies over time. Finally, the authors discuss ways to ensure that tenders contribute to the sustainability of the vaccine ecosystem and suggest that a more flexible procurement system of multiple winners, shorter tender durations (<3 years) and appropriate delivery timelines that take into account the complexity of vaccine manufacturing could help encourage suppliers to remain in the market such that supply issues are not exacerbated by price-based tenders. They also suggest the usefulness of moving towards more value-based procurement methods such as price and reembursement which can positively impact vaccination coverage rates. Some similar considerations regarding the need for more flexible procurement systems were made in the report analysing vaccine shortages in EU countries.

Another survey on procurement systems for yearly seasonal influenza vaccination campaigns in European countries identified two main procurement systems in Europe: public tenders at the national (5 countries) or regional (3 countries) levels, and direct purchase from manufacturers or wholesalers at the clinic level by general practitioners (1 country) or pharmacies (4 countries). There was a high level of brand diversity in vaccination clinics especially where procurement occurred at the clinic level (36).





# 4. Survey on financial mechanisms for vaccine procurement used in EU/EEA and EU-JAV consortium Member States

From August to October 2020, we conducted a survey among persons in charge of the national or subnational immunisation programme(s) or of vaccine supply/procurement in EU/EEA and EU-JAV consortium Member States. The aim of the survey was to collect detailed information on the financial mechanisms for vaccine procurement used, to supplement information already collected in a previous survey. In addition, the survey aimed to collect MS's opinions on joint procurement of vaccines in EU.

### a. Methodology

Twenty-eight countries were invited to participate, including all 20 EU-JAV partners and eight EU/EEA countries not participating in the EU-JAV. EU-JAV countries include 18 EU/EEA and two non-EU/EEA countries (Bosnia-Herzegovina and Serbia).

Countries were invited to participate by email. We included a link to the survey and attached an information sheet to inform participants of the objectives of the survey and the way any personal data (contact details) would be handled. Questionnaire responses were analyzed using MS Excel software. Variables were reported as absolute number and proportions. Results from open-ended questions were summarized.

### b. Questionnaire

Following a review of the literature, a draft questionnaire was developed, made up of multiplechoice and open-ended questions, and pilot-tested for clarity and completeness by two EU-JAV consortium partners (Finland and Netherlands). The questionnaire was also sent for comments to WHO. Relevant comments and suggestions were integrated into the final version. The final questionnaire was divided into five sections:

- SECTION 1. Questions 1-3: General information (country, name, affiliation, contact details of respondent).
- SECTION 2. Questions 4-18: Financing mechanisms for vaccine procurement. In this section we collected information on:
  - main sources of vaccine funding for vaccines included in the national vaccination schedule (e.g. central government, subnational authorities, health insurance contributions with central allocation for procurement; health insurance contributions





with reimbursement of costs; private funding mixed scheme; no funding (citizens purchase own vaccines);

- whether there is an endorsed annual budget line item in place for vaccine procurement (specific funds allocated annually to vaccines, at either national, regional or local levels);
- the main difficulties encountered in budgeting for vaccines;
- the basis for decision making to finance introduction of a vaccine (e.g., NITAG decision, epidemiology of the disease in the country, cost-effectiveness evaluation, etc.);
- the basis for vaccine needs forecasting and quantification (e.g., target population including demography, immunisation schedule, coverage objectives, wastage rate, buffer stock; previous consumption level; others);
- Type of budget planning used (annual, mid-term i.e. 2-3 years, long-term i.e. >3 years)
   budget
- The existence of any major budget planning and allocation issues in the last five years;
- The current framework for vaccine tenders, level at which they are carried out and criteria used (lowest price, best offer);
- Presence, in national regulations, of specific requirements regarding the language of tender documents and framework contracts, and of any restrictions to participation in vaccine procurement tenders (i.e restriction to only local wholesalers, suppliers or manufacturers);
- Whether any interactions occur between vaccine procurement representatives at the national or local level and pharmaceutical companies, to allow industry to present their products prior to issuing a vaccine tender;
- Lastly, we asked participants whether they are satisfied with the procurement process in the country, and to describe its strengths and weaknesses.

### • SECTION 3. Questions 19-25: Cross-country cooperation to improve access to vaccines.

This section was aimed at collecting information about participation in any joint procurement initiatives and other forms of cross-border collaboration to support decision making during national procurement (i.e., sharing vaccine price information, conducting joint market research) with other European countries. Participants were asked to indicate who the major stakeholders to be consulted would be in the event of a joint procurement collaboration. We





then tried to explore respondents' perception about joint procurement by asking them to indicate the degree of agreement with several statements on joint procurement.

• SECTION 4. Joint procurement system with other European countries. Questions 26-41

In this section, respondents whose countries were participating or had participated in any joint procurement system with other European countries were asked to provide details of the initiative, in particular:

- the vaccines/biological products involved;
- whether a formal agreement was signed;
- main points covered by the agreement (e.g., type of products, quantities allocated to each country, mechanism of payment and/or of transferring funds, duration of contract, etc.).
- the most important processes and tools to be agreed upon before initiating a joint crossborder procurement process (e.g. product specifications, regulatory requirements, language requirements, applicable procurement procedures, tender documents / forms / procedures, award criteria, contracting documents, other);
- need for a legal act and main points covered by the legal act;
- who was in charge of the procurement process (e.g. one of the countries involved, EU agency or competent body such as ECDC or European Commission, an international agency such as WHO, or other agency);
- whether a specific web platform was available to manage the procurement process;
- time in months from request to vaccines being available at the vaccination centres;
- whether the joint procurement process required a longer/shorter/same amount of time compared to the standard procurement process;
- strengths and weaknesses of the joint procurement process.

Participants whose countries had not participated in any joint procurement system with other European countries were asked to indicate:

- the main reasons for not participating;
- their level of interest in participating in joint procurement of vaccines (high, moderate, low, null) and reasons for their answer (indicating also what they believe to be the main strengths /weaknesses of joint procurement systems).





This section collected information on steps that were being taken by countries *while vaccines against COVID-19 were still in development,* to secure timely access and deployment of vaccines once they would become available (e.g. advance purchase agreements). Participants were also asked about any ongoing development of deployment and vaccination plans, and their participation in WHO's ACT Accelerator program (the global collaboration to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines*)*.

### c. Ethics

The final questionnaire (attached, Appendix) was administered via the online tool, Surveymonkey® (https://www.surveymonkey.com/). Two reminders were sent to countries that had not responded by the given deadline. Participants could review and change their answers until closure of the survey which originally was on October 26, 2020. Because of the Covid-19 pandemic, the last questionnaire was completed in February 2021.

All persons who agreed to complete the survey were sent a privacy statement (according to GDPR 2018) and asked to provide permission to be contacted.

#### d. Results

Fourteen of 28 invited countries responded to the survey (Bulgaria, Finland, France, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Norway, Portugal, Slovakia, Slovenia and Spain). All responding countries are EU/EEA and all except Bulgaria (which is a high middle-income country) are high-income countries according to the World Bank classification. All countries, except Hungary and Ireland, participate in the EU-JAV.

### Financing mechanisms for vaccine procurement

Nine of 14 countries (64%) (Bulgaria, Finland, Hungary, Ireland, Italy, Latvia, Malta, Norway, Portugal) specified that the main source of funding for vaccines included in the national immunization programme was the *central Government (i.e public funds obtained from taxation)*.

*Slovakia* reported several modes of vaccine financing, including public funding. Vaccines included in the national immunization schedule are covered partly from the state budget, partly from the health insurance system. For some vaccines, there may be partial reimbursement or no funding.





*Lithuania and Slovenia* reported that vaccines are funded by health insurance contributions with central allocation for procurement. In *France* they are funded by health insurance contributions with reimbursement of costs, detailing that only in season 2020/21, the Government acquired a stock of flu vaccines to anticipate an increased demand in the context of the COVID 19 pandemic.

Finally, in *Spain* subnational authorities are in charge of funding for vaccines (Table 1).

No countries indicated Private funding (i.e. donor funding by GAVI, UNICEF) nor a mixed scheme (government and donor).

Table 1. Main sources of funding for vaccines included in the national vaccination schedulein 14 EU/EEA countries which responded to the survey.

		Main sources of funding for vaccines						
Country	Central government (e.g. public funds obtained from taxation)	Subnational authorities	Health Insurance contributions with central allocation for procurement	Health Insurance contributions with reimbursement of costs	Private funding (Donor i.e., Gavi, Unicef)	Mixed scheme (Government and Donor)	No funding (citizens purchase own vaccines)	
Bulgaria	Х							
Finland	Х							
France*				Х				
Hungary	Х							
Ireland	Х							
Italy	Х							
Latvia	Х							
Lithuania			Х					
Malta	Х							
Norway	Х							
Portugal	Х							
Slovakia**	Х			Х			Χ	
Slovenia			Х					
Spain		Х						
Total	10	1	2	2			1	

\* Only in season 2020/21, the Government acquired a stock of flu vaccines to anticipate an increased demand in the context of the COVID-19 pandemic

\*\* The mandatory or selected recommended vaccinations are covered partly from the state budget, partly from health insurance system; the recommended vaccination depends on the financial setting by the MoH and might be mixed with partial reimbursement or no funding





In four countries, the main sources of funding for vaccines not included in the national immunization schedule are the same as those for included vaccines (in three of four countries, source of funding is the central government public funds obtained though taxation, in one country there are several modes of financing). In the remaining countries, vaccines not included in the national vaccination schedule may be completely or partially funded, funded through health insurance contributions with reimbursement of costs, or funded if they are included in regional programmes. Responses were as follows:

- "There are differences in funding between regions (some vaccines may be funded by one region but not by another)."
- "There could be different sources of funding for vaccines not included in the national vaccination schedule: 1. citizens purchase own vaccines, 2. there could be 100% compensation for vaccines (there is reference payment detected) or citizen's co-payment if price is greater than the reference."
- "Some vaccines sold in the private market under prescription are partly funded by the government. However, some of the vaccines that are nationally procured and payed, are not included in the national vaccination schedule (e.g. influenza, yellow fever)."
- "If the vaccine is included in the regional schedule, the same source of funding will be applicable."
- "Recommended vaccinations are paid by patient."
- "Not reimbursed vaccines are available on a private market."
- "Central government for vaccines that are used within the National Health System but not on national immunisation schedule. Private sector through community pharmacies/doctors for vaccines that are bought by patients."
- "Health Insurance contributions with reimbursement of costs."
- "Vaccines are not reimbursed. Patients have to pay the full price."

All participating countries, except Finland and France, allocate an annual budget line item for vaccine procurement regardless of the sources of funding: nine at national level, two at local (regional) level, one both at national and local levels; one country did not specify at which level budget is allocated.

The decision-making process to finance introduction of a vaccine is based on a NITAG decision in nine countries, epidemiology of the disease in 11 countries, and cost-effectiveness evaluations in 12 countries (Table 3).





## Table 3. Basis for decision-making to finance the introduction of a vaccine in 14 EU/EEA countries participating in the survey.

	Criteria			
Country	NITAG decision	Epidemiology of the disease in the country	Cost- effectiveness evaluation	Other
Bulgaria	Х		Х	
Finland		Х	Х	
France	Х	X	Х	Independent commission
Hungary		X		Expectation of the society
Ireland	X		X	Government decision based on NITAG recommendations
Italy	Х	X	Х	National vaccination plan
Latvia	Х	Х		
Lithuania		Х	Х	
Malta		Х	Х	Other priorities
Norway	Х	Х	Х	·
Portugal	Х	X	Х	Government decision
Slovakia			Х	
Slovenia	X	X	x	National advisory committee on health
Spain	X	Х	X	X
Total	9	11	12	

The main difficulties encountered in budgeting for vaccines (more than one answer was possible) were reported to be lack of information on the size of the population to be vaccinated (e.g. size of high-risk populations) and difficulties relating to estimating the exact coverage levels to be achieved, in 7 and 6 countries respectively.

Moreover, some countries indicated additional difficulties: one country (Hungary) indicated also the global vaccine market situation, one country (Portugal) timely planning, one country (Norway) complained that prices were not known for tenders, and Spain that the budget was not unlimited (Table 4).





## Table 4. Main difficulties encountered in budgeting for vaccines in 14 EU/EEA countries participating in the survey.

		Difficulties	
Country	Lack of information on the size of the population to be vaccinated	Estimating the exact coverage levels to be achieved	Other
Bulgaria	Х	Х	
Finland	Х	X	
France			Not applicable
Hungary			Global vaccine market situation
Ireland	Х		
Italy	Х		
Latvia		Х	
Lithuania	Х		
Malta	Х	X	
Norway			For tenders (existing or introduction of new vaccines) the prices is not known
Portugal			Timely planning
Slovakia		X	
Slovenia	X	X	
Spain			Not unlimited budget
Total	7	6	

Regarding the criteria used for vaccine needs forecasting and quantification, all countries based their evaluation on the target population characteristics (demography, immunisation schedule, coverage objectives, wastage rate, buffer stock) and 11 states also on previous consumption levels. Slovenia took into account also the *Vaccination centres plans and needs*.

Nine countries plan the vaccine budget on an annual basis. Three countries (Hungary, Latvia and Slovenia) plan their budget for a mid-term period (2-3 years), one country (Norway) depend on long-term (>3 years) planning. In Spain, the budget planning depended on the region (Table 6).





## Table 5. Criteria used for vaccine needs forecasting and quantification in 14 EU/EEA countries that responded to the survey.

	Criteria		
Country	Target population (demography, immunisation schedule, coverage objectives, wastage rate, buffer stock)	Previous consumption level	Other
Bulgaria	Х		
Finland	Х	Х	
France	Х	Х	
Hungary	Х		
Ireland	Х	Х	
Italy	Х	Х	
Latvia	Х	Х	
Lithuania	Х	Х	
Malta	Х	Х	
Norway	Х	Х	
Portugal	Х	Х	
Slovakia	Х	Х	
Slovenia	Х	Х	Vaccination centers plans and needs
Spain	X	Х	
Total	14	12	

### Table 6. Type of budget planning for vaccination used in 14 EU/EEA countries that responded to the survey.

	Type of budget planning					
Country	Annual budget	Mid-term budget (2-3 years)	Long term budget (>3 years)	Other		
Bulgaria	Х					
Finland	Х					
France				Not applicable - No budget defined in advance		
Hungary		Х				
Ireland	Х					
Italy	Х					
Latvia		Х				
Lithuania	Х					
Malta	Х					
Norway			Х			
Portugal	Х					
Slovakia	Х					
Slovenia	Х	Х				
Spain				Depends on the Region		
Total	9	3	1	-		





Participants were asked whether their country had experienced any major budget planning and allocation issues regarding vaccines in the last 5 years. Only three countries reported experiencing such issues. In detail, Malta had issues of budget reallocation due to shortages and spikes in pricing and Spain has had to manage the inclusion of new vaccines in the national immunization schedule. The third country did not specify the issue faced.

Regarding the current framework for vaccine tenders and the level at which the tenders are carried out and the criteria used, responses are detailed below:

- Bulgaria: "The vaccine tenders are carried out on national level and the main criterion for vaccines choice is lowest price."
- Finland: "Lowest price and quality"
- Hungary: "We procure vaccines at national level, and we use the best offer criteria. "
- Ireland: "National level based on quality criteria and cost. "
- Italy: "Each region organizes their own tenders through their Regional Health Authorities, in line with the European procurement directive. All regions use a similar tender process but there are some differences: lot requirements; success criteria (best offer); number of winners per tender and length of contract. "
- Latvia: "National Health Service announce the call for vaccine tender at national level. Representatives of manufacturing companies apply for participation. The tender is carried out at national level and the lowest price is the main criteria used. "
- Lithuania: "Framework: open tender. Criteria: lowest price, the most economically advantageous tender."
- Malta: "We mainly use tenders. In 2014, we issued all vaccines in one tender with lots, since from a market research it indicated that forecasting for 4 years in a bundle would aid access and so it did excluding international shortages. Where the item is still under patent there is a negotiation process."
- Norway. "Normally use a mix between quality (effect and safety) and price. Balance between quality and price may vary from tender to tender and that some tenders may only have price if relevant vaccines are deemed to be similar in quality. "
- Portugal: "In Portugal, the vaccines that are included in the national vaccination programme are purchased centrally. The award criteria applied to technically compliant tenders is price."





- Slovenia: "Procurement with reimbursed vaccines are centralized on national level. National institute of public health is responsible for procurement Slovenia with reimbursed vaccines (purchase, storage, distribution). Vaccines are purchased through a public tender system. The criteria used are as follows: - the lowest price - for equivalent vaccines according to registration documentation, - the quality and price - for not equivalent vaccines (for exp. conjugated pneumococcal vaccines)."
- Spain. "Besides vaccine tender at regional level also carry out a vaccine tender coordinated by the MoH for the Regions to voluntarily join and buy the vaccines at an homogeneous price. Joint Procurement Agreement. Specific regional tenders. "
- France and Slovakia do not launch vaccine tenders.
   Slovakia: "There is no centralised system of vaccine purchase, so no tendering process. The system is the way that each company/distiributor might ask the ministry of health to put their vaccine into the categorisation list, which ensure the vaccine will be used within the mandatory or recommended vaccination. However, first the vaccine must have been registered by the national body the State Institute for Drug Control. If the company/distributor is not initiative and does not ask, the vaccine is automatically fully paid by the public. However, it still must be registered by the national registration body."

In all participating countries, national regulations do not restrict participation in vaccine procurement tenders only to local wholesalers, suppliers or manufacturers' representatives. However, in Bulgaria, only suppliers or manufactures authorised for wholesale of medicinal products in the country can participate in tenders.

Five countries (Finland, France, Ireland, Italy and Norway) reported that prior to issuing a vaccine tender, interactions take place between vaccine procurement representatives at the national or local level and pharmaceutical companies, to allow industry to present their products. In detail, Ireland reported "*annual horizon scanning meetings with manufacturers*, Italy *meetings and audits of industry with health authorities at the national and regional level*, and Norway that *prior to tender normally a separate meeting is held with all manufacturers having a vaccine with marketing authorization: agenda for meeting is information about tender process and an opportunity for supplier to present vaccine and any new information associated with vaccine."* 





Finally, participants were asked whether in general, they were satisfied with the procurement process in their country, and about the main strengths and weaknesses of their current procurement systems. All countries except Slovakia reported being satisfied with their procurement process: Slovakia reports that it "*does not apply the usual procurement system, which is known in other countries. It must be the initiative of the company to come to the market and to start the communication with the Ministry of Health. Too many institutions and too many people involved into the vaccination field that the healthcare workers (HCW) and public health institutions might not be informed well ahead or at the right time. However, HCW know the system and are quite flexible to communicate with the pharmacies on the vaccines availability."* 

The main strengths of current procurement systems, as reported by survey participants, were transparency, homogeneous and adequate prices, and equal access to vaccine. In detail, participating countries reported:

- *"Transparency, cost effectiveness."* (Finland)
- "Price fixing based on recommendations of different independent commissions, with multidisciplinary discussion and negotiation." (France)
- "Secured budget background that covers the whole country." (Hungary)
- "Experienced team of experts and efficient process in place; monthly meetings with the national vaccine stock management team and suppliers ensuring long lead-time for procurement process." (Ireland)
- "Transparent (i.e. web-platforms to applying for tender), cost-saving process." (Italy)
- "Tender procedures transparent and checkable (web-platform developed for applying for tender)." (Latvia)
- "Competitive tender allows for price transparency and adequate prices." (Malta)
- "Multidisciplinary team (medical, procurement, legal); capability of early start of tender process (1-2 years before first delivery); transparent process between Norwegian Institute of Public Health and suppliers." (Norway)
- "Centralised purchasing promotes equal access to the vaccines nationwide." (Portugal)
- "Safe supply of vaccines; quality of vaccines; lower prices." (Slovenia)
- "Homogeneous prices nationwide and savings in vaccine procurement." (Spain)





Eleven of 14 countries reported weakness in the current procurement systems of their countries. The main reported weaknesses were mainly bureaucracy and long tendering procedures, as indicated below:

- "*Bureaucracy*" (Finland)
- "*Inflexible, bureaucratic system*" (Hungary)
- "Bureaucratic process; subnational budgeting makes the procurement process too long" (Portugal)
- "Small team and no experienced back up" (Ireland)
- "Sometimes, long tendering procedures" (Italy)
- "Regulatory documents will not allow a quick procurement process. All tender procedures must be followed" (Latvia)
- "Appeals but they are needed for transparency's sake. However, this represents delays that may eventually affect supply" (Malta)
- "Late publication of the annual vaccination program" (Slovenia)
- "Not every region is in the national Joint Procurement Agreement; need to do horizon scanning every year with the industry; need to conduct more long-term agreements" (Spain)
- "No centralized procurement, no negotiation or discount for high volumes of vaccine doses purchased" (France)
- "Slovakia does not apply the usual procurement system, which is known in other countries. It must be the initiative of the company to come to the market and to start the communication with the Ministry of Health"

### Cross-border cooperation to improve access to vaccines

Excluding JP for Covid vaccines, nine countries (Lithuania, Malta, Slovenia, Bulgaria and Spain) reported participating in a Joint procurement system with other European Countries in the past.

Respondents indicated that the major stakeholders to be consulted in the event a JP option is considered are: Council of Ministers, and in particular, Ministries of Health; national Public Health agencies; national procurement offices, where they exist; vaccine manufacturers associations; national experts.





### Opinions about Joint procurement systems

Participants were asked to indicate whether they agreed with a series of statements on joint procurement (Yes/No). Their answers are summarized in Table 7.

### Table 7. Opinions about joint procurement of survey participants

Country	Joint procurement of vaccines will improve Member States' preparedness to mitigate serious cross-border threats to health caused by vaccine preventable diseases	My country is dependent on just a few local wholesalers for the cold storage and internal distribution of vaccines, and joint procurement may disrupt this	Joint procurement ensures a more equitable access to vaccines	I fear that joint procurement may lead my country to lose its ability to make decisions concerning evaluation criteria and vaccine selection	Joint procurement strengthens the purchasing power of individual countries	Limited cooperation and political ties between countries is a barrier to joint procurement	Joint procurement ensures more balanced vaccine prices	In my country, irregular and inadequate vaccine funding would be a major barrier to participating in joint procurement	In my country there are policies protecting local producers and this is a barrier to joint procurement	In my country, vaccine evaluation criteria are very restrictive, and this is a barrier to joint procurement.	I think that joint procurement can seriously affect the vaccine market.
Bulgaria	Yes	No	Yes	Yes	No	Yes	No	No	No	No	Yes
Finland	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	No	Yes
France	Yes	No	Yes	No	Yes	Yes	Yes	-	No	No	No
Hungary	Yes	No	No	No	Yes	Yes	Yes	Yes	No	No	No
Ireland	Yes	No	Yes	No	Yes	No	Yes	No	No	No	No
Italy	Yes	No	Yes	Yes	Yes	Yes	Yes	No	No	No	No
Latvia	No	No	No	No	Yes	No	Yes	No	No	No	No
Lithuania	-		Yes	-	-	-	-	-	-	-	-
Malta	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	No	Yes
Norway	No	No	No	Yes	No	No	No	No	No	No	Yes
Portugal	Yes	No	Yes	Yes	Yes	Yes	Yes	No	No	No	No
Slovakia	Yes	No	No	No	Yes	No	Yes	No	No	No	No
Slovenia	Yes	No	Yes	No	Yes	Yes	Yes	No	No	No	No
Spain	No	No	*	No	*	*	Yes	No	No	No	No
Total	N. 10 Yes N. 3 No	N. 2 Yes N. 11 No	N. 8 Yes N. 5 No	N. 5 Yes N. 8 No	N. 10 Yes N. 2 No	N. 8 Yes N. 4 No	N. 11 Yes N. 2 No	N. 1 Yes N. 11 No	N. 0 Yes N. 13 Yes	N. 0 Yes N. 13 NO	N. 4 Yes N. 9 No

\* Responses depend on the specific situation and type of product





Most participants (10/14) agreed that "joint procurement of vaccines will improve Member States' preparedness to mitigate serious cross-border threats to health caused by vaccine preventable diseases" and that "Joint procurement strengthens the purchasing power of individual countries".

Eleven countries agreed that "*joint procurement ensures more balanced vaccine prices*" and eight countries that "*joint procurement ensures a more equitable access to vaccines*" (for Spain it depends on the specific situation and type of product).

Among the barriers to joint procurement:

- All countries (except Lithuania, who did not express an opinion), agreed that "policies protecting local producers and restrictive vaccine evaluation criteria are barriers to joint procurement";
- Two countries indicated that they are dependent on just a few local wholesalers for the cold storage and internal distribution of vaccines, and JP may disrupt this;
- Two countries did not trust that joint procurement strengthens the purchasing power of individual countries and ensures more balanced vaccine prices
- Eight countries indicated that limited cooperation and political ties between countries are barriers to joint procurement;
- One country reported that irregular and inadequate vaccine funding would be a major barrier to participating in joint procurement.
- Four countries thought that JP can seriously affect the vaccine market.

Some participants added additional comments. In detail:

- Malta "the main issues were people round the table taking long to decide and the different national legislations on language, labelling";
- Norway "joint procurement of vaccines to immunisation programs may disturb a healthy market and that for preparedness it is important to keep as many manufacturers as possible";
- Portugal "the process is generally very complicated and long, due to the need for agreement of many countries, not very useful for urgent needs",
- Slovakia "joint procurement system has advantages when it comes to the power of the participating countries in negotiation processes"





Besides JP, seven participants indicated that their country currently participates in, or has previously participated in, other forms of cross-border collaboration (besides joint procurement) to support decision making during national procurement:

- Italy and Spain share vaccine price information;
- Lithuania conducted joint market research;
- Norway sharing and discussing tender processes and supplier insight;
- Slovakia extending communication with the Czech colleagues.

### *Joint procurement initiatives with other European countries*

This section was completed only by countries who were participating in (at the time of survey completion) or had participated in any joint procurement system with other European countries.

The countries completed the questionnaire at different time points from August 2020 to February 2021. For this reason, some countries reported participating in the European joint procurement initiative for COVID-19 vaccines (countries who responded to the questionnaire at a later point in time) while others did not report participation in this JP. Ultimately, all responding countries participated in the European joint procurement initiative for COVID-19 vaccines. Therefore, we did not consider this response in the analysis.

Nine countries reported participating or having participated in joint procurement initiatives (excluding the joint procurement initiative for COVID-19 vaccines). Of these, four countries reported having participated in JP initiatives for pandemic vaccine (H1N1) and five for other vaccines or biological products (diphtheria, DTaP-IPV-Hib-HepB hexavalent, pneumococcal, and rotavirus vaccines; Botulism and Diphtheria Antitoxin – Table 8).





# Table 8. Countries participating or having participated in a joint procurement system for vaccine(s) or biological products.

	Participating in JP*	Vaccine/biological product		
Country		Pandemic vaccine (H1N1)	Other	
Bulgaria	Х		X	
Finland				
France				
Hungary				
Ireland	Х		Botulinum antitoxin, Diphtheria antitoxin	
Italy				
Latvia	x		PCV-10, Rotavirus Vaccine, DTaP-IPV-Hib- HepB (hexavalent vaccine)	
Lithuania	Х		Pneumococcal vaccine for newborns	
Malta	Х	Botulinum antitoxin, BCG, Diptheria		
Norway				
Portugal	Х	X		
Slovakia	Х	X		
Slovenia	X	X		
Spain	X	X		
Total	9	4	5	

\* Excluding EU Joint Procurement of COVID-19 vaccines

Nine countries signed a formal agreement with other participants. The main points covered by the agreement were type of products, allocation to each country, duration of the contract, mechanism of payment and/or of transferring funds, and award criteria.

The most important processes and tools the countries agreed upon before initiating a joint cross-border procurement process were product specifications, regulatory requirements, tender documents forms/procedures and contracting documents language requirements, applicable procurement procedures and award criteria.

- In Latvia and Lithuania experiences, one of the countries involved in the JP was in charge of the whole process.
- An EU agency/competent body (e.g. ECDC, European Commission) was in charge of the process for Ireland, Portugal, Slovakia, Slovenia, and Spain.
- Malta reported that who is in charge of the process depends on the cycle: most of the times the countries were involved in the different groups in liaison with ECDC and/or EC.

A specific web platform to manage the procurement process was available only in two countries:

• Lithuania (<u>https://cvpp.eviesiejipirkimai.lt/</u>)





• Spain (<u>https://contrataciondelestado.es/wps/portal/plataforma</u>).

The duration of the process of joint procurement ranged from 4-5 to 15 months, from the time the request was sent to the time the vaccines were available at the vaccination center. Seven countries (Ireland, Latvia, Lithuania, Malta, Slovakia, Slovenia, and Spain) reported that the JP process has taken a greater length of time compared to the standard procurement process.

The main strengths of the JP system reported by MS were lower vaccine price, more equity in distribution of products, more negotiating power, forecasts and possibility of reallocating stocks, expertise of the competent bodies for JP. In detail:

- Supply available difficult to get products (Ireland)
- Lower vaccine price (Latvia)
- Lower price of the vaccine (Lithuania)
- Forecasts; price (Malta)
- Expertise of the European Commission and other international institutions; negotiating power (Portugal)
- Joint procurement system good as there is one joint document prepared agreement, invoicing etc.; The national bodies do not need to prepare such papers; all the MS have the same point of departure; in case there is produced some quantity of the product, the distribution starts on the same day and time for all MS with % proportion of the total amount; there should be no inequity in supplying the products; the negotiations might run better for MS as the negotiating power of more members is bigger when only one MS conducts the discussions; the price might be also better as more countries is equal to more amount of the product (Slovakia)
- Equal access to the vaccine for all participating countries; the same price for the vaccine for all allocating countries; the possibility of reallocating the vaccine between countries, for Slovenia
- Same criteria for procurement (Spain)

The main weak points of the JP system was the long duration of the process, reported by six countries.





### In detail:

- "Too slow" (Ireland);
- "Duration of process" (Malta);
- "It required more time, the deadlines are not respected" (Slovenia);
- "Procurement process takes a longer time period" (Latvia);
- "To harmonize tender documents took much more time than during standard procurement process" (Lithuania);
- "The preparation of documents necessary for the negotiation process might take a very long time since there are different MS with different opinions and legislation. There might be several working groups, several meeting until the agreement by all MS involving is reached. In some MS JP might be a political issue. Therefore, the agreement is adopted but there is no political will of the particular minister or higher politicians. All such agreements must be approved on the political level by the government itself" (Slovakia).

Respondents whose country did not participate in any joint procurement system with other European countries were asked to indicate the main reasons they did not participate. The main reasons given by both countries (Hungary and Norway) was that they never received any proposal to participate. One country (Hungary) added that the process required too much time and the second country (Norway) that it did not appear economically advantageous. Finland did not specify the reason. When asked what their level of interest in participating in joint procurement of vaccines is, one country (Hungary) expressed a moderate level of interest, one country (Norway) a low level of interest.

### Other forms of cross-border collaboration

Besides JP, seven participants reported other forms of cross-border collaboration to support decision making during national procurement, such as sharing vaccine price and other information, conducting joint market research; sharing and discussing tender processes and supplier insight.

### COVID-19 vaccines

This survey was developed before the COVID-19 pandemic, while this section was added in the last phase, just before sending the questionnaire to countries, in August 2020. Participants were asked whether their respective countries had taken any steps, including advance





purchase agreements, to secure swift access to COVID-19 vaccines once they would become available, whether their countries had developed deployment and vaccination plans for COVID-19, and whether they were participating in WHO's ACT accelerator program, the global collaboration to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines.

Participants completed the questionnaire at different time points from August 2020 to February 2021. Since all countries gradually started developing plans to secure access to COVID-19 vaccination, responses to the survey are dependent on the point in time when the questionnaire was completed. Ultimately all countries participated in the EC advanced purchase agreement initiative. Responses to the questionnaire are therefore misleading and we have decided to not include them in this report.

### 5. Discussion

In this report, following a description of some key concepts of vaccine procurement from the literature, including advantages and disadvantages of self versus joint vaccine procurement methods, we describe the results of a survey to describe local financial mechanisms for vaccine procurement in EU/EEA, member state participation in and opinions on joint procurement of vaccines and other forms of cross-border collaboration. The survey was conducted during the COVID-19 pandemic (but prior to the availability of COVID-19 vaccines) and only 14 of 28 invited countries participated in the survey. All participating countries are Member States of the EU/EEA and all except one are high income countries (one country is high middle income). Some of the information collected with this survey and our previous work on vaccine shortages will also be useful to complete the final deliverable of EU-JAV WP6 (D6.2 Guidelines on procedures to estimate vaccine needs and procurement in EU).

It is known that national immunization programmes and policies vary across Europe, with differences in funding mechanisms across Member States. The survey highlighted that vaccines included in the national vaccination schedules are entirely funded by the national or subnational government in the majority of countries. Other reported sources of funding include health insurance contributions either directly funded by the central government or with reimbursement of costs. Two of the participating countries are high middle income countries but none use private donor funding.





The survey also highlighted that not all vaccines included in national vaccination programmes are completely state funded, some being purchased out-of pocket. Lack of funding may lead to access issues, for e.g. for some adult vaccines not included in the national immunisation plans or for vaccines that are state-funded only for risk groups. Also, if EU countries (or sometimes regions within the same country) differ in the list of vaccinations that are provided free of charge (or heavily subsidized) to their population, this may lead to confusion by the public and may give the impression that a lack of consensus exists on the vaccines to be provided. In some cases, there may be a rationale for such differences (e.g. different epidemiology) but then these differences need to be explained.

Importantly, most countries allocate specific funds to vaccines with a budget line item for vaccine procurement. Most countries use annual budget planning, while midterm or long-term planning is seldom used by countries. Budget planning is centralised in most countries. When asked about any major budget planning and allocation issues, one country reported having to reallocate budget due to shortages and spikes in pricing and another having to manage the inclusion of new vaccines in the immunization schedule. Indeed, adequate financing of immunization programmes has been reported in the literature as one of the challenges facing NIPs (25).

Decision-making to finance introduction of a vaccine is based, among other things (epidemiology of the disease and cost-effectiveness evaluations), on NITAG recommendations. However, lack of information on the size of the population to be vaccinated (e.g., size of high-risk populations) and estimating the exact coverage levels to be achieved, were reported by some countries as main difficulties in forecasting and budget planning. Accurate forecasting is indeed key to avoid vaccine shortages and will be addressed in the next deliverable of WP6, whose aim is to develop guidelines for procedures to estimate vaccine needs and procurement in EU-MS in the short and long-term.

Regarding the current framework for vaccine tenders, most countries reported using price criteria, with only three countries using quality criteria. As highlighted in the literature, while price-based tenders can bring short-term financial savings they can also contribute to vaccine supply issues, discourage the provision of value-added services and be a disincentive for future research and development (35). Using only price criteria may result in prices that are so low that manufacturers will not be interested in participating because of the very limited business





margins, with constrained supply being diverted to other countries with more sustainable market conditions (35, 37).

Survey results suggest that overall, the current financial mechanisms for vaccine procurement used in the surveyed countries seem to function well and that in general, these countries are satisfied with their procurement process. Survey respondents identified as main strengths of current procurement systems, transparency, homogeneous and adequate prices and equal access to vaccine even though sometimes procurement methods are characterised by bureaucracy and long tendering procedures. One country highlighted the need to conduct more long-term agreements. Another factor identified as a weakness is that in three countries there is no centralised process for vaccine purchasing.

Regarding joint procurement, prior to the EU Joint Procurement for COVID-19 vaccines (in which all EU countries participated), several countries had participated or were participating in other more limited joint procurement initiatives with other European countries. The general perception of these countries is that JP has several advantages but also disadvantages. However, most participants agree about the usefulness of JP during serious cross border health threats caused by vaccine preventable diseases. Most participants also agreed that JP strengthens the purchasing power of individual countries, ensures more balanced vaccine prices and more equitable access to vaccines. Some, however, reported concerns that JP could seriously affect the vaccine market and disturb a healthy market, highlighting, in one case, that for preparedness it is important to keep as many manufacturers as possible. Indeed, short-term versus long-term impacts of joint procurement (e.g. on the sustainibility of the suppliers), should be analysed and considered (38). There is some evidence that joint procurement mechanisms may lead to lower vaccine prices compared to self-procurement. According to a recent WHO report, on average, pooled procurement prices were 60% lower for middle-income countries procuring from UNICEF or the PAHO Revolving Fund (39).

According to a 2016 WHO policy brief on voluntary cross-border collaboration in public procurement and how these can improve access to health technologies in Europe (17), there is a growing interest and a sound rationale in further developing voluntary cross border collaborations in the field of health, both at a bilateral and multilateral levels. However, developing sustainable cross-border collaborations in procurement is challenging, and experiences in Europe are limited, as are data on effectiveness and impact (17).





Besides joint procurement, half of responding countries reported participating in other forms of cross-border collaboration to support decision making during national procurement, such as sharing vaccine price information, conducting joint market research, sharing information and discussing tender processes and supplier insight. According to respondents, possible advantages of these collaboration models include increased transparency on prices, increased negotiating power, decreased prices and administrative costs. An important component of cross border collaborations is also the lending of vaccines, which could help mitigate shortages when they occur. These intiatives are recommended and are particularly relevant for smaller countries, where the target population is limited and self procurement may be more difficult because of smaller number of vaccines needed and therefore increased costs. Possible advantages of these collaboration models include increased transparency on prices, increased negotiating power, and decreased prices and administrative costs (6, 40). A concept analysis for a regional EU data warehouse for sharing data/information of supply and demand is ongoing in the framework of the EU-JAV Work Package 6 (41).

The procurement of COVID-19 vaccines, led by the European Commission, with the participation of all EU Member States, is a very recent and important example of a common approach taken to procuring vaccines during a cross-border health threat, as well as the financing mechanism used. At the European Council in June 2020, the Member States of the European Union mandated the Commission to organise the joint procurement of COVID-19 vaccines (42). The Commission started talks with the most promising vaccine manufacturers and carried out negotiations jointly with a Joint Negotiation Team (with members representing seven MS appointed by a Steering Committee). All EU Member States are represented in the Steering Committee. An innovative financial mechanism for vaccine procurement was used: the European Commission (EC) ran a single central procurement procedure on behalf of Member States and signed EU-level Advance Purchase Agreements with various individual vaccine producers on behalf of the MS (43). THE APAs make reference to Article 4, paragraph 5, point (b) of Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union which provides that the Commission may grant emergency support in the form of procurement on behalf of the Member States based on an agreement between the Commission and Member States (44).

In return for the right to buy a specified number of vaccine doses in a given timeframe and at a given price, the Commission financed a part of the upfront costs faced by vaccine producers.





The related funding came from a significant part of the €2.7 billion Emergency Support Instrument, with additional support available through loans from the European Investment Bank (45). The process is as follows: the Joint Negotiation Team first holds exploratory talks with the company to find out if there is sufficient common ground to proceed with detailed contractual negotiations. In the negotiation process, Member States tell the Commission how much of a certain vaccine they want to order but they themselves are then responsible for purchasing the vaccines once they prove to be safe and effective and become available. The Commission does not sign contracts for deliveries to individual countries. Advance Purchasing Agreements allow the Commission to secure a certain number of doses. It is then for Member States to purchase these doses, activate potential options included in the APA to order additional doses, and conclude specific contracts with the companies. Once contractual negotiations are completed, a tender invitation is sent to the manufacturer, which then has to propose an offer. An important point and principle is that the price of the vaccine is the same for all EU Member States. An APA is concluded when both sides have finalised the contractual work and there is approval of the Commission. Before signature, the Steering Committee discusses and reviews all aspects of the APA contracts. The APA may provide for an obligation for the Member States to purchase vaccine doses but MS may opt out if they notify this within five working days. The contract is signed if at least four Member States agree to be bound by it (45).

Advanced purchase agreements have been a crucial element contributing to the European response to fight the COVID-19 pandemic. Thanks to the common EU Vaccines Strategy, the Commission was able to build a diversified portfolio of several vaccines, based on different technologies, from several suppliers, at a fair price, and has ensured access to COVID-19 vaccines for all Member States. Tasks that were traditionally considered to be national decisions were delegated to the Commission to avoid having MS competing with each other for fewer doses from fewer producers. Had this not been done, MS would have faced a higher risk of seeing significant variations in the speed of vaccination and of inequity (46). The strategy also enabled the support and speeding up of development and manufacturing at scale of COVID-19 vaccines and allowed the exportation of doses to over 100 countries worldwide. Several difficulties were encountered such as problems in scaling up manufacturing and production capacity, and being dependent on the global supply chains (46). A recent paper evaluated the role of the JPA during the COVID-19 pandemic and highlighted that this





economic instrument could open the way to further cooperation between MS healthcare systems (47).

In order to strengthen EU preparedness and response in future health emergencies, in November 2020, the Commission, among other initiatives, set out the main elements of the future Health Emergency Response Authority (HERA), to be proposed by the end of 2021 (48, 49). HERA is part of the European Health Union and will provide a dedicated structure to support the development, manufacturing and deployment of medical countermeasures (including vaccines) during a health crisis of natural or deliberate origin.

### Limitations.

This report is based on a survey conducted during the COVID-19 pandemic, among persons in charge of the national or subnational immunisation programme(s) or of vaccine supply/procurement in EU/EEA and consortium Member States. The questionnnaire was first sent to participants in August 2020. The survey was affected by a number of limitations, mainly due to the overwhelming workload of all health professionals involved the management of the COVID-19 pandemic. A limited number of invited countries responded to the questionnaire (50% response rate), some responses were delayed and sometimes incomplete. Another limitation is the scarcity of published literature on vaccine procurement at European level, since much of the literature on vaccine procurement is limited to low- and middle-income countries and therefore may not be generalizable to most European countries.

### 6. Conclusions

There are several conclusions we can draw from this survey. In EU/EEA, vaccines included in the national vaccination schedules are entirely funded by the national or subnational government in the majority of countries and none of the participant countries use private donor funding. Most countries use annual budget planning cycles (mostly centralised), while mid-term or long-term planning is seldom used by countries. Longer term planning is recommended because it allows a more comprehensive view of future vaccine demand. Overall, countries are satisfied with their procurement process; however, most countries reported using price criteria which may be a disincentive for manufacturers to participate in tenders and invest in R&D. One of the requirements of a healthy market is that a range of suppliers be available; in order to achieve this requirement, price should not be the only





criterion considered in vaccine tenders. The majority of participants reported being favourable to joint procurement of vaccines during serious cross-border health threats caused by vaccine preventable diseases. Other forms of cross-border collaboration (such as sharing vaccine price and other market information), and lending of vaccines in case of vaccine shortages have been used in EU and should be encouraged. Availability of a regional EU data warehouse of supply and demand coud be a step in this direction. A concept for such a data warehouse is being developed in the framework of the EU-JAV Work Package 6.





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# APPENDIX 1. Questionnaire: Survey on financing mechanisms for vaccine procurement in EU/EEA and EU JAV consortium Member States.

Dear Colleagues,

Thank you for agreeing to participate in the *Survey on financing mechanisms for vaccine procurement*. (Task 6.1 of the EU-Joint Action on Vaccination). The aim of the survey is to collect detailed information on the main financing mechanisms for vaccine procurement used in EU/JAV countries. In addition, the survey aims to explore the possibility of establishing a joint procurement system across EU/JAV countries, at least for some vaccines, by highlighting the key barriers and enablers of success for these type of systems. The results of this survey may have important implications for policy makers.

The survey is divided into five sections and will take about 30 minutes to complete:

SECTION 1. General information (contact details).

SECTION 2. Financing mechanisms for vaccine procurement.

SECTION 3. Cross-border cooperation to improve access to vaccines.

SECTION 4. Joint procurement system with other European countries.

SECTION 5. COVID-19 vaccines.

Parallel interviews will be also carried out with other stakeholders and experts involved in vaccine procurement in the EU/EEA.

Results from the survey and interviews will be summarised into a report that will be sent to you for your revision. Should you have any questions regarding the survey, please do not hesitate to contact us at any time at: <u>antonietta.filia@iss.it</u>.

Sincerely, ISS team, Italy Work Package 6 EU-JAV





### SECTION 1. General information (contact details)

1. Please provide your country, name, affiliation and contact details

Country:	
Name of Respondent:	
Affiliation:	
Qualification and Role:	
E-mail:	
Office Telephone N.:	
Mobile N.:	

- 2. May we contact you if we need clarifications on the responses given or any further information? Yes  $\square$  No  $\square$
- 3. Comments\_

SECTION 2. Financing mechanisms for vaccine procurement

Part 1

- 4. What are the main sources of vaccine funding in your country, for vaccines included in the national vaccination schedule?
  - o Central government (e.g. public funds obtained from taxation)
  - o Subnational authorities
  - o Health Insurance contributions with central allocation for procurement
  - o Health Insurance contributions with reimbursement of costs
  - o Private funding (Donor es. Gavi, Unicef)
  - o Mixed scheme (Government and Donor)
  - o No funding (citizens purchase own vaccines).
  - o Other, please provide details:





- 5. Are the sources of vaccine funding for vaccines NOT included in the national vaccination schedule different from above?
- o No
- o Yes, please specify any differences:
- 6. Regardless of the source(s) of funding, are there funds that are specifically allocated annually to vaccines in your country, at either national, regional or local levels? (i.e.; is there an endorsed annual budget line item in place for vaccine procurement?)
- o No
- o Yes. Specify at which level or levels:
- 7. In your country, the decision making to finance introduction of a vaccine is based on which of the following? (more than answer is possible)
- o NITAG decision
- o Epidemiology of the disease in your country
- o Cost-effectiveness evaluation
- o Other: \_\_\_\_\_\_
- 8. In your country, what are the main difficulties encountered in budgeting for vaccines?
- lack of information on the size of the population to be vaccinated (e.g. size of high-risk populations)
- estimating the exact coverage levels that will be achieved
- other, please specify: \_\_\_\_\_\_
- 9. In your country, vaccine needs forecasting and quantification are based on (more than one choice is possible, choose all that apply):
- Target population (demography, immunisation schedule, coverage objectives, wastage rate, buffer stock)
- o Previous consumption level
- o Other, please specify: \_\_\_\_\_

10. What type of budget planning is used in your country?

- o Annual budget
- o Mid-term budget (2-3 years)
- o Long-term budget (< 3 years)
- o Other, please specify: \_\_\_\_\_





- 11. In the last 5 years, has your country experienced major budget planning and allocation issues regarding vaccines?
- o No
- o Yes, please provide details:
- 12. Can you describe the current framework for vaccine tenders in your country? At which level are they carried out and what are the criteria used (lowest price, best offer)?
- 13. Do national regulations restrict participation in vaccine procurement tenders only to local wholesalers, suppliers or manufacturers' representatives?
- o No
- o Yes, please provide details
- 14. Prior to issuing a vaccine tender, do any interactions (e.g. meetings or other forms of interaction) take place between vaccine procurement representatives at the national or local level and pharmaceutical companies, to allow industry to present their products?
- o Yes
- **No**

If Yes, please describe briefly:

- 15. In general, are you satisfied with the procurement process in your country?
- o Yes
- **No**

16. Please describe strengths of the current procurement system in your country.

17. Please describe weaknesses of the current procurement system in your country.





18. Comments

SECTION 3. Cross-country cooperation to improve access to vaccines.

- 19. Does your country currently participate or has it participated in any joint procurement system with other European countries?
- Yes, it has participated
- Yes, it is currently participating
- **No**
- 20. Who would be the major stakeholders to be consulted in the event a joint-procurement option is considered?
- 21. Please indicate whether you agree with each of the below statements on joint procurement:
- a. Joint procurement of vaccines will improve Member States' preparedness to mitigate serious cross-border threats to health caused by vaccine preventable diseases Yes  $\square$  No  $\square$
- b. My country is dependent on just a few local wholesalers for the cold storage and internal distribution of vaccines and joint procurement may disrupt thisYes  $\Box$  No  $\Box$
- c. Joint procurement ensures a more equitable access to vaccines Yes  $\square$  No  $\square$
- d. I fear that joint procurement may lead my country to lose its ability to make decisions concerning evaluation criteria and vaccine selection Yes  $\square$  No  $\square$
- e. Joint procurement strengthens the purchasing power of individual countries Yes 

  No 

  f. Limited cooperation and political ties between countries is a barrier to joint procurement Yes

  No
- g. Joint procurement ensures more balanced vaccine prices Yes  $\square$  No  $\square$
- h. In my country, irregular and inadequate vaccine funding would be a major barrier to participating in joint procurement. Yes  $\square$  No  $\square$





- i. In my country there are policies protecting local producers and this is a barrier to joint procurement. Yes  $_{\Box}$  No  $_{\Box}$
- j. In my country, vaccine evaluation criteria are very restrictive and this is a barrier to joint procurement. Yes  $_{\Box}$  No  $_{\Box}$
- k. I think that joint procurement can seriously affect the vaccine market. Yes  $\hdots$  No  $\hdots$
- 22. Would you like to add your personal opinion on joint procurement?
- 23. Besides joint procurement, does your country currently participate in, or has it previously participated in, any other form of cross-border collaboration, to support decision making during national procurement?
- o Yes
- o **No**
- 24. If yes, please specify the type of cross-border collaboration:
- o sharing vaccine price information
- o conducting joint market research
- o Other, please specify: \_\_\_\_\_

25. Comments

If YES to Question 19 (i.e. your country currently participates or has participated in any joint procurement system with other European countries), you will be redirect *to Q. 26 (SECTION 4 Joint procurement system with other European countries Sub-section A)* 

If NO to Question 19 (i.e. your country HAS NOT participated in any joint procurement system with other European countries), you will be redirect to Q 39 SECTION 4 Joint procurement system with other European countries Sub-Section B

SECTION 4. Joint procurement system with other European countries





Sub-Section A. According to the answer to question Q 19 your country currently participates or has participated in any joint procurement system with other European countries; please respond to the following questions)

- 26. If your country currently participates or has participated in any joint procurement system with other European countries, for which vaccine or vaccines has this occurred?
  - o Pandemic vaccine (H1N1)
  - o Other vaccines/biological products. Specify product and countries involved:
- 27. Was a formal agreement signed between the participating countries?
  - o Yes (attach document)
  - o No
- 28. What are the main points covered by the agreement (e.g. type of products, quantities allocated to each country, mechanism of payment and/or of transferring funds, duration of contract, etc.)
- 29. What were the most important processes and tools your country agreed upon before initiating a joint cross-border procurement process:
- o Product specifications
- o Regulatory requirements
- o Language requirements
- o Applicable procurement procedure
- o Tender documents / forms / procedures
- o Award criteria
- o Contracting documents
- o Other (specify)
- 30. Was it necessary for your country to emit a legal act in order to be able to participate in the joint procurement?
- o Yes (attach document)
- o **No**





- 31. If yes, what are/were the main points covered by this legal act?
- 32. Who was in charge of the procurement process? (i.e. who had procurement manager responsibilities)
- o One of the countries involved
- o EU agency / competent body (e.g. ECDC, European Commission).
- o International agency (e.g. WHO).
- o Other agency (please specify: \_\_\_\_\_)
- 33. Was/is a specific web platform available to manage the procurement process?
- o Yes (if possible, please indicate the web address: \_\_\_\_\_)
- o **No**
- 34. How long does/did the process of joint procurement take (in months), from the time the request is sent to the time the vaccines are available at the vaccination centre?
- 35. In your experience, did the joint procurement process take a longer length of time compared to the standard procurement process?
- o Yes, it required more time
- o No, it required the same amount of time
- o No, it required a shorter amount of time

36. What are/were strengths of the joint procurement system in which your country participated?

- 1.\_\_\_\_\_

   2.\_\_\_\_\_
- 3.\_\_\_\_\_





37. What are/were weak points of the joint procurement system in which your country participated, that you would improve?

1	 
2	 
3	 
38. Comments	

### SECTION 4. Joint procurement system with other European countries

**Sub-Section B.** According to the answer to question Q 19 your country did not participate in any joint procurement system with other European countries; please respond to the following questions:

- 39. Can you indicate the main reasons you did not participate? (more than one answer is possible)
- o We never received any proposal to participate
- o Our legislation does not allow or support joint procurement
- o Joint procurement requires a steep initial investment
- o Not economically advantageous
- o The process required too much time
- o Other, please specify: \_\_\_\_\_

40. What would be your level of interest in participating in joint procurement of vaccines?

- o **High**
- o Moderate
- o Low
- o Null

41. Can you explain the reasons for your answer?

(indicating what you believe are the main strengths /weaknesses of joint procurement systems)





### SECTION 5. COVID-19 vaccines

There are now hundreds of vaccines in development against COVID-19 and hopefully we will have one or more vaccines that will be shown to be safe and effective in the upcoming months.

- 42. Has your country taken any steps, including advance purchase agreements, to secure swift access to COVID-19 vaccines once they will become available?
- o Yes, please provide details:
- o **No**
- o Not yet
- 43. Has your country developed deployment and vaccination plans for COVID-19?
- Yes, please provide details:
- o No
- o Not yet
- 44. Is your country participating in WHO's ACT accelerator program, the global collaboration to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines? and vaccination plans for COVID-19?
- o Yes
- o No

#### Comments

Please enter any additional comments to the survey in the box below:

Thank you for completing the questionnaire.