

Deliverable D6.6:

Final report and recommendation of mechanisms of management of forecasting supply and stocks

Grant Agreement No.:	801495
Start Date:	01/01/2018
End Date:	31/03/2022
Project title	European Joint Action on Vaccination — EU-JAV
WP number	WP6
Deliverable number	D 6.6
Title	Final report and recommendation of mechanisms of management of forecasting supply and stocks
Responsible partner No.	14
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Nature	
R-report	R
O-other (describe)	
Dissemination Level	
PU -public	PU
CO -only for consortium members	
Delivery Month Planned	M44
Actual Delivery Date (dd/mm/yyyy)	25/3/2022

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Contents

Acknowledgments	5
List of abbreviations.....	5
1. Introduction.....	6
2. Methodology.....	7
3. Mechanisms to ensure sufficient size of supply and stockpiles, including their sustainability.....	8
4. Gap and options to enable exchange on vaccine supply/demand between the EU member states 10	
5. Outlook – Policy recommendations	13
References	15

Acknowledgments

We are grateful to all participants and respondents to the survey and work in WP6.2 as well as all EU-JAV partners who contributed to the discussions and gave feedback to the report.

List of abbreviations

CHAFEA	Consumers, Health, Agriculture and Food Executive Agency
COVAX	COVID-19 Vaccines Global Access
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EU	European Union
EAA	European Economic Area
EU-JAV	European Union Joint Action on Vaccination
EWRS	Early Warning and Response System
GDPR	General Data Protection Regulation
HADEA	Health and Digital Executive Agency
HERA	Health Emergency preparedness and Response Authority
HSC	Health Security Committee
ISS	Istituto Superiore Di Sanità, Italy
MS	Member State
NIPH	Folkehelseinstituttet (FHI), Norway
SOP	Standard Operation Procedure
WP	Work Package

1. Introduction

The European Joint Action on Vaccination (EU-JAV) aims to strengthen cooperation between European countries to fight vaccine preventable diseases. EU-JAV focuses on sharing best practices on national immunisation policies, delivering, and sharing concrete tools for stronger national response to vaccination challenges. As such, it will contribute to the implementation of the European Council recommendations on vaccine-preventable diseases.

Vaccination is one of most significant public health achievements. However, national immunisation programmes depend on an adequate supply of high-quality vaccines to function properly. 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 diseases. The main activity of work package (WP) 6 of the EU-JAV is related to vaccine supply and preparedness. The aim of WP6 was to better understand the problem of vaccine shortages in the European Union (EU), and reinforce mechanisms of vaccine supply, procurement, and stockpile management.

The work package 6 (WP6) was organized as follows:

- **Task 6.1 - Mapping needs and demand (led by ISS):** its aim was to define basic principles for vaccine demand planning and forecasting and other issues related to preparedness
- **Task 6.2 - Reinforce mechanisms of management of vaccine supply (led by NIPH):** Its aim was to reinforce mechanisms of forecasting and management of vaccine supply

More specifically, through these 2 tasks we wanted to understand important mechanisms to ensure sufficient size of supply and stockpiles, including their sustainability and explore possibilities, gaps, and options for regional or European sharing of data on stockpiles on vaccine management.

While Task 6.1 focused on investigating vaccine shortages among member states as well as financing mechanisms for vaccine supply, Task 6.2 wanted to investigate what kind of mechanisms and tools would be helpful for the member states to rapidly exchange stocks in case of a need or to exchange surplus vaccines.

One of the needs to be explored through task 6.2 of the WP from the beginning of the EU-JAV and throughout the project, was to investigate mechanisms to accurate forecast vaccine

needs, and better understand how exchange of vaccines between member states could be facilitated. The project was asked to explore if a concept of an online platform to act as a

data repository where countries could exchange information of vaccine supply and demand data would be a useful tool for the member states (MS).

This report focuses on synthesizing the overall results from Task 6.2 and propose some future recommendations on important mechanisms that should be in place in Europe to improve and ensure vaccine supply and reduce shortages. The recommendations are based on results reported in two previous reports and deliverables of the WP6, deliverable 6.4 – Report on the anticipated needs to ensure sufficient size of supply and stockpiles, including their sustainability (1) and deliverable 6.5 – Report on Possibilities, Gaps and Options for Concept Analysis (2). We have additionally gained feedback and knowledge from the partners and through dissemination of our results throughout the project. Finally, the covid-19 pandemic has taught us a lot of lessons in terms of ensuring proper vaccine supply, equity and delivery and the need to have systems in place to exchange vaccine stocks between countries in need of vaccine supply.

The final objective is to promote better and more predictable understanding on these issues and to discuss possible future tools to ensure vaccine supply among member states in the EU.

The covid-19 pandemic has taught us a lot of lessons in terms of ensuring proper supply and equity in vaccine delivery. This crisis is an extreme situation and might not reflect the situation when the WP6 was originally planned in 2018. However, the establishment of EU vaccine strategy on one hand, and COVAX, the global vaccine equity sharing mechanism to ensure covid-19 vaccines particularly in low- and middle-income countries, in other hand, has elevated some of the key challenges regarding exchange of vaccine stocks.

One of the main learnings from this work is that vaccine supply management, to exchange vaccine stocks in case of need in supply may seem straightforward from the outside, however, it is in fact very complex. To ensure vaccine deliverable in terms of shortages, there must be political commitment, but additionally the country must have in place proper mechanisms to accept vaccines, storage capacity, regulatory approval, import approval, indemnification, and liability agreements. These processes might seem like very detail management for some but must be in place before legally binding purchase orders and transport arrangements can be made.

2. Methodology

The methodology used to gather the information was a combination of literature review, workshops during the EU-JAV meetings, Member State Committee meetings, as well as a survey where we gathered information on stakeholders and EU member state's opinion on key mechanisms to evaluate the anticipated need to ensure sufficient volumes for supply of

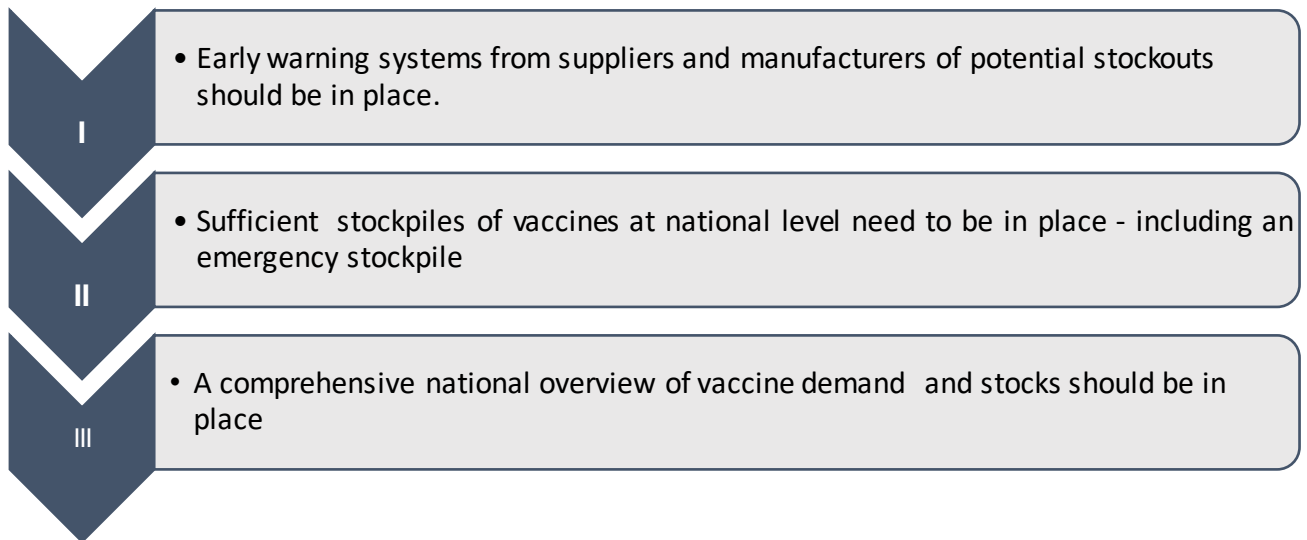
vaccines. Additionally, we aimed to understand the range of possible concepts and options for rapid sharing mechanisms of vaccine supply as well as the member states view on an EU data warehouse to exchange information on European vaccine demand and supply data. We wanted to understand if these mechanisms should be restricted to only a voluntary sharing mechanisms or standard common procedures for rapid exchange mechanism, or if members states believed a stockpile-monitoring tool or other type overview of stock of vaccines could be useful to ensure vaccine supply and help to ensure correct overview of vaccine demand. We additionally explored if these tools should be restricted to specific vaccines to secure public health and national security. A more detailed overview and copies of the survey can be found in the earlier published reports (1,2).

Regarding the timing of these works in relation with the covid-19 pandemic, the first knowledge was gathered prior to the pandemic via a survey directed to member states and organisations participating in the EU-JAV and from participants in the EU-JAV member states committee to increase the number of participating countries. The literature review was focused on other organisations working with vaccine supply at the European member states level.

3. Mechanisms to ensure sufficient size of supply and stockpiles, including their sustainability

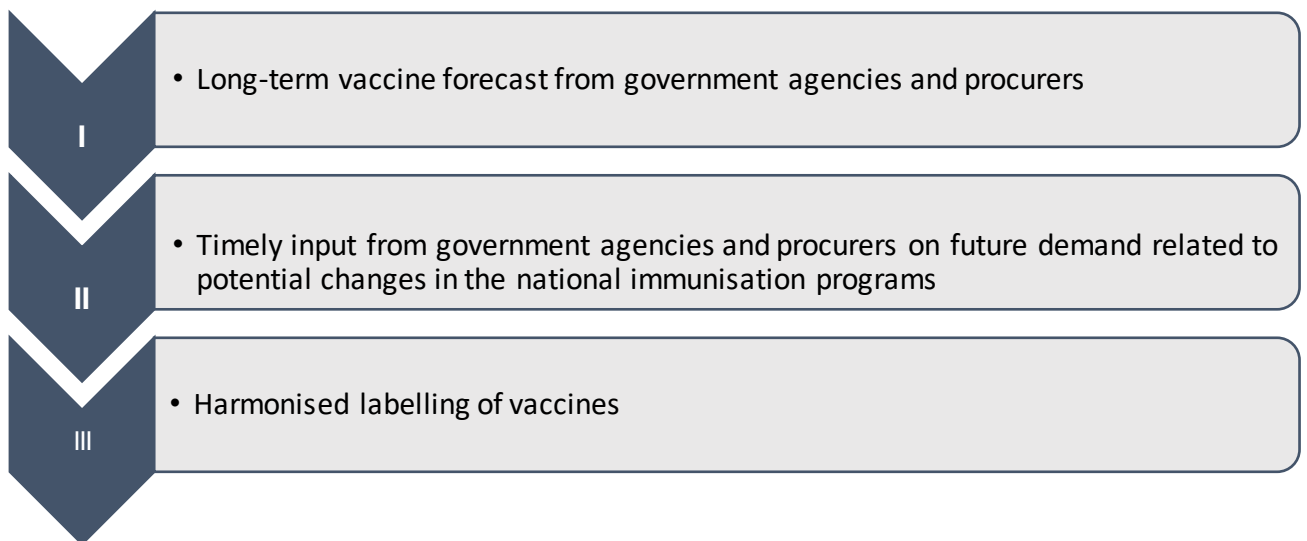
A set of recommendations on key mechanisms to ensure sufficient size of vaccine supply and stockpiles are presented below. The recommendations are based on results and findings during the EU-JAV, feedback from the partners and the main results from our first deliverables of the work package, deliverable 6.4 – Report on the anticipated needs to ensure sufficient size of supply and stockpiles, including their sustainability (1). The main results have been summarised in different areas.

Key mechanisms to ensure sufficient supply for immunisation programs and preparedness in EU



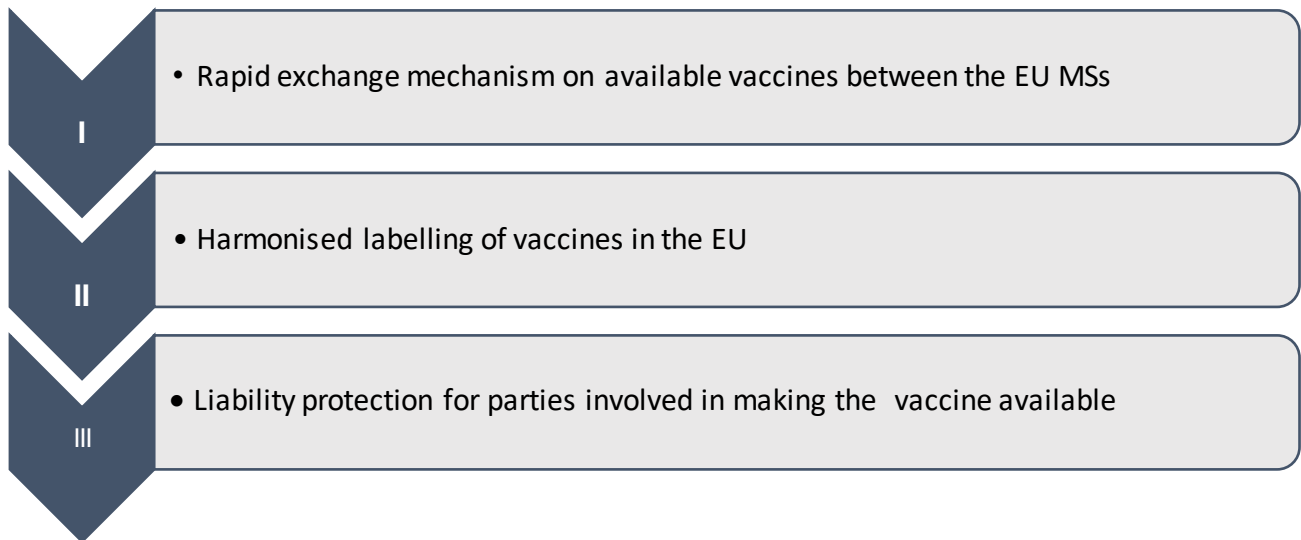
There should be further work to define what is meant to be a sufficient stockpile and what level of emergency stockpile is needed to prevent shortages in the member states.

Key mechanisms to improve forecast of vaccine demand and manufacturing



Recommended mechanism to better enable exchange of vaccines between the European countries was one of the other areas of interest in our research. Key mechanisms to better enable exchange of vaccines between EU countries identified were:

Key mechanisms to better enable exchange of vaccines between EU countries



We aimed to explore the feasibility of an online platform to act as an EU data warehouse for sharing of vaccine supply and demand data among dedicated stakeholders; and to determine whether a virtual stockpile monitoring tool or other type of rapid exchange

mechanism could be useful, and if such a tool should be restricted to specific vaccines only to secure public health and national security.

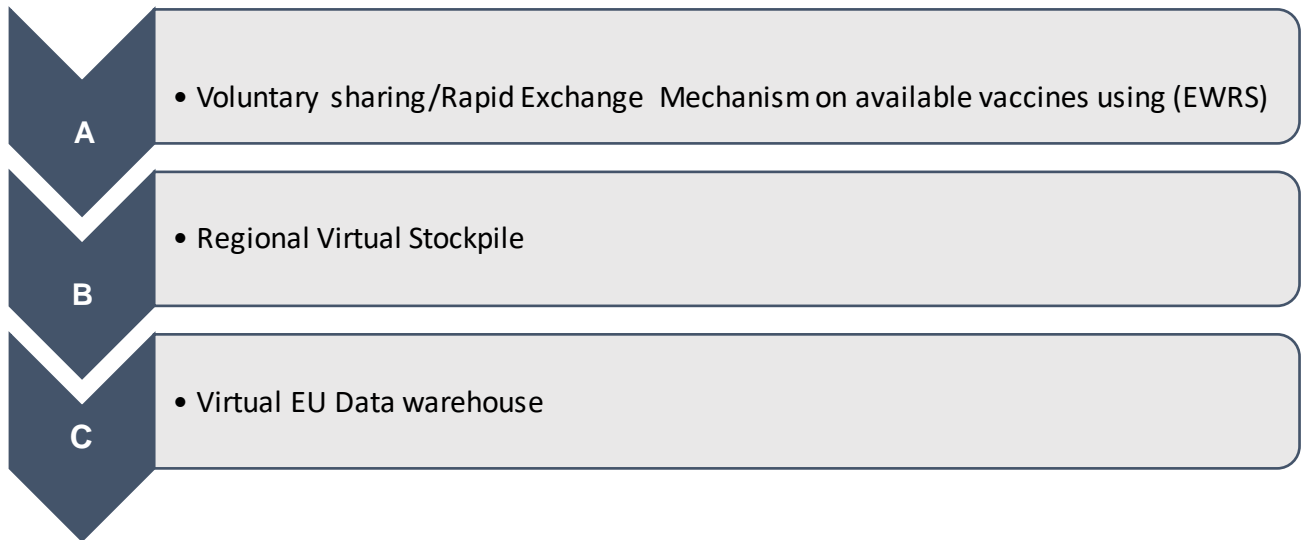
Very few of the participating countries believed establishing a virtual data repository would in general prevent shortages in the EU. On the other hand, several of them gave feedback regarding the fact that specific priority vaccines should be under focus for potential sharing or exchange mechanisms in case of shortages or need for shared vaccine supply and for a potential data repository:

- Rarely used vaccines and specific immunoglobulins
- Vaccines to be used during epidemic outbreaks
- Vaccines for emerging infectious diseases, such as i.e., Ebola vaccines

4. Gap and options to enable exchange on vaccine supply/demand between the EU member states

The second report, deliverable 6.5 – Report on Possibilities, Gaps and Options for Concept Analysis (2), published just prior to the covid-19 pandemic was an update on further steps taken to explore the feasibility to develop a concept for an EU data warehouse for sharing of vaccine supply and demand data among dedicated stakeholders. The report further discussed if a virtual stockpile monitoring tool or other type of rapid exchange mechanism could be useful and if such a tool should be restricted to specific vaccines only to secure public health and national security. The options reported are presented below.

Options to enable exchange of data on vaccines supply/demand between member states



These options were reported prior to the covid-19 pandemic. And some key features of these options were listed.

A. The voluntary sharing/Rapid Exchange Mechanism on available vaccines using (EWRS) should facilitate availability and exchange of vaccines using the EWRS as a platform to share information. There should be further development of functioning Standard Operating Procedures (SOPs) and templates to facilitate exchange.

B. A regional virtual stockpile. In addition to the exchange mechanisms developed for option A, a virtual regional stockpile could establish to facilitate rapid exchange of vaccines in cases of urgent need or sudden shortages. The Nordic countries reported experiences with such a mechanism, and this could be further explored.

C. A virtual EU Data warehouse. In addition to tools to be used for option A and B, functionality to share information and exchange of data could be developed through a data platform. One could consider to further develop the web-based EWRS platform linking the EU, ECDC and public health authorities in EU/EEA countries responsible for measures to control serious cross-border threats to health. Alternatively, one could build a new platform for data sharing and response for this purpose with visualisation solution and access to data for the MS.

The feedback received from the countries on these questions reflects the fact that most failures in vaccine supply is the unpredictable nature of outbreaks and rare events. Some member states have national stockpiles to protect against potential disease outbreaks. However, a global overview of the size of these stockpiles and how they are forecasted in each member state is still lacking. Due to these uncertainties, it is likely that this may impact the supply of vaccines needed to contain emerging threats and unpredicted outbreaks of

e.g., measles, rather than all the vaccines included in the national standard immunisation programme.

It is the responsibility of each Member State (MS) to assure sufficient stockpiles of vaccines. A variety of solutions have been implemented for management and governance of national stockpiles and not all MS hold a preparedness stock at national level. The size of the stockpiles varies from country to country, and it normally reflects the long lead-time for vaccines.

Other ongoing initiatives in this field and relevant to inform about exchange of vaccine stocks are:

- Ongoing discussions between the EU MS and the Health Security Committee (HSC) on rapid exchange mechanisms for vaccines or medical countermeasures
- Development of functioning SOPs for a simple exchange mechanism and necessary templates
- The procedure should continue to be based on the EWRS, without seeking to collate information on existing stocks
- Further testing and exercise through the EWRS of the SOPs should be organised prior to implementation
- Early warning systems from suppliers and manufacturers of potential stockouts
- CHAFAE announced a tender to explore the feasibility of and identifying options for physical stockpiling of vaccines and to develop a concept for a mechanism for exchanging vaccine supplies from EU Member State to another in case of an outbreak

We believe there is a need for more work on different options to facilitate exchange of vaccines or donate surplus vaccines, or to establish stockpiles for vaccines, especially those targeted against emerging diseases. The experience with the common EU strategy and purchase of covid-19 vaccines has now resulted in a large surplus of covid-19 vaccines in the member states and the need for rapid exchange mechanism and tools to donate these vaccines to other countries in need. Particularly, one should look more detailed into the functionality and scope of the options we started to explore.

We also recommend doing further work and more in-depth analysis of:

Legal risks

The exchange of medical countermeasure is a bilateral transaction. As such, all legal aspects need to be covered in a contract between the parties and not through an online data platform. The early work with the HSC has resulted in a procedure for the exchange as well as prototypes of standard templates. The template contract includes paragraphs which is considered important to address from a legal and liability point of view and by that a risk reducing measure. Work with covid-19 vaccines and the exchange of surplus vaccines have given the member states new experience with handling these issues.



Legal issues regarding a potential online data platform to exchange information on vaccine needs, expected needs and supplies, must also be further discussed. Exchange of data between and among member states must have a legal basis. Information security and quality control regarding the development and operation of the data platform must be explored. The handling of the data must be according to GDPR. A data controller must be defined and agreed upon. Data processor must be defined, and data processor agreements must be considered among the MSs. Access to data and control must be regulated.

Liability risks

Liability issues may be a hurdle for transactions of products between MSs. This issue is especially related to transaction and use of investigational products or vaccines used off-label (for instance vaccines with an emergency use authorisation). According to HSC discussions on which global mechanism exists and could provide both compensation for victims and liability protection for parties involved in making the medical countermeasures

available. Similarly, at EU level there is no compensation mechanism that could be accessed in cases of injury. The transaction between MSs will be a bilateral transaction and liability and other arrangements must be addressed and agreed in an agreement between the parties.

5. Outlook – Policy recommendations

A better understanding of important mechanisms to ensure sufficient size of supply and stockpiles, including their sustainability on an EU level, was needed. There were uncertainties of EU MS opinion on the need to share data on supply and demand, and for which types of vaccines. The WP6 work on this topic have identified future options that need further in-depth analysis to enable exchange of data on vaccines supply/demand between MS.

The countries responding to the survey and the early work pointed at the key mechanisms important to enable exchange of vaccines between EU countries as presented above. Concerning the current legal or regulatory hurdles related to the exchange of available vaccines between member states in case of shortages, many of the respondents pointed out liability issues and regulations concerning authorisation of the vaccines as the main hurdles, but also a need for common electronic packaging leaflets.

Based on these observations we have concluded that these results reflect the need for further discussion among the member states, and additionally future work should consider developing a standard operating procedure to be put in place and possible to be used when *ad hoc* urgent exchange of medical countermeasures is needed. The Early Warning and Response System (EWRS) raised by the European Health Security Committee (HSC) could be used as a mechanism for alerting other member states.

Further work on a European online platform to exchange information of vaccine supply and demand among dedicated stakeholders should include several options, and better understand if the willingness of the member states to pursue this option is still lacking. One could attempt to establish a new European tender call to explore vaccine stockpiles especially targeted against emerging diseases and explore different models of voluntary sharing of specific vaccines with the use of a rapid exchange mechanism on available vaccines between EU member states.

In addition, we believe that not only the early feedback from the member states but also the experience with the common purchase of covid-19 vaccines and the establishment of HERA, clearly reflect the respondents' preferences for need and collaboration on joint purchase and rapid exchange and sharing mechanisms for vaccines to be used during an epidemic situation. This should drive the discussion further, rather than the actual challenges the countries face today to ensure supply for their national immunisation schedule and outbreak vaccines.

It is important to note that our survey and the early results reported were performed prior to the Covid-19 pandemic, which presumably has strongly changed the preparedness response and EU vaccine strategy during an emergency.

The European member states have ensured sufficient supplies for vaccines through a new instrument called Advance Purchase Agreements (APAs). The European commission has addressed the need for new instruments in EU to address fragmentation of countermeasure R&D efforts in the EU and implemented a new Health Emergency Preparedness and Response Authority (HERA) department. HERA has been established during late 2021 and will continue to be developed in the years to come.

The common procurement of Covid-19 vaccines has additionally provided the EU member states with experience in sharing mechanisms for surplus vaccines during an emergency:

- Through the advanced purchase agreements with individual vaccine producers, the Commission secured the right to buy a specified number of vaccine doses in a given timeframe.
- Moreover, through the EU vaccine strategy, the surplus vaccines have been donated, and the donor-funded vaccines have been shared with the global collaboration COVAX, which enables low and middle -income countries to access Covid-19 vaccines.
- In addition, the member states have gained experience with mechanisms and procedures for bilateral donations, i.e., import and export of covid-19 vaccines.

These new experiences will probably affect the member states view on these questions and our results need to be considered in this context.

References

Links to the published reports on the EU-JAV webpage during the project.

1. Deliverable 6.4 – Report on the anticipated needs to ensure sufficient size of supply and stockpiles, including their sustainability
https://eu-jav.com/wp-content/uploads/2019/07/D30-WP64-EU_JAV_Understanding-mechanisms_gaps-and-option-for-a-concept-type-WP6_2_final-report-July-2019.pdf
2. Deliverable 6.5 – Report on Possibilities, Gaps and Options for Concept Analysis
https://eu-jav.com/wp-content/uploads/2021/07/EU_JAV-WP6_2_D-6.5_Report-on-possibilities-gaps-and-options-for-concept-analysis.pdf