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Work Package 6 – Task 6.2

Report on:

D 6.5 Report on possibilities, gaps and options for building a " concept type" for regional or European virtual stockpiles on vaccine management needs and stocks, 2020-02-01

(Additional update to report delivered in July 2019)

Grant Agreement No.: Start Date: End Date:	801495 01/08/2018 31/07/2021
Project title	**European Joint Action on Vaccination — EU-JAV**
WP number **Deliverable number**	WP6 D 6.5 Report on possibilities, gaps and options for building a " concept type" for regional or European virtual stockpiles on vaccine management needs and stocks
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Nature Report	Report on concept analysis for regional or European virtual stockpiles on vaccine management needs and stocks Further exploring possibilities, gaps and options for building a "concept type" for regional or European virtual stockpiles

Remember to number the pages

This project has received co-funding from the European Union's Health Programme under Grant Agreement no. 801495

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Acknowledgements

We would like to thank the EU-JAV partners for all the comments and feedbacks we have received to the work with the task 6.2.

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List of abbreviations

Consumers Health Agriculture and Food Executive Agency	**CHAFEA**
European Centre for Disease Prevention and Control	**ECDC**
European Commission	**EC**
European Economic Area	**EEA**
European Joint Action on Vaccination	**EU-JAV**
European Medicines Agency	**EMA**
European Union	**EU**
Early Warning and Response System	**EWRS**
Falsified Medicines Directive	**FMD**
General Data Protection Regulation	**GDPR**
Health Security Committee	**HSC**
Marketing authorisation	**MA**
Member States	**MS**
Mutual Recognition Agreements	**MRA**
The Directorate – General for Health and Food Safety	**DG SANTE**
Work Package	**WP**

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1. Introduction

The European Joint Action on Vaccination (EU-JAV), co-funded by the Health Program of the European Union, 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 (1). As such, it will contribute to the implementation of the European Council Recommendation on Vaccine-preventable Diseases (2).

One of the activities for the Joint Action is related to mechanisms for strengthened vaccine forecasting vaccine supply management through work package 6 (WP6).

WP6 follows two objectives:

- Improve mapping of needs and vaccine demand at European level in states belonging to the consortium (EU and non-EU) and define basic principles for vaccine demand planning and forecasting and other issues related to preparedness (including availability of other biological products such as diphtheria antitoxin and immunoglobulin), based on experience.
- Reinforce mechanisms of management at national level of vaccine forecasting, supply and stocks, and explore the feasibility and develop a concept for a European data warehouse for sharing of data/information on vaccine supply and demand at EU level among relevant stakeholders.

The specific objective of the EU-JAV on vaccine supply and preparedness is to improve the predictability of vaccine supply and demand and to strengthen preparedness of Member States (MS), while increasing the cooperation between suppliers and public health authorities.

The purpose of task 6.2 is to reinforce mechanisms of management of forecasting, supply and stocks of vaccine and to explore a concept analysis for an EU data warehouse for European vaccine demand and supply data, including evaluation of options to develop a virtual stockpile for exchange of vaccines. The aim is to understand 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 main part of the deliverable 6.5 “Report on possibilities, gaps and options for building a “concept type” for regional or European virtual stockpiles on vaccine management needs and stocks” was delivered in July 2019 through the report:

I. Understanding mechanisms for defining the anticipated needs to ensure sufficient size of supply and stockpiles, including their sustainability
II. II. Possibilities, gaps and options for building a “concept type” for regional or European virtual stockpiles on vaccine management needs and stocks

which is provided as an appendix to this summary report (Appendix 1).

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This summary report is an update of further steps taken to explore the objective of task 6.2, the concept analysis for a regional or European data warehouse for sharing data/information of vaccine supply and demand among relevant stakeholders.

2. Summary of the gap and options for a European wide data repository on vaccine demand and supply data to inform the concept analysis (Deliverable July 2019)

It is the responsibility of each Member State (MS) to assure sufficient stockpiles of vaccines, and they seem to do so in different ways. One of the main challenges is that not all MS hold a preparedness stock and both the management and the governance of national stockpiles varies across the MS. The MS, the supplier or a combination of both hold preparedness stocks. The size of the stockpiles varies from country to country and it normally reflects the long lead-time for vaccines.

The situation on demand and supply of vaccine to the MS as well as shortages (Task 6.1) have been described in the previous report of WP6 shared with the EU JAV partners in July 2019.To gain feedback in this area from the EU-JAV participating countries, a specific survey was developed. The results of this deliverable are briefly summarised below and form the basis for the choice of the different scenarios chosen in our future work with the concept analysis.

The results and a summary of the report from July 2019 were presented at the EU-JAV General Assembly and the workshop in Rome 2nd and 3rd of October 2019.

One of the main findings is that there seem to be uncertainty about the need and options for an EU virtual data repository. Only four countries believed establishing a virtual data repository would prevent shortages in the EU, while eight countries said they were unsure and four said no. On the other hand, several of them gave feedback on which specific priority vaccines should be under focus. 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 MS have national stockpiles to protect against potential disease outbreaks. However, a global overview of size of these stockpiles and how they are forecasted in each MS 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 i.e. measles, rather than the national standard immunisation programme.

The countries responding to the survey listed the following focus areas as most important for such EU data repository:

- **Rarely used vaccines and immunoglobulins**
- **Vaccines to be used during epidemic outbreaks**
- **Vaccines for emerging infectious diseases**

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The countries responding to the survey listed the following key mechanisms to enable exchange of vaccines between EU countries:

- **Rapid exchange mechanism on available vaccines between EU MSs**
- **Harmonised labelling of vaccines in the EU**

This was followed by the need for liability protection for parties involved in making the vaccine available. Concerning current legal or regulatory hurdles related to the exchange of available vaccines between MS in case of shortages, many of the respondents pointed out liability issues and regulations concerning authorisation of the vaccines as the main hurdles.

Our conclusion was that this reflects the need for further discussion and for developing a standard operating procedure regarding the ad hoc urgent exchange of medical countermeasures through the Early Warning and Response System (EWRS) raised by the European Health Security Committee (HSC).

The result in the report from July indicated that further work on the concept analysis for a regional European data warehouse for sharing data/information of vaccine supply and demand among dedicated stakeholders should include options such no data warehouse (status quo) and voluntary sharing of specific vaccines with the use of a rapid exchange mechanism on available vaccines between EU MS. In addition one should explore improvements of more concrete tools like “EU-harmonised labelling of vaccines” and “standard operating procedure to enable the ad hoc urgent exchange of vaccines”, to support stronger national response to vaccination challenges regarding vaccine supply management.

Some examples on rarely used vaccines and immunoglobulins, vaccines to be used during and epidemic outbreak and vaccines for emerging infectious diseases were given (table 1).

Table 1: Most important focus area for an EU virtual data repository and some listed examples

Specific focus for priority	Listed Examples
Rarely used immunoglobulins, antitoxins and vaccines	Rabies immunoglobulin, Tetanus immunoglobulin, Hepatitis B immunoglobulin, Human normal immunoglobulin, Varicella zoster immunoglobulin, botulinum antitoxin, diphtheria antitoxin, Bacillus Calmette-Guerin (BCG) vaccines, Ebola vaccines, Smallpox-vaccine, Rabies vaccines
Specific vaccines in the immunisation schedule	BCG vaccine, Measles vaccine, Hepatitis B vaccine
Emerging infectious diseases	Ebola vaccines, Ebola antivirals

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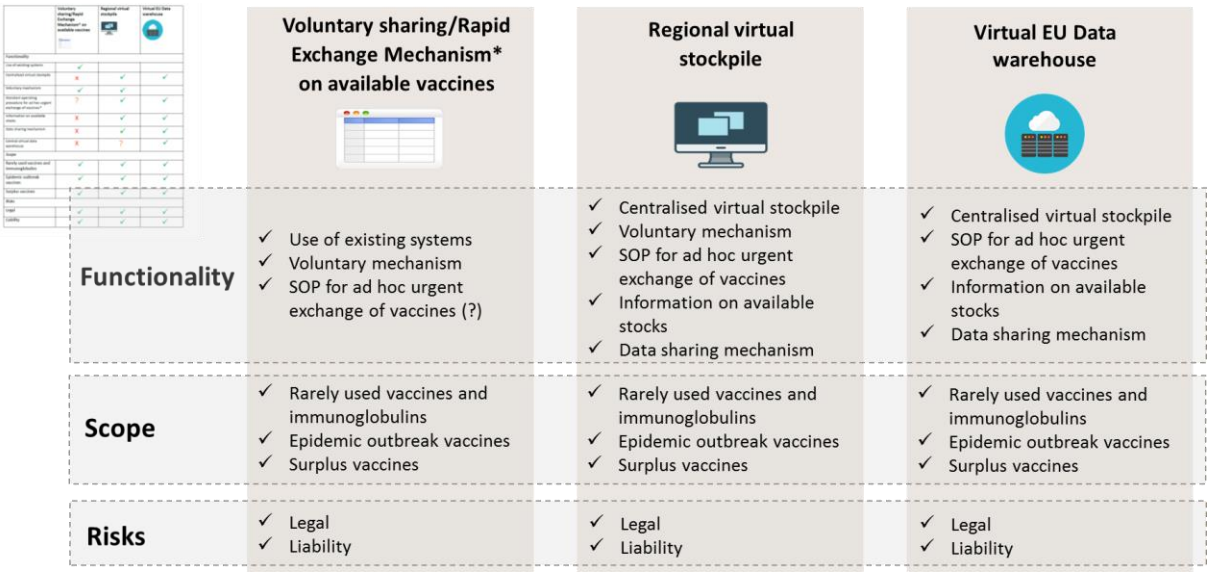
The list of priority vaccines may reflect the respondents' preferences for the content of a potential future virtual data repository, rather than the actual challenges the countries face today to ensure supply for their national immunisation schedule and outbreak vaccines.

A preliminary draft of potential options we have started to further explore in the concept analysis was discussed with the partners and stakeholders in the EU-JAV at the General Assembly in Rome (figure 1).

Figure 1. Potential options to be further explored in the concept analysis



3. Overview and status of other relevant work and actors

3.1 Discussion between EU Member states and the Health Security Committee - rapid exchange mechanisms on available vaccines between EU member states

Developing standard operating procedures (SOP) to exchange medical countermeasures in case of shortage or an emergency was discussed in the Health Security Committee (HCS) in 2016. The background for the discussions were MSs facing shortages and a need for a mechanism facilitating availability and exchange of medical countermeasures. A non-paper was prepared by a drafting group with experts from MSs, together with European Centre for Disease Prevention and Control

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(ECDC), European Medicines Agency (EMA) and The Directorate – General for Health and Food Safety (DG SANTE) B. The non-paper was further discussed in the HCS working group on preparedness.

The SOP was intended to describe a voluntary mechanism for exchanging medical countermeasures between MSs in case of shortages or an emergency. The term "virtual stockpile" was used for this mechanism.

Discussion on a voluntary mechanism for rapid exchange of medical countermeasures between EU Member States took place at the European Commissions (EC) Health Security Committee (HCS) November 2016 (3).

Two options were considered:

- SOP based on exchange mechanism through EWRS
- Exchange mechanism based on virtual stockpile

The SOP options refers to setting up a mechanism for rapid exchange of specific medical countermeasures related to high-risk threats to health (from communicable diseases, biological or chemical agents) in cases of sudden shortages due to unexpected outbreaks, unforeseen spike in demand (e.g. due to migration) or terrorist attacks that overpower the capacity of a given MS to provide an effective response. The main underlying rationale is to support MSs in improving preparedness by setting up a SOP that can be quickly activated in cases of urgent need. The main advantage of developing such an SOP in advance is to gain time, which can be of critical importance when reacting to an emergency.

The MSs and the option paper preferred development of a draft SOP. Several MSs raised concerns to share information about stockpiles due to security considerations and resource need for regular updating.

A proposal for the creation of a standard operating procedure regarding the ad hoc urgent exchange of medical countermeasures through the Early Warning and Response System (EWRS) have been further discussed at the HSC in 2018 (4). The MSs have expressed support for the proposal if the procedure and the work on templates would not create extra burden. MSs have reiterated that the mechanism should remain voluntary and that legal or liability issues should be dealt with on a bilateral basis. It has been proposed that the mechanism can also be used to exchange medical countermeasures, which may be of surplus for a given country and are coming close to their expiry date but could still be useful for another country. Further information sharing on initiatives regarding stockpiling including medical devices, was considered an important issue.

During discussions in 2018 in the Working Group of the HCS on Preparedness and Response Planning, it was agreed to drop using the term "virtual stockpile" related to having a SOP for rapid voluntary exchange of medical countermeasures. The term "virtual stockpile" was seen to create more confusion than clarity. It was reaffirmed that it would be difficult to have a virtual stockpile as several

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agencies were involved in the management of medical countermeasures and that some products were held at regional/local levels; thus making it difficult to maintain a good overview at national level.

In the plenary of the HCS in December 2018 it was agreed that the Commission should proceed creating functioning SOPs for a simple exchange mechanism and to develop necessary templates. The procedure should continue to be based on the Early Warning and Response System (EWRS), without seeking to collate information on existing stocks.

3.2 Early Warning and Response System (EWRS)

The EWRS is a web-based platform linking the EC, ECDC and public health authorities in EU/EEA countries responsible for measures to control serious cross-border threats to health, including communicable diseases. The platform was set up in 1998 to allow exchange of information on risk assessment and risk management for more timely, efficient and coordinated public health action.

The system has restricted access granted by the EC to a competent authority or authorities responsible at national level for notifying alerts and determining the measures required to protect public health, for the purposes of Articles 8, 9 and 10 of Decision No 1082/2013/EU (5). In 2017, the Commission adopted the Commission Implementing Decision 2017/253 (6), laying down procedures for the notification of alerts as part of the EWRS established in relation to serious cross-border threats to health, and for the information exchange, consultation and coordination of responses to such threats.

The EWRS is used for notifications on outbreaks, exchanging information and decisions about the coordination of measures among Member States. Over the years, it has played an important role to support health crisis related to severe acute respiratory syndrome (SARS), Ebola virus disease, avian influenza in humans and other communicable diseases.

3.3 Early warning systems from suppliers and manufacturers of potential stockouts – timely input from government agencies

Shortages of medicinal products are dealt with at national level by the national competent authorities. According to article, 23a of Directive 2001/83/EC the holder of the marketing authorisation (MA) shall notify the national competent authority if the product ceases to be placed on the market of the MS, either temporarily or permanently.

Furthermore, the MA holder shall also notify the European Medicines Agency (EMA) if the withdrawal of the product is based on any of the grounds set out in Art.116 or Art.117 (7) of the Directive 2001/83/EC, e.g. the medicinal product is harmful, it lacks therapeutic efficacy, the risk-benefit balance is not favourable, its qualitative and quantitative composition is not as declared etc.

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EMA created an HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use in December 2016 to provide strategic support and advice to tackle disruptions in supply of human and veterinary medicines and ensure their continued availability (8). The task force provides support to regulators.

One of the important feedback in the report from July 2019 (Appendix 1) was that timely input from both government agencies and procurers on future demand related to potential changes in the immunisation program was important.

Government agencies and national/regional procurers of vaccines estimate their future demand in relation to their national vaccine programs and communicate them to the vaccine manufactures. In case of potential changes to the national immunisation programs, mechanisms must be in place to ensure timely (meaning 1-2 years in advance) feedback to manufacturers on these future changes in the demand (9).

3.4 Harmonised European labelling of vaccines (EMA)

Labelling and packing requirements across EU (European Economic Area (EEA)), **MSs is one** of the factors that have been raised to impact vaccine supply, and risk of shortages. Vaccines are sometimes delivered in small volumes of country-specific packs. When vaccines are labelled or packed in a country-specific format, they cannot longer be transferred to another country without formal agreement from authorities of the new destination country without repacking. In case of shortages with potential impact on public health, the possibility to use vaccines initially packed for another EU/EEA Member State has to be discussed on a case-by-case basis with the national competent authorities (NCAs).

MSs is plural not singular, please adapt the sentence consequently

This has raised to discussion that the number of presentations should be reduced across EU/EEA. Vaccine packs should be harmonised across EU/EEA and a common label on the vaccine container.

Harmonisation of EU labelling of vaccines could be further challenged for the vaccines on the market today, which are regulatory approved in the centralised procedure in EU, where the labelling of the vaccines contains the same information, but in different languages. Proposed harmonisation efforts have been focusing on:

i. Using the same abbreviations and language on the immediate pack across all EU/EEA Member States
ii. Using of multilingual secondary packaging and leaflets in all EU/EEA Member States
iii. Replacing the paper leaflet by an e-leaflet

An E-leaflet could be introduced on top of the paper leaflet to facilitate the transfer of vaccines for a period of time and to demonstrate the feasibility and absence of negative impact on patient information. Implementation of the Falsified Medicines Directive (FMD) should not block the transfer of vaccine doses between EU/EEA Member States.

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3.5 Nordic project on preparedness products

A Nordic project was established to investigate the interest and possibility for cooperation on a joint Nordic Strategic Stockpile on preparedness products (10). A collaboration agreement regarding Nordic preparedness for vaccines, antitoxins and immunoglobulins was signed between Nordic countries with the exception of Sweden. A working group was set up with representatives from each country. A virtual stockpile was established to facilitate rapid exchange in cases of urgent need or sudden shortages. The stockpile was updated on a regular basis. Over time it was learned that it is hard to maintain such information up-to-date as stocks volumes change frequently. The working group decided to cease updating the virtual stockpile. Focus for the group was concentrated on setting up rapid exchange mechanisms. Templates to facilitate rapid exchange of products was developed. Several transactions have been done with success between countries related to out of stock situations. The group meets on a regular basis to discuss and share best practice related to vaccine supply and preparedness.

3.6 Discussions and tender to identify options for physical stockpiling of vaccines in the EU

The current EU health instruments do not enable the procurement of routine vaccines at EU level. For this reason, methods for working with MSs for mutual exchange of surpluses and the possibility of developing a concept for a possible physical stockpile at EU level, particularly in case of an outbreak, has been discussed.

Consumers, Health, Agriculture and Food Executive Agency, "CHAFEA" launched in 2019 an invitation to a tender on physical stockpiling.

The tender was in line with the Council Recommendation on strengthening cooperation against vaccine preventable diseases. The purpose of the contract was to (i) examine the feasibility of and identify options for physical stockpiling of vaccines in the European Union and to (ii) develop a concept for a mechanism for exchanging vaccine supplies from one Member State to another in case of an outbreak.

However, the tender was closed without any contract signed. A new tender has now been announced 17.01.2020 with a deadline for submission 23.03.2020. (11)

In completing this tasks, the contractor shall also take into account work undertaken by the Joint Action on Vaccination, in particular the Work Package focused on Vaccine Supply and Preparedness, that aims to explore the feasibility of and develop a concept for an EU data warehouse for sharing of vaccine supply and demand data/information among dedicated stakeholders.

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4. Analysis performed to inform the concept analysis

4.1 Results from a survey to further inform the concept analysis

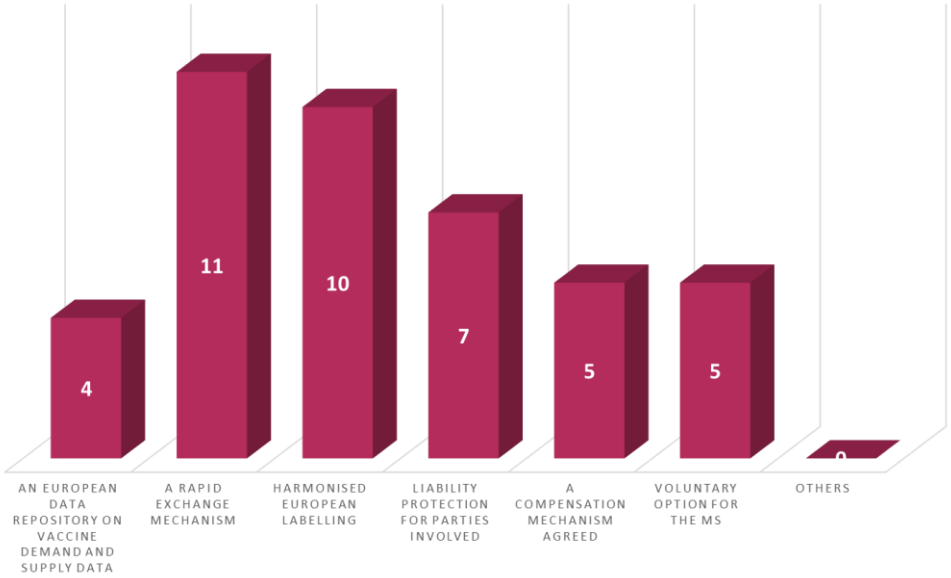
To better understand the key mechanism (s) to enable exchange of vaccines between the EU countries, some proposed mechanism listed below were included Report Delivered in July 2019 (Appendix 1).

The following mechanisms were listed and maximum three options were allowed

- An European data repository on vaccine demand and supply data
- A rapid exchange mechanism on available vaccines between EU member states
- Harmonised European labelling of vaccines
- Liability protection for parties involved in making the vaccine available
- A compensation mechanism agreed between the parties involved
- Voluntary option for the member states
- Others

A rapid exchange mechanism on available vaccines between EU MSs and harmonised European labelling of vaccines were listed as priority key mechanisms to enable exchange of vaccines between EU countries, followed by liability protection for parties involved in making the vaccine available. Only four respondents listed a European data repository on vaccine demand and supply data as key mechanism to improve forecast of vaccine demand and manufacturing (figure 2).

Figure 2. Recommended mechanisms to enable exchange of vaccines between the EU countries



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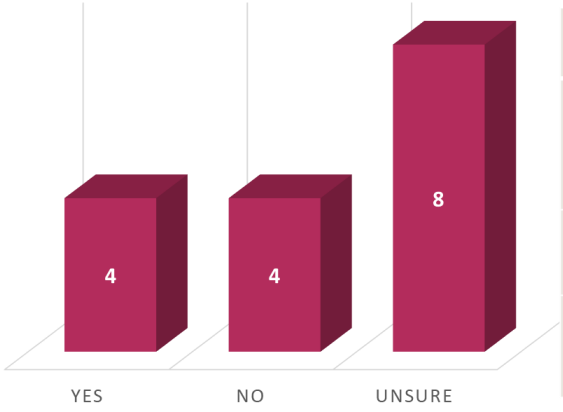
The respondents were asked if they believe establishing a virtual data repository will prevent shortages in EU. The question was followed by asking whether the focus should be on specific priority vaccines, among those listed below:

- Vaccines for emerging infectious diseases
- Rarely used vaccines and immunoglobulins
- Pandemic vaccines
- Specific vaccines in the national immunisation schedule
- Vaccines to be used during an epidemic outbreak
- Others

Only four countries believed establishing a virtual data repository will prevent shortages in EU, eight were unsure and four responded no, and their opinions on specific priority vaccines are presented as well in figure 3.

Figure 3. Respondents view on if establishing a virtual data repository will prevent shortages in EU and focus area



Specific focus for priority	Listed Examples
Rarely used immunoglobulins, antitoxins and vaccines (10)	RIG, TIG, HBIG, HNIG, variZIG, botulinum antitoxin, diphtheria antitoxin, BCG vaccines, Ebola vaccines, smallpox-vaccine, rabies vaccines
Specific vaccines in the immunisation schedule (5)	BCG vaccine, measles vaccine, hepatitis B vaccine
Emerging infectious diseases/ Vaccines to be used during an epidemic outbreak (7/9)	Ebola vaccines, Ebola antivirals

Rarely used vaccines and immunoglobulins, vaccines to be used during an epidemic outbreak and vaccines for emerging infectious diseases were listed as most important focus area for an EU virtual data repository and some examples were given. See the report “Delivered in July 2019” (Appendix 1) for further details.

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4.2. Results from a qualitative analysis to further inform the concept analysis

The last part of the survey consisted of more in-depth questions concerning specific challenges. The questions and responses concerning the EU data repository were reported in chapter 5.4 of the report delivered in July 2019. These results will further be used as input to the concept analysis for a data warehouse for European sharing of vaccine supply and demand/data information among dedicated stakeholders. See the report "Delivered in July 2019" (Appendix 1) for further details.

5 Description of the different concepts to be further explored

The further work with the concept analysis should be read in the context of the report delivered by the EU-JAV WP6 in July 2019 (Appendix 1) as well as the ongoing activities in this area described in chapter 3 of this report.

Other ongoing initiatives in this field and relevant to inform the concepts are:

- HSC work on a SOP based on exchange mechanism through the EWRS
- Exchange mechanism based on virtual stockpile
- Nordic project on preparedness products or similar projects
- Early warning systems from suppliers and manufacturers of potential stockouts
- CHAFEA's tender to explore the feasibility of and identifying options for physical stockpiling of vaccines and to develope a concept for a mechanism for exchanging vaccine supplies from EU Member State to another in case of an outbreak.

Important constraints and limitations: The concept analysis will not considered the design of a solution, the number of IT systems or suppliers as a part of a regional, or EU-wide solution, but assumes that this must be considered at a later stage in a potential procurement situation. It-solutions, design and IT-architecture will not be considered.

However, the opportunity for interaction between the member states in the different scenarios is proposed to be expressed through three levels of interaction:

1. Data sharing

2. Transparency, access to the necessary information is granted

3. A common solution for collaboration is established

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5.1 Concept A - Voluntary sharing/Rapid Exchange Mechanism on available vaccines

This is a concept where the MSs independent responsibility for the vaccine procurement and the stockpiling is remained. The ongoing work and discussions in the HSC and their tools developed forms the basis for this scenario.

What does the concept entail
The concept entails facilitating availability and exchange of vaccines **in the event a MSs face shortages** or potential surpluses of vaccines. In these situations, MSs use the EWRS as a platform to share this information. The concept is based on development of functioning Standard Operating Procedures (SOPs) for a simple exchange mechanism and necessary templates are developed to simplify the procedure. The procedure do**es** not seek to collate information on existing stocks in the member states.
Functionality
Use of existing system – an existing mechanism is used. The EWRS is an existing web-based platform linking the European Commission, ECDC and public health authorities in EU/EEA countries responsible for measures to control serious cross-border threats to health, including communicable diseases. The platform was set up in 1998 to allow exchange of information on risk assessment and risk management for more timely, efficient and coordinated public health action.
The mechanism is a voluntary mechanism. In case of urgent need or sudden shortage, the mechanism is dependent on Member States willingness to share medical countermeasures.
SOP for ad hoc urgent exchange of vaccines is developed (description) The procedure outlines the process and facilitating templates for voluntary exchange of medical countermeasures. The procedure refers to the available platforms for assistance from other Member States for medical countermeasures. These are the EWRS and Union Civil Protection Mechanism (UCPM).
Scope
The scope of the procedure is exclusively for medical countermeasures. Typical products would be: • Rarely used vaccines and immunoglobulins

MSs is plural. If you are talking about 1 MS, remove the 's' at the end of the acronym and add one at the end of 'face'

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- Epidemic outbreak vaccines

Handling surplus of medical countermeasures has been suggested to be included in the scope of the procedure.

Implementation Risks

Legal risks:

The exchange of medical countermeasure is a bilateral transaction. As such, all legal aspects needs to be covered in a contract between the parties. The work in the HSC has resulted in a procedure for the exchange as well as 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.

Liability risks:

Liability issues may be a case for transactions of products between MSs. Especially related to use of investigational products or those used off-label. According to HSC discussions no global mechanism exists which provides both compensation for victims and liability protection for parties involved in making the medical countermeasures available. Equally, 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.

Information security:

None considered, as there will be no storage of inventory data**.**

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5.2 Concept B Regional virtual stockpile

This is a concept where the cooperation takes place at the regional level or a group of countries make an overall agreement, such as the collaboration agreement regarding Nordic preparedness for vaccines, antitoxins and immunoglobulins signed between the Nordic countries with the exception of Sweden. The MSs independent responsibility for the vaccine procurement and the stockpiling is remained.

What does the concept entail
The concept entails facilitating availability and exchange of vaccines in the event in which a MS that has signed the collaborative agreement faces shortages or potential surpluses of vaccines. In these situations, the MS may use the EWRS or other means according to their regional agreement as a platform to share this information. The concept is based on functioning Standard Operating Procedures (SOPs) for a simple exchange mechanism and necessary templates are developed to simplify the procedure. The procedure additionally seeks to collate information on existing stocks in the selected region and the MS that has signed the collaborative agreement.
Functionality
Use of existing system: An example on cooperation in this area already exist. A Nordic project was established to investigate the interest and possibility for cooperation on a joint Nordic Strategic Stockpile on preparedness products. A collaboration agreement regarding Nordic preparedness for vaccines, antitoxins and immunoglobulins was signed between Nordic countries with the exception of Sweden. A working group was set up with representatives from each country. A virtual stockpile was established to facilitate rapid exchange in cases of urgent need or sudden shortages. The stockpile was updated on a regular basis. Over time it was learned that it is hard to maintain such information up-to-date as stocks volumes change frequently. The working group decided to cease updating the virtual stockpile.
The mechanism is a voluntary mechanism. In case of urgent need or sudden shortage, the mechanism is dependent on MS willingness to share medical countermeasures. A collaboration agreement regarding Nordic preparedness for vaccines, antitoxins and immunoglobulins was signed between Nordic countries with the exception of Sweden.
SOP for ad hoc urgent exchange of vaccines. Focus for the group was concentrated on setting up rapid exchange mechanisms. Templates to facilitate rapid exchange of products has been developed. Several transactions have been done with success between countries related to out of

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stock situations. The group meets on a regular basis to discuss and share best practice related to vaccine supply and preparedness.

Scope

The scope of the procedure is exclusively for medical countermeasures. Typical products would be:

- Rarely used vaccines and immunoglobulins
- Epidemic outbreak vaccines

Handling surplus of medical countermeasures can potentially be included in the scope of the procedure.

Implementation Risks

Legal risks:

The exchange of medical countermeasure under the collaborative agreement is a bilateral transaction. As such, all legal aspects are covered in a contract between the parties. The work in the HSC has resulted in a procedure for the exchange as well as 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.

Liability risks:

Liability issues may be a case for transactions of products between MSs. Especially related to use of investigational products or those used off-label. According to HSC discussions no global mechanism exists which provides both compensation for victims and liability protection for parties involved in making the medical countermeasures available. Equally, 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.

Information security:

At the start of the Nordic collaborative agreement a virtual stockpile was established to facilitate rapid exchange in cases of urgent need or sudden shortages. The stockpile was updated on a regular basis. Over time it was learned that it is hard to maintain such information up-to-date as stocks volumes change frequently. The working group decided to cease updating the virtual stockpile.

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5.3 Concept C Virtual EU Data warehouse

This is a concept where the MS agree to establish, procure and set-up a data warehouse. The management and operation must be solved in an EU context. The MSs independent responsibility for the vaccine procurement and the stockpiling is remained. Physical stockpiling is not included in this scenario, however a recent tender announced through CHAFEA could further explore and inform such a concept.

What does the concept entail
The concept facilitates the availability and exchange of vaccines in the event in which a MS faces shortages or potential surpluses of vaccines. In these situations, MSs use the EWRS as a platform to share this information. The concept is based on functioning Standard Operating Procedures (SOPs) for a simple exchange mechanism and necessary templates are developed to simplify the procedure. The procedure does not seek to collate information on existing stocks in the member states. The concept additionally seeks to establish a central solution with submission of data to a data warehouse and the management, operation and response are solved in an EU context.
Functionality
Functionality to share information and exchange of data must be developed through the data platform. The concept could consider to further develop the web-based Early Warning and Response System (EWRS) platform linking the European Commission, ECDC and public health authorities in EU/EEA countries responsible for measures to control serious cross-border threats to health, including communicable diseases. An alternative would be to build a new platform for data sharing and response for this purpose. Visualisation solution and access to data for the MS must be built into the data platform.
Voluntary mechanism The mechanism is a voluntary mechanism, both data sharing and exchange of vaccines in case of urgent need or sudden shortage. The mechanism is dependent on MSs willingness to share medical countermeasures.
SOP for ad hoc urgent exchange of vaccines. SOP for ad hoc urgent exchange of vaccines is developed (description) The procedure outlines the process and facilitating templates for voluntary exchange of medical countermeasures. The procedure refers to the available platforms for assistance from other

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Member States for medical countermeasures. These are the EWRS and Union Civil Protection Mechanism (UCPM).

Scope

The scope of the procedure is exclusively for medical countermeasures. Typical products would be:

- Rarely used vaccines and immunoglobulins
- Epidemic outbreak vaccines

Handling surplus of medical countermeasures may be included in the scope of the procedure.

Implementation Risks

Legal risks:

The exchange of medical countermeasure is a bilateral transaction. As such, all legal aspects needs to be covered in a contract between the parties and not through the data platform. The work in the HSC has resulted in a procedure for the exchange as well as 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.

Legal issues regarding the data platform: Exchange of data 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 MS. Access to data and control must be decided.

Liability risks:

Liability issues may be a case for transactions of products between MSs. Especially related to use of investigational products or those used off-label. According to HSC discussions no global mechanism exists which provides both compensation for victims and liability protection for parties involved in making the medical countermeasures available. Equally, 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.

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Appendix 1

The report Appendix 1 must appear completely on that document, as we can only upload 1 file per deliverable. Please send it to me with both documents reunited in one.

"Report on possibilities, gaps and options for building a "concept type" for regional or European virtual stockpiles on vaccine management needs and stocks". Delivered in July 2019.

I. Understanding mechanisms for defining the anticipated needs to ensure sufficient size of supply and stockpiles, including their sustainability

II. Possibilities, gaps and options for building a "concept type" for regional or European virtual stockpiles on vaccine management needs and stocks

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