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Work Package 6 – Task 6.2

Report on:

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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Responsible partner No. **Organisation** **Name** **E-mail address**	14 Folkehelseinstituttet (FHI) Karianne Johansen Karianne.Johansen@fhi.no
Nature Report	Report on possibilities, gaps and options for building a "concept type" for regional or European virtual stockpiles on vaccine management needs and stocks

Report prepared by

Karianne Johansen, Knut Jønsrud, Margrethe Greve-Isdahl, Kjersti Rydland, Britt Wolden and Ingeborg Aaberge, Norwegian Institute of Public Health, Norway

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List of abbreviations

European Centre for Disease Prevention and Control	ECDC
European Commission	EC
European Directorate for the Quality of Medicines	EDQM
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
Good Distribution Practice	GDP
Good Manufacturing Practice	GMP
General Data Protection Regulation	GDPR
Health Security Committee	HSC
Human Papilloma Virus	HPV
Integrated monitoring of vaccines in Europe	I-MOVE
Marketing authorisation	MA
Member States	MS
Mutual Recognition Agreements	MRA
National Immunisation Technical Advisory Groups	NITAG
Neutrophil Activating Protein	NAP
Official Control Authority Batch Release	OCABR
Official Medicines Control Laboratories	OMCL
Post-Approval Change	PAC
US Food and Drug Administration	FDA
Vaccine European New Integrated Collaboration Effort	VENICE
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 and 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.

After the development of the Grant Agreement of the EU-JAV the team responsible for task 6.2 have received feedback from stakeholders and the evaluation team in WP3 concerning the semantic difference between the two tasks 6.1 and 6.2. There has been some challenges explaining the difference between these two objectives.

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-

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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.

Therefore, this report also aims to better explain the objective of task 6.2 and focus on the two main deliverables: i) understanding mechanisms for defining the anticipated needs to ensure sufficient size of supply and stockpiles and ii) explore possibilities, gaps and options for the concept analysis for a regional or European data warehouse for sharing data/information of vaccine supply and demand among relevant stakeholders.

To gain feedback in this area from the EU-JAV participating countries, a specific survey was developed. The purpose of the survey was to understand the stakeholders' and EU Members States' opinion on key mechanisms to define the anticipated needs to ensure sufficient volumes of supply, as well as their opinion on the need, relevance and specifications for a European wide data repository on vaccine demand and supply. The survey intended to explore the needs, goals and requirements and better define the potential alternatives to be included in the concept analysis and not make the options too narrow.

The survey was first launched on February 12th 2019, and subsequently on March 10th 2019 to countries participating in the EU-JAV Member States Committee, to increase the number of countries responding to the Survey.

2. Executive summary

It is the responsibility of each Member State to assure sufficient stockpiles of vaccines, and they seem to do so in different ways. 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.

2.1 Recommended mechanisms to improve forecast of vaccine demands and manufacturing to ensure sufficient supply for immunisation programs and preparedness in EU

The survey revealed a high need for sufficient and timely planning of vaccine supply and stock at national level. There are a limited number of manufacturers and production capacity worldwide, affecting the supply and demand situation for vaccines. The countries responding to the survey listed the following key mechanisms to ensure sufficient supply:

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- **Early warning systems from suppliers and manufacturers of potential stockouts**
- **Sufficient stockpiles of vaccines at national level including an emergency stockpile**
- **A comprehensive national overview of vaccine demand and stocks**

Additionally, the countries identified the following key mechanisms for improving forecast of vaccine demand and manufacturing:

- **Long term vaccine forecast from government agencies and procurers**
- **Timely input from government agencies and procurers on future demand related to potential changes in the national immunisation programs**

Harmonising labelling of vaccines was also mentioned by many as one of the important mechanisms. More detailed feedback provided in the qualitative part of the survey stressed the constraints posed by different marketing authorisation procedures for existing vaccines on the market and the need to agree on common wording to be used on the packaging and labelling of vaccines. The lack of regulatory acceptance to use electronic leaflets on vaccines for informing patients was also highlighted. On the other hand, some responders were uncertain if more harmonised labelling would prevent the risk of vaccine shortage.

2.2 Recommended options for a European wide data repository on vaccine demand and supply data

There seem to be more 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 opinions 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:

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

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.

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 HSC. The MS have expressed support to the proposal, provided that the procedure and the work on templates would not create additional burden. MSs have stressed again 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 as an important issue.

The result of this gap and option analysis indicates 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 also include options such as:

- **No data warehouse (status quo)**
- **Voluntary sharing of specific vaccines**
- **Rapid exchange mechanism on available vaccines between EU MS**

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and 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.

A preliminary draft of potential options to be further explored in the concept analysis and discussed with the partners and stakeholders in the EU-JAV is presented in the discussion part of this report.

3. Background and overview of existing work

The purpose of this report is to describe the national/regional mechanisms used to define the anticipated need to ensure sufficient size of supply and stockpiles, including their sustainability and to present the stakeholders and EU MS views on a European wide data repository on vaccine demand and supply, while assessing their relevance in relation to the MS needs.

This report will support the ongoing discussion in EU to collaborate on stockpiles on vaccine to ensure sufficient supply. The WP6 will use this information to better inform the concept analysis on the possibilities for regional and/or European virtual stockpiles on vaccine management needs and stocks. This report is mainly based on review of relevant literature, relevant input obtained through a Survey on Supply and Preparedness and feedback from relevant stakeholders.

3.1 Vaccine forecasting

Vaccine forecasting is the first step in ensuring adequate immunisation supplies and is the foundation of vaccine preparedness. The accuracy of the forecast is important to ensure sufficient supply, reduce the risk of shortages, and not overestimate resulting in excess stocks. Forecasting of vaccine demand is an important process to assure predictability for the vaccine manufacturers.

In order to communicate accurate forecast, the procurement agents needs to have predictable demand data for vaccines in the immunisation programmes, such as type of vaccine, the quantity and timing of delivery of the vaccine.

To forecast vaccines included in the immunisation program, the following data is needed per MS: the number of people per age cohort, which vaccine to be given, the number of doses

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and the anticipated vaccine coverage. This information must be developed for every vaccine in the MS immunisation program. Based on this information the vaccine forecast can be calculated.

Normally the forecast should be carried out annually, covering a 3-5 year period. A proper, regular dialogue between manufacturers and public health authorities in charge of immunisation programmes is important to better anticipate the forecast demand requirements and to ensure sufficient supply and reduce risks for both parties. On this basis the vaccine forecast for every MS should be relatively stable and easy predictable if changes to any MS vaccination programme is communicated in advance – (if possible, 1-2 years).

Some vaccines and immunoglobulins are used for a limited number of individuals. The demand of these vaccines and immunoglobulins are normally forecasted based on data related to the number of doses administrated in previous years.

3.2 Ongoing discussion between EU Member states

Discussion on a voluntary mechanism for rapid exchange of medical countermeasures between EU MS (also referred to as "virtual stockpile"), has taken place at the European Commissions (EC) Health Security Committee (HSC) on 10 November 2016 (3).

The "virtual stockpile" is based on a procedure outlined in a non-paper developed by the HSC Permanent Working Group on Preparedness, is envisaged as a mechanism whereby the European Commission will collect and maintain prior information on available stocks of specific medical countermeasures to high-risk diseases/agents, which MS are willing to share in cases of urgent need or sudden shortages.

The "virtual stockpile" proposed by the HSC 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 standard operating procedure (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.

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

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(EWRS) have been further discussed at the HSC in 2018 (4). The MSs have expressed support for the proposal provided that the procedure and the work on templates would not create much 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.

3.3 Description of key mechanisms to improve forecast of vaccine demand and manufacturing to ensure sufficient supply for immunisation programs and preparedness in EU

To better understand mechanisms to improve forecast of vaccine demands and manufacturing and to ensure sufficient supply for immunisation programs and preparedness in EU some proposed key mechanism listed and briefly described below were included in the survey:

- Sufficient stockpiles of vaccines at national level including an emergency stockpile.

MSs assure sufficient stockpiles in different ways. The MS, the supplier or a combination of both holds preparedness stocks. The size of the stockpiles varies from country to country. It normally reflects the long lead-time for vaccines.

- Early warning systems from suppliers and manufacturers of potential stockouts.

Most medicine shortages are dealt with at national level by the national competent authorities. Some member states have local legislation requiring the holder of the marketing authorisation (MA) to report to medicines agency disruption in supply. According to article, 23a of Directive 2001/83/EC the MA holder shall notify the national competent authority if the product ceases to be placed on the market of the MS, either temporarily or permanently. However, the European Medicines Agency (EMA) can be involved in certain situations, for example when a medicine shortage is linked to a safety concern or affects several MSs. 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

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advice to tackle disruptions in supply of human and veterinary medicines and ensure their continued availability (5). The task force provides support to regulators.

- A comprehensive national overview of vaccine demand and stocks.

The size of the immunisation program demand is normally linked to the birth cohort in a MS. Assuming that the MS has overview of the birth cohort, the demand for vaccine for the immunisation program can be estimated and forecasted. A vaccine warehouse management system is a prerequisite to maintain control of stock levels.

- Rapid exchange mechanisms on available vaccines between EU member states

The EU HSC working group has discussed the development of a standard operating procedure for a voluntary mechanism for rapid exchange of medical countermeasures between EU MSs. This is further outlined in a paper (3,4) envisaged as a mechanism whereby EC will collect and maintain prior information on available stock of specific medical countermeasures which the member states are willing to share in case of urgent need or sudden shortages. 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 stockpile at EU level should be explored.

- Harmonised European labelling of vaccines

Labelling and packing requirements across EU (European Economic Area (EEA)), MSs is one of the factors that has 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). 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

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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

- Timely input from government agencies and procurers on future demand related to potential changes in the immunisation program

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 (6).

- Long-term vaccine forecast from government agencies and procurers

Forecasting demand is a normal process in the pharmaceutical industry where the buyer communicates long-term demand to the manufacturer. Forecast is not normally a binding contract and provides input to the planning process at the manufacturer. This is of key importance for vaccines with long lead times. Typically, forecast is 2-5 years. Feedback from industry is the longer the forecast the better.

- Data from national vaccine registries and surveillance systems

National vaccine registries estimate the vaccine coverage in a specific population. They are an important tool for vaccination programmes. They gather data both at the personal and population levels and are valuable resources for the community to make informed decisions on vaccination and improving the ability to detect patterns of vaccinations. Thus, they could lead to better targeted vaccination programs and inform vaccine demand.

- A comprehensive overview of vaccine demand and stocks at EU level

Manufacturers plan to supply member states and other countries they have contracted with. The aggregated demand is used for long term planning purposes. Even though the manufacturer may have insight into stocks at member states, it is the demand which is they

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key element for planning. A comprehensive overview of vaccine demand and stock at EU level could potentially better inform overall vaccine demand.

- Horizon scans from industry

The pharmaceutical industry and vaccine manufacturer continuously develop and improve their vaccine portfolio. Communication to the purchasers and national governmental agencies in charge of national vaccination programs is important to anticipate and plan for potential future changes. Some national governmental agencies arrange pipeline/horizon scanning meetings with manufacturers. This will provide better input to the future planning of national immunisation programs.

- Understanding financial barriers that can impact forecasting of vaccine demand.

Demand for a given vaccine is linked to type of contract the member state has with the manufacturer. Financial barriers can impact on countries ability to forecast vaccine demand. i.e. immunisation financing and sustainability can be related to demand if specific budget lines for purchasing of vaccines at the national budgets level exists. This may impact long term contracts and by that failing to provide long term demand to manufacturers.

3.4 ECDC vaccine scheduler

The European Centre for Disease Prevention and Control (ECDC) Vaccine Scheduler is an interactive tool that informs on vaccination schedules for individual EU/EEA countries and specific age groups (7). With this tool, comparisons can be made for vaccination schedules between two countries or by disease for all or a selection of countries. Despite this platform being continuously monitored, it is suggested the national competent authorities are also consulted for the most up to date schedules. Combining the ECDC Vaccine scheduler with exact information on the birth cohort in a given MS, the demand for immunisation programs in a MS and at EU level can be estimated. ECDC could play a more active role in providing guidelines to MS to ensure consistent data collection and inform future national immunisation policies. One of the limitations with the database is the lack of exact information on the vaccines used in the national immunisation programmes, in particular, combinations of antigens in combined vaccines or the number of genotypes/serotypes in the antigen composition of vaccines.

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3.5 Outbreak preparedness – surveillance, vaccine demand and supply

Public health emergency preparedness aims to minimise the risks posed by communicable diseases and to mitigate their impact during a public health emergency, regardless of the scale of the event (local, regional, national, European). This requires capacities and capabilities for effective planning, coordination, early detection, assessment, investigation, response to, and communication in public health emergencies. Preparedness is now being more and more integrated in public health activities, and in a more generic approach, as planning processes and other tools necessary for emergency preparedness, mitigation and response are often similar regardless of the nature of the hazard.

Preparedness planning is essential in order to respond effectively to outbreaks and epidemics. Sharing and aligning activities at European and international level in the area of public health emergency preparedness adds value to the efforts of single countries to strengthen their capacities and ensure coordinated and effective support when faced with cross-border health threats.

In this context, the new Joint Action SHARP started in April 2019, supported by the EC and coordinated by Finland under the Health Programme of DG SANTE, which focuses on strengthening preparedness in the EU against serious cross-border threats to health and support the implementation of the International Health Regulations, will be useful to address the vaccine supply coordination issue in case of emergency situation in the EU.

EU/EEA MS and local authorities are responsible for the control measures in public health emergencies. The capacity of the national health sectors needs to be flexible and resilient to face all types of major communicable disease risks, from epidemics to biosecurity accidents, and from well-known risks to new or re-emerging threats.

Typically failures in vaccine supply to meet natural or deliberate outbreaks originate from the unpredictable nature of such events. Some MS have national stockpiles to protect against potential disease outbreaks, however, an overview of size of these stockpiles, how they are forecasted, remain considerably unknown. 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, and therefore preparedness and its coordination should be improved at EU level.

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3.6 Other relevant projects

3.6.1 ECDC - The Vaccine European New Integrated Collaboration Effort, VENICE I-III

The VENICE III project is an evolution of two previous projects (VENICE I and VENICE II) in the field of vaccination (8). The first VENICE was performed in the years 2006-2008, sponsored by EC. VENICE II was committed and funded by ECDC and carried out in the years 2009-2013. Twenty-seven EU member states and two EEA/EFTA countries (Iceland and Norway) participated in the project. The two VENICE projects have had a relevant impact in the Union:

- A collaborative European network of experts working in immunisation programs was created
- A common interest in sharing experience and expertise in theme of vaccination was documented
- Tools and procedures to facilitate exchanges were designed; immunisation strategies, vaccination adverse events surveillance systems, modalities for vaccine coverage assessment, computerized immunisation registries were explored
- Relevant information on immunisation programs were collected at national and sub national level
- The process of introduction of two recently licensed vaccines, Human Papilloma Virus (HPV) and rotavirus vaccination, was monitored
- The opportunity of collecting immunisation coverage data at European level was investigated and a model for coverage data collection (EVACO) was designed, built and successfully piloted in the VENICE network

VENICE III started in December 2013 with the aim of collecting, sharing and disseminating information on national immunisation programmes through a network of professionals and providing information useful to build up methodologies and provide guidance for improving the overall performance of the immunisation systems in the EU/EEA MSs.

VENICE III covered several important topics in the field of vaccination:

- Collection of information on selected vaccination programs at national and sub national level
- Monitoring of the status of introduction of new vaccinations in MSs
- Investigation and improvement of the quality of vaccination coverage data
- Updating of immunisation schedules

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- Sharing of data and improvement of methodology and resources of the National Immunisation Technical Advisory Groups (NITAG) in the EU/EEA countries.

The VENICE network is going to migrate into an official ECDC Vaccine Preventable Diseases network, with experts appointed by the competent bodies of each MS.

3.6.2 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 (9). 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.

4 Survey on supply and preparedness

4.1 Methodology

A survey was developed to support the EU-JAV understanding of: i) MS's challenges to ensure vaccine supply and preparedness, ii) National or regional vaccine providers and distributors challenges to ensure vaccine supply and preparedness iii) Industry specific issues and challenges to ensure vaccine supply and preparedness iv) The current state of supply and preparedness of vaccines in EU; including the needs and opportunities for further development and improvements. The goal is to understand how to best improve exchange of information to support vaccine demand.

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The methodology was validated with the partners of the EU-JAV. Based on the partner's feedback, comments, and internal discussions, the draft survey was further developed for pilot testing. The Survey was pilot tested by two of the partners contributing to the WP, the Netherlands and Spain.

The questionnaire was divided into 3 sections, A, B and C. Section A focused on overall organisational questions. Section B and C focused on mechanisms to ensure sufficient supply for immunisation programmes and preparedness in Europe and mechanisms to improve forecast of vaccine demand and manufacturing planning and questions to gain more insight to the WPs gap and option analysis on the possibilities for establishing a virtual data repository on vaccine management needs and stocks. A copy of the survey is provided in annex 1.

The Survey was built into a Questback web-based survey and submitted via email correspondence to relevant respondents.

4.2 Ethics

In addition to the survey, all persons invited to participate were sent a privacy statement according to GDPR 2018.

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5. Results

5.1 Response rate and survey participants

The survey was launched on the 12th February 2019, and on the 10th March 2019 also submitted to the participating countries at the EU-JAV Member States Committee meeting 28 February 2019, to increase the number of countries responding to the Survey. Twenty-five European countries were invited to participate in the survey and sixteen countries responded to the survey (see table 1 for list of participating countries and affiliation of respondents). Two countries responded with more than one individual feedback (the results for these countries are shown combined, where possible).

Table 1. List of countries responding to the survey and affiliations of respondents per country.

Country	Institution
Austria	Federal Ministry of Labour, Social Affairs, Health and Consumer Protection
Denmark*	Statens Serum Institut
Estonia	Estonian Health Insurance Fund
Finland*	National Institute for Health and Welfare
France*	French Ministry of Health
Germany	Federal Ministry of Health (Bundesministerium für Gesundheit)
Greece*	Ministry of Health
Hungary	National Public Health Centre
Ireland	Health Service Executive National Immunisation Office
Italy*	Ministry of Health and regional health authorities
Latvia*	Centre for Disease prevention and Control of Latvia State Agency of Medicines, Ministry of Health, National Health Service of the Republic of Latvia
Norway*	Norwegian Institute of Public Health
Slovenia*	National Institute of Public Health
Spain*	Ministry of Health
Sweden*	Public Health Agency of Sweden
The Netherlands*	National Institute for Public Health and the Environment (which resorts under the Ministry of Health, Welfare and Sport)

**countries participating in EU-JAV*

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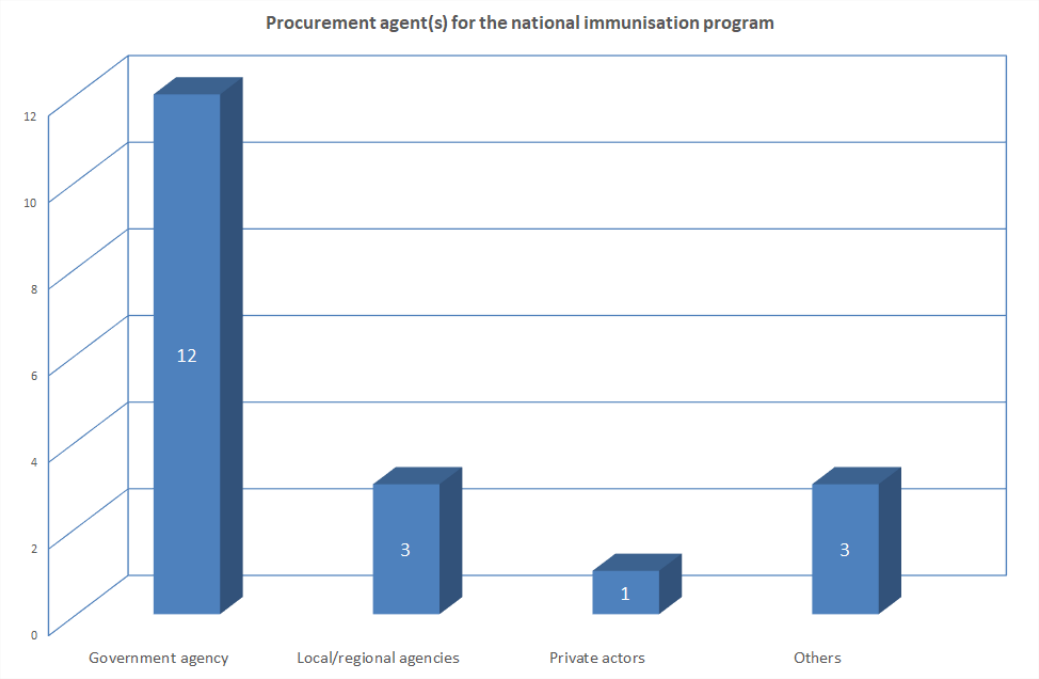
5.2 Results from part A - overall organisational questions.

A majority of the countries have government agencies acting as procurement agents for the national immunisation program in their country, a few respondents listed regional/local agents and one listed private actors (figure 1).

Figure 1. Procurement agent(s) for the national immunisation program



Additional comments from the respondents

In France private actors such as, pharmacists, wholesalers, hospitals, vaccination centers, as well as public vaccination centers and hospitals act as procurement agents for the national immunisation program. In Greece, no central procurement agent exist. (Pharmaceutical companies estimate, import, distribute vaccines that are fully reimbursed. For emergency vaccines there are shortages).

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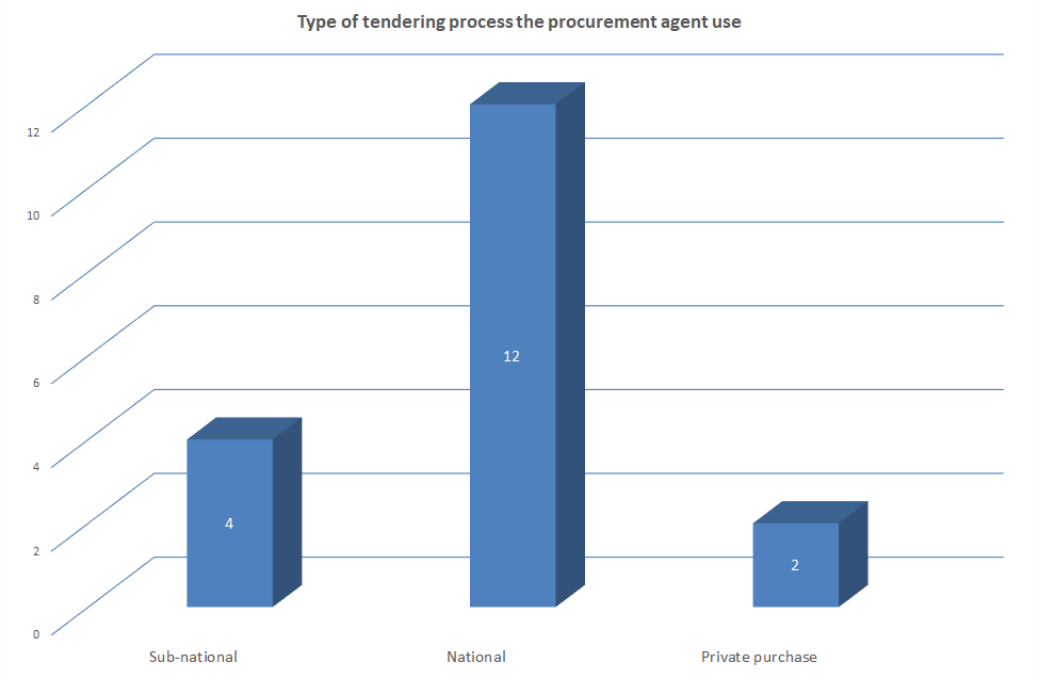
A majority of the countries responded that a national tendering process is used by their procurement agencies for their national immunisation program; a few respondents listed subnational processes (figure 2).

Figure 2. Type of tendering process the procurement agent use



No additional comments were made by the respondents.

There seem to be a mix of government agencies, local regional/agencies and private actors distributing vaccines for the national immunisation program in the different countries. Eight countries use government agencies, six countries use local/regional health authorities. Nine respondents indicate use of private actors, national and international wholesalers (figure 3).

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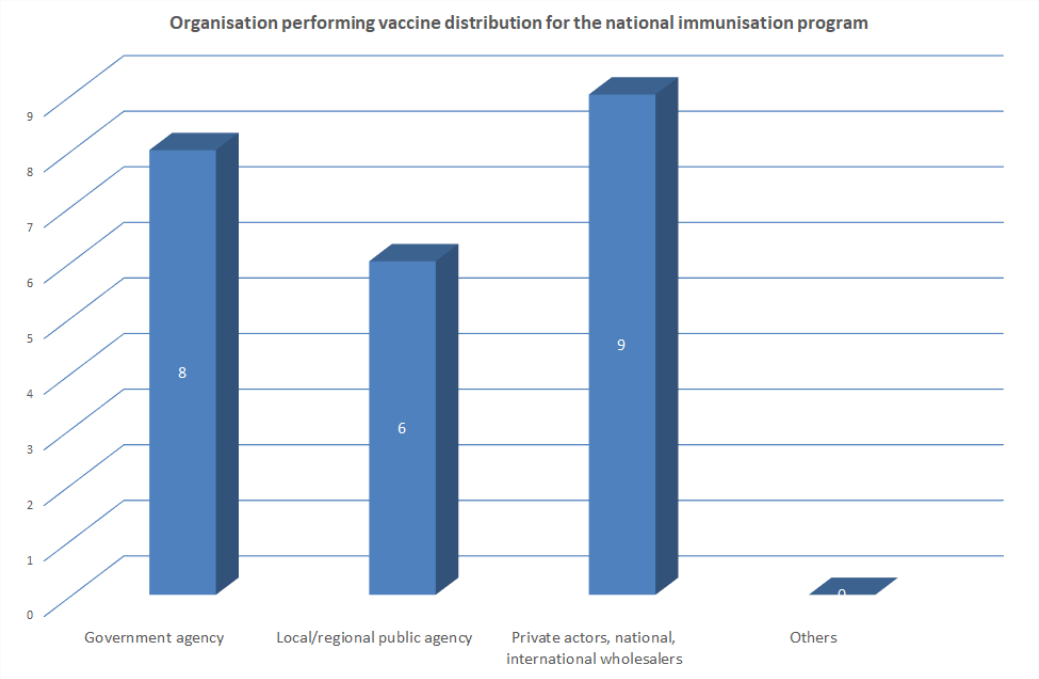
Figure 3. Organisation performing vaccine distribution for the national immunisation program



Additional comments from respondents:

Latvia: Private actors are authorised national wholesalers; Italy: Local health authorities are distributing vaccines; Ireland: Private actors are national wholesalers contracted by the government agency; Sweden: Private actors are pharmaceutical company distributors; Slovenia: The national institute of public health holds the wholesale marketing authorisation for medicinal products for human use; Greece and Germany have a distribution chain from the marketing authorization holder to the wholesalers and then to the pharmacies; Austria: regional public offices and large private wholesalers are involved.

5.3 Results from part B - questions to understand mechanisms to ensure sufficient supply

To better understand mechanisms to ensure sufficient supply for immunisation programs and preparedness in EU some proposed key mechanism were included in the survey.

The following mechanisms were listed and maximum three options were allowed

- Sufficient stockpiles of vaccines at national level including an emergency stockpile
- Early warning systems from suppliers and manufacturers of potential stockouts
- A comprehensive national overview of vaccine demand and stocks
- A rapid exchange mechanisms on available vaccines between EU member states

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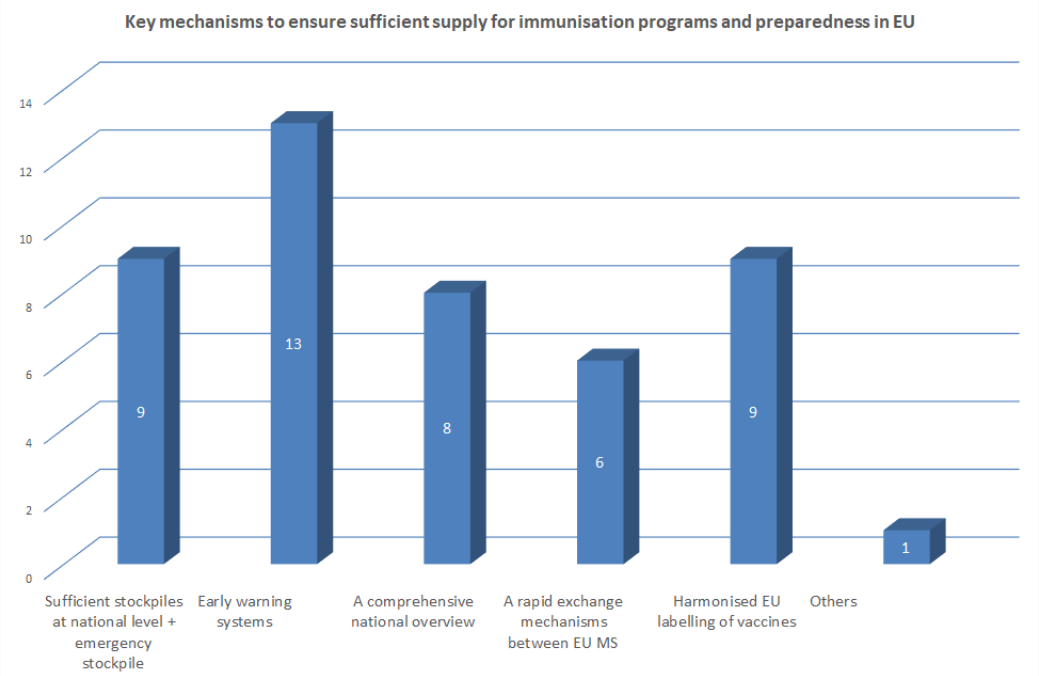
- Harmonised European labelling of vaccines
- Others (please specify)

Early warning systems from suppliers and manufacturers of potential stockouts**,** sufficient stockpiles of vaccines at national level including an emergency stockpile, a comprehensive national overview of vaccine demand and stocks and harmonized European labelling of vaccines were listed as the key mechanisms to ensure sufficient supply (figure 4)

Figure 4. Key mechanisms to ensure sufficient supply for immunisation programs and preparedness in EU



Additional comments from respondents:

Comments under the category “others” were: promote long term tender contracts, stimulate / facilitate the entrance of more manufacturers to the market.

To better understand mechanisms to improve forecast of vaccine demand and manufacturing some proposed key mechanism listed below were included in the survey.

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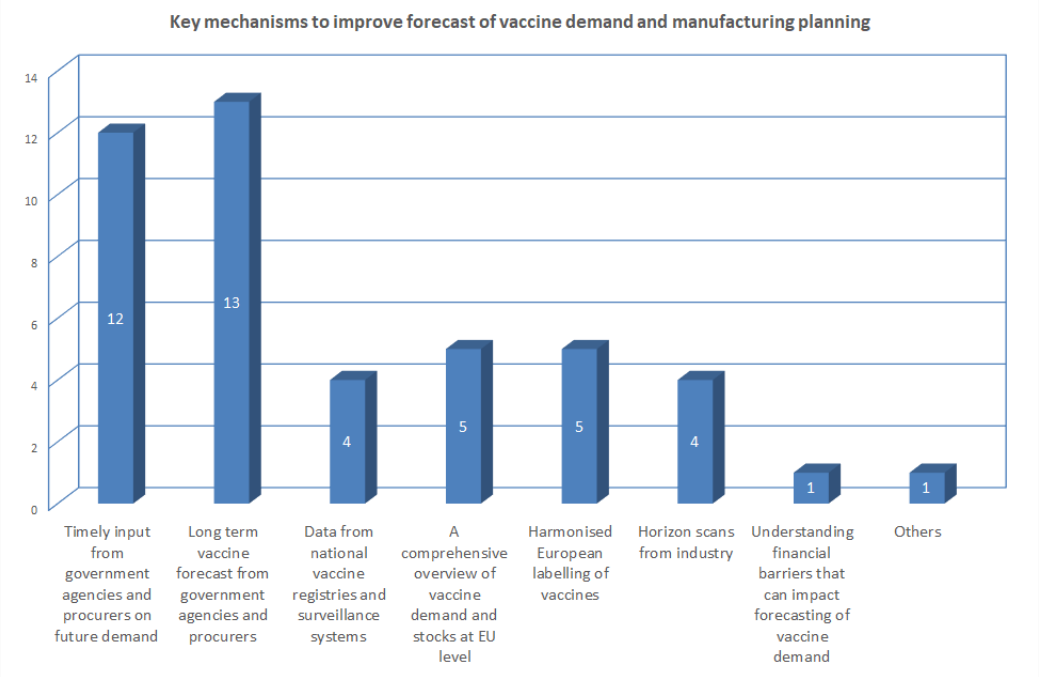
The following mechanisms were listed and maximum three options were allowed

- Timely input from government agencies and procurers on future demand related to potential changes in the immunisation program
- Long term vaccine forecast from government agencies and procurers
- Data from national vaccine registries and surveillance systems
- A comprehensive overview of vaccine demand and stocks at EU level
- Harmonised European labelling of vaccines
- Horizon scans from industry
- Understanding financial barriers that can impact forecasting of vaccine demand
- Others

Long term vaccine forecast from government agencies and procurers, timely input from government agencies and procurers on future demand related to potential changes in the immunisation program were listed as key mechanisms to improve forecast of vaccine demand and manufacturing, then followed by a comprehensive overview of vaccine demand and stocks at EU level and harmonised European labelling of vaccines (figure 5).

Figure 5. Key mechanisms to improve forecast of vaccine demand and manufacturing



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Additional comments from respondents

The Netherlands additionally listed horizon scans from industry as the 4th important mechanism.

To better understand the respondents' view on key mechanism (s) to enable exchange of vaccines between the EU countries, some proposed mechanism listed below were included in the survey.

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 6).

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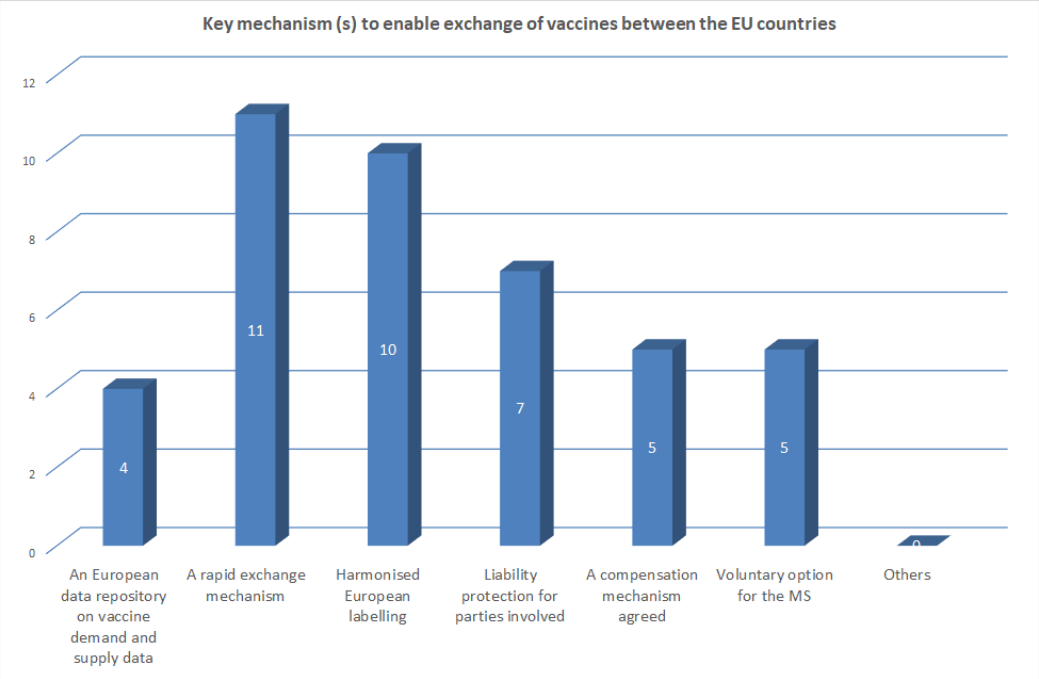
Figure 6. Question on key mechanism (s) to enable exchange of vaccines between the EU countries



Additional comments from the respondents

Comments under the category "others" were: One of the respondents explained their choice for voluntary options, due to that this cannot be regulated or forced and this is each country's own responsibility. One country additionally commented the need for harmonised national legislations and harmonised marketing authorisations.

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.

Only four countries believed establishing a virtual data repository will prevent shortages in EU, eight are unsure and four responded no (Figure 7). Their opinions on specific priority vaccines are presented in Figure 8.

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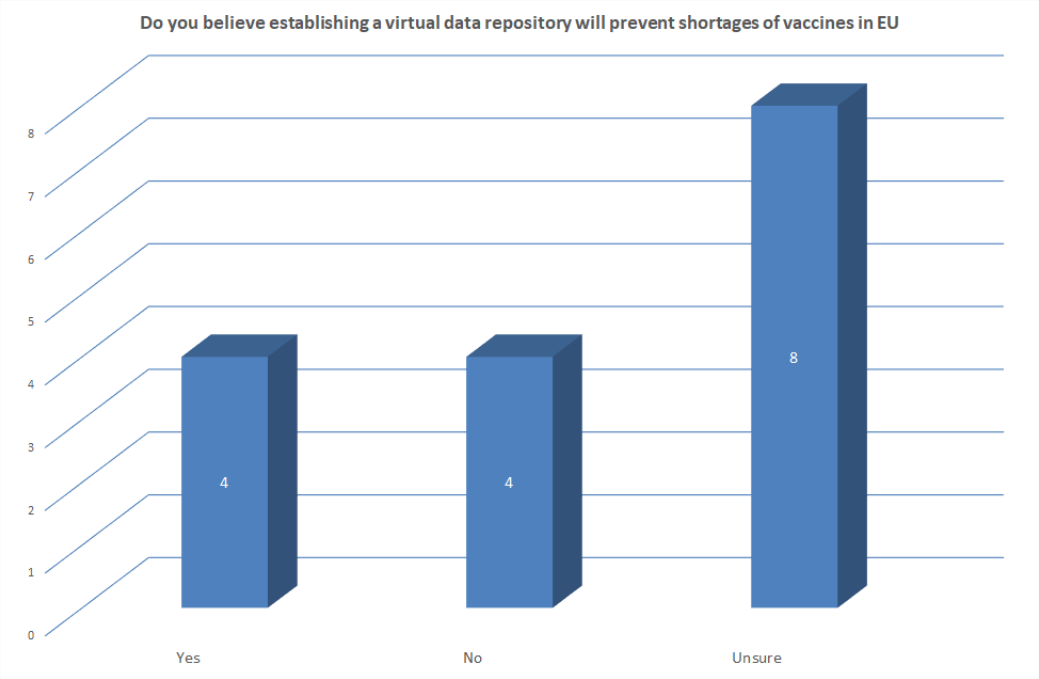
Figure 7. If the respondents believed establishing a virtual data repository will prevent shortages in EU



In the planning phase of the EU-JAV, there were discussions on if an EU repository on data sharing should focus on specific priority vaccines instead of the full range of vaccines in the national immunisation schedules. The respondents were therefore asked to consider if an EU data repository system should focus on specific 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

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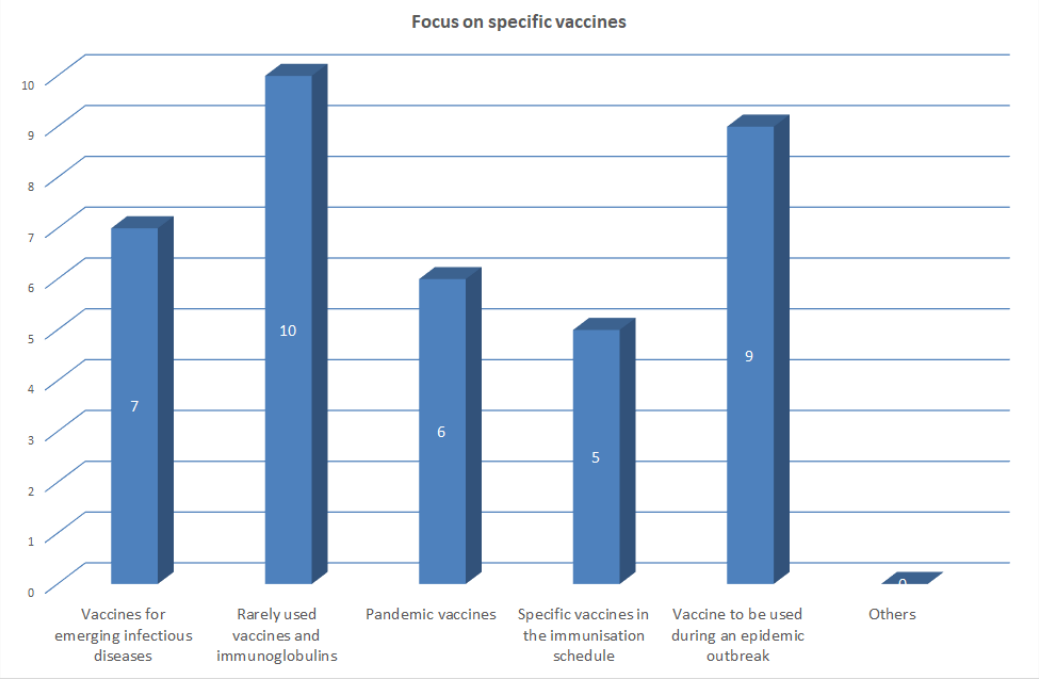
Figure 8. If the respondents believed the focus should be on specific priority vaccines.



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.

Rarely used vaccines and immunoglobulins

Examples given: Antitoxins, BCG (Bacille Calmette-Guerin) vaccines, rabies immunoglobulin, tetanus immunoglobulin, human normal immunoglobulin, tuberculin, botulinum antitoxin, diphtheria antitoxin, Ebola vaccines, smallpox-vaccine, rabies vaccines (to some extent also tetanus, hepatitis B, varicella zoster immunoglobulins)

Specific vaccines in the immunisation schedule

Examples given: BCG vaccine, measles vaccine, hepatitis B vaccine

Emerging infectious diseases

Examples given: Ebola vaccine, antivirals

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5.4. Results from Part C Qualitative analysis

The last part of the survey consisted of more in-depth questions concerning specific challenges. An overview of the main results are highlighted in this report, and the questions and responses concerning the EU data repository will be further used for the critical assessment of options and possible scenarios for the concept analysis for a data warehouse for European sharing of vaccine supply and demand/data information among dedicated stakeholders. The responses are listed by country, but for privacy purposes, the name of the country is removed.

5.4.1 Questions focusing on challenges to ensure sufficient supply and harmonisation of European labelling of vaccines

The respondents were asked about their view on the current uncertainties and potential future hurdles related to planning for sufficient vaccine supply for Immunisation programmes and preparedness in EU. Many of the respondents commented on the limited number of global vaccine manufacturers and differences in the immunisation schedule between countries. Received feedback comments are listed below (Table 2).

Table 2. Current uncertainties and potential future hurdles related to planning for sufficient vaccine supply for immunisation programmes and preparedness in EU

• Suppliers and manufacturers may be elusive to plan sufficient supply to the market of small states • Unpredictable shortages leading to longer disruption without sufficient alternatives in other markets • The substantial part of vaccines are authorised via different procedures in different countries which can make it difficult to recognise them as substitutes
• Very few producers of childhood vaccines for the European market • Very strict country specific packaging makes it difficult to share products with other countries in case of shortages
• Different vaccines (combinations of antigens, number of antigen serotypes/genotypes) are used • Different vaccination schedules • Different procurement intervals • Different procurement and distribution mechanisms

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• There is no mechanism for purchasing of vaccines that already have been purchased for the state programs in other country
• Differences between immunisation programmes in EU • Protection of data about manufacturing capacities and stockpiles by the pharmaceutical companies • Commitment from all players
• Few manufacturers on the market. Therefore, an increased demand, or manufacturing problems have huge effects • Many countries have no or insufficient safety stocks and/or insufficient vaccine forecasting/long-term contracts
• Limited number of manufacturers per vaccine type creating non-competitive markets • Only one manufacturer per vaccine (or vaccine strain) could lead to stockouts or shortages if issues arises with the manufacturing process • Continuous changes in the national programmes • Vaccine shelf life could be improved • Restrictive temperature parameters could be broadened
• Decentralisation of public health in our country • The limited number of vaccine suppliers and limited production capacities • Increased demand for vaccines worldwide • Limited communication between public health authorities an industry
• Delay in shipments • Quality problems of vaccines
• Regular deliveries
• Globalization of vaccine production, few vaccine producers who have large share of the market which make it vulnerable if something happens • Decentralised responsibility of ensuring the access to vaccines
• Long lead times for manufacture of vaccines • Limited safety stock at manufacturer
• The very limited number of producers globally and especially in Europe
• The vaccine manufacturers don't want to increase their production capacities, the shortage or the risk of the shortage of vaccines are favourable for them, because the prices are increasing
• Production of essential vaccines are concentrated to very few producers • Too little margin if one producer is struck with problems. If there are two producers on the market of a certain vaccine product, which in reality is the case, the other cannot maintain the necessary capacity to compensate the falloff of the competitor in trouble • Too little competition as well
• Anti-vaccination movements/ news and their sudden vast impact on the coverage of the routine vaccinations • Sudden shifts in the marketing strategies (monopoly situations etc.) • No quick alternative solution in case of valid contract deliveries are interrupted

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• Funding of immunisation programmes • Aging European population • Migration influx in Europe • Emerging and re-emerging diseases • Lack of vaccine data repository systems
• Determination of an assured demand and also supply • Demand of vaccines is related to a willingness of citizens for vaccination • Status of national marketing authorisations for vaccines in MSs are different; small number of manufacturers and limited alternatives of products and different mechanisms in procurement and pricing contribute further

The respondents were asked about their view on main hurdles for harmonising European packaging and labelling of vaccines. Many of the respondents commented on language differences and some were uncertain if this would prevent the risk of vaccine shortage. Received feedback comments are listed below (Table 3).

Table 3. Main hurdles for harmonising European packaging and labelling of vaccines

• Only a part of vaccines on the market are authorized via centralised procedure, a big part is authorised in MRP, DCP and national procedure • Harmonising registration documentation of nationally authorized medicinal product primarily demands willingness of marketing authorization holder • Only when documentation is harmonised it would be possible to harmonize packaging and labelling.
• This would be the biggest step to help out in case of shortages in the short term • However, with only a few producers of vaccines on the market, a long-term production failure would affect almost everybody sooner or later
• Not sure that the harmonization of packaging and labelling of vaccines can significantly influence availability of vaccines in EU/EEZ. There are many other obstacles to solve
• Regulatory hurdles, but we can deal with these subjects
• Language preferences. With three languages on the labels already, a better flexibility is possible • User preferences. Ten-packs or single-packs, with or without needle, cheaper vials or more expensive syringes, blisters or cardboard, etc
• There is no uniformity of national programmes • Potential liability issues
• All European languages should be represented by areas (for example, French, Spanish, English and Portuguese) • Inclusion of several languages in the same packaging and labelling of vaccines
• Different languages

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• Different marketing authorisations, packaging insert leaflet (PIL), summary of product characteristics (SmPC)
• National language legislation.
• Harmonisation of legislation in different countries
• Regulatory hurdles and national requirements • Lack of regulatory acceptance to use electronic patient information leaflets
• Not a big issue with vaccines as health personal and not private persons handle them • Most countries should be able to have packs in English, French or German
• If there is a centralized distribution system for the national immunisation program, they can accept any vaccine with the standard packaging (English, German, French) or any other packaging with Latin letters (not Cyril) • The harmonized packaging and/or labelling system doesn't solve anything • It won't prevent any vaccine shortage
• Too many languages • There should be a possibility in the law to recline on electronic leaflets and other information for vaccine products • They are administered by health professionals so that should not be a problem
• If there are clear rules regarding the language, the name of the vaccine etc, we do not see major hurdles for harmonising packaging and labelling of the vaccines
• Reluctance of marketing authorisation holders to engage to the relevant regulatory actions
• Acceptance of common languages used, readability issues of labelling using multinational labelling and different vaccination policies across MS

The respondents were asked about their view on current legal or regulatory hurdles related to exchange of available vaccines between MS in case of shortages. Many of the respondents commented on liability issues and regulations concerning authorisation of the vaccines. Received feedback comments are listed below (Table 4).

Table 4. What are the current legal or regulatory hurdles related to exchange of available vaccines between member states in case of shortages?
• Prior to defining the mechanism of exchange of vaccines available on the market of specific state we need to take into account that vaccines are property of third party before the supply • States have little stock for current needs on their disposal • Major stocks are on the disposal of specific manufacturer or supplier • Regulatory procedure would ask some party to take charge of stockpiling in order to provide any stock for exchange • Any country can make estimates for their needs, but there is a hurdle to define any additional estimates and stocks for the needs of another country

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• Vaccines should be handled safely in a legal way though the legal supply chain - which need a harmonised transnational regulatory procedure if it happens on behalf of member states.
• The regulation about foreign packs in the market often makes it difficult and time consuming to bring a needed product on to the market
• There is no legal regulation regarding procurement/selling vaccines from/to other country that already were purchased within state tendering procedure
• National procedures authorisation - if authorisation importation has to be used, it will be an important administrative burden for the national agency • There is a problem with the price of the imported vaccine and the conditions of reimbursement, in case of authorization importation. It will be easier with the centralized authorization
• Getting permission from the manufacturer • Liability issues • Responsibility for Good Distribution Practice (GDP) transportation • Pricing / confidentiality • A suggestion can be selling stocks back to the supplier with the purpose of sale to another country
• Falsified Medicines Directive • National legal issues
• Marketing authorisation and packaging • Price approval • Certificates: Good Manufacturing Practice (GMP) , Official Control Authority Batch Release (OCABR)
• National language legislation
• Legislations, marketing of the product with the labelling in other languages than the origin is not allowed • You have to apply for a permission from drug product agency to use product with another labelling
• Falsified medicines directive is expected to give less flexibility regarding exchange between member states
• The responsibilities for the vaccines • The producers are not able to assist when vaccines are delivered from one country to another
• There is no strict legal or regulatory barrier for the exchange of vaccines • It depends on the willingness and/or the national regulation of the MSs • Already provided BCG vaccines (as a donation) to handle the shortage in another member state without any legal or regulatory problem
• Shift of pharmacovigilance responsibilities • Transport and storage chain of responsibility must be cleared

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• The national medicines authorities must define a routine for this kind of transaction in order to make it smooth • The responsibility of the producer must be defined in this kind of cases
• Main problems are related to marketing authorisations • If there is a medicine with a valid marketing authorisation available, it is not allowed to accept equivalent medicine without marketing authorisation (even if it has a valid marketing authorization in some other EU country) • There could be a situation where we would lend a vaccine that has a valid marketing authorisation but would receive back another manufacturer's vaccine which does not have valid marketing authorisation in a country • A good mechanism must be in place to organise the lending procedure fast and without any major delays (Some regions have harmonised a lending agreement for this type of situations)
• Lack of relevant legal or regulatory framework (liability issues, compensation issues, authorisation, etc.)
• Non-conformance with national marketing authorisations, i.e. labelling, indication • General supply issues with vaccines in different MS due to i.e. quality defects, GMP issues

5.4.2 Questions focusing on options for a European-wide data repository on vaccine demand and supply data

The respondents were asked about their view on how a European wide data repository on vaccine demand and supply data be built and look like in the future. Received feedback comments are listed below (Table 5).

Table 5. How could a European-wide data repository on vaccine demand and supply data be built and look like in the future?
• Data repository on vaccine demand and supply should be designed for provision of depreciated information for specific group of data users - supervisory body, member states and suppliers • Member states would need information on available stocks, their amounts, location, contact information of stockholder and delivery options • In return member states could provide information on their estimated demands and procurement procedures
• Access to information and contact details about who to contact in the other countries would be a great start
• The WHO already collects (Joint Reporting Form) annual data reading number of doses purchasing/used in MS for all vaccines that are used in the National Immunisation Programmes

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• It is possible to estimate forecast demand based on standard annual data. • MS can assess and correct estimates
• Either all participating member states put in money and together they set up one or more physical repositories for certain products (and put the contents in a database) • After agreement on the terms and conditions, the participating MS built a virtual database • In each case it must be clear e.g. what each country contributes, what are the revenues, rights and costs – an agreement must be reached
• Bonus on manufactures to supply timely data regarding vaccine stock throughout Europe
• It should be based on coverage data
• Summarizing and updating regular national reports
• Based on voluntary reporting
• List of vaccines and doses needed in national programmes and annual update of birth cohort for each member state. • Can give overview of total demand for vaccine type
• We don't support a European database on the vaccines available at Member States • In many MS there is no centralised stockpile, they provide the vaccines for the national immunisation system through the pharmacies • They cannot provide any data about their stockpile, because they haven't got any stockpile • This task would not be balanced for the MSs. Some MSs has to work a lot with this database the other do nothing
• This is too resource consuming for too little benefit. If it can be automated.
• A central data warehouse linked to all national warehouses • Interoperability among central and national warehouses • Central administrator • Authorised European and national agencies to manage it with distinct responsibility and in compliance with the General Data Protection Regulation (GDPR) requirements
• The proposed tool is deemed inappropriate for the intended purpose.

The respondents were asked about their view on the main hurdles for a European wide data repository on vaccine demand and supply data to take place – related to the willingness of the actors. Received feedback comments are listed below (Table 6).

Table 6. What are the main hurdles for this to take place related to willingness of the actors?
• Small MS states sometimes face low interest of manufacturers to take into account their demand and needs of small markets and to fit with any regulatory requirements in case they are the only suppliers • Suppliers may not be interested to disclose full information available at their disposal on stocks, prices and other details
• Personal relations and working groups are better than obligations
• We do not see significant hurdles

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• Financial and sustainability aspects - who will pay? A European fund will be the best and a coordination by the EMA
• Does not seem to be a rationale to participate for countries that are well organized • The impression could be that less well-organized (and/or less rich) countries will only profit, not contribute • Suppliers/manufacturers will worry about liability a.o. related to cold chain issues, and market disturbance.
• Commercial sensitivities
• Decentralisation is the main hurdle for us and a well-developed IIS
• Price
• Confidentiality for MS and pharmaceutical industry • Data is also constantly in need for updating - today it would be difficult to put the data together and updating it just for one country • This will be further complicated on a European level, due to very different systems and setups of distribution and stocks • In countries where procurement and stockpiles are held at regional level
• Willingness to participate and to update on a regular basis • Willingness to participate for better vaccine coverage on EU-Level
• Limited resources. We need dedicated people to take responsibility
• Like to see how member states where there is no centralised system provide data • Only after that we are going to provide data
• Resources. Can this be provided? Can the actors see the benefit of the effort put in?
• Potential unwillingness of marketing authorisation holders to share data due to trade confidentiality issues • Uncertainty of political will and commitment for member states to share data on stocks
• Doubt in benefit of an EU wide data repository to solve major problem with overall availability of vaccines, which is also a global issue • Established national responsibilities and structures have been working for the national market

The respondents were asked about their view on the main hurdles for a European wide data repository on vaccine demand and supply data to take place – related to legal aspects. Received feedback comments are listed below (Table 7).

Table 7. What are the main hurdles for this to take place related to legal aspects?
• To proceed with fair and transparent procurement to avoid corrupted competition legal procedure for procurement can't be abolished • Commercial data have to be protected

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• In case of distribution from state to state, distribution procedure should be defined (taking into account legal chain requirements, good distribution practice, legal status of vaccines in the destination country etc.)
• We do not see significant hurdles
• We may have a European reflection for a facilitation of import authorisations
• Commercially confidential information from manufacturers, especially prices. Government agencies are not commercial vaccine suppliers. Illegal market disturbances?
• No legal problems when talking of aggregated data
• Pan-European legislation harmonisation
• Liability issues, labelling, confidentiality due to different procurement aspects
• No legal issues related to information about immunisation programmes
• The legal aspects of the liability is different in the MISs, this can cause problem. The level of the involvement of the manufacturers are different
• I think the legal aspects can be solved but it takes some effort and time. Requires motivation. What is the effort - benefit ratio? • Are there any confidentiality issues between the national authorities and the suppliers that must be solved?
• Lack of a harmonized legal and regulatory framework on EU level in a form of a Directive

The respondents were asked about their view on the main hurdles for a European wide data repository on vaccine demand and supply data to take place – related to the technical aspects. Received feedback comments are listed below (Table 8).

Table 8. What are the main hurdles for this to take place related to the technical aspects?
• There are a lot of question which should be answered prior further evaluation, which body in which country will hold the repository, who will be data holder, who will have access to data, how often data have to be updated etc.
• We do not see significant hurdles
• Conditions of access to the repository and data protection
• It will take a long time (years) to reach an agreement on a procedure and the wording of it (analogy Joint Procurement Initiative) • Once everything is ready, countries want to share vaccines and the manufacturer gives permission, it is quite easy • Just hire a certified logistics supplier and monitor the transport. Or let the process go via the supplier/manufacturer
• Timely and accurate data
• Lack of resources to have a well-developed IISs in every region
• Harmonization of national standards and vaccination schedules

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• Which body should lead and handle data? Confidentiality and security aspects. Keeping the data updated to make it relevant
• Depends on technical solution. Dedicated resource to maintain solution
• The Medicines directive and the national medicines agencies
• We can provide data easily
• I believe the technical environments in different countries are very different and continuously changing
• There has to be a very clear view of what kind of data, when and by whom is inserted to the system (comparability issues)
• Harmonized labelling • Interoperability • Common terminology • Data security

The respondents were asked about their view on the main hurdles for a European wide data repository on vaccine demand and supply data to take place – related to affordability of the actors. Received feedback comments are listed below (Table 9).

Table 9. What are the main hurdles for data sharing related to the affordability for the actors?
• It is hard to estimate and allocate necessary resources for vaccine exchange in transnational system opposite to normal and fair procurement procedure
• There should at least be resources dedicated to the job
• We do not see significant hurdles
• Risk for the own population after reduction of the stocks. Price information. Substantiating the costs of the provision and in case of delivery
• Well-developed IISs at regional level so aggregated data at central level is of good quality and comprehensive
• If data in some way affects procured prices, this would be complicated. Problem already with different procured prices in different MS
• Need for precise estimate of costs (including human resources). Insure sustainability through allocation of funding at national and EU level. Agreement with marketing authorisation holders

The respondents were asked about their view on the best ways to ensure access to data for a European wide data repository on vaccine demand and data. Received feedback comments are listed below (Table 10)

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Table 10. What are the best ways to ensure access to data?
• Access should be restricted and predefined to reduce unnecessary stockpiling and corruption of competition on the market
• Through a common platform where data of interest can be extracted and through alert systems if a country is asking for help
• Through dedicated website
• Secure and adapted access to actors
• Clear benefits
• Secure website with password
• Create a repository with only essential data
• unified platform internationally available
• Common platform, jointly governed body for holding data.
• Open solution. No login and passwords.
• Legal framework / authorisation process. • Registry • Confidentiality / Data security

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6. Stakeholder comments

6.1 Vaccine Europe

Among the most relevant stakeholders are the manufacturers supplying the vaccines to the MSs. A face-to-face meeting with Vaccine Europe took place on the 27th May 2019 in Rome.

Vaccine Europe communicated that the supply and demand situation is affected by increasing global demand and limited number of manufacturers and production capacity worldwide. Each vaccine lot is tested several times with risk of out-of-specifications (and retesting). Redundant testing and animal testing are impacting timely supply and public health.

Further, Vaccine Europe listed multiple causes for shortages:

- Complex manufacturing and testing requirements with long lead times (up to 24 months)
- High number of post-approval changes often impacting several products
- Lack of anticipation of demand and inflexible purchasing mechanisms
- Increased and often unpredictable global demand

Vaccine Europe proposals to strengthen shortages prevention and establish sustainable vaccine supply are listed below:

The European Directorate for the Quality of Medicines (EDQM) should lead initiatives towards elimination of animal testing, optimise Official Medicines Control Laboratories (OMCL) testing strategies, procedures and guidelines to ensure concomitant availability of testing results at manufacturer and OMCL even in case of testing repeat, lead harmonisation of methods within the EU OMCL network and further lead harmonisation of testing strategies, methods and specifications as well as of pharmacopoeia between EU and non-EU countries.

Mutual Recognition agreements (MRA) should be established for batch release by EU OMCLs and selected non-EU NCLs (eg. US and Canada). EDQM should consider public health learnings from Canada, Australia and US where the WHO recommended risk-based approaches related to National Control Laboratories (NCL) testing have been implemented.

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Due to the global supply of vaccines and the complexity of portfolios with multiple vaccines impacted by the same change, regulatory requirements should be further harmonised within EU/EEA countries as well as between EU/EEA and non-EU countries, with implementation of risk-based approaches allowing more flexibility on a case-by-case basis.

MRAs should be established for inspections of vaccine facilities by EMA and US Food and Drug Administration (FDA), and approvals of Post-Approval Change (PAC)s by recognised stringent Regulatory Authorities.

The number of presentations should be reduced across EU/EEA. Vaccine packs should be harmonised across EU/EEA. There should be a common label on the vaccine container and same pack requirements for Neutrophil Activating proteins (NAP).

Paper leaflet should be replaced by e-leaflet: 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.

In light of long lead-times, better anticipation of demand is necessary. Early and continuous dialogue between manufacturers and health authorities should be established (in compliance with competition law) to better anticipate the evolution of vaccine recommendations and more accurately forecast vaccine demand. Procurement practices should be adapted to enable better manufacturing planning and reduce risks (longer lead times, split tenders for interchangeable vaccines).

A harmonised and fit-for-purpose definition of vaccine shortage should be established and implemented across EU/EEA.

A platform composed of regulatory and quality authorities should be established to allow manufacturers and authorities to find joint solutions to ensure continuity of immunisation programmes in case of anticipated or ongoing shortage of nationally and centrally approved vaccine(s).

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7. Discussion

7.1 Mechanisms to ensure sufficient supply for immunisation programs and preparedness in EU

Early warning systems from suppliers and manufacturers of potential stockouts**,** sufficient stockpiles of vaccines at national level including an emergency stockpile, a comprehensive national overview of vaccine demand and stocks and harmonised European labelling of vaccines were listed as the key mechanisms to ensure sufficient supply.

Long term vaccine forecast from government agencies and procurers, timely input from government agencies and procurers on future demand related to potential changes in the immunisation program were listed as key mechanisms to improve forecast of vaccine demand and manufacturing, then followed by a comprehensive overview of vaccine demand and stocks at EU level and harmonised European labelling of vaccines.

There seem to be a high need for sufficient and timely planning of supply of vaccines and sufficient stock at national level. There is a limited number of manufacturer and production capacity worldwide, affecting the supply and demand situation for vaccines. Vaccine production is more globalised with long lead times for the existing vaccines on the market. This was also communicated to the WP6 from Vaccine Europe. Some additional feedback from the manufacturers was the batch release requirements (EDQM), more harmonisation of methods and specifications as well as pharmacopoeia between EU and non-EU countries.

Many of the respondents to the survey commented on the limited number of global vaccine manufacturers and differences in the immunisation schedule between countries as the current uncertainties and potential future hurdles related to planning for sufficient vaccine supply for immunisation programmes and preparedness

However, most medicine shortages are dealt with at national level by the national competent authorities. Some member states have local legislation requiring holder of the marketing authorization to report to medicines agency disruption in supply. The European Medicines Agency (EMA) can be involved in certain situations, for example, when a medicine shortage is linked to a safety concern or affects several MSs.

It is the MS responsibility to assure sufficient stockpiles of vaccines, and they seem to do so in different ways. The MS, the supplier or a combination of both holds preparedness stocks. The size of the stockpiles varies from country to country. It normally reflects the long lead-time for vaccines. Rarely used vaccines and immunoglobulins, vaccines to be used during

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and epidemic outbreak and vaccines for emerging infectious diseases were listed as most important focus area for an EU virtual data repository, by the respondents of the survey. This reflects the fact that most failures in vaccine supply are the unpredictable nature of outbreaks and rare events. Some MS have national stockpiles to protect against potential disease outbreaks, however, an overview of size of these stockpiles, how they are forecasted, remain considerably unknown. 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.

More harmonised labelling of vaccines was listed as one of the mechanisms. However, feedback received in the qualitative part mentioned the constraints with different marketing authorisation procedures for the existing vaccines on the market and the need for more agreement on common language to be used on the packaging and labelling of vaccines, as well as lack of regulatory acceptance to use electronic patient information leaflets. Some were uncertain if more harmonised labelling would prevent the risk of vaccine shortage.

Many of the respondents commented on liability issues and regulations concerning authorisation of the vaccines.

7.2 Gap and options for a European wide data repository on vaccine demand and supply data

The purpose of the survey was to identify the stakeholders and EU MS opinion on a European wide data repository on vaccine demand and supply data and to assess the relevance in relation to the MS needs. Additionally, the survey intended to explore the needs goals and requirements to define a space for the concept analysis and not make the options to be explored too narrow.

A rapid exchange mechanism on available vaccines between EU MSs and harmonised European labelling of vaccines were listed as 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. In the qualitative part, the respondents were asked about their view on current legal or regulatory hurdles related to exchange of available vaccines between MS in case of shortages. Many of the respondents commented on liability issues and regulations concerning authorisation of the vaccines as the main hurdles for this to take place.

This reflect the need for further discussion and need to create a standard operating procedure regarding the ad hoc urgent exchange of medical countermeasures through the

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Early Warning and Response System (EWRS) raised by the European HSC. MSs have expressed support for the proposal provided that the procedure and the work on templates would not create much 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.

However, only four countries believed establishing a virtual data repository will prevent shortages in EU, while eight countries said they were unsure and four said no. On the other hand, several of them listed their opinions on which specific priority vaccines should be focused.

Rarely used vaccines and immunoglobulins, vaccines to be used during and epidemic outbreak and vaccines for emerging infectious diseases were listed as most important focus area for an EU virtual data repository and some examples given in table 11.

Table 11. 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	RIG, TIG, HBIG, HNIG, variZIG, botulinum antitoxin, diphtheria antitoxin, 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

The list of priority vaccines clearly reflects the difference and the challenge the countries face to ensure supply for the national immunisation schedule versus more uncertain demand of vaccines during outbreak situations.

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The qualitative part focused on how the respondents view on the architecture of a potential data repository, hurdles in terms of willingness, legal and technical aspects, affordability and access to data. The feedback received reflected the wide spread in opinion on the need for a European wide data repository.

7.3 Future outlook for the options to be explored in the concept analysis

The result of this gap and option analysis indicates that further work on the concept analysis for a regional/European data warehouse for sharing of vaccine supply and demand data/information among dedicated stakeholders should also include alternatives like voluntary sharing/ rapid exchange mechanisms on available vaccines between EU MS, and improvements of more concrete tools like “harmonised European labelling of vaccines” and “standard operating procedure to enable the ad hoc urgent exchange of vaccines”, to enable stronger national response to vaccination challenges regarding vaccine supply management. A preliminary draft (figure 9) of potential options to be further explored in the concept analysis and discussed with the partners and stakeholders in the EU-JAV is presented below.

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Figure 9. Preliminary reflections and feedback to be taken forward in the concept analysis

	Voluntary sharing/Rapid Exchange Mechanism* on available vaccines 	**Regional virtual stockpile** 	**Virtual EU Data warehouse** 
Functionality			
Use of existing systems	✓		
Centralised virtual stockpile	X	✓	✓
Voluntary mechanism	✓	✓	
Standard operating procedure for ad hoc urgent exchange of vaccines*	?	✓	✓
Information on available stocks	X	✓	✓
Data sharing mechanism	X	✓	✓
Central virtual data warehouse	X	?	✓
Scope			
Rarely used vaccines and immunoglobulins	✓	✓	✓
Epidemic outbreak vaccines	✓	✓	✓
Surplus vaccines	✓	✓	✓
Risks			
Legal	✓	✓	✓
Liability	✓	✓	✓

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*With reference to the ongoing discussions at the EC HSC (3,4)

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Annex 1

Questionnaire: Vaccine supply and Preparedness

The specific objective of the EU JAV on vaccine supply and preparedness is to improve the predictability of vaccine supply and demand and strengthening preparedness of Member States, while increasing the cooperation between suppliers and authorities.

The information from this questionnaire will support the EU-JAV understanding of:

- Member states challenges to ensure vaccine supply and preparedness
- National or regional vaccine providers and distributors challenges to ensure vaccine supply and preparedness
- Industry specific issues and challenges to ensure vaccine supply and preparedness
- The current state of supply and preparedness of vaccines in EU; including the needs and opportunities for further development and improvements

This questionnaire begins with some overall organisational questions (Part A) and then a few high-level questions (Part B) followed by some more in-depth questions concerning specific challenges (Part C).

Please note:

- all questions are optional, if you find the questionnaire too long; please provide comment on those challenges that are most pressing to your organisation.

Deadline: **15.03 2019**.

Contact Karianne.Johansen@fhi.no if you find any of the questions unclear, or need any additional guidance.

1) If completing on behalf of an organisation, state its name

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2) Can we contact you if we have questions about your responses? Please fill in your email address and telephone number.

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Part A

Which organisation is in charge of the national immunisation program in your country?

3) Name of the organisation:

4) Which organisation act as procurement agent(s) for the national immunisation program in your country? (you can choose multiple options)

☐ Government agency ☐ Local/regional agencies ☐ Private actors ☐ Others

5) Private actors (please specify)

6) Others (please specify):

7) What type of tendering process does the procurement agent use? (you can choose multiple options)

☐ Sub-national ☐ National ☐ Private purchase

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8) Which organisation is performing vaccine distribution for the national immunisation program in your country? (you can choose multiple options, please specify)

☐Government agency ☐Local/regional public agency ☐Private actors, national, international wholesalers

9) Private actors, national, international wholesalers (Please specify)

10) Others (please specify)

11) If you choose multiple options, please explain

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Part B

12) What do you believe are the key mechanisms to ensure sufficient supply for immunisation programs and preparedness in EU? (maximum 3 options are allowed)

- [ ] Sufficient stockpiles of vaccines at national level including an emergency stockpile
- [ ] Early warning systems from suppliers and manufacturers of potential stockouts
- [ ] A comprehensive national overview of vaccine demand and stocks
- [ ] A rapid exchange mechanisms on available vaccines between EU member states
- [ ] Harmonised European labelling of vaccines
- [ ] Others

13) Others (please specify):

14) What do you believe are key mechanisms to improve forecast of vaccine demand and manufacturing planning? (maximum 3 options are allowed)

- [ ] Timely input from government agencies and procurers on future demand related to potential changes in the immunization program
- [ ] Long term vaccine forecast from government agencies and procurers
- [ ] Data from national vaccine registries and surveillance systems
- [ ] A comprehensive overview of vaccine demand and stocks at EU level
- [ ] Harmonised European labelling of vaccines

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☐ Horizon scans from industry

☐ Understanding financial barriers that can impact forecasting of vaccine demand

☐ Others

15) Others (please specify):

16) What do you believe is key mechanism (s) to enable exchange of vaccines between the EU countries (maximum 3 options are 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

17) Others (please specify):

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18) Do you believe establishing a virtual data repository will prevent shortages of vaccines in EU?

Yes No Unsure

If yes, should the focus be on specific priority vaccinesIf yes, should the focus be on specific priority vaccines

19) In the planning phase of the Joint Action, there have been discussions on if an EU repository on data sharing should focus on specific priority vaccines instead of the full range of vaccines in the national immunisation schedule. We ask you to consider if an EU repository system should focus on specific vaccines and your rationale behind the choices:(You can choose multiple options)

- [ ] Vaccines for emerging infectious diseases (please give examples)
- [ ] Rarely used vaccines and immunoglobulins (please give examples)
- [ ] Pandemic vaccines
- [ ] Specific vaccines in the immunisation schedule (please give examples)
- [ ] Vaccine to be used during an epidemic outbreak
- [ ] Others (please give examples)

20) Rarely used vaccines and immunoglobulins (please give examples)

21) Specific vaccines in the immunisation schedule (please give examples)

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22) Others (please give examples)

23) Please include your rationale:

24) If yes, what are the best ways to develop a concept for a virtual European data repository?

- Voluntary cooperation between countries
- Mandatory implementation through a EU directive
- Aided by draft procedures/agreements made by the EC
- Others

25) Others (please specify):

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Part C

What are the current uncertainties and potential future hurdles related to **planning for sufficient vaccine supply for immunisation programmes and preparedness in EU?** Please include your rationale.

What do you believe are the main hurdles for **harmonising European packaging and labelling of vaccines?** Please include your rationale.

What are the current **legal or regulatory hurdles related to exchange of available vaccines between member states in case of shortages?** Please include your rationale.

How could a European wide **data repository on vaccine demand and supply data be built and look like in the future?** Please include your rationale.

What are the main hurdles for this to take place related to **willingness of the actors?** Please include your rationale.

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What are the main hurdles for this to take place related to **legal aspects**? Please include your rationale.

What are the main hurdles for this to take place related to the **technical aspects?** Please include your rationale.

What are the main hurdles for data sharing related to the **affordability for the actors?** Please include your rationale.

What are the best ways to ensure **access to data?** Please include your rationale.

Are you aware of repositories of data or data platforms in other areas that can be used as a model for this task? Please give examples.

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