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WORK PACKAGE 6 Vaccine Supply and Preparedness

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Background and rationale for WP 6 - Vaccine Supply and Preparedness

- Vaccination is one of most significant public health achievements. However, national immunisation programmes depend on an adequate supply of high-quality vaccines in order to function properly
- Vaccine shortages are a serious public health issue as they can lead to missed opportunities for vaccination and a greater risk of occurrence of deadly vaccine-preventable disease
- There is a need to understand the entity of the problem of vaccine shortages in EU/EEA, and reinforce mechanisms of vaccine supply, procurement and stockpile management

WP6: Aims and deliverables

- Define basic principles for vaccine demand planning and forecasting and other issues related to preparedness
- Reinforce mechanisms of forecasting and management of vaccine supply

Task 6.1: Mapping vaccine needs and demand (ISS - Italy)

- 1) Report on previous experience about vaccine shortages and responses of EU countries
- 2) Guidelines on procedures to estimate vaccine needs and procurement in EU
- 3) Report on financial mechanisms for vaccine procurement

Task 6.2: Reinforce mechanisms of management of vaccine supply (FHI - Norway)

- 1) Report on the anticipated needs to ensure sufficient size of supply and stockpiles, including their sustainability
- 2) Report on possibilities, gaps and options for building a “concept type” for regional or European virtual stockpiles on vaccine management needs and stocks
- 3) Final report and recommendations





Task 6.1: Mapping vaccine needs and demand (ISS - Italy)

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Task 6.1: Mapping vaccine needs and demand (ISS - Italy): Methodology

- Surveys, discussions with main vaccine stakeholders, workshop with EU-JAV partners and stakeholders, consultation of the literature
- Surveys aimed at collecting information on :
 - vaccine shortages and stockouts in years 2016-2019 and responses at national and EU level
 - financial mechanisms for vaccine procurement,
 - procedures/methods adopted by EU countries to forecast vaccine needs
 - introduction of new/improved vaccines, upcoming changes to vaccine recommendations (NITAGs)

1) Report on previous experiences with vaccine shortages in EU/EEA countries (and non-EU consortium member countries), and responses at national and European levels

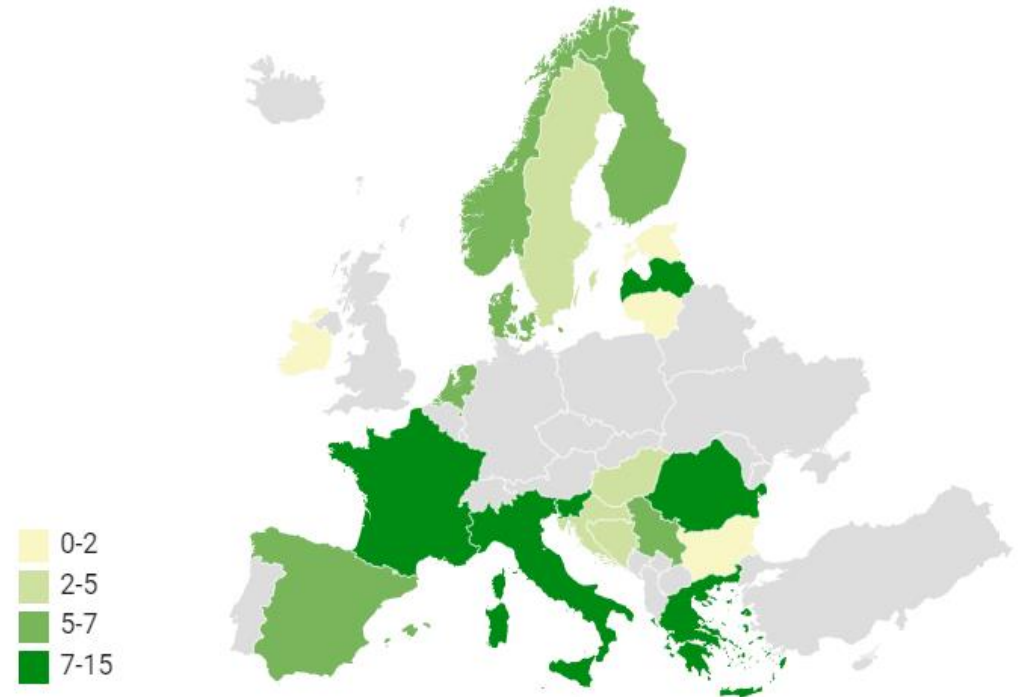
Survey on vaccine shortages conducted by ISS February - May 2019

- ★ 21/28 countries responded: 19 experienced ≥ 1 shortages
- ★ 115 shortage/stockout events reported (median 5/country; range 0-15)
- ★ Median duration of shortages: 5 months (19% lasted >2 years)
- ★ 6/21 countries reported ongoing shortages
- ★ Shortages/stockouts of other biological products (e.g. diphtheria antitoxin) was also reported.

A. Filia, A. Grossi, M.C. Rota, G. Rezza. Report on previous experiences with vaccine shortages in EU countries (and non-EU consortium member countries), and responses at national and European levels (Deliverable D.6.1.)

<https://eu-jav.com/wp-content/uploads/2019/10/Report-on-Vaccine-shortages-WP6-Task-6.1-FINAL-mod.pdf>

Number of vaccines shortages and stockouts in EU JAV and other EU/EEA countries, 2016-2019.



Vaccines most frequently affected by shortages and main causes of shortages (EU-JAV survey, 2016-2019)

Vaccine	Percent of total shortage events	N. countries reporting shortages
DT-containing vaccines	25%	14
Hepatitis B	16%	13
BCG	10%	11
Hepatitis A	10%	7

Most commonly reported causes of shortages:

- ★ production issues (34% of shortages)
- ★ global shortage (30%)
- ★ higher than expected demand (15%).

Causes are complex and multifaceted.

Filia, A. Grossi, M.C. Rota, G. Rezza. Report on previous experiences with vaccine shortages in EU countries (and non-EU consortium member countries), and responses at national and European levels

<https://eu-jav.com/wp-content/uploads/2019/10/Report-on-Vaccine-shortages-WP6-Task-6.1-FINAL-mod.pdf>

Impact of shortages on vaccine services

★ Vaccine shortages had a relevant impact on vaccine services, in terms of temporary changes to the vaccination schedule and of time resources spent to find adequate solutions to mitigate the shortages.

★ 23/115 shortages led to a disruption in immunization services

★ Example: 9/27 countries who experienced a shortage of DT containing vaccines had to temporarily change their immunization programmes (mostly primary and booster programmes) to mitigate the impact of the shortage.

★ Only about half of participating countries reported having recommendations or procedures in place regarding the use of alternative vaccine products or vaccination schedules in case of shortage.

Other findings

★ Most countries reported to procure vaccines at national level by the public sector. The preferred purchase mechanism is one based on competitive bidding and majority of countries purchase all or at least some vaccines from more than one manufacturer. Fourteen countries report using multiyear contracts for all vaccines. Sixteen countries stated that they keep stockpiles of vaccines.

★ Most countries stated that they regularly inform manufacturers about planned changes to immunization programmes and about VPD outbreaks.

Stakeholders' views

★ Main stakeholders' perspectives (Vaccines Europe, EMA) on the most relevant problems leading to shortages, on what is being done and on what should be done to avoid or mitigate shortages, were also included in the report.

★ Timely communication between supply and demand fundamental to avoid and mitigate shortages



Vaccine

Available online 19 February 2022

In Press, Corrected Proof 



Are vaccine shortages a relevant public health issue in Europe? Results from a survey conducted in the framework of the EU Joint Action on Vaccination

Antonietta Filia ^a  , Maria Cristina Rota ^a, Adriano Grossi ^{a, b}, Domenico Martinelli ^{c, d}, Rosa Prato ^{c, d}, Giovanni

Antonietta Filia, Maria Cristina Rota, Adriano Grossi, Domenico Martinelli, Rosa Prato, Giovanni Rezza, Are vaccine shortages a relevant public health issue in Europe? Results from a survey conducted in the framework of the EU Joint Action on Vaccination, Vaccine, 2022. <https://doi.org/10.1016/j.vaccine.2022.02.041>.

<https://www.sciencedirect.com/science/article/pii/S0264410X22001876>



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2) Report on financial mechanisms for vaccine procurement, based on a survey among EU/EEA and EU-JAV consortium Member States

- ★ Workshop with participating EU JAV consortium member states and main stakeholders.
- ★ Key concepts of vaccine procurement from the literature, including advantages and disadvantages of self-procurement versus joint/centralized- vaccine procurement methods.
- ★ Results of survey among EU/EEA and EU-JAV consortium Member States (MS), to collect information on local financial mechanisms for vaccine procurement used, experiences of MS and opinions on joint procurement of vaccines and other forms of cross-border collaboration.

<https://eu-jav.com/wp-content/uploads/2021/09/Deliverable-D6.3-FINAL-WP6-Report-on-financial-mechanisms-for-vaccine-procurement-submitted.pdf>

Report on financial mechanisms for vaccine procurement: Main findings

- ★ In the majority of EU/EEA countries, vaccines included in the national vaccination schedules are entirely funded by the national or subnational governments.
- ★ Current financial mechanisms for vaccine procurement seem to function well and in general, the countries surveyed are satisfied with their procurement process.
- ★ Most countries use annual (not long-term) budget planning cycles (mostly centralized)
- ★ Most countries report using price criteria, which may be a disincentive for manufacturers to participate in tenders and invest in R&D.
- ★ The majority of participants reported being favorable to joint procurement of vaccines during serious cross-border health threats caused by vaccine preventable diseases.
- ★ Other forms of cross-border collaboration (such as sharing vaccine price and other market information), and lending of vaccine doses in case of vaccine shortages have been used in EU, and should be encouraged.

3) Survey on procedures to estimate vaccine needs and procurement in EU: Main findings (1)

- ★ Few EU countries reported forecasting vaccine demand for at least 3-4 years; most countries use annual budget planning cycles (mostly centralised), while mid-term or long-term planning is seldom used.
- ★ Main strengths of current procurement systems identified are transparency, homogeneous and adequate prices and equal access to vaccine, even though sometimes procurement methods are characterised by bureaucracy and long tendering procedures
- ★ Most countries do not have written procedures for forecasting but use a combination of size of the target population and previous year consumption methods.
- ★ Not all countries reported using a template or any electronic tools to forecast vaccine demand; these can facilitate and speed up the estimation of vaccine needs even in the long term.



Survey on procedures to estimate vaccine needs and procurement in EU. Main findings (2)

- ★ Many countries report difficulties in estimating the numbers of individuals with chronic medical conditions for which specific vaccines may be indicated. There is a need to identify innovative tools for this.
- ★ Vaccine hesitancy is difficult to estimate when forecasting vaccine demand.
- ★ Vaccine wastage should be considered when forecasting vaccine needs and if not calculated correctly, there may be overestimation or underestimation of vaccine needs.
- ★ Many countries do not hold sufficient buffer stock and only few countries reported to consider the state of stockpile when forecasting vaccine needs.
- ★ Only three countries reported to interact with their country's NITAG during the forecasting process, prior to finalizing the number of vaccine doses needed per vaccine.



Conclusions

- A comprehensive view of vaccine shortages and stockouts experienced in EU/EEA, their impact on vaccines services, and their main causes, and the financial mechanisms used for procurement in the EU/EEA was missing.
- Public health strategies to assure a stable and adequate vaccine supply for immunization programmes are identified and recommendations given for preventing or mitigating vaccine shortages, including stakeholder views.
- Experiences/opinions of Member States on joint procurement of vaccines and other forms of cross-border collaboration, and identifying main strengths and weaknesses of current procurement and financial mechanisms serve as a basis for identifying ways to strengthen vaccine supply and cooperation between MS.
- Continued dialogue between manufacturers and health authorities, including NITAGs, is necessary for more accurate forecasting of vaccine needs.



Recommendations and future outlook (1)

- ★ More research is needed on the causes of vaccine shortages (including analysis of the economic and market-related causes) and on how the different causes interplay with each other.
- ★ There is a need for all countries to have an immunization supply chain improvement plan, defining strategies to assure a stable and adequate vaccine supply, and recommendations or procedures should be available regarding the use of alternative vaccine products or vaccination schedules in case of shortage.
- ★ Shortages of biological products deserve the same consideration as vaccine shortages
- ★ Timely communication between public health authorities, NITAGs, and manufacturers on expected shortages, upcoming changes to vaccine schedules or to targeted groups are essential
- ★ Procurement and tender mechanisms should be improved by taking into consideration multisource suppliers, other factors besides price, and the length of contracts. One of the requirements of a healthy market is that a range of suppliers be available; in order to achieve this requirement, price should not be the only criterion considered in vaccine tenders



Recommendations and future outlook (2)

- ★ Longer term planning of vaccine demand is strongly recommended. Long-term forecasts allow a more comprehensive view of future vaccine demand, reducing the negative impacts of demand uncertainty on price.
- ★ Continuous dialogue between manufacturers and health authorities, including NITAGs, is recommended.
- ★ Sufficient stockpiles of vaccines at national level need to be in place including an emergency stockpile, as well as a comprehensive national overview of vaccine demand and stocks.
- ★ Rapid exchange mechanisms between EU countries should be improved, by harmonised labelling and liability protection for parties involved in making the vaccine available.
- ★ Results of research carried out by WP 5, Task 5.2 and by WP8 should be used in synergy with results of WP6 to improve forecasting of vaccine needs and ensure vaccine supply and preparedness.





WP6 Team.

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Reinforcing mechanisms of management of vaccine supply

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



Background

- *Understanding important mechanisms to ensure sufficient size of supply and stockpiles, including their sustainability*
- *Explore possibilities, gaps and options for regional or European sharing of data on stockpiles on vaccine management*

Explore the feasibility to develop a concept for an EU data warehouse for sharing of vaccine supply and demand data among dedicated stakeholders

Survey - Directed towards EU-JAV partners and member states
Literature review – other organisations working with this topic

Two reports delivered:



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Work Package 6 – Task 6.2

Report on:

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

Grant Agreement No.:	801495
Start Date:	01/08/2018
End Date:	31/07/2021
Project title:	European Joint Action on Vaccination – EU-JAV
WP number:	WP6
Deliverable number:	D6.4/D6.5
Responsible partner No.:	14
Organization:	Folkehelseinstituttet
Name:	Karianne Johansen
E-mail address:	karianne.johansen@fi
Nature:	Report on possibilities
Report:	for regional or Europe stockpiles

Report prepared by
 Karianne Johansen, Knut Jensrud, Margret Ingeborg Aaberge, Norwegian Institute of I



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.:	801495
Start Date:	01/08/2018
End Date:	31/07/2021
Project title:	European Joint Action on Vaccination – EU-JAV
WP number:	WP6
Deliverable number:	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
Responsible partner No.:	14
Organization:	Folkehelseinstituttet (PH)
Name:	Karianne Johansen
E-mail address:	karianne.johansen@fhi.no
Nature:	Report on concept analysis for regional or European virtual stockpiles on vaccine management needs and stocks
Report:	Further exploring possibilities, gaps and options for building a "concept type" for regional or European virtual stockpiles



Exchange of vaccine stocks in case of need in supply

- Not a straightforward process - is indeed very complex
- To ensure vaccine deliverables in terms of need for rapid exchange there must be:
 - Political commitment
 - The member state must have in place proper mechanisms to accept vaccines and capacity
 - Regulatory approval, import approval, indemnification and liability agreements
- **These processes might seem like very detail management for some, but must be in place before legally binding purchase orders and transport arrangements can be made**



Main Results



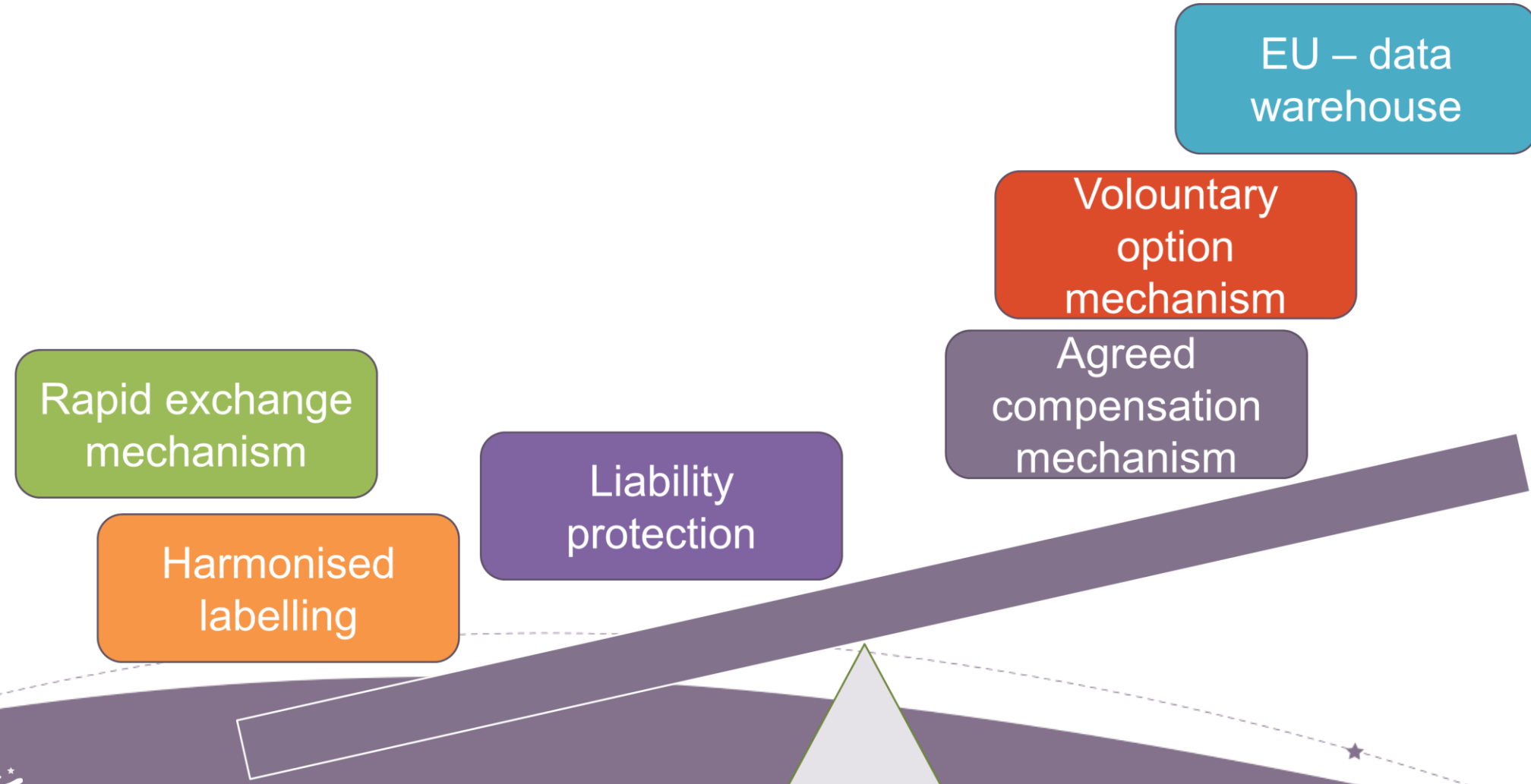
Key mechanisms to ensure sufficient supply for immunisation programs and preparedness in EU

- Early warning systems from suppliers and manufacturers of potential stockouts should be in place
- Sufficient stockpiles of vaccines at national level need to be in place - including an emergency stockpile
- A comprehensive national overview of vaccine demand and stocks

Key mechanisms to improve forecast of vaccine demand and manufacturing

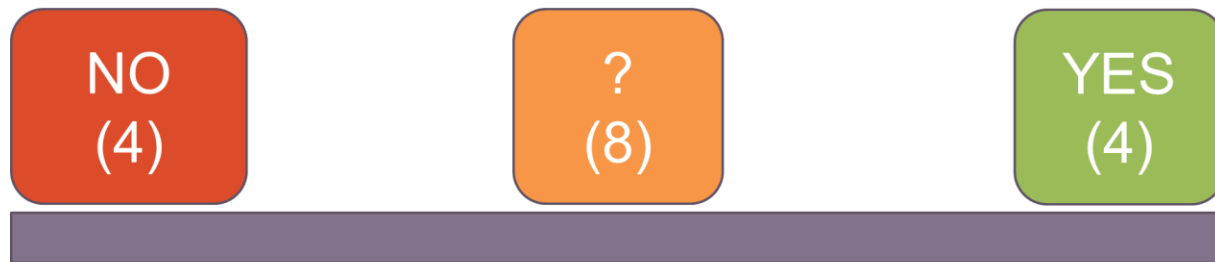
- Long term vaccine forecast from government agencies and procurers
- Timely input from government agencies and procurers on future demand related to potential changes in the national immunisation programs
- Harmonizing labelling of vaccines

Recommended mechanisms to better enable exchange of vaccines between the EU countries



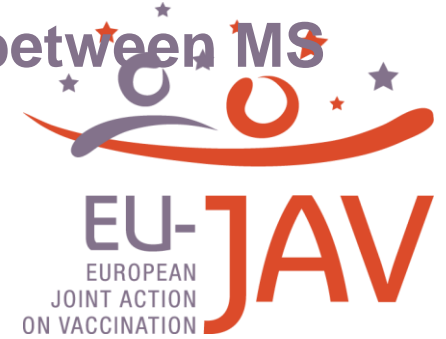
Will European sharing of data on vaccine supply and demand prevent shortages in EU?

- uncertainty about the need and options for an EU virtual data repository



Specific focus for priority	Listed examples
Rarely used immunoglobulins, antitoxins and vaccines	Botulinum antitoxin, diphtheria antitoxin, smallpox and rabies vaccines
Specific vaccines	BCG vaccines, Measles vaccines, Hepatitis B vaccines
Emerging infectious disease vaccines/Outbreak vaccines	Ebola vaccines, Ebola antivirals

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



Options reported prior to the covid-19 pandemic

- A. Voluntary sharing/Rapid Exchange Mechanism on available vaccines using (EWRS)
- B. Regional virtual stockpile
- C. Virtual EU Data warehouse

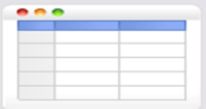


During 2019

- Ongoing discussions between the EU MS and the Health Security Committee on rapid exchange mechanisms for vaccines or MCM
- Development of functioning Standard Operating Procedures (SOPs) for a simple exchange mechanism and necessary templates
- The procedure would continue to be based on the EWRS, without seeking to collate information on existing stocks
- It was proposed that in order to implement SOPs these should first be tested by organizing an exercise through EWRS

Other discussions

- Early warning systems from suppliers and manufacturers of potential stockouts
- Discussions and tender to identify options for physical stockpiling of vaccines in the EU

Further work needed on options to enable exchange of vaccine demand and supply data

	Voluntary sharing/Rapid Exchange Mechanism* on available vaccines 	Regional virtual stockpile 	Virtual EU Data warehouse 
Functionality	<ul style="list-style-type: none"> ✓ Use of existing systems ✓ Voluntary mechanism ✓ SOP for ad hoc urgent exchange of vaccines ✓ Agreed templates 	<ul style="list-style-type: none"> ✓ Use of existing systems ✓ Voluntary mechanism ✓ SOP for ad hoc urgent exchange of vaccines ✓ Information on available stocks ✓ Collaboration agreement 	<ul style="list-style-type: none"> ✓ Need to develop platform for data sharing ✓ SOP for ad hoc urgent exchange of vaccines ✓ Information on available stocks – use of EWRS web? ✓ Data sharing mechanism
Scope	<ul style="list-style-type: none"> ✓ Rarely used vaccines and immunoglobulins ✓ Epidemic outbreak vaccines ✓ Surplus vaccines? 	<ul style="list-style-type: none"> ✓ Rarely used vaccines and immunoglobulins ✓ Epidemic outbreak vaccines ✓ Surplus vaccines? 	<ul style="list-style-type: none"> ✓ Rarely used vaccines and immunoglobulins ✓ Epidemic outbreak vaccines ✓ Surplus vaccines?
Implementation Risks	<ul style="list-style-type: none"> ✓ Legal ✓ Liability 	<ul style="list-style-type: none"> ✓ Legal ✓ Liability ✓ Information security 	<ul style="list-style-type: none"> ✓ Legal/GDPR ✓ Liability ✓ Information security

Conclusion – added value of this work

- A better understanding of important mechanisms to ensure sufficient size of supply and stockpiles, including their sustainability on an EU level was needed
- There was uncertainties of EU MS opinion on the need to share data on supply and demand data, and for which types of vaccines
- The analyses have identified future options that need further in-depth analysis to enable exchange of data on vaccines supply/demand between MS
- Vaccines to be used during an epidemic outbreak and vaccines for emerging infectious diseases were identified as the most important focus area for a future EU virtual data repository



Limitations

- The survey and the results reported were performed prior to the COVID-19 pandemic
- preparedness response and EU vaccine strategy during an emergency has been changed



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Recommendation and future outlook (1)

- Further work on sharing data/information of vaccine supply and demand among dedicated stakeholders should include several options:
 - not having a data warehouse (status quo)
 - different aspects of voluntary sharing of specific vaccines with the use of a rapid exchange mechanism on available vaccines between EU MS
- Member states should explore improvements of more concrete tools
 - like “EU-harmonised labelling of vaccines”
 - “standard operating procedure to enable the ad hoc urgent exchange of vaccines”
- Stronger national response to vaccination challenges regarding vaccine supply management should be supported



Recommendation and future outlook (2)

- The common procurement of COVID-19 vaccines has additionally provided the EU MS with experience in sharing mechanisms for surplus vaccines during an emergency
 - Donations of surplus COVID-19 vaccines
 - Global sharing mechanisms - global collaboration COVAX
 - Mechanisms and procedures for bilateral donations

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



WP6.2 Team

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