



Networking among countries: sharing for building

ProVacMed Project
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Principle of subsidiarity

- Vaccination policy is a competence of the Member States
- The Commission supports Member States to complement national vaccination policies



Decision 1082/2013/EU on serious cross-border threats to health

- ▶ To strengthen preparedness planning.
- ▶ To improve risk assessment and management of cross-border health threats.
- ▶ To establish the necessary arrangements for the development and implementation of a joint procurement of medical countermeasures.
- ▶ To enhance the coordination of response at EU level by providing a solid legal mandate to the Health Security Committee.




Health Security Committee

- ▶ Enables EU governments to exchange information and evaluate health events.
- ▶ Functions as a discussion forum that advises health ministers.
- ▶ Facilitates coordinated crisis response by EU governments.



"Soft law" on vaccination

- ▶ Council Recommendation on seasonal influenza vaccination (2009)
- ▶ Council conclusions on childhood immunisation (2011)
- ▶ Council conclusions on vaccinations as an effective tool in public health (2014)



High level hearing on seasonal influenza, April 2015

- To contribute to comprehensive understanding of the impact and benefits of vaccination
- To share best practices in implementing seasonal influenza vaccination programmes
- To identify measures to increase seasonal influenza vaccination coverage rates



Vaccine shortages: Improving cooperation, communication and management

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Vaccine shortages

- Problems related to shortage of a-cellular pertussis containing vaccines.
- Difficult situation related to available quantities of Bacillus Calmette-Guérin (BCG) vaccine against Tuberculosis.
- Commission and Member States discussed options for policy interventions and actions to address current vaccine shortages.

Possible policy interventions

- ▶ Flexible handling of immunisation calendars
- ▶ Mutual assistance
- ▶ Regulatory clarifications
- ▶ Forecasting/predictability of vaccine demand
- ▶ Priority setting of vaccine development
- ▶ Management of vaccine procurements
- ▶ Communication /Dialogue with industry and other stakeholders



Possible way forward

- To continue work on vaccine shortages
- To establish dialogue with stakeholders
- To prepare a joint action on vaccination
- To support collaboration of national immunisation advisory groups

Change to vaccination policy to respond to shortages = Flexible handling of immunisation calendars

Key considerations:

- Preservation of infant primary immunisation schedule and of those in contact with the most vulnerable
- Prefer the use of alternative vaccines rather than a change to vaccination policy
- ▶ In some EU countries, sudden changes were driven solely by shortage (e.g. reduction in number of doses given, change in vaccine formulation):
 - Should be part of informed / evidence-based decision.
 - Need to address the impact on a full cohort, the requirements for follow-up, the appropriate information to professionals and the public etc...
- ▶ Risk-assessments prepared by ECDC discussed potential impact of changes and mitigation measures



Mutual assistance

Standard Operating Procedures (SOPs) to exchange medical countermeasures, including vaccines, in case of shortages or an emergency.

- ▶ To expand vaccine supply options for EU MS.
- ▶ Voluntary mechanism to request, receive and distribute medical countermeasures.
- ▶ Addressing operational and regulatory aspects.
- ▶ Involving ECDC, EMA, national regulatory agencies.



Regulatory clarifications

Exploring possibilities

- To accelerate scientific assessment and decision making process
- To operationalize provisions to impose the obligation of continuous supply
- To ensure that marketing authorisation holders investigate methods to strengthen their supply chain
- To strengthen the use of the Rapid Alert Notification System to inform about any notification of interruption of supply or quality defect



Vaccine demand forecasting

Exploring possibilities

- To define basic principles of vaccine demand forecasting
 - Benefits for all stakeholders involved
 - Investment in demand forecasting
 - Research on the use of electronic health records
 - Establishment of central repository of vaccine supply and demand data



Vaccine R&D priority setting

Exploring possibilities

- To identify common stages and criteria for prioritization of vaccine research and development
 - Use of "established priority setting tools"
 - Evidence-based AND consensus-based
 - Disease-based AND gaps-related
 - Priority setting as a political process
 - Priority setting framework



Management of vaccine procurements

- To review national procurement objectives, procedures and requirements in order to identify potential areas for improvement.
- To continue exploring the possibility to use the Joint Procurement Agreement in order to support countries which have not received offers to their tenders.
 - Examination of possibilities to organize joint procurements for BCG vaccines & Tuberculin, for antitoxin against Diphtheria, for antitoxin against Botulinum and for Hepatitis C treatments



Communication/stakeholder dialogue

To agree on topics, format and setting of stakeholder dialogue

- ▶ Dialogue between regulatory and public health authorities
- ▶ Dialogue with civil society and industry
- ▶ Linkage of research and public health agenda



EpiSouth

Network for the Control of Public Health Threats
in the Mediterranean Region and South East Europe

- **Networking of institutions**
- Training in field/applied epidemiology
- Cross border epidemic intelligence
- Epidemiology and preparedness to cross border emerging zoonosis
- **Vaccine-preventable diseases and migrant population**
 - assessing the **access to immunization** and **exchanging information** on cases/outbreaks of vaccine-preventable diseases of migrant populations,
 - **Collect data and exchange information** on cases/outbreaks
 - Provide an **overview of existing programmes** for monitoring and improvement of immunization coverage of migrant populations,
 - To formulate **recommendations facilitating the evaluation and improvement of immunization activities** among migrant populations and immigrants in the EpiSouth region



- Collecting, sharing and disseminating information on national immunization programmes through a network of professionals
- Providing information useful to build up methodologies
- Provide guidance for improving the overall performance of the immunization systems in the EU/EEA Member States.
- http://venice.cineca.org/project_outputs.html



Some links for further information

► DG SANTE pages

- http://ec.europa.eu/health/vaccination/policy/index_en.htm
- http://ec.europa.eu/health/vaccination/events/ev_20121016_en.htm

► DG RESEARCH & INNOVATION pages

- <http://ec.europa.eu/research/health/index.cfm?pg=projects>
- <http://ec.europa.eu/research/health/index.cfm?pg=area&areaname=emerging>
- http://cordis.europa.eu/search/result_en?q='vaccine'&p=1&num=10&srt=Relevance:decreasing

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