



Vaccine shortages: Improving cooperation, communication and management

Michael Sulzner

**Public Health Directorate
DG Health & Food Safety
13 April 2016, Geneva**

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.

Council conclusions on vaccination as an effective tool in public health (2014)

Invite the Commission to **identify and encourage synergy between** the promotion of **immunisation and** the implementation of **relevant EU legislation and policies**, in particular **focusing on** the identification and development of integrative and coherent approaches for **better preparedness and coordination in health emergencies**, while fully respecting national competences

Vaccine shortages - possible policy interventions

- Flexible handling of immunisation calendars
- Mutual assistance
- Regulatory clarifications
- Vaccine demand forecasting
- Vaccine R&D priority setting
- Management of vaccine procurements
- Communication/stakeholder dialogue

Change to vaccination policy to respond to shortages - Pertussis vaccine, EU 2015

- 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

Thank you for your attention



Commission web page on vaccination:

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

Conference web page:

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