Dealing with vaccine shortages: current situation and ongoing activities

Impact of shortages and solutions set up by countries

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Presentation outline

- Access to quality vaccine supply & GVAP/EVAP objectives
- Vaccine supply disruptions: Geography and products
- Vaccine supply disruptions: Problems, country response & impact
- WHO response & Member States’ expectations
- Managing vaccine supply challenges: The way forward
Is access to quality vaccine supply assured?

Apparently, trend in the right direction

Baseline

Total no. of countries reporting a stockout


20 18 12

Target: 2/3 reduction from baseline

Meeting of the Strategic Advisory Group of Experts on Immunization (SAGE)
Geneva, Switzerland, 12-14 April 2016
2015 Vaccine supply disruptions: reports in Europe & worldwide

SUBJECT: REQUEST FOR AID TO GET VACCINES FOR LITHUANIAN NATIONAL IMMUNISATION PROGRAMME

Dear Ms Jakab,

The Ministry of Health of the Republic of Lithuania would like to inform you that our country is facing shortage of BCG (tuberculosis) and Diphtheria, Tetanus Pertussis (acellular), Poliomyelitis, Haemophilus influenza type B vaccine (DTaP-IPV-Hib) because of difficulties in receiving the planned shipments.
Access to quality vaccine supply: Known problems & new challenges

THE SAGE RECOMMENDS THAT:

- Technical agencies conduct urgent assessments of (i) the extent to which the reported national-level stockouts are affecting local vaccine supply and delivery, and (ii) the root causes of these stockouts.


FIVE PRIORITY PROBLEMS

The Global Vaccine Action Plan is far off track. In response, the SAGE recommends that actions focus particularly on addressing five priority problems. Each problem is major, but each can be tackled, with a reasonable expectation that doing so will improve progress considerably.

- Weak GVAP implementation
- Poor data quality and use
- Vaccine affordability and supply
- Failures of basic integration
- Situations disrupting immunization

New challenges in 2015

- Stagnant vaccination coverage
- Eradication and elimination goals repeatedly missed
<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Countries Impacted</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yellow fever</td>
<td>28</td>
<td>28 countries impacted. Enough to cover just 40% of regional demand.</td>
</tr>
<tr>
<td>IPV</td>
<td>33</td>
<td>33 countries impacted. High risk of stock-outs – May 2016.</td>
</tr>
<tr>
<td>DPT</td>
<td>29</td>
<td>29 countries impacted. High risk of stock-outs.</td>
</tr>
<tr>
<td>aP-containing</td>
<td>5</td>
<td>5 countries impacted. High risk of stock-outs.</td>
</tr>
<tr>
<td>vaccines</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Supply shortage questionnaire (Sept)
- Responding MS -33
- Vaccine shortages - 22

+ Others known.... (min 6MS)

+ ETAGE (1 Oct-2015)
  - “Continuing efforts should be made to strengthen capacity for vaccine supply planning and procurement in the Region, and all countries should be encouraged to review their vaccine supply interruption contingency plans”.

Vaccine supply disruptions in
28 / 53 Member States

Source: WHO Europe supply shortage survey, Sep 2015
WHO European Region: Vaccine supply disruptions, products involved, 2015

- Various products (17)
- Supply shortages:
  - 1 product – 6 countries
  - 2 or more products – 16 countries
- No. of countries in short supply of:
  - pertussis-containing products – 18
  - BCG – 13
- Shortages of pertussis-containing products – 29
  - Incl. wP – 5
  - Incl. aP – 24
  - primary immunization – 12
  - booster – 17

Source: WHO Europe supply shortage survey, Sep 2015
### WHO European Region: Vaccine supply disruptions – problems & response

<table>
<thead>
<tr>
<th>Problems</th>
<th>Country response</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BCG shortages</strong></td>
<td><strong>REACTIVE</strong></td>
</tr>
<tr>
<td>✦ BCG SSI vaccine production</td>
<td>✦ Suspended immunization for 1–4 mos (HUN, IRE, LTU)</td>
</tr>
<tr>
<td>✦ Regulatory barriers</td>
<td>✦ Identified alternative suppliers</td>
</tr>
<tr>
<td><strong>aP-containing vaccines</strong></td>
<td>✦ Addressed regulatory barriers</td>
</tr>
<tr>
<td>✦ Problems started in 2014</td>
<td>✦ Mutual support (BUL/TUR, CRO/NOR)</td>
</tr>
<tr>
<td>✦ Lack of tender offers/contracts</td>
<td>✦ Switched to new products (penta &gt; hexa &gt; tetra)</td>
</tr>
<tr>
<td>(CRO, ESP, FRA, BUL, PRT)</td>
<td>✦ Modified the schedule (HUN, BUL, ROM, FRA)</td>
</tr>
<tr>
<td>✦ 1–8 months delays</td>
<td>✦ Used products off-label (low antigen level)</td>
</tr>
<tr>
<td>✦ Fractioned supply</td>
<td></td>
</tr>
<tr>
<td>✦ Regulatory barriers (BUL)</td>
<td></td>
</tr>
<tr>
<td><strong>PROACTIVE</strong></td>
<td></td>
</tr>
<tr>
<td>✦ Risk assessment &amp; response options (ECDC/EC HSC)</td>
<td></td>
</tr>
<tr>
<td>✦ Vaccine supply security strategy (FRA)</td>
<td></td>
</tr>
<tr>
<td>✦ Procurement procedure changed (CRO, LTU)</td>
<td></td>
</tr>
</tbody>
</table>

Source: WHO Europe supply shortage survey, Sep 2015
Vaccine supply disruptions impact: country cases

IRELAND
- BCG vaccination stopped in May 2015 – NOT resumed yet

SPAIN (dTap)
- Pregnant women immunization prioritized
  - Booster dose (6y) stopped in May 2015 – coverage – 63%
  - Further shortages expected

BELGIUM
- IPV shortage – vaccination for asylum seekers affected

BULGARIA
- DTPa-IPV-HIB-HepB
  - Introduced in Sept. 2014 due to pentavalent shortages; no tender offers in 2015
  - Booster tetravalent (DTaP-IPV) & donated pentavalent (TUR) used for primary vaccination during 2014-2015
  - DTPa-IPV-HIB (4d) - stopped in March 2015, coverage – 60%
  - DTPa-IPV (6y) – coverage 2014–62%; 2015–49%

Source: WHO Europe supply shortage survey, Sep 2015 & Follow up in March 2016
WHO advice to Member States

- Optimize use of current stocks:
  - Reduce wastage (BCG)
  - Prioritize doses to primary immunization (P containing)
- Review and expand vaccine supply options:
  - Improve communication with vaccine manufacturers
  - Seek mutual assistance opportunities;
  - Review regulatory / programmatic considerations to expand supplier base –i.e. access to WHO PQ vaccines
- Increase the country purchasing power:
  - Multi-year vaccine forecasting, financing and procurement;
  - Use joint procurement mechanisms (i.e. EU JPA, UNICEF SD)
- Adopt supply risk mitigation strategies:
  - Streamline procurement procedures;
  - Establish, maintain and monitor safety vaccine stocks;
  - Have a plan B (for aP -containing products);
  - Communicate to health workers, communities, media
Q. What type of support do you expect from WHO or other international partners in regard to this problem?

- Increasing visibility of demand and supply
- Updated information on current and expected shortages
- Advanced notification to allow taking preventive actions
- List of alternative products / suppliers
- Encourage manufacturers to expand supply capacity to meet the demand
- Expanding list of WHO prequalified vaccines;
- Addressing regulatory barriers

* Source: WHO Europe supply shortage survey, Sep 2015
Responding to country expectations: Business as usual vs Strategic Risk Management

Global challenges

- Increasing vulnerability
  - Global supply chains
  - Limited supplier base
- Asymmetry
  - Long-term policy vs short-term supply
  - Global challenges vs local response
- Fragmented information
  - Global supply & global demand
- Lack of global mechanisms
  - To identify supply risks
  - To manage risks

The way forward

- Paradigm change
  - Global solutions to address global challenges
  - Strategic supply management vs transactions
- Risk management ESSENTIALS
  - Identification & assessment & management
- Systemic approach
  - Articulated policy & strategies
  - Monitoring & early-warning systems
- Commitment & collaboration
  - WHO, Member States, regional institutions, partners & industry
Thank you!