



Dealing with vaccine shortages: current situation and ongoing activities

Impact of shortages and solutions set up by countries



**World Health
Organization**

REGIONAL OFFICE FOR

Europe



**Organisation
mondiale de la Santé**

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**Всемирная организация
здравоохранения**

Европейское региональное бюро

Dr Oleg Benes

**Vaccine-preventable Diseases and Immunization
VPI/DCE**

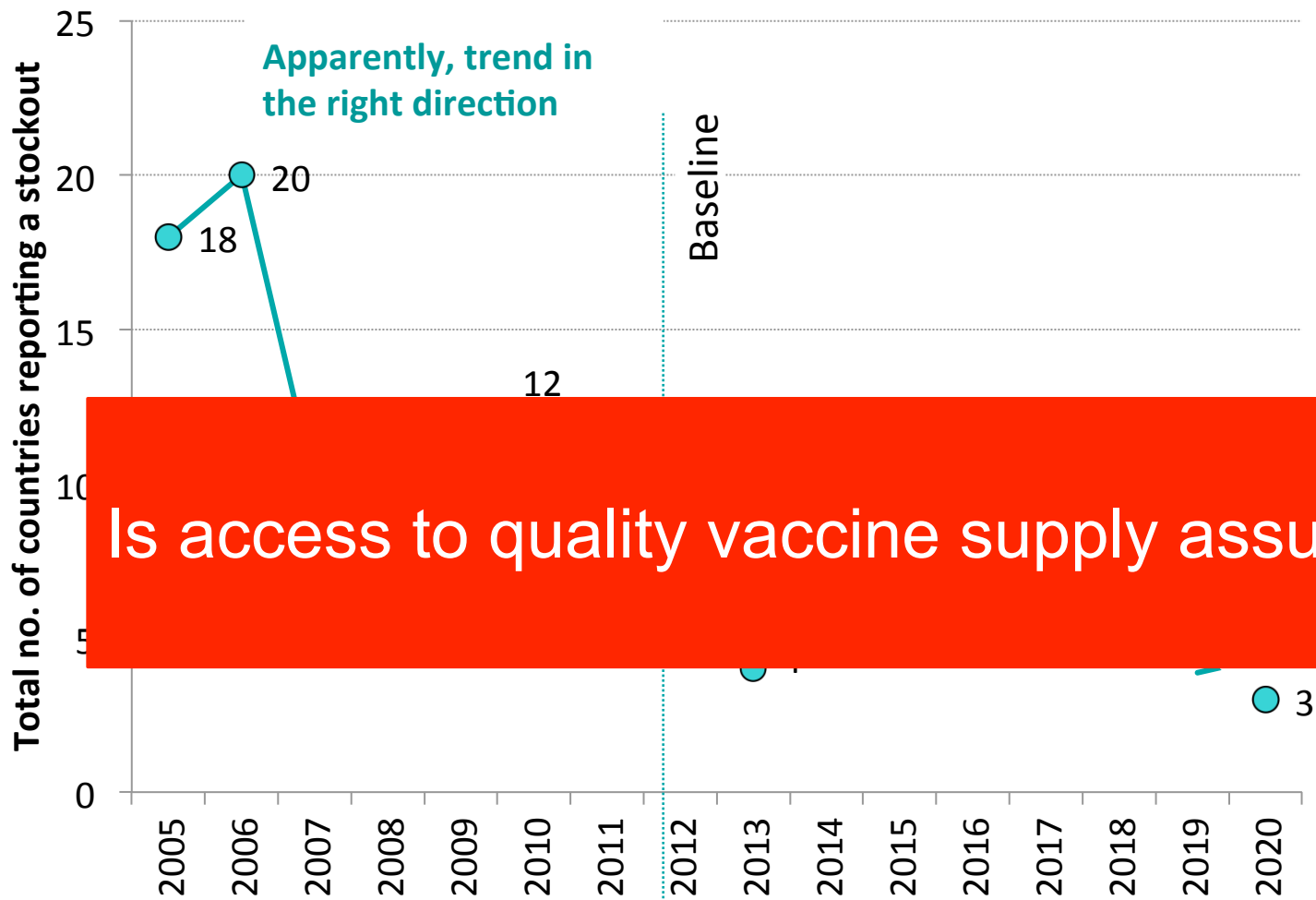
**World Health Organization
Regional Office for Europe**

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

GVAP/EVAP: Monitoring access to vaccine supply

Vaccine stock outs in EURO Member States



Target:
2/3 reduction
from baseline

2015 Vaccine supply disruptions: reports in Europe & worldwide

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La Suisse manque de certains vaccins importants

Santé Pour la première fois, une pénurie de vaccins combinés de base sévit en Suisse. Ces produits sont souvent destinés aux bébés pour leur première vaccination.

Mots-clés
Office fédéral de la santé publique
GlaxoSmithKline (GSK)

Avec la Tribune de Genève en numérique

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Canadian company offers help for Irish BCG vaccine shortage

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Updated: August 06 2015 08:49:00

Shortage of 6-in-1 vaccine leaves children vulnerable

BangaloreMirror
News Aug 20 2015 08:50:00 AM BANGALORE MIRROR / ANNEKADABALI BANGALORE / PUNE MIRROR

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Babies hurting as shortage hits painless DPTP vaccines

By Vandana Kanath, Bangalore Mirror Bureau Jun 22, 2015, 04:00 AM IST

Indian Academy of Paediatricians asks doctors to counsel parents to accept the more painful vaccine's after-effects, which it says are 'common'

Vaccination schedules will be more painful - although with a higher guarantee of immunity - for your new-born now. A severe shortage of the painless and reactionless combination vaccine Pentaxim has led to parents having to settle for the older whole-cell vaccine, which the Indian Academy of Paediatricians (IAP) says provides better immunity although more painful with more severe

A medical worker vaccinates a girl at the Kir Province. The country will face a shortage of Photo Pham Minh Tuan

HA NOI (VNS) — Six-in-one vaccines are until next year, Ministry of Health's Previ Phu said on Tuesday.

france bleu

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Recommander 70 Twitter 10 Partager Ajouter aux favoris

par France Bleu 107.1, Martine Brisson

Il y a pénurie de vaccins en Ile-de-France

Lundi 27 juillet 2015 à 05h30

Certains vaccins sont pré obligatoires pour les enfants. Des parents commencent à s'inquiéter.

Acute BCG vaccine shortage: Denying newborns precious gift of life

ASIF CHAUDHRY - UPDATED JUN 03, 2015 08:20AM

Twitter 6 COMMENTS EMAIL PRINT

Independent Balkan News Agency
Balkan News in English

Turkey to donate 100 000 vaccines to Bulgaria

By Clive Lewis/Agence of The Sofia Globe

Turkey is to donate 100 000 vaccines to Bulgaria to enable the country to R&D its child immunisation calendar to the end of the year. Balkan Health Minister Peter Mladenov said.

India, June 18, 2015/ Independent Balkan News Agency

By Clive Lewis/Agence of The Sofia Globe

Turkey is to donate 100 000 vaccines to Bulgaria to enable the country to R&D its child immunisation calendar to the end of the year. Balkan Health Minister Peter Mladenov said.

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.

VOA Voice of America
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News / Health

Africa Faces Acute Shortage of Meningitis C Vaccines

By Press Share

FILE - A child receives a meningitis vaccination at the community center in Al team camp for Internally Displaced People in Si-Dawin, East Darfur, Oct. 6, 2012.



FILE - A child receives a meningitis vaccination at the community center in Al team camp for Internally Displaced People in Si-Dawin, East Darfur, Oct. 6, 2012.

Access to quality vaccine supply: Known problems & new challenges

2014 ASSESSMENT REPORT OF THE GLOBAL VACCINE ACTION PLAN

STRATEGIC
ADVISORY
GROUP OF
EXPERTS ON
IMMUNIZATION



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.

Source: 2014 Assessment Report of the Global vaccine Action plan

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

Stagnant
vaccination
coverage

Eradication
and elimination
goals repeatedly
missed

New challenges
in 2015



Challenges in the Americas

Ensuring timely and sufficient vaccine supply



Insufficient supply

Yellow fever

- **28** countries impacted
- Enough to cover just 40% of regional demand

IPV

- **33** countries impacted
- **High** risk of stock-outs – May 2016



Late availability

DPT

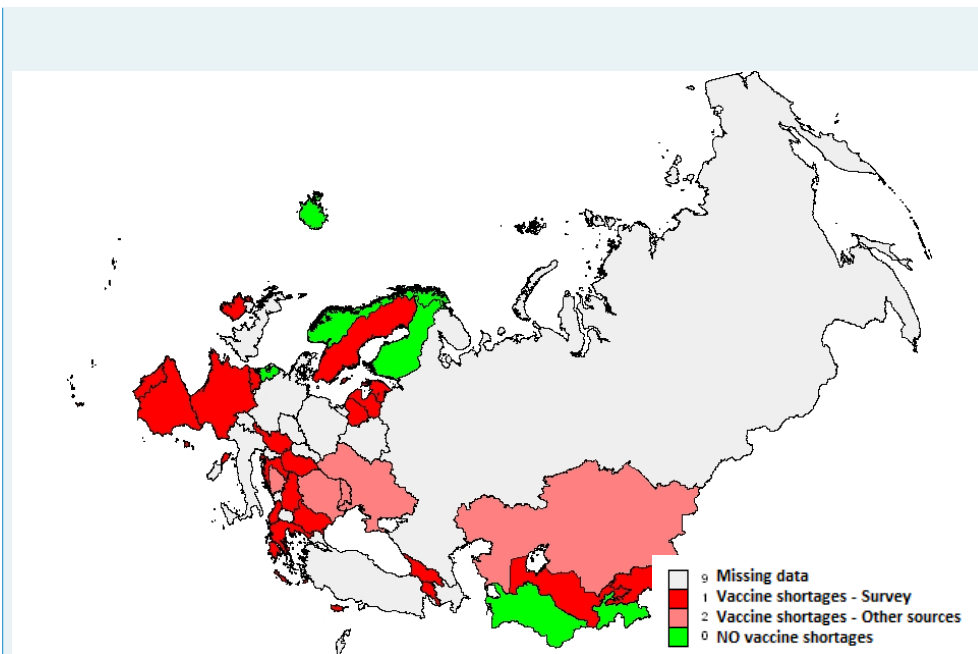
- **29** countries impacted
- Used as booster dose
- DPT components allocated by manufacturers for Penta production

aP-containing vaccines

- **5** countries impacted
- Sole source with production problems
- Stock-outs in 2015

WHO European Region: Vaccine supply disruptions – 2015

- ✦ 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”.



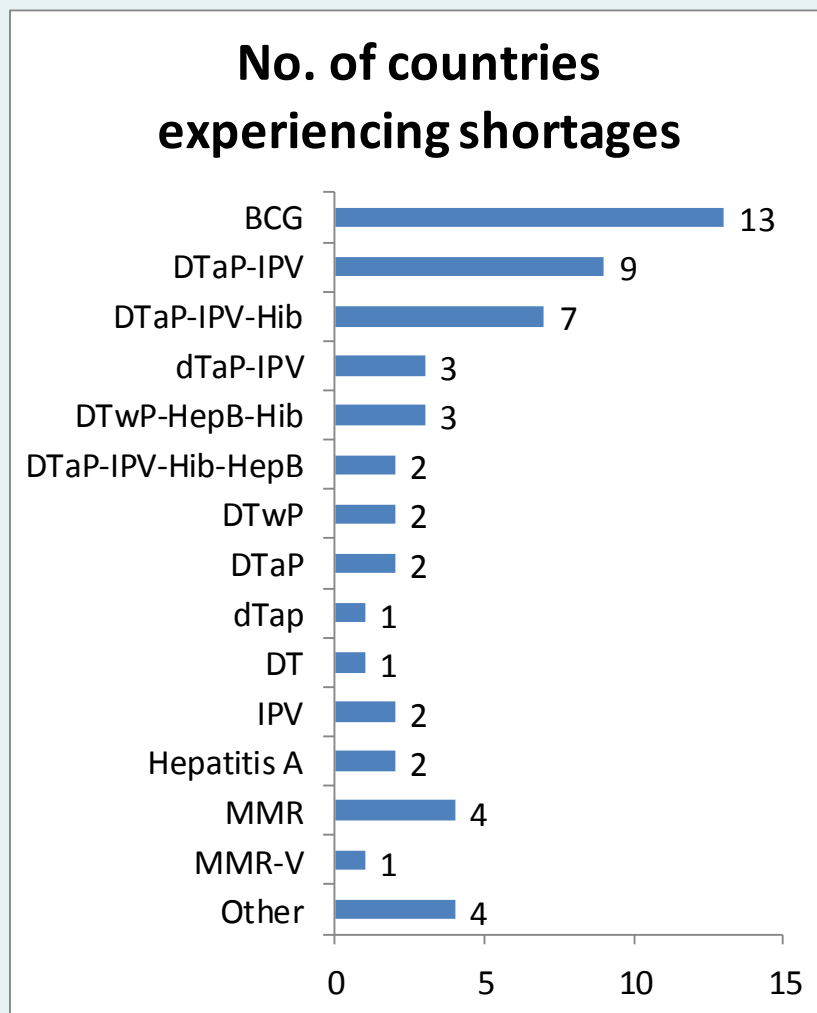
**Vaccine supply disruptions in
28 / 53 Member States**

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

Problems

BCG shortages

- ✦ BCG SSI vaccine production
- ✦ Regulatory barriers

aP-containing vaccines

- ✦ Problems started in 2014
- ✦ Lack of tender offers/contracts (CRO, ESP, FRA, BUL, PRT)
- ✦ 1–8 months delays
- ✦ Fractioned supply
- ✦ Regulatory barriers (BUL)

Country response

REACTIVE

- ✦ Suspended immunization for 1–4 mos (HUN, IRE, LTU)
- ✦ Identified alternative suppliers
- ✦ Addressed regulatory barriers
- ✦ Mutual support (BUL/TUR, CRO/NOR)
- ✦ Switched to new products (penta > hexa > tetra)
- ✦ Modified the schedule (HUN, BUL, ROM, FRA)
- ✦ Used products off-label (low antigen level)

PROACTIVE

- ✦ Risk assessment & response options (ECDC/EC HSC)
- ✦ Vaccine supply security strategy (FRA)
- ✦ Procurement procedure changed (CRO, LTU)

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

Guidance on how to prioritize globally constrained BCG vaccine supply to countries

produced by WHO Dept. of Immunizations, Vaccines and Biologicals, the WHO Global Tuberculosis Programme and UNICEF Supply and Programme Divisions
22 July 2015

Context

Over the past three years, there has been a decline in global availability of BCG vaccine. At the same time, demand from 70 countries traditionally procuring through one procurement agency, UNICEF Supply



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ORGANISATION MONDIALE DE LA SANTÉ
WELTGESUNDHEITSORGANISATION
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Date: 17 April 2015

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Our reference: Let to MoH/ Vaccine supply (10.2.3.4-40)
Notre référence: /OBN 10-3503
Unsere Zeichen: Ihre Zeichen:
CM. HSH: Ho BSH:
HOMSP: HOMSP:

Dear Madam,

Vaccine supply disruptions in Lithuania

The WHO Regional Office for Europe appreciates receiving the request for supporting the Lithuanian immunization programme and shares the concerns of the Ministry of Health of Lithuania in regard to supply status of BCG (tuberculosis) vaccine and combined diphtheria, tetanus toxoids, acellular pertussis, Haemophilus influenzae type b and inactivated poliovirus (DTaP-Hib-IPV) vaccine.

Contributions to EC HSC meeting

PMM discussion

ETAGE discussion

Sub-regional workshop on vaccine procurement (Dec)

Member States expectations from WHO (*):

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!