

Tbilisi Vaccine Procurement Workshop:
April 10-April 12, 2019

Securing access to affordable vaccine supply:
Joint vaccine procurement experience in EURO Region:
The progress made & the way forward



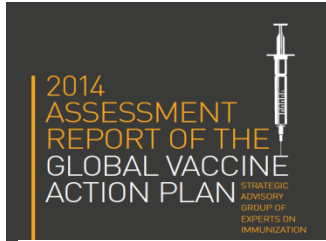
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Presentation outline

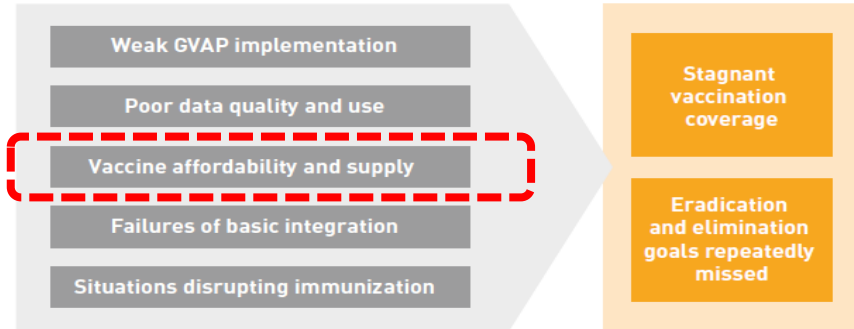
- Access to affordable vaccine supply: the Global call
- Vaccine market & procurement performance in SEEHN
- Procurement success Drivers: Strategic approach
- Joint cross-border procurement: Baltics States experience
- The (proposed) way forward

Access to affordable vaccine supply: Essential to reaching immunization goals



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.



REGIONAL OFFICE FOR Europe

BUREAU REGIONAL DE L' Europe



Weltgesundheitsorganisation
REGIONALBÜRO FÜR Europa



Всемирная организация
здравоохранения
Европейское региональное бюро



World Health Assembly, *URGES Member States*

Resolution 68.16.4 (2015): *to increase affordability ... by pooling vaccine procurement volumes... through transparency by providing vaccine price data to WHO for publication....*

Resolution 69.25 (2016)
to develop strategies to forecast, avert or reduce shortages/stockouts ...

Working strategically to secure affordable supply

During the last two decades public procurement has evolved from a clerical signoff-ridden set of activities to a strategic tool **to enhance efficiency** in public organizations, **to regulate markets** and **promote sustainable development** (OECD)

Goal: Aligning supply to reach health objectives

SECURING SUPPLY

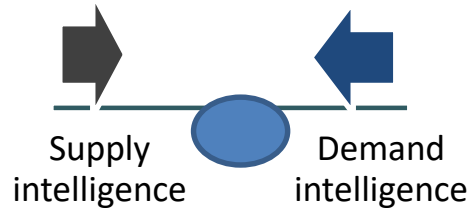
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R&D support
Manufacturing guidelines
Production capacity
Technology transfer
Prequalification (PQ)
Producing country NRAs

3

COMMUNICATION

Risk notification & information exchange



2

PREDICTABLE DEMAND

Policy setting: EVAP/NIP
Decision making: TAGs
Long term planning: сМYP
Forecasting: Multi-year
Budgeting: Annual/MTF
Procurement: Efficiency/Effectiveness
Regulatory frameworks: PQ/MR
V3P - Transparency

Voluntary cross-border joint procurements of vaccines in Baltic countries: Estonia, Latvia and Lithuania

Political framework: Inter-parliamentary and intergovernmental co-operations on the initiative

- The Baltic Assembly
- The Baltic Council of Ministers (*Task Force for Health Affairs*).
- Accountability mechanisms (*once a year- reporting results to the Baltic Assembly*)

The Partnership Agreement

- 2nd May 2012: Signing the Partnership Agreement on Joint Procurements of Medicinal Products and Medical Devices and Lending of Medicinal Products and Medical Devices Procured Centrally.
- The end of 2012: final approval of the annexes (including lending agreement to prevent and manage shortages of the medicines in all Baltic States)

The purpose:

„...to facilitate joint procurements of medicinal products and medical devices with the overall aim to reduce the expenditure of the State, as well as to ensure the continuity of the access to the medicinal products and medical devices procured centrally.“

Implementation of the Partnership Agreement: Structures & Operation

The Working Group:

- Members from each country (expert level)
- Identify the Needs / Products to perform a specific joint procurement
- agree on the Lead Partner –
- ✓ application of the procurement procedure
- ✓ development of the procurement documentation
- ✓ co-ordination with other Partners
- ✓ invitation to other Partners to submit a Delegation Letter for the relevant procurement
- ✓ establishment of the Procurement Commission for application of the procurement procedure

Baltics states joint procurement: Lessons learned

Topic	Initial approach	Final solution
Procurement commission	Representatives from all participating countries	One lead partner
Lead time for the 1 st procurement	6 months	Min 9 months
MA Requirements	Valid MA in all 3 Baltic states	Possible alternative options
Market research	In advance	Before procurement announcement
Information exchange between WG members	Meetings	E-mail
Official language of the tender	Two languages (national & Eng)	English
Terminology of tender documents		EU Public Procurement Directives
Incoterms	Central store/In-country transport	Central store
Evaluation criteria	Price	Economic efficiency (Price & Content)

Joint procurement for vaccines 2015-2018

Procurement target:	Estonia	Latvia	Lithuania
1) BCG vaccine (2015)	X	X	X
2) Rotavirus vaccine (2016)	X	X	Not in the immunization schedule
3) Pneumococcal vaccine (2017)	Not in the immunization schedule	X	X
4) Rotavirus vaccine; hexavalent vaccine (2018)	X	X	RV- first introduction in 2018, time-line mismatch Hexavalent- not in the immunization schedule

Rotavirus vaccine;

hexavalent vaccine (2018)

Topic	BCG vaccine (2015)	Rotavirus vaccine (2016)	Pneumococcal vaccine (2017)	Rotavirus vaccine; hexavalent vaccine (2018)
Partners	Latvia, Lithuania, Estonia	Estonia and Latvia	Latvia and Lithuania	Estonia and Latvia
Lead partner	All 3 Baltic countries in the procurement commission	Estonia	Lithuania	Estonia
Procedure	Open	Open	Open	Open
Evaluation criteria	Lowest price per one dose	Lowest price per one vaccination course	MEAT (85% price/ 15% quality: number of serotypes)	Lowest price per one dose (hexavalent), lowest price per one vaccination course (rotavirus)
Results	No tenders were submitted, procurement terminated	Price reduction 25% (Estonia), less than 10% (Latvia)	Price reduction 15%	Price reduction 20% (hexavalent); price increase 23% (rotavirus, still 9% cheaper than 2015 price)

Next steps: JTA assessment

	Estonia	Latvia	Lithuania
HPV vaccine	Quality- 67%, price- 33% (CEA, QALY-s based on their effectiveness against different types of cancers, also genital warts (not only cervical cancer!). Merit-point system)	Lowest price	Quality- 15%, price- 85% (based on the number of serotypes. Merit-point system)

Vaccine market in SEE countries: Opportunities & Challenges

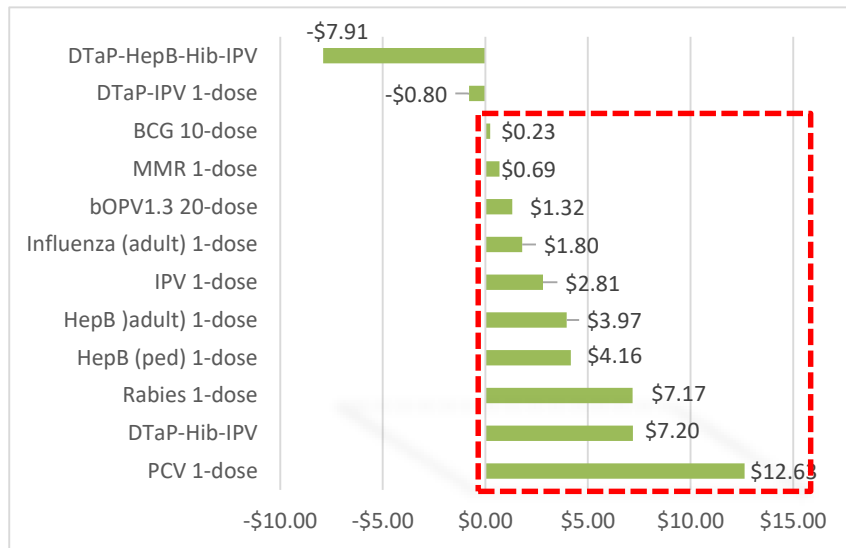
- **Small market size (by volume):**
 - < 4% Euro; 0.24% Global
- **Low Predictability:**
 - Exclusive 1-year contracts in 5/9 countries
- **Fragmented demand:**
 - 11/18 Products used by 4 countries or less (i.e. most are new and expensive vaccines)
- **Limited competition:**
 - Restricted supplier base
 - Products from >10 manufacturers not procured by SEE countries
- **Diverse procurement mechanisms:**
 - Self-procurement
 - Pooled procurement (UNICEF SD; EU JPA)

Vaccines by Country	ALB	BIH	BUL	CRO	MKD	MDA	MNE	ROM	SRB	Total
BCG	X	X	X	X	X	X	X	X	X	9
MMR	X	X	X	X	X	X	X	X	X	9
Td	X	X	X	X	X	X	X	X	X	9
HepB (ped)	X	X	X	X	X	X	X	X	X	9
OPV	X	X			X	X	X		X	6
DT	X	X				X	X		X	5
DTaP-Hib-IPV*		X	X		X		X		X	5
DTwP	X	X			X	X				4
DTaP-Hib-HepB-IPV*			X	X	X			X		4
DTaP-IPV*		X	X				X	X		4
HPV*				X	X	X				3
PCV*	X		X			X				3
TT		X		X	X					3
DTwP-Hib-HepB*	X					X				2
Hib		X					X			2
IPV*	X			X						2
DTaP*				X						1
Rota*						X				1
Total	10	11	8	9	10	11	9	6	7	

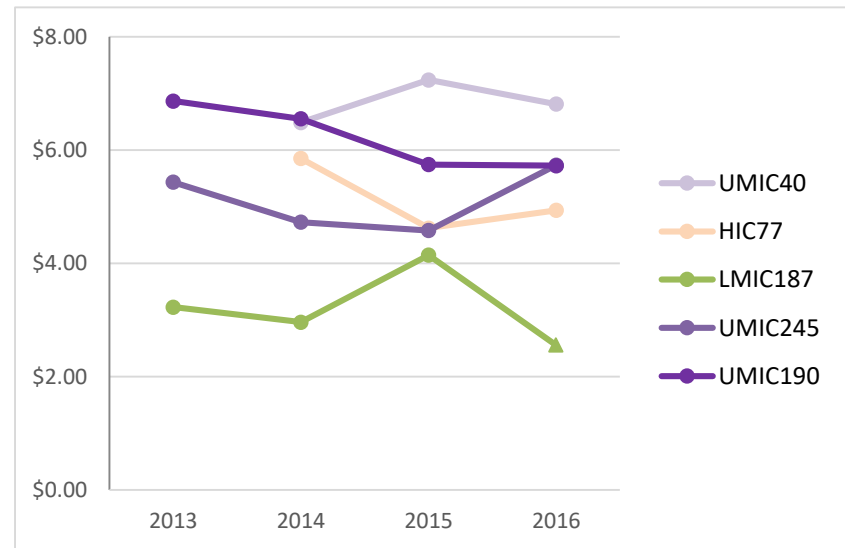
* - new and the most expensive vaccines

Vaccine procurement performance in SEEHN countries: Vaccine price paid

Extra price paid by SEEHN country group



MMR price paid by individual countries



SEEHN Cross-border joint vaccine procurement: The vision

An opportunity to strengthen procurement performance

Commitment & Country initiative & Flexibility

Based on strategic procurement approaches

Product tailored approaches

Evidence based decision making

Building trust & delegating authority

Political support is essential

- possible / complex / may take time
- based on common interests & leadership
- to improving demand predictability
- no universal solutions / specific product demand and supply patterns
- details matter / information exchange, market research & consultations
- shared values, policies, processes & tools
- harmonization / legislation / regulations

SEEHN cross-border joint vaccine procurement: The steps & forms of engagement

- I. Sharing vaccine price & procurement information (i.e. JRF/V3P)
 - foundation to support transparency and building trust
- II. Joint product market research
 - coordination & shared roles
- III. Joint tenders & framework contracts + individual supply contracts
 - delegation of authority / country group and product specific (i.e Baltics states)
- IV. Central tender & contracting structure (i.e. PAHO, UNICEF SD)
 - Market size / Political support / Funding

Thank you!

Additional slides

Baltics states joint procurement: BCG vaccine

Who? How? When? What?

- Partners: *Latvia, Lithuania, Estonia*
- Lead partner: *Latvia. Accordingly to the Public Procurement Law of Latvia*
- Procurement commission: *Representatives from all participating countries*
- Timeline: *6 months till signing of the Framework Agreement*
- Requirements: *Valid marketing authorization in all three Baltic states*
- Procurement procedure: *Open procedure*
- Market research: *Estonia*
- Information exchange mechanism: *Meetings between working group members*
- Announcement of the procurement: *May 2015*
- Termination of the open procedure: *June 2015*
- Tender results: ***NO tender offers submitted***

The only registered BCG vaccine's producer was Danish Statens Serum Institute who announced serious production problems by the tender submission time

Baltics states joint procurement: Rotavirus vaccine

Who? How? When? What?

- Partners: ***Estonia & Latvia***
- Lead partner: **Acc. to the Public Procurement Law of Estonia. E-procurements. Registry**
- Procurement commission: ***Estonian representatives only. Latvia delegated all obligations up until the signing of the framework agreement***
- Timeline: ***9 months till signing of the Framework Agreement***
- Requirements: ***Valid marketing authorization***
- Procurement procedure: ***Open procedure***
- Market research: ***WHO V3P platform & consultations with manufacturer's representatives***
- Information exchange mechanism: ***E-mails***
- Announcement of the procurement: ***October 2016***
- Termination of the open procedure: ***December 2016***
- Tender results: ***2 offers, joint tenderers***

Framework Agreement- for 3 years
25% price reduction (Estonia),
< 10% price reduction (Latvia)

Baltics states joint procurement: Next procurements

2017- Latvia-Lithuania: Pneumococcal vaccine

- Lithuania as the lead partner
- Open procedure
- Evaluation criteria: the economic efficiency (85% price/ 15% quality: serotype content)
- Minimum quantity, maximum quantity (range 50% from the minimum quantity)
- Public Supply Contract / each party
- 30 calendar days or more lead

Price reduction 15%

2018- Latvia- Estonia

Rotavirus & Hexavalent vaccine

- Estonia as the lead partner
- Open procedure
- Evaluation criteria: lowest price
- Framework agreement, Public Supply Contracts for the separate lots
- 9 months lead time from order to delivery
- Tender opening: July 2018