



Vaccine Procurement
Practitioners Network

Learning from sub-regional experiences in cross-country collaboration in the procurement of medicines and vaccines

29 October 2020

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World Health Organization
Europe



CROSS-COUNTRY COLLABORATIONS

to improve access to medicines and vaccines in the WHO European Region

Panelists

- Ms Tifenn Humbert, Technical Officer, Access to medicines and health products, Division of Country Health Policies and Systems, WHO, Copenhagen, Denmark
- Dr Oleg Benes, Technical Officer, Vaccine-preventable Diseases and Immunization at WHO/Europe
- Ms Eveli Bauer, Chief specialist, Pharmaceuticals and Medical Devices Department, Estonian Health Insurance Fund
- Mr Francis Arickx, Advisor general, Head of Directorate, Directorate Pharmaceutical Policy, Health Care Department, National Institute for Health and Disability Insurance (RIZIV INAMI), Brussels, BE, Representative of BeNeLuxa Initiative

Moderators

- Andrea Papan, VPPN, Community of Practice Manager, UNICEF
- Loïc Sanchez, Supply Officer (Immunization), Supply Division, UNICEF

Key Learning Objectives are:

- To share research findings from WHO EURO report on Cross-Country Collaborations to improve access to medicines and vaccines
- To understand benefits of cross-country collaboration for vaccine procurement
- To provide lessons learned about cross-country collaboration from sub-regional examples including the 'Baltic Procurement Initiative' and BeNeLuxa Initiative

Agenda

TIME	AGENDA POINTS	RESPONSIBLE
9.00-9.04	Welcome/Introduction	Andrea
9.05-9.14	Findings from the WHO EURO report on Cross-Country Collaborations to improve access to medicines and vaccines	Tifenn and Oleg
9.15-9.26	Baltic Procurement Initiative: lessons learned	Eveli
9.27-9.38	Collaboration Initiative on the reimbursement of medicines: BeNeLuxa Initiative on Pharmaceutical Policy	Francis
9.39-9.52	Plenary Q&A	Plenary
9.53-10.00	Summary and Key Reflections and Close and Thank you	Loïc

IMPROVING ACCESS TO MEDICINES & VACCINES

Access to affordable
vaccines & cross-country
collaboration: WHY?

Findings & Conclusions
from WHO EURO study on
Cross-Country
Collaborations

Ms. Tifenn HUMBERT
Dr. Oleg BENES

World Health Organization Regional Office for Europe



CROSS-COUNTRY COLLABORATIONS

to improve access to medicines and
vaccines in the WHO European Region

Access to medicines & vaccines is key to achievement of SDG3



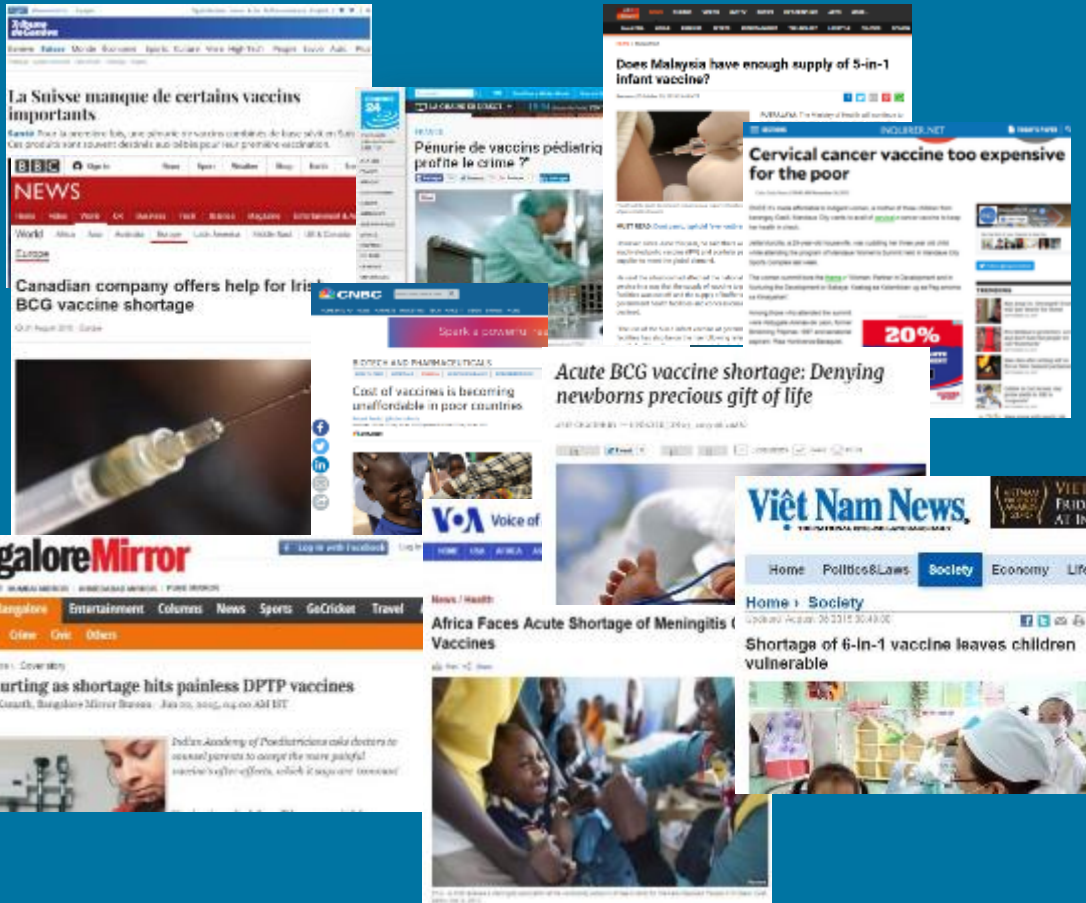
SUSTAINABLE DEVELOPMENT GOALS



SDG 3 – Target 3.8

Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

The WHA has repeatedly called for action on access to vaccine supply



Total of 50 WHA Global Resolutions on access to medicines and vaccines + 45 regional Resolutions.

- ❖ **Over 60 member states spoke at 71st WHA** on vaccine shortages, high prices, continuous need for information/support
- ❖ **Call for action** also from **GVAP** (objective 5), **SAGE**

Supply shortages in SEEHN countries, Euro, 2017

Antigens	No. of countries	Longest Duration
BCG	1	1 month
DTP	2	5-6 months
HepB	2	1 - 6 months
Hib	2	5-6 months
HPV	1	12 months
IPV	3	11 months
Measles	1	1-2 months
OPV	2	1 month
PCV	1	1 month

✓ Vaccine Pricing and Procurement identified as 1 of 5 priority areas of collaboration
SEEHN Ministerial Meeting, Montenegro, Feb -2018

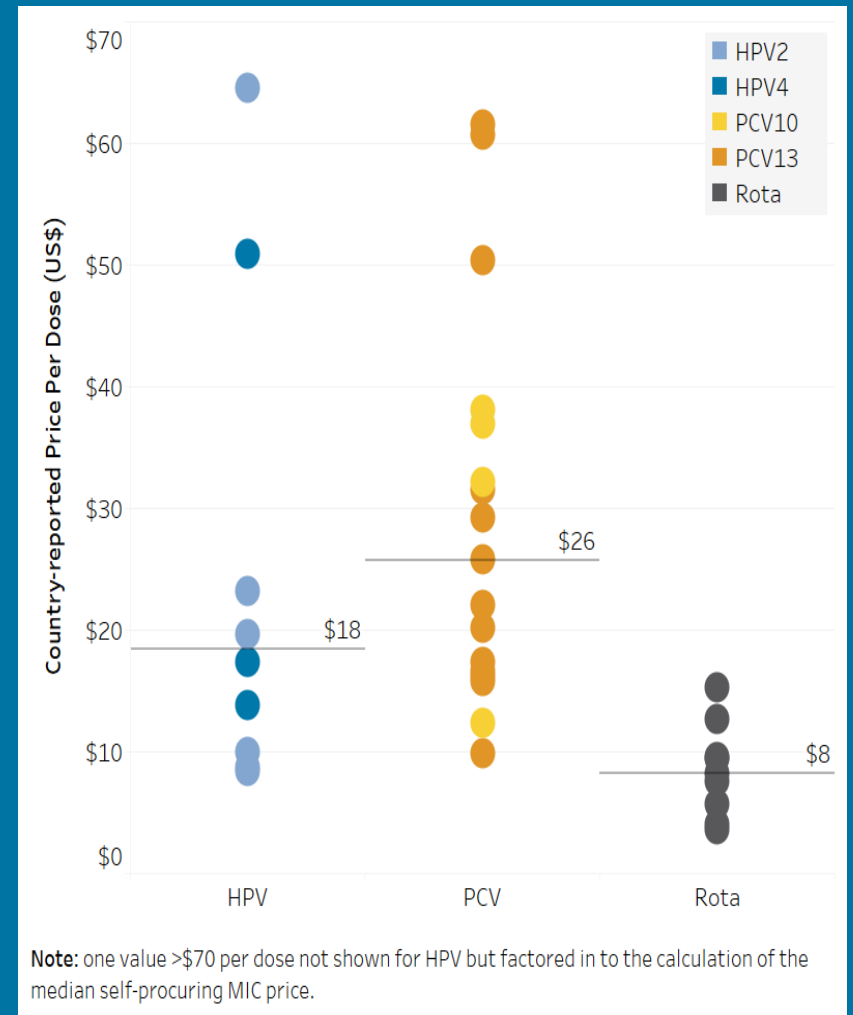
Affordability remains a barrier for Middle-income countries

GLOBAL VACCINE MARKET REPORT

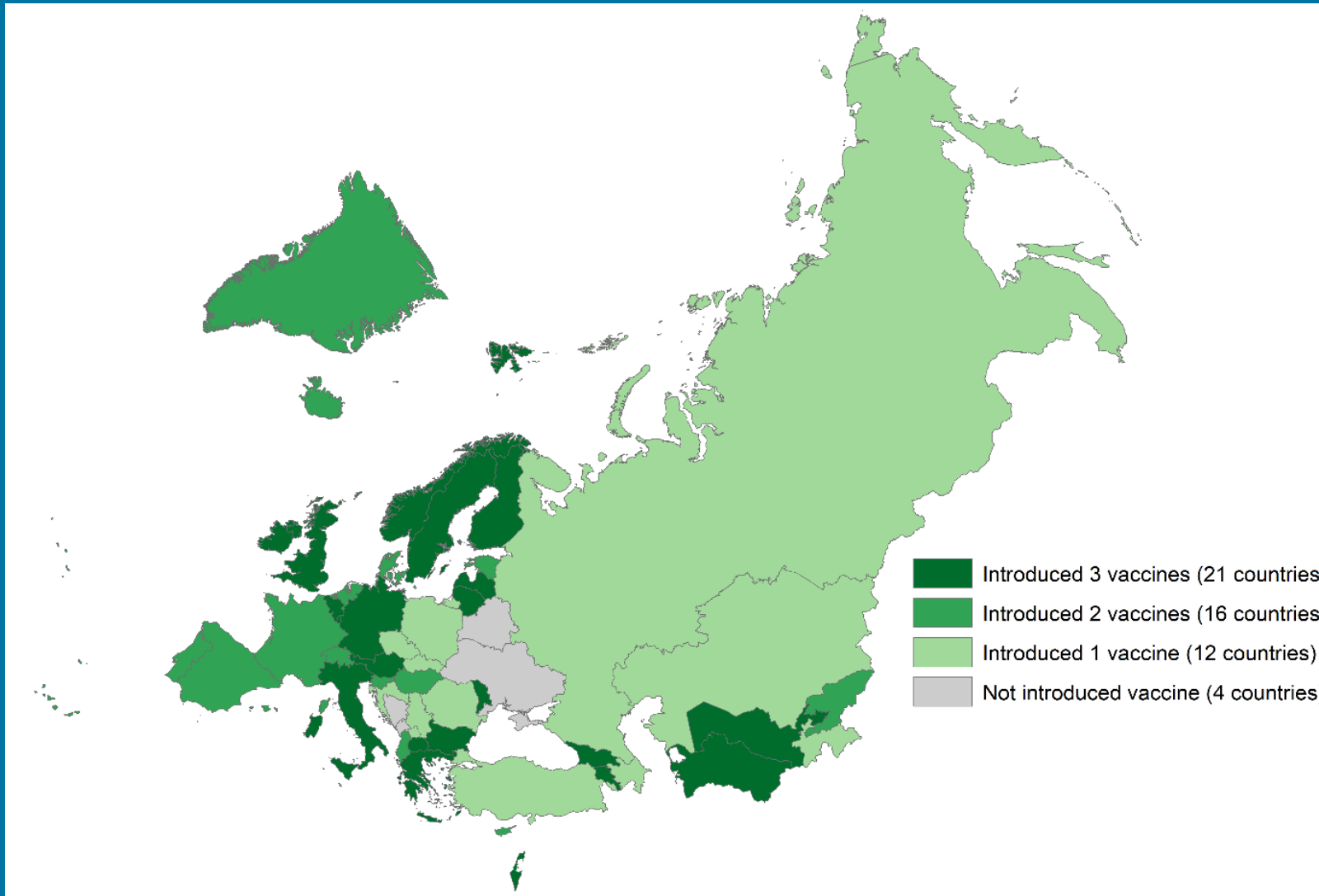
Figure 4.3 Price per dose (USD) for all vaccines by procurement/income group (2018)

	UNICEF-procuring MICs			Self-procuring MICs	
	UNICEF (Gavi)	UNICEF-procuring MICs	PAHO RF	Self-procuring MICs	Self-procuring HICs
BCG	0.11	0.11	0.21	0.20	1.03
bOPV	0.14	0.14	0.15	0.22	0.27
DT	0.16	0.16	0.17	0.35	4.00
DTaP			15.00		14.65
DTaP-HepB-Hib-IPV			20.60	29.52	35.89
DTaP-Hib-IPV			14.20	22.20	26.61
DTaP-IPV			11.50	16.69	20.58
DTwP	0.22	0.22	0.17	0.22	3.82
DTwP-HepB-Hib	0.87	0.87	1.08	1.20	4.96
HepA			10.66	9.59	21.02
HepB	0.27	0.27	0.24	1.40	5.73
Hib			2.05	5.16	9.50
HPV	4.55	13.57	9.04	11.59	50.92
IPV	1.68	2.38	3.65	4.99	8.53
JE	0.41			0.76	10.43
Measles	0.31	0.31		0.90	
MenACWY			20.30	21.17	30.73
MMR	2.50	2.50	3.26	5.65	7.54
MR	0.73	0.73	1.43	0.86	

- ✓ Supply security issues in MICs:
- ✓ 32% of vaccines having < 4 suppliers
- ✓ 63% with ≤ 2 (PQ'd) products.
- ✓ prices-paid overlap HICs' prices-paid
- ✓ regularly voice affordability concerns



Middle-income countries are lagging behind in introducing new vaccines*



* New vaccines introduced (PCV, Rotavirus & HPV), as of 2019

Country groups	# of new vaccines out of 3
MICs (#13)	1.23
Gavi supported (#7)	2.29
HICs (#33)	2.27
EUR	2.02

Disclaimer: The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement. © WHO 2020. All rights reserved.

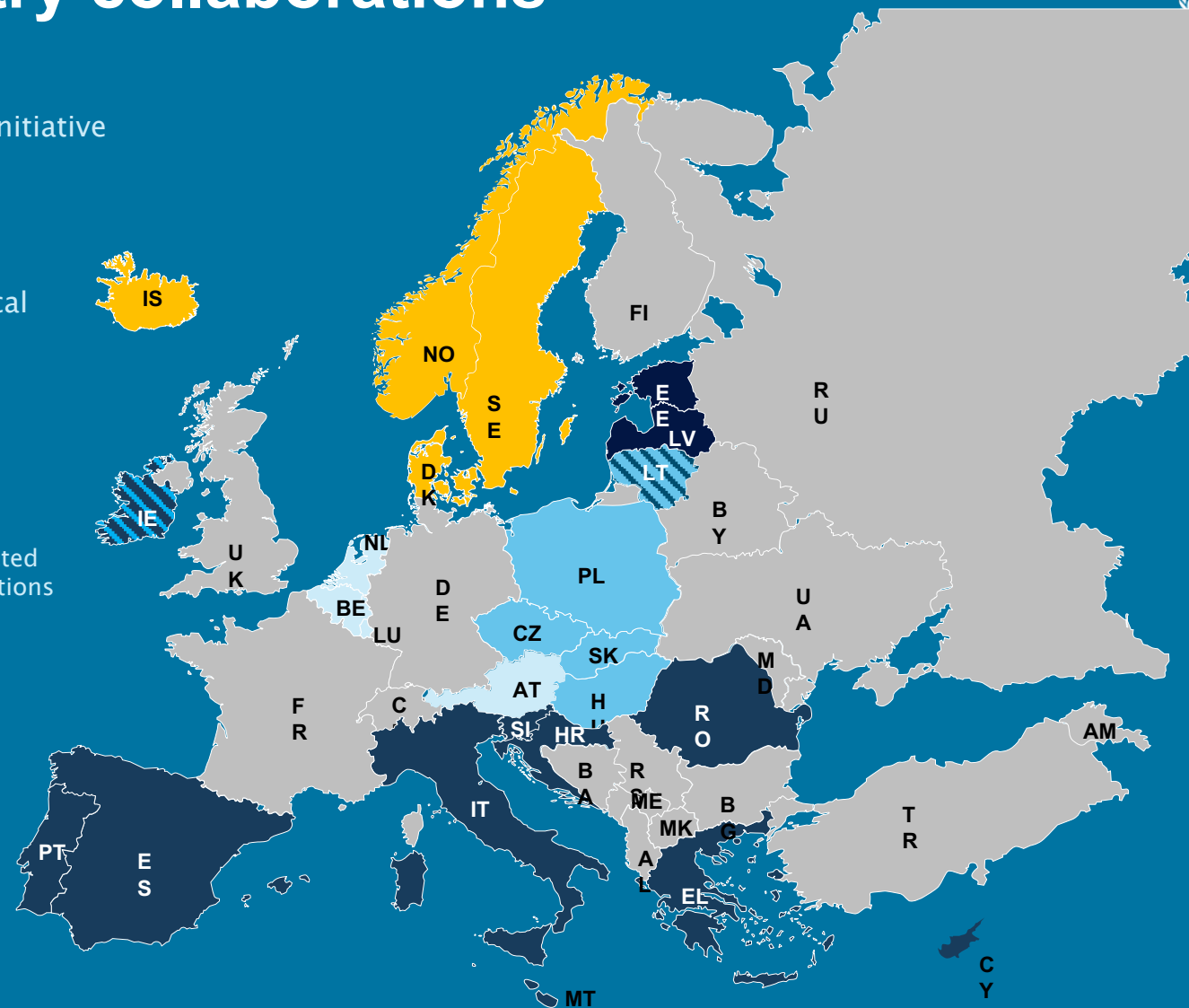
Countries joining forces to balance Demand & Supply market forces

- In recent times, cross-country collaborations of governments in the area of access to medicines have been established in Europe
- Increase of medicines shortages/ pooling volumes
- Lack of a systematic overview & assessment of country collaborations, their results, opportunities and challenges



Studied cross-country collaborations

-  Baltic Procurement Initiative
-  Beneluxa Initiative
-  Nordic Pharmaceutical Forum
-  Valetta Declaration
-  Visegrad
-  No participation in selected cross-country collaborations



Performed by:

WHO Collaborating Centre for Pharmaceutical Policy and Regulation, Utrecht
 WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Vienna
 Study protocol development in collaboration with WHO Collaborating Centre for Pharmaceutical Policy, Boston

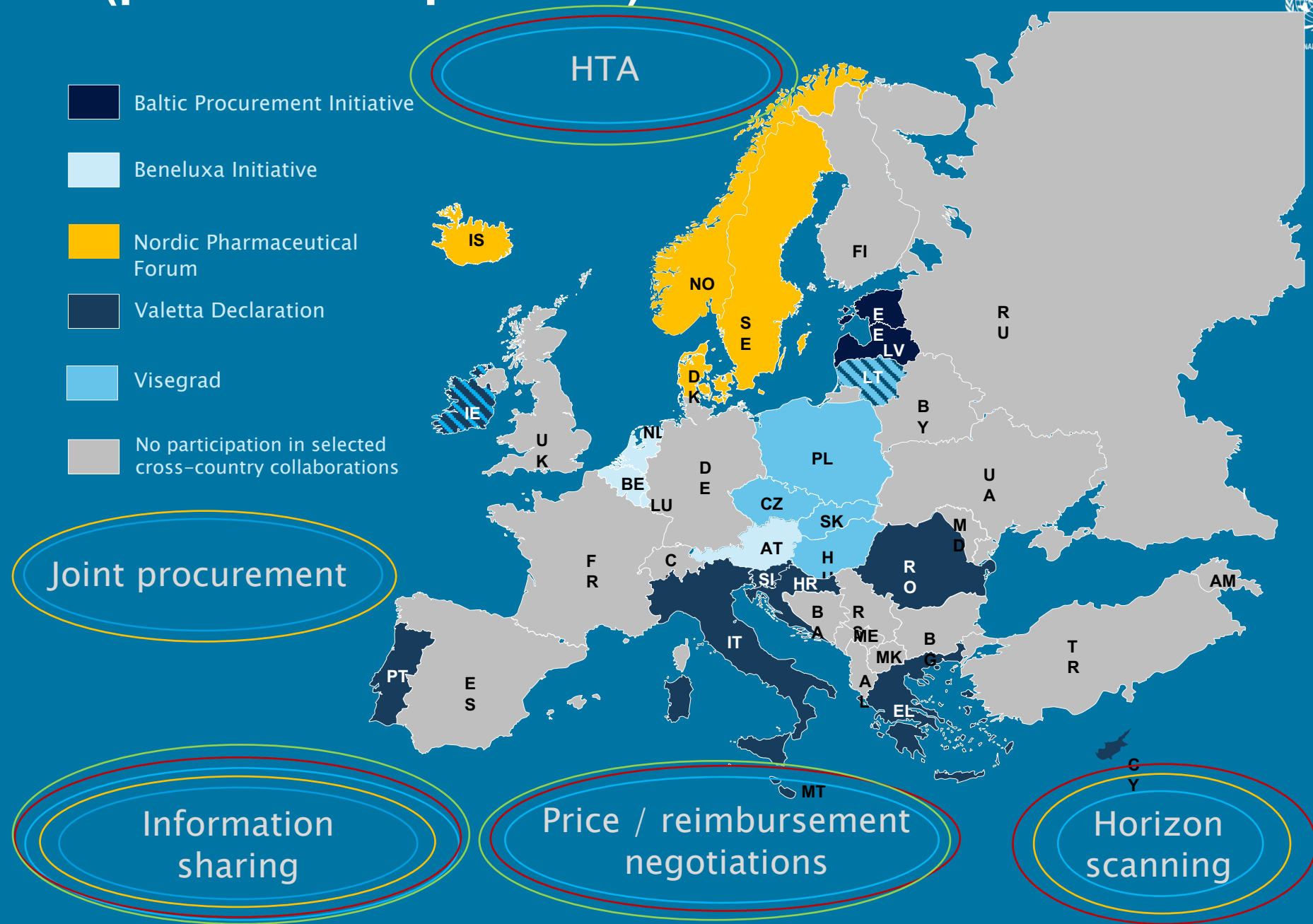
Methods

Literature & document review
 Semi-structured interviews
 Timeline: March 2018 – December 2019

Comments:

Ireland is part of two collaborations, the Beneluxa initiative and the Valetta Declaration
 Lithuania is part of two collaborations, the Baltic Procurement initiative and Visegrad

Activities (performed / planned)



Facilitating Factors

- Trust
- Enthusiasm and commitment and time
- Highly qualified technical experts
- Based on long-term collaboration
- **Political commitment**
- Structure within which to work
- Information technology
- One: Language

Challenges

- Language
- Different Procurement + Reimbursement systems (standardization of procedures, rules)
- Legal barriers
- Reluctance of industry to negotiate
- Identifying right people to work in the collaboration
- Communication to the public
- Resources (particularly time resources)
- Fragmentation of system (hospital sector)
- To identify products and lead partner (in procurement)

Lessons learned

Political will and commitment are key to collaboration and success

Funding is essential as is getting **cooperation** and **time of experts**, and to push the process forward

Information sharing is of the utmost importance

Getting into collaborative action takes time

Alignment of processes and even legal changes may be needed

Evaluations of performance may offer lessons to be learned

Communication process is a big challenge

- Different actors with a different level of knowledge → can sometimes lead to misunderstandings
- Language for official documents can be a barrier, too

Conclusion

Importance of political commitment

High expectations within collaboration and pressure from “outside”

Need to produce “tangible results”

At the same time, information sharing is (considered) key

Processes take time

Publication is available in English:

<https://www.euro.who.int/en/health-topics/Health-systems/health-technologies-and-medicines/publications/2020/cross-country-collaborations-to-improve-access-to-medicines-and-vaccines-in-the-who-european-region-2020>

Baltic Procurement Initiative

Eveli Bauer

Medicines and medical devices department

Estonian Health Insurance Fund

The Partnership Agreement

The initiative-

Task Force for Health Affairs- inter parliamentary and intergovernmental co-operations among Estonia, Latvia and Lithuania.

The Partnership Agreement (effective as of 2012)

- Main goals:
 - **reduce the expenditure**
 - **ensure the continuity of the access** to medicinal products and medical devices
 - **prevent and facilitate shortages** of the medicines in Baltic States
- Strategic management:
 - cross-border joint procurement mechanism
 - lending agreement
- Operational management:
 - Working Group (members from 3 Baltic States)
 - One lead partner for each joint procurement procedure (voluntary basis)
 - Delegation letter to delegate rights to lead partner

Implementation of the Partnership Agreement

The Working Group-

- Members from each country (expert level)
- identify the necessity 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

- *First procurement objects:*

national health programmes-> vaccines

Joint procurements 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

Results 2015-2018

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	Latvia (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%	Hexavalent: price reduction 20% (Estonia), less than 10% (Latvia); Rotavirus: price increase 23% (9% cheaper than 2015 price)

Lessons learnt 2015-2018

Topic	Initial approach	Amendments	Final amendments
Procurement commission	Representatives from all participating countries	One lead partner	One lead partner
Lead time before the procurement announcement	6 months	Minimum 9 months	3-9 months (first time tender /basic procurement terms remain the same)
MA requirements	Valid MA in all 3 Baltic States	Possible alternative options in tender conditions	Depending on the market research
Market research	In advance	Before the procurement announcement	Ongoing, up to date before the procurement announcement
Information exchange between WG members	Meetings	E-mail	E-mail, minimum once a year meeting
Official language of the tender	Two languages (national+ English)	English	English+ national language for informational purposes
Terminology of the tender documents	English translation of national Public Procurement Law	EU Public Procurement Directives	EU Public Procurement Directives
Incoterms	Central storage/ In-country transportation	Central storage	Central storage/ In-country transportation (separate procurement)
Evaluation criteria	Price	Price/ Economic efficiency	Price/ Economic efficiency (MEAT-most economically advantageous tender)

Joint procurements for vaccines 2019-2020

2019:

Pilot projects -> Harmonization of the procurement plan for vaccines in Baltic States

2020:

New cross-border joint procurements: **full list of vaccines** (*ongoing*)

Risk management

Cross-border joint procurements:

- aggregation of the demand
- Framework Agreements: possibility to share the reserved volumes
- information sharing: prices, availability of the stock, market research results: different „middlemen“ -> different possibilities (crisis management!), contact persons (trustful relationship)
- Harmonization of procurement plans: overview of the stock situation, effective planning
- Lending agreement: possibility to lend stock quickly and effectively (no additional bureaucracy)

Next steps

Review of the Working Group procedures: harmonization of the project management strategy (including market research strategy, communication strategy.....)

Development and expansion of the cross-border joint procurement procedures

CPBs (central purchasing body) in the health sector (COVID-19!). Central procurement procedures for crisis management- when and how Baltic Procurement Initiative could contribute...

Thank you!

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BeNeLuxA - IHSI


Francis Arickx

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National Institute for Health and Disability Insurance (RIZIV INAMI),
Brussels, BE, Representative of BeNeLuxa Initiative

Background

National Institute for Health and Disability Insurance

- Social Security
- Manages Compulsory Health Insurance
- Stakeholders and Management

A map of Europe with a white diagonal band across it. Countries IE, UK, NL, BE, LU, DE, CZ, and AT are labeled. The countries IE, NL, BE, LU, and AT are highlighted in yellow, while UK, DE, and CZ are in light blue. The white band is wider on the left and tapers towards the right.

Collaboration Initiative
on the reimbursement
of medicines

BeNeLuxA– in practice..

Proof of concept for the ‘coalition of the willing’

Main goal: To ensure access to innovative drugs at affordable cost

Cooperation is part of the policy-mix

- Information gathering on global markets benefits from joint approach
- National context determines course of action
- Joint negotiations only in select cases

What works?

- Setting clear, common goals
- Mutual benefit needs to be clear
- Pragmatic approach
 - Focus on desired outcomes
 - Lean organisational structure

BeNeLuxA– in practice..

‘coalition of the willing’ on 4 domains

- 1) Health Technology Assessment
- 2) Horizon Scanning
- 3) Exchange of information on pharmaceutical markets, prices and disease specific cross border registries
- 4) Pricing and reimbursement including joint negotiation



The Beneluxa Initiative aims to ensure sustainable access to innovative medicine at affordable cost for our patients.

Joint HTA assessment of Zolgensma

On May 19 the European Commission granted conditional approval for Zolgensma (onasemnogene aeparvovec) for the treatment of patients with 5q spinal muscular atrophy (SMA) with a bi-allelic mutation...

[more](#)

Beneluxa Position Statement on CAR-T

Because of considerable upfront costs, CAR-T(*) treatments are in the process of being reviewed by a number of countries to determine whether they represent value for money. Many countries have...

[more](#)

No "lottery for life" - Statement by Beneluxa Health Ministers addressing the global managed access program designed by Novartis and Avexis

BRUSSELS, Jan 30th, 2020. The Health Ministers of Belgium, the Netherlands, Luxembourg, Austria and Ireland have strong reservations in relation to the plans of Novartis and AveXis to let chance...

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Ministère de la Santé



An Roinn Sláinte
Department of Health

 Federal Ministry
Republic of Austria
Social Affairs, Health, Care
and Consumer Protection

BeNeLuxA– in practice..

Information Sharing

- Drug consumption
- Prevalence and burden of disease
- Best practices in (health budget) management (e.g. hep. C approach, reference pricing, generic policy, biosimilar policy,..)
- Post marketing evidence gathering (e.g. registries)
- Policy questions (e.g. KCE-ZIN Study 2013-03-HSR_on drug pricing scenarios)

BeNeLuxA– in practice..

Joint Health Technology Assessment

Based on previous experience/expertise with MEDEV, EUnetHTA, JA2, informal collaboration,...

- Coherent and compatible with Joint Action 3

‘testing’ models for implementation:

- Mutual recognition of Assessments (operational)
- Joint ‘writing’/editing (operational)
- Sharing expertise (operational), eg. Dutch ‘Wetenschappelijke AdviesRaad’ of ZIN acts as external expert in Belgian reimbursement procedure

BeNeLuxA– in practice..

Pricing and Reimbursement, including joint negotiations

By structural exchange of information and testing through pilots of procedures or scenarios for joint negotiations that lead to financial arrangements and contracts

That are compatible with and respect national legislation and competence and responsibility of the different stakeholders in the decision-making process

That respect confidentiality of the commonly negotiated financial details
(..nothing changes compared with today..)

THIS IS NOT JOINT PROCUREMENT
THIS IS NOT LIMBO DANCING.. *how low can you go..*

BeNeLuxA– in practice..

Joined Horizon Scanning

Prioritisation – potential to improve access

- Allows for prioritisation of policy-making
- Allows for capacity planning for HTA bodies
- Allows for earlier planning for guidelines and registries

Budget planning – potential for savings

- Flags potential issues of displacement.
- Allows for better tools for budget allocation

Efficiency gains – potential to improve access

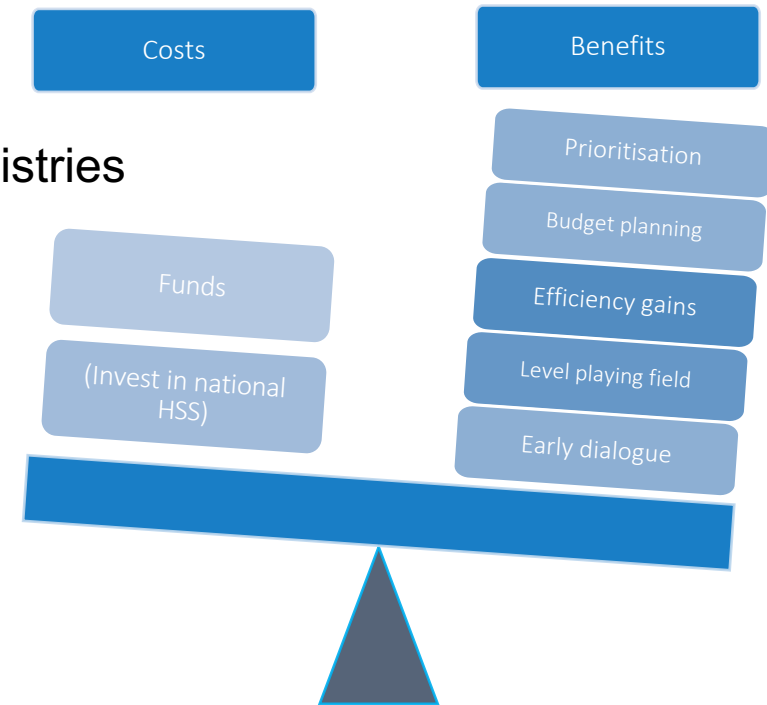
- Allows for streamlining procedures

Level playing field – potential for savings

- Allows for sharing earlier and lessening the current information asymmetry with industry

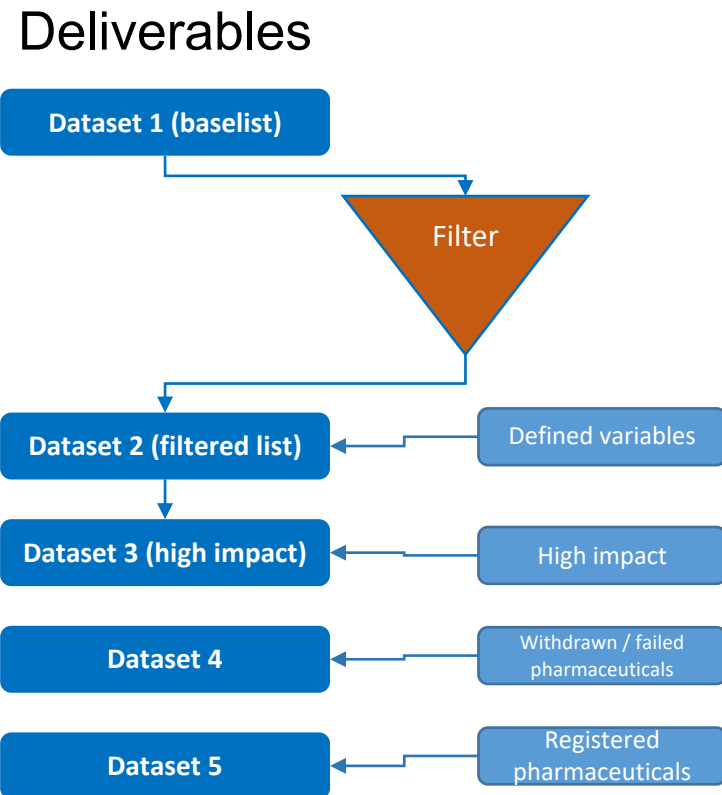
Early dialogue – strengthens collaboration

- Allows for stakeholders to share information at an earlier stage, e.g. Beneluxa



BeNeLuxA– in practice..

Joined Horizon Scanning



High impact reports

Priority Area 02: Cancer

Topics	High-Impact Potential
1. Afatinib (Gilotrif) for treatment of advanced head and neck cancer	No high-impact potential at this time
2. Anamorelin for treatment of cancer-related cachexia/anorexia	No high-impact potential at this time
3. * Blinatumomab (Blinicyto) for treatment of acute lymphoblastic leukemia	Lower end of the high-impact-potential range
4. Cabozantinib (Cometriq) for treatment of renal cell carcinoma	No high-impact potential; archived November 2015 on basis of experts' comments
5. Capsule endoscopy (PillCam Colon 2) for colorectal cancer screening	No high-impact potential; archived September 2015 on basis of experts' comments
6. * Crizotinib (Xalkori) for treatment of <i>ROS1</i> -positive nonsmall cell lung cancer	Lower end of the high-impact-potential range
7. * Daratumumab (Darzalex) for treatment of multiple myeloma	Moderately high
8. Denosumab (Xgeva) for treatment of refractory hypercalcemia of malignancy	No further potential for high impact; archived November 2015 on basis of being broadly diffused
9. * Dinutuximab (Unituxin) for treatment of neuroblastoma	Lower end of the high-impact-potential range
10. * Elotuzumab (Empliciti) for treatment of multiple myeloma	Moderately high

Real time database



*AHRQ high impact report 2015

<https://effectivehealthcare.ahrq.gov/sites/default/files/cancer-horizon-scan-high-impact-1512.pdf>

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Horizon scanning for pharmaceuticals: proposal for the BeNeLuxA collaboration



KCE Reports 283 (2017)



Publication year: [2017](#)

Report number: 283

Type: Health Services Research (HSR)

Authors: [Lepage-Nefkens Isabelle](#), [Douw Karla](#), [Mantjes Gertjan](#), [de Graaf Gimon](#), [Leroy Roos](#), [Cleemput Irina](#)

Language: The report is available in English. The synthesis is available in English.

Keywords: [Technology Assessment](#), [Biomedical](#), [Program Development](#), [Policy Making/trends](#), [International Cooperation](#), [Information Dissemination](#), [Health Policy](#), [Europe](#), [Economics](#), [Pharmaceutical](#), [Costs and Cost Analysis](#), [Awareness](#)

[Export the bibliographical reference \(.RIS\)](#)

DOCUMENTS

[Download the synthesis in English \(17 p.\) \(337 KB\)](#)



[Download the report in English \(168 p.\) \(2.61 MB\)](#)



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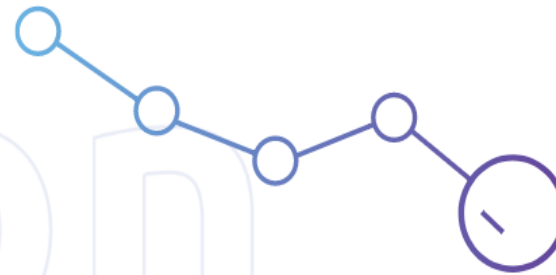
Governments change the conversation with real data.

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Mission

IHSI provides data that empowers political decision-makers and payer organisation negotiators to drive for better pricing in medicinal products. IHSI data enables healthcare systems to prepare for disruptive technologies through data insights that deliver the leverage required to confidently assess new products coming to market.

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QUESTIONS and ANSWERS



Using your Q&A function, please:

- Type in your question – please identify which speaker you would like to address i.e. Tifenn, Oleg, Eveli or Francis.
- Upvote for other questions you would like to see prioritized
- Write in supplementary answers to questions with your own knowledge and expertise

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Thank You



Vaccine Procurement
Practitioners Network

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