

Regional vaccine market dynamics (Supply/Demand) in South East Asia Region.

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Session 5: Topics

- Key features of SEAR vaccine market.
- Vaccines used in SEAR including PCV, HPV, RV.
- SEAR concerns about vaccine security
- SEAR country vaccine procurement policies
- Principle and requirements for pool procurement mechanisms
- Proposed discussion points for plenary

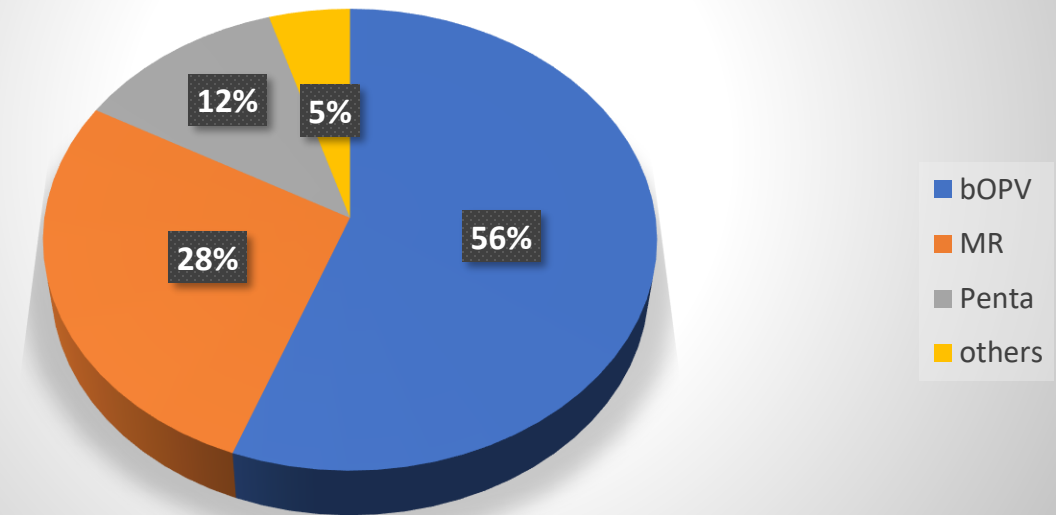
Key features of SEAR vaccine market.

- ✓ All countries reported 2018 data to JRF 2019 enabling V3P and MI4A market analysis. https://www.who.int/immunization/programmes_systems/procurement/v3p/platform/en/
- ✓ Size of the vaccine market in SEAR is 35% of the global market by volume and about 8% by value.
- ✓ In 2018, SEAR countries used reduced vial size 1 to 5 doses; for Penta (5 COs); IPV (8 COs); PCV and HPV (5COs).
- ✓ Sri Lanka, India, Bangladesh and Nepal have introduced fractional dose of ID-IPV.
- ✓ MDVP is in fix and out reach immunization sessions in 3 countries and for 9 countries in fix immunization session only.

Key features of SEAR vaccine market

- More than half of doses procured in 2017-2018 in SEA countries were bOPV followed with MMR/MR and Penta accounting for 30% and 12% of total doses.
- Other vaccine (5%) include BCG, DTP, Measles, HepB, TT, DT/Td, HPV, JE, PCV, Influenza and Rotavirus.
- Vaccine supplier sources
 - 8 suppliers from Europe, USA, Japan and South Korea
 - 16 suppliers from IND (12); THA (1) and INO (1); CHN (1); BUL (1)

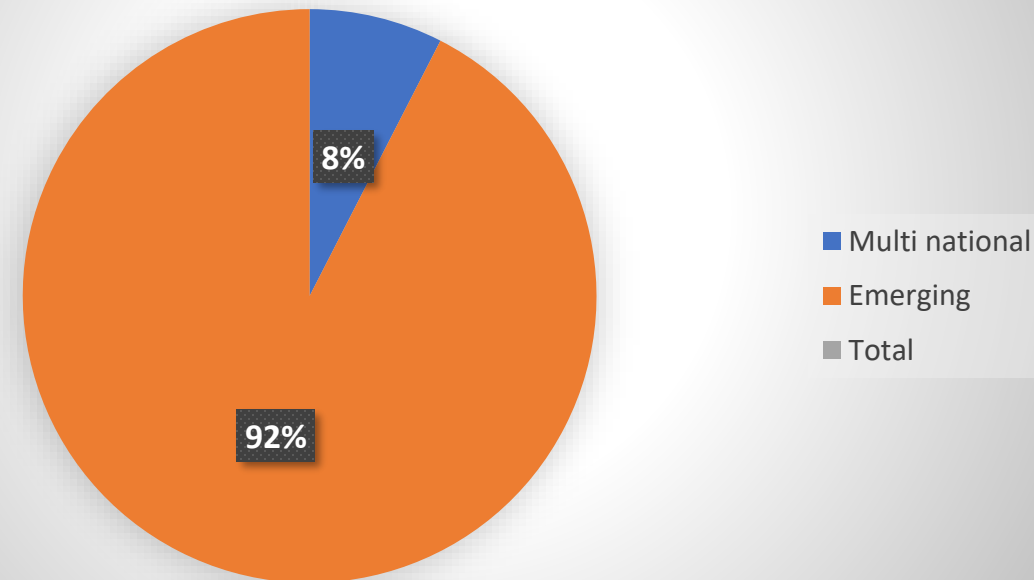
Number of vaccine doses as percentage of total vaccine doses in SEAR NIPs 2017-2018



Vaccine used in SEAR NIPs 2017-2018

- In 2017-2018, SEAR countries represented a market of 1.350 billion doses of vaccines for NIPs.
- 92% doses procured from SEAR emerging suppliers except JE LAV (China) and some BCG, Diphtheria containing vaccine (Bulgaria).
- Supplier lists same among self-procuring and through UNICEF.
- 8% doses sourced from multi-national in Europe, USA, Japan and S.Korea mostly for PCV, HPV and IPV.

Total doses of vaccines supplied to SEAR NIPs by Supplier Sources 2017-2018



New vaccine introductions

- ✓ Pentavalent vaccine in 11 countries by end of 2019
- ✓ MMR/MR replace Measles in all countries for routine and SIAs (DPRK MR in Oct 2019)
- ✓ IPV in all and fIPV in 4 countries
- ✓ JE (LAV/Inact) in IND, INO, MMR, NEP, SRL, THA
- ✓ Introduction lagging behind in SEA countries for HPV, PCV and Rota Virus vaccine

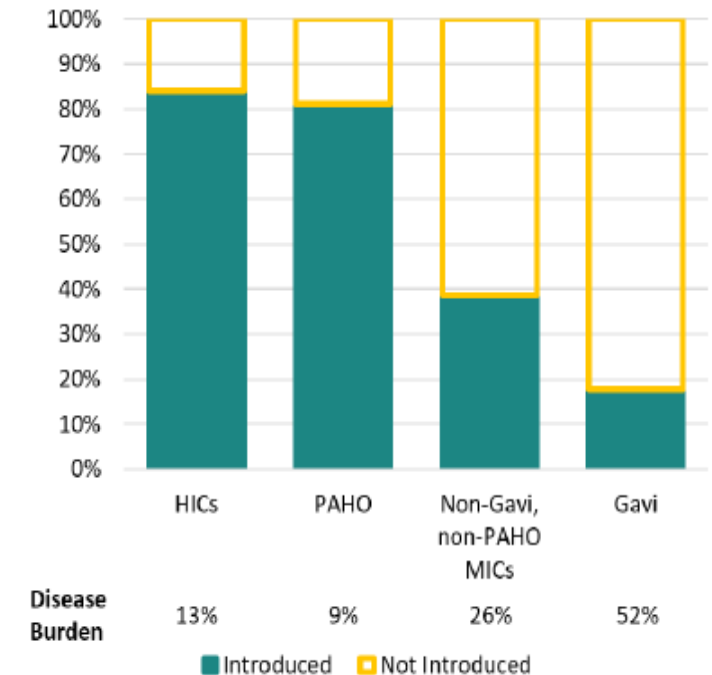
Market trends and global availability of selected vaccines

HPV vaccine, Global trends

[https://www.who.int/immunization/programmes_systems/procurement/v3p/platform/module2/WHO HPV market study public summary.pdf](https://www.who.int/immunization/programmes_systems/procurement/v3p/platform/module2/WHO_HP_V_market_study_public_summary.pdf)

- In 2018, HPV introduced in 81 countries (42% of WHO MS). 70% of countries self-procured. LIC and MIC with lower introduction rate.
- Currently three HPV (bi.-quadri.-ninevalent) WHO PQ vaccine are available on the market from 2 suppliers
https://extranet.who.int/gavi/PQ_Web/
- 3 products in advanced clinical trial development
- Supply is insufficient to fully meet existing demand. Recommendations from SAGE is expected this autumn.

FIG. 1: HPV INTRODUCTION STATUS (% OF COUNTRIES) AND DISEASE BURDEN BY COUNTRY GROUP



Market trends and global availability of selected vaccines (2)

HPV vaccine in SEAR:

- HPV in BHU, INO, MAL, SRL and THA NIPs in 2018. INO and THA self-procured HPV. HPV procurement in THA and SRL meets the needs (BHU: 61%); (INO: 4%)
- HPV requirement estimated 41 million doses for the region (half birth cohort x 2 doses)
- Procurement of HPV in 2018 cover an estimated 3.5% of SEAR requirements
- HPV Self-Procuring countries (THA, INO) negotiated a median price 2.7 folds higher than UNICEF median price for HPV.

<https://public.tableau.com/profile/supply.division#!/vizhome/UNICEFPricedataoverviewforvaccines/Fulldashboard>

Market trends and global availability for selected vaccines (3)

PCV vaccine, global trends:

https://www.who.int/immunization/programmes_systems/procurement/v3p/platform/module2/PCV_fact_sheet.pdf

- PCV: Five products WHO PQ are available from two manufacturers.
https://extranet.who.int/gavi/PQ_Web/
- As of August 2017, 142 out of 194 countries (73%) had introduced or were in the process of introducing PCV.
- Significant uncertainty in ~ 2020-2023 due to India & INO intro
- With 3 doses schedule, longer term demand of ~200-230m per year with India and INO complete intro. (source: GAVI estimates)
- GAVI independent study on country preferences showed that countries representing 10-15 mds annually willing to switch to a “low cost” PCV. 30% discount would justify “lower valency”

Market trends and global availability of selected vaccines

PCV vaccine in SEAR:

- In 2018, 4 SEAR countries: BAN, INO, MMR and NEP reported the use of PCV. BAN and MMR procurements meet demand, INO procured 1.5% of the demand and NEP around 50%.
- BAN accounting for 48.5% of administered PCV doses in the region.
- BAN, MMR and NEP procured PCV through UNICEF (median price US\$ 3.05) and INO self-procured at a price 6.5 folds higher than UNICEF median price.

HPV, PCV, RV vaccine market trends and global availability

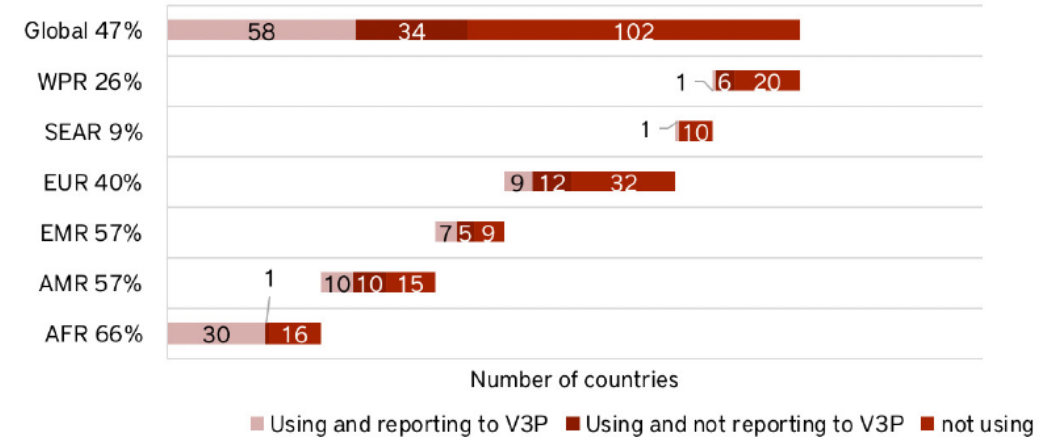
Rota vaccine Global trends:

- 8 WHO PQ products available from 4 manufacturers https://extranet.who.int/gavi/PQ_Web/
 - ✓ 6 products liquid-ready-to-use:
 - ✓ 3 x Plastic tube 1 producer (1+ 5 ds) + 1 producer (1ds)
 - ✓ 1 x with applicator 1 ds
 - ✓ 2 x Vials 5, 10 ds
 - 2 products lyophilized:
 - ✓ 2 x vial set (active + excipient) 1 & 2 ds
- Increased choice and complexity for countries due to different valency, schedules and formulations <https://www.gavi.org/library/gavi-documents/supply-procurement/rotavirus-vaccine-profiles/>)
- New products expected to be WHO PQ in 2020
- 2018-2019 limited capacity - production expected to increase with arrival of new manufacturers and new products.

HPV, PCV, RV vaccine market trends and global availability

Rota vaccine SEAR:

- SEAR has the lower RV introduction rate with India using RV
- In 2018, India procured ~ 56 millions doses from domestic producers.
- India RV is 2% of market value and 13% of global volume.
- GOI negotiated median price/dose significantly lower than UNICEF median price of US\$ 2.72.
- The risk of RV supply is limited



Concerns of vaccine security in SEA countries

- SEAR GAVI graduating countries 5 years access to UNICEF vaccine prices.
- SEAR countries experienced shortages of vaccines.
- MoH Sri Lanka, Bhutan and Maldives requested IVD to explore options for cost-effective mechanisms to procure vaccines post-GAVI support.
- Out of the 11 SEAR Member States, 3 have significant manufacturing capacity (India, Indonesia and Thailand) or are in the process of building it (Bangladesh).

Challenges and opportunities

Coordinated collaboration among countries to share vaccine suppliers information e.g.:– WHO/V3P/MI4A, UNICEF SD/vaccine products and prices.

Foster regional regulatory environment that ensure access to quality vaccines with MA procedures taking into account WHO PQ for LMIC importing vaccines through UNICEF and/or self-procuring

understand WHO PQ and implement regulatory pathway taking into account

Active collaboration with medical institutes and faculties of public health to conduct operational studies and other post-marketing vaccine safety monitoring activities.

* Temperature Time Sensitive Pharmaceutical Products (TTSP)

Challenges and opportunities

Va

Involve private/public partners to make informed decision for vaccine R&D at national and regional levels.

Exchange suppliers information and explore feasibility of pool-procurement mechanisms for selected countries and vaccine in the region.

MA procedures take into account WHO PQ products quality assessments and implement expedited approvals in GAVI supported countries and MICs

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SEAR countries vaccine procurement policy for NIPs

Category	Self-proc.	UNICEF	Mix*	Comments
LIC			NEP	2017: 78% doses self-procured 2018: 70% doses self procured
LMIC	INO, IND, THA	BAN, BHU, MMR, TLS	SRL**	IND and INO: domestic production to supply NIPs SRL: in 2017, 92% doses self-procured and in 2018 90% doses.
UMIC	THA	MAL		THA mostly imported from the region 80% in 2017 and 60% of procured vaccines in 2018. Influenza locally produced 50% of the needs in 2017 and 35% in 2018. BCG locally produced meets demand.

* Self-procured vaccines with some through UNICEF

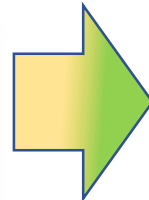
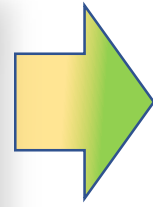
**Sri Lanka soon to be graduated UMIC

Vaccine categories for NIPs.

Vaccine for routine NIPs e.g.: BCG, Measles and/or MCV, DTP-HepB-Hib, Td, DT, PCV, HPV, RV and where disease epidemiology supports them e.g. JE, HPV, TCV

Vaccine for Supplementary Immunization Activities e.g. Polio, MMR/MR, JE

Vaccine for outbreaks, emergence, re-emergence of pathogens.



Enhancers

Good visibility demands, multi-year vaccine forecasts, suitable for Long Term Agreement (LTA) and/or pool-procurement mechanisms.

Global/regional SIAs in partnership to coordinate with manufacturers to coordinate mass production in short period of time. Limited suitability for LTAs. Pool procurement for MICs ?

Difficulties to anticipate outbreaks and vaccine requirements. WHO/UNICEF global vaccine stockpiles including: Meningococcal; Yellow Fever; Influenza; Cholera; mOPV2; Ebola; and Small pox.
Preparedness to produce and store bulks/vaccines for rapid deployment to respond to outbreaks and pandemics.

Group procurement models

- Product specifications
- Harmonized regulatory pathways WHO PQ products
 - TORs pool procurement
 - Request for Proposal ?
 - Tender specifications and process
- Bids review and adjudication processes
 - Shipping and payments
 - Etc...

Pool procurement requires transparency, political commitments across countries, expertise, financial support and agreed procedures.

A gradual approach with informed buying mechanisms to acquire product knowledge, vaccine market understanding and to have better analysis of demand and supply forecasts

Thank you

For plenary discussions

- SEA MLICs procuring vaccine through UNICEF encouraged to implement MA procedures that take into consideration WHO PQ to avoid duplication.
https://www.who.int/immunization_standards/vaccine_quality/expedited_review/en/
- To explore with self Procuring countries feasibility to establish multi-year LTAs to improve manufacturers predictability of vaccine requirements.
- Among the four models of pool procurement mechanisms which model and for which products to address current access challenges ?
- Current country self-procuring interactions with producers e.g.: MA, GMP, procurement, AEFI reporting, etc.
- Do we need regional information sharing with manufacturers to address current LMICs self-procuring challenges and contribute to stimulate regional vaccine R&D ?