

Procurement Strategy for Rotavirus and Pneumococcal Conjugate Vaccines

Supplier meeting
UNICEF Supply Division 3-4 April 2008
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Strategic decisions leading to procurement of Rotavirus and Pneumococcal Conjugate Vaccines

- Nov 2000 4th GAVI Board approved the recommendation of the GAVI Task Force on R&D to **focus** initially on **pneumococcal**, **rotavirus** and meningococcal A (or A/C) vaccines
 - No currently registered vaccine – or drawbacks
 - High potential impact: significant reduction of morbidity and mortality
 - High probability of success in short/medium term
 - Strategic gap, i.e. no other efforts focusing on disease
 - Lack of other, non-vaccine solutions

Strategic decisions leading to procurement of Rotavirus and Pneumococcal Conjugate Vaccines

- June 2002 8th GAVI Board Meeting first budgets for establishing the Accelerated Development and Introduction Plan (ADIP) for Pneumococcal and Rotavirus Vaccines were approved
- November 2006 the ADIPs presented Investment Cases to the GAVI Board proposing an overall strategy for accelerating vaccine introduction 2007 to 2015
 - Approved envelope of US\$ 200M to cover vaccine procurement (US\$ 78M) and strategic and technical activities 2007-2010
- Prequalification of the first Rotavirus Vaccine
- First possibility to apply to GAVI at the September 2007 Round

Procurement preparation for Rotavirus and Pneumococcal Conjugate Vaccines in GAVI-eligible non-PAHO countries

1. Appointment of UNICEF as Procurement Agency
 - ✓ 25 September 2007 by GAVI Executive Committee
2. Establishment of MoU between the GAVI Fund and UNICEF
 - ✓ In place December 2007
3. Establishment of Procurement Reference Group
 - ✓ Appointed late November
4. Establish Procurement Objectives and Strategy
 - ✓ Procurement Reference Group meeting January 17-18
 - ✓ DO endorsement in principle

Rotavirus Vaccines



Procurement Objective Rotavirus Vaccines

Support the **accelerated** introduction of Rotavirus Vaccines in developing countries through an **uninterrupted supply** of vaccines of **assured quality**.

Procurement Strategy for Rotavirus Vaccines

- Request for Proposal for Rotavirus Vaccine to be shared with industry
- Duration through 2010
- Pre-qualified vaccine to be awarded
- Offers for non-prequalified vaccines to be considered for allocation upon pre-qualification

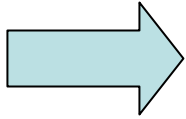
Demand for Rotavirus Vaccine

Standard principles for demand categorization

- **Predictable demand** – countries that have been approved by GAVI Board or **recommended** for support by the GAVI Independent Review Committee
- **Likely demand** – countries that have received conditional **approval** or approval with clarification that they will need to respond to
- **Possible demand** – countries that are expressing **continued interest** in introducing vaccines

Demand for Rotavirus Vaccine

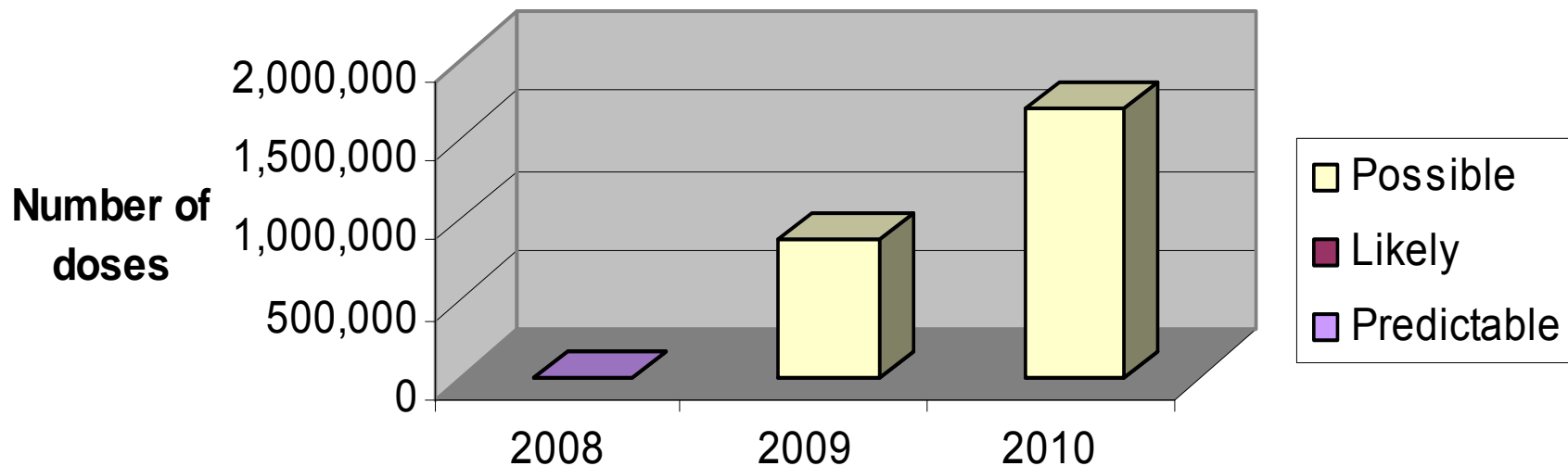
- Prequalification of the current vaccine is based on quality, safety and efficacy data generated in Latin America and Western Europe



Global indication for usage by the Strategic Advisory Group of Experts to WHO awaits proof of concept in Africa and Asia

Rotavirus vaccine demand forecast 2008-2010

	2008	2009	2010	Total
Predictable	0	0	0	0
Likely	0	0	0	0
Possible	0	869,321	1,695,803	2,565,124





Next procurement steps Rotavirus Vaccine

1. Establish demand forecast in collaboration with WHO and RotaADIP
 - ❑ Process started December, country monitoring ongoing, to reassess in August
2. Issue Request for Proposal (Q4 2008)
3. Evaluation and award recommendations (Q4 2008)
4. Establishment of Long Term Arrangement (Q4 2008)
5. First shipments in countries (Mid 2009)

Pneumococcal Conjugate Vaccine

Procurement Objectives for Pneumococcal Conjugate Vaccine

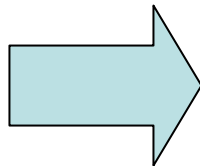
1. Support the **accelerated** introduction of Pneumococcal Conjugate Vaccines in developing countries through an **uninterrupted supply** of vaccines of **assured quality**;
2. **Meet demand** until the first approval of a second generation vaccine which will initiate the Advanced Market Commitment.

Procurement Strategy for Pneumococcal Conjugate Vaccine

- Request for Proposal
- Pneumococcal Conjugate vaccine 7-valent
- One year tender – mid 2008 to mid 2009
- An option to extend for six months

Advanced Market Commitment

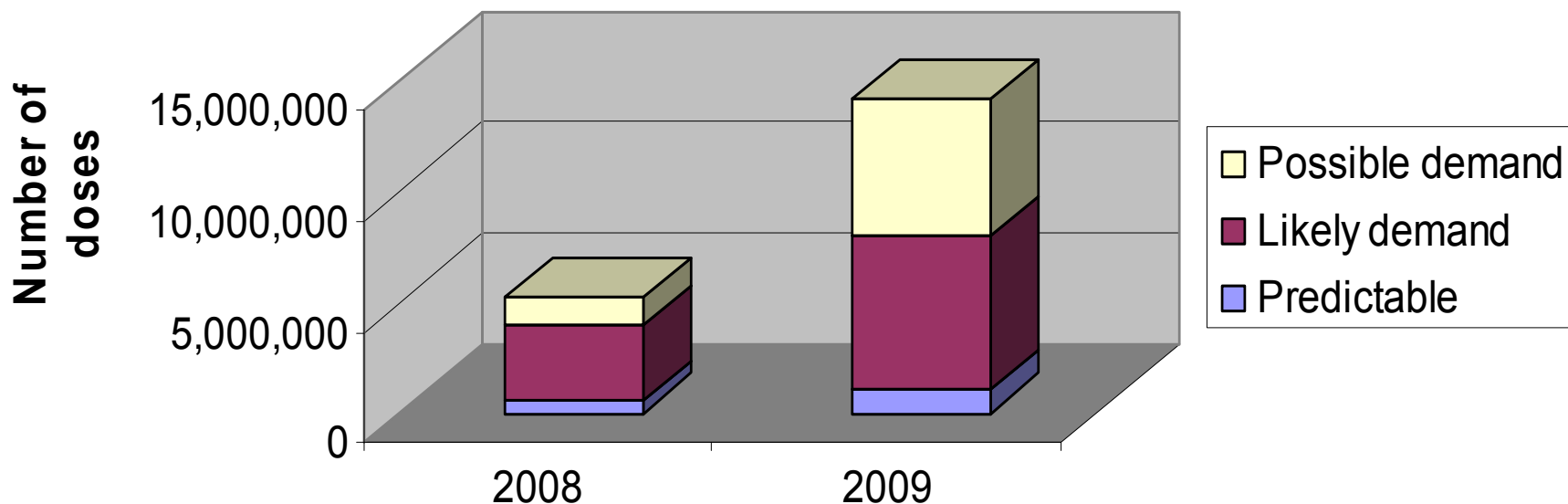
- An offer from donors to suppliers to fund vaccines that meet specific requirements and are in demand from GAVI-eligible countries in exchange for long term supply commitments
- First disbursement from US\$1.5B AMC funds to take place upon approval of the first vaccine to meet the Target Product Profile (must contain serotypes 1, 5 and 14 and over at least 60% of the invasive disease isolates in the target region)
- First vaccine to meet the TPP is expected in 2009



Different funding source and different procurement mechanism than for the short term procurement of PCV

Maximum PCV7 forecast 2008-2009

	2008	2009	Total
Predictable	543,380	1,086,759	1,630,139
Likely	3,404,616	6,928,780	10,333,396
Possible	1,308,123	6,185,084	7,493,207
Total	5,256,119	14,200,623	19,456,742



Request for Commercial Interest

- To issue to industry at the time of Request for Proposal a Request for Commercial Interest in PCV
 - Equal access to information
 - Transparency
 - Long term signaling to industry including strategic demand forecast
- To have input from industry in a commercial framework (non-binding and confidential)
 - Type of pipeline vaccines
 - Project status and expected timelines to prequalification
 - Indicative pricing
 - Capacity available to developing countries

Next procurement step

1. Issue Request for Proposal and Request for Commercial Interest for Pneumococcal Conjugate Vaccine
 - Documents in draft
 - Prequalification of first PCV
2. Evaluation of offer and sole source negotiation
3. Establishment of Supply Arrangement Q2 2008
4. First shipments in countries Q4 2008 to allow for introduction January 2009

Conclusion

- Procurement processes are in place and on track for Pneumococcal Conjugate and Rotavirus Vaccines to support the **accelerated** vaccine introduction in GAVI-eligible non-PAHO countries through an **uninterrupted supply** of vaccines of **assured quality**
- Procurement mechanism for second generation Pneumococcal Conjugate Vaccine through AMC funding is currently under preparation and to be in place at time of prequalification of first eligible vaccine

New challenges with new vaccines

- Which diseases should countries prioritize?
- Cold chain challenges
- First introductions
- Differentiation between vaccine formulations – how to allocate?
- Stand alone vaccines vs. adding on antigens to existing vaccines
- Different funding mechanisms – implications for procurement mechanisms
- Non global recommendations for usage – influence on demand
- Simultaneous introduction in developing and industrialised countries – competition for capacity?

Thank you!