Update on Rotavirus Vaccine

Industry Consultation Meeting
UNICEF Supply Division
25-26 January 2012
Overview of presentation

- Update on country demand for Rotavirus Vaccine
- Procurement activities and results for Rotavirus Vaccine
Update on country demand for Rotavirus Vaccine
Sept 2009: 8 country applications received, 3 recommended for approval in 2010 for two vaccines

First introduction in a GAVI supported African country in July 2011

May 2011, 25 countries requested GAVI support:
- 14+2 countries approved, of which 8 for introduction in 2012
- 8 conditional approvals – to be reviewed in February 2012
- 3 countries requested to resubmit new applications – next round expected September 2012
GAVI Strategic Demand Forecast projects a total of 46 countries to introduce by 2015, of which another 14 countries are expected to introduce by 2015 at the latest.

Current estimate for required supply through UNICEF for 2012-2016 of 124 million courses.
GAVI SDF projects demand in 73 GAVI countries to reach 205 million doses by 2026

**AVI SDF v4.0: Total required supply from GAVI 73 including countries graduating before introduction**

![Graph](image)

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Source: AVI-PATH
Procurement activities and results for Rotavirus Vaccine
Steps leading up to first procurement

• First two vaccines WHO pre-qualified in Jan 2007 and Oct 2008

• First 3 country applications to GAVI for support for Rotavirus vaccines in Latin America accepted and approved in 2007

• WHO position paper (Dec 2009) recommends:
  • Rotavirus vaccine for infants should be included in all national immunization programmes.
  • In countries where diarrhoeal deaths account for ≥10% of mortality among children aged <5 years, the introduction of the vaccine is strongly recommended.
UNICEF procurement activities to support planned country introductions

- Request for Proposal to meet demand in a single country for 1 year for a specific vaccine (December 2010)

- Expression of Interest sent to 39 manufacturers to provide confidential advice to UNICEF on supply factors, including public sector prices to guide procurement strategy (March 2011)

- Request for Proposal for GAVI countries (April 2011)
  - 5 year tender duration to facilitate access to lower prices and to allow access for pipeline products
  - Issued to manufacturers indicating to have products of assured quality available for supply within the duration of the tender
  - Offers accepted for any Rotavirus vaccine product with WHO PQ or expected WHO during the tender timeframe
UNICEF procurement activities to support planned country introductions

With the objectives to a) ensure a low vaccine price per course, b) an adequate supply base, and c) appropriate products:

- Awards made to two suppliers with WHO prequalified vaccines
- Total awards of 68 million courses (out of 88 million courses included in the tender)
- Contracts currently being established with alternative payment/contracting terms

UNICEF, in consultation with a GAVI Procurement Reference Group, opted to reserve demand quantities for future awards in order to provide incentives for manufacturers with products in development to accelerate, if possible

- 20 million courses left unawarded (but likely +50 million courses more to be needed through 2016, based on current demand forecasts)
- Dependent on timing of country readiness for introduction, some countries may be required to postpone introduction from 2013.

- Additional awards will be required and likely a new tender in a few years to meet the considerable increase in requirements.
In Summary

A high level of demand for Rotavirus vaccine to be supported by GAVI:
• 1 new country introduced in 2011, 8 scheduled for 2012 and 8 more approved for 2013

Considerable scale up of supplies, however, supply gaps likely in 2013

Innovative contracting provisions applied in order to meet procurement objectives related to lower/affordable prices in addition to ensuring continued supply

Supplier base limited due to early stage of market development

Quantities left un-awarded to incentivize new manufacturers to develop products and enter the market
Thank You