Middle Income Country (MIC) New Vaccine Procurement
(MINErVA Procurement Initiative)
6 December 2012

1. Background:

Nearly 75% of the world’s poor live in countries classified as Middle Income Countries (MICs). Most Lower Income Countries (LICs) receive significant financial support for the introduction of new vaccines benefitting their national immunization programs. In contrast, only 21 out of 108 of the MICs are eligible to receive GAVI financial support. Without any access to preferential pricing structures, many MICs either pay high prices for new vaccines or forego procurement due to lack of alternative affordable options. These high prices have been identified as one of the principal barriers preventing the introduction of new vaccines in MICs. In order to address the growing disparities in vaccination coverage, UNICEF is launching a procurement initiative to support MICs. The goal is to accelerate access and the introduction of the following newly developed vaccines which prevent some of the larger contributors to Under-5 Mortality and Cervical Cancer: Human Papillomavirus (“HPV”), Pneumococcal Conjugate (“PCV”) and Rotavirus (“Rotavirus”) vaccines.

In addition to facilitating vaccine introduction through procurement, UNICEF seeks to help these vaccines to reach children via a more efficient and sustainable market. To support this, UNICEF will pool MIC demand, will provide aggregated demand forecasts to industry, and will channel supply availability and product information to countries to optimize procurement. Simultaneously, UNICEF will seek to establish reference pricing for countries opting to continue self-procurement. UNICEF intends for this initiative to be a temporary (“time bound”) intervention, with the aim of these countries incorporating HPV, PCV and Rotavirus into their regular immunization programmes.

1.1. Hybrid Approach to the Initiative

- **Pooled Procurement:** A multi-stage tender process soliciting country-level subscription. In response to estimated country demand, Manufacturers will formally offer prices and volumes. Country-level subscription with then be followed by tender awards to Manufacturers for each product. This process would create a pooled demand, over a multi-year period, combining countries that already procure these vaccines through UNICEF together with those countries representing an un-penetrated market. The combined birth cohort will represent a significant market opportunity to Manufacturers. Additionally, by providing multi-year visibility and UNICEF’s credibility as a manager of the procurement process, we expect Manufacturers to offer improved prices. Over the past 6 months, UNICEF has solicited (non-binding) country interest to build a provisional demand forecast to present to Manufacturers. Once Manufacturers have submitted offers of available volumes and prices (expected in January-February 2013), Countries will have the opportunity to formally subscribe to target volumes prior to the award of a tender.

- **Reference Prices:** Approaching vaccine Manufacturers and pre-negotiating price levels that can be accessed by those countries already self-procuring, or used as a reference point in future bilateral negotiations. Through this initiative, UNICEF offers a modality which provides increased transparency of prices. It supports Countries with solid procurement capacity that wish to benefit from the initiative, but still continue to self-procure. UNICEF expects that while the prices will be publicly available (via UNICEF’s website), the actual utilisation of any Reference Pricing in Country-Manufacturer negotiations may come
with specific terms and conditions from individual suppliers (e.g., letters of credit and other standard commercial terms).

2. **Strategy:**

2.1. **Goals and Objectives**

- **MIC “price discovery” and transparency.** This initiative aims to improve price transparency which will in turn support other objectives such as incremental affordable pricing. Opaque pricing and a lack of comparable price levels have been some of the hurdles constraining country-level decision making.

- **Improved & accessible MIC vaccine affordability.** This initiative aims to improve the overall aggregated pricing of new vaccines available to Countries. Improved pricing will be principally accomplished through pooling of substantial volumes and improved visibility to Manufacturers (in addition to other mechanisms). Improved MIC vaccine affordability should lead to:
  - **Increased introduction of new vaccines in MICs.** Affordable new vaccines will eliminate one of the barriers to HPV, PCV and Rotavirus vaccine introduction.
  - **Improved equity of new vaccine uptake and use.** An increased rate of introduction should contribute to the convergence between the introduction of new vaccines, its uptake and use between the MICs and other income classifications.

- **Establish an accessible mechanism for countries graduating from GAVI support.** This initiative seeks to give countries that have entered or will enter the GAVI graduation process, a mechanism through which their immunization momentum could be sustained. This would apply to countries whose procurement is no longer secured in a post-graduation period through existing mechanisms (e.g., the PCV AMC already provides longer-term access to preferential pricing).

- **Expansion of capacity and new suppliers (long-term).** By facilitating country-level access to Manufacturers (and vice-versa), this initiative supports incentives for suppliers to expand their production capacity, particularly in those product markets which are currently “supply constrained”.

- **Build an efficient, sustainable mechanism that can “graduate” from UNICEF management.** UNICEF engagement will be on a “time-bound” basis. UNICEF intends to exit the market as objectives are met, and as a healthy, efficient and self-sustaining market is generated.

2.2. **Procurement Approach**

- **Open access to new markets through pooled demand.** By supporting the introduction of new vaccines in untapped markets, UNICEF looks to promote an increasingly affordable pricing structure. This would be accomplished through increasing volumes and substantially improved visibility, planning, and predictability.

- **Seek reference prices for countries that wish to procure independently.** UNICEF will secure quotes for Reference Prices together with associated qualifying terms and conditions. These Reference Prices can be utilised by countries that continue to self-procure when engaging the traditional levers of independent negotiations. These Reference Prices will additionally provide increased transparency for a broader global community.

- **Avoid over-organization / over-segmentation of the market.** UNICEF is promoting a MIC vaccine market which will function efficiently after UNICEF’s eventual exit, and will especially maintain un-interrupted
supply. Reliance on rational pricing models that do not over-organize the market should support long-term sustainability.

- **Provide increased visibility and credibility of demand to Manufacturers.** By providing increased visibility for demand, timing and procurement credibility, UNICEF seeks to receive increasingly attractive offers from Manufacturers.

The initial tender process will also be noted by the following:

- UNICEF will consult with countries to review details and preferences of their demand during the tender process in order to ensure accurate updates and to better assess the final volume of those demands.
- Manufacturers will be asked to formulate pricing that is sensitive to the overall development level of countries which could reflect, for example, macroeconomic development, disease incidence, ability to pay and income inequality.
- UNICEF will initially present the forecasted demand based on the respective birth cohort / target population during specified time periods. Manufacturers will be asked to respond to this demand in terms of doses required, subject to the specifications and presentation of their vaccines.

### 2.3. Duration

The expected duration established for this tender will be multi-year (i.e., 2.5 years), with Purchase Order (PO) placements starting in June/July 2013.

### 2.4. Early Country Indications on Strategy Preferences

19 countries have expressed interest in at least one of the proposed procurement options (Pooled Procurement vs. Reference Prices). These countries alone have a combined birth cohort of 7.2 million infants per year. This makes up over half of the identified realistically addressable MIC birth cohort. The vast majority of countries, 13 in total, have expressed interest in introducing all 3 vaccines covered by this initiative. However, plans and scheduled timing of introduction do vary significantly from country to country. While these expressions of interest are still indicative and non-binding, they do point to a strong interest among MICs in a comprehensive procurement strategy that supports the adoption of new vaccines.

### 2.5. Solicitation Method

- **Issuance of an open, multi-product RFP:** This will include the potential downstream request for (indicative) offers of currently non-WHO-prequalified product or products in development.
- **Tender with approximate demand:** This process will be followed by a “pause” to collect country data on subscriptions with offered volumes and prices, before the final tender awards.
- **Reference price request:** UNICEF will make a simultaneous request for the quotation of Reference Prices. The demand will be generated from the initial demand from the non-binding surveys.
3. Implementation Plan:

3.1. Timeline and Milestones

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| 2012 | NOVEMBER | • Procurement strategy is discussed with countries, partners and Manufactures. Tender documents designed and prepared.  
          • UNICEF Regional Offices (RO), Country Offices (COs) and Country Ministries of Health (MoH) Webinars held to describe basic mechanism. |
|      | DECEMBER | • Follow-up with Countries for final assessment of demand and categorization revision ahead of RFP launch.  
          • Issuance of RFP document.  
          • Tender meeting review with Manufacturers.  
          • Update Manufacturers with clarification note following expectation of any newly revised country interest. |
| 2013 | JANUARY  | • Responses due from Manufacturers (likely late January).                  |
|      | FEBRUARY | • Evaluation of RFP responses and compilation of offers into ‘menu’ for Countries.  
          • WHO Technical Assessment.  
          • Brief consultation with PRG body (including country representatives).  
          • Consultation with subscribing Countries to determine demand and formal subscription. |
|      | MARCH    | • Clarifications and negotiations and revised formal subscription.  
          • Final consultation with PRG body. |
|      | APRIL/MAY| • UNICEF recommendations and approvals, including Contracting Review Committee (CRC).  
          • Award Letters. |
|      | JUNE/JULY| • POs to commence. |
3.2. Invitee List

- **Manufacturer invitee list:** UNICEF will invite to the tender all manufacturers with a confirmed product or product in development, in addition to an explicit note to all current LTA holders. Additionally, UNICEF will also post the tender on its web-page for ease and accessibility to all those who may consider a response.

- **Country invitee list:** UNICEF’s initial list of candidate countries includes those qualified as a MIC according to the World Bank income (GNI) ranking. It is assumed that all countries from TACRO (i.e., Americas region), which procure through the PAHO Revolving Fund, would continue to do so. Also, UNICEF assumes that all self-producing countries will continue to do so. UNICEF welcomes any interest and encourages countries to contact their CO and / or the individuals listed at the end of this document for more information.

3.3. Criteria for Evaluation of Offers from Manufacturers

The evaluation of offers will follow UNICEF standards. It will consist of a technical evaluation of the individual products, assessment of the manufacturer’s capacity to comply with set requirements: manufacturing standards, experience and capacity; followed by a commercial evaluation: price, payment terms, lead time, delivery point, landed costs and past performance. The criteria, both quantitative and qualitative, will be used to evaluate the merit of proposals to meet the objectives of the tender (listed before in the “objectives” and below):

- Sustainable low per course price.
- Uninterrupted and sustainable supply.
- Appropriate quality vaccines.

3.4. Publication of Awards

In relation to this bid, the following information will be made public:

- Suppliers awarded Long-Term Agreement (LTAs) for supply of each of the vaccines.
- Duration of the award.
- Total contract value per supplier.
- Awarded prices.
- Potential Range of Pipeline Prices.
- Reference Prices + Terms.
3.5. Procurement Process through UNICEF SD

Procurement on behalf of MICs will be conducted through UNICEF Procurement Services. The process comprises of 5 simple steps:

1. Planning
2. Cost Estimate
3. Commitment
4. Procurement & Delivery
5. Accounts Settled

In order for UNICEF to issue a PO, the following must be in place:

a) Signed MOU (Customer / Director SD). The MOU outlines UNICEF Procurement Services processes and sets out the Terms and Conditions for individual transactions. The Procurement Services Centre is the Supply Division focal point for establishing the MOU, which includes:
   - Co-operation Agreement
   - UNICEF Procurement Services processes
   - Terms and Conditions for the transactions
   - Validity or termination information for either party.

b) Funds received by UNICEF SD. Upon the acceptance by recipient partners of issued cost estimates, financial resources are required to be deposited prior to the issuance of a PO.

4. Related Links

- Memorandum of Understanding (MoU) for Procurement Services (for Countries):
  [http://www.unicef.org/supply/index_23869.html](http://www.unicef.org/supply/index_23869.html)
- UNICEF SD Procurement Services (PS) Resources (for Countries):
  [http://www.unicef.org/supply/index_purchasing.html](http://www.unicef.org/supply/index_purchasing.html)
- UNICEF Most Recent MIC Tender Plan and Implementation (Webinars, 28-29 November 2012):
  [http://www.unicef.org/supply/index_66523.html](http://www.unicef.org/supply/index_66523.html)
- UNICEF MIC Strategy Presentation (at WHO November 2012 SAGE):
- UNICEF MIC Strategy Hand-out (at WHO November 2012 SAGE):
5. Contact

For further questions or additional information, please contact:

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