UNICEF UPDATE:
Plans and Priorities in Procurement to achieve Vaccine Security

Vaccine Industry Consultation
Copenhagen, 17 September, 2019
UNICEF procures vaccines & vaccine related supplies for around 100 countries annually.

Immunization Supplies:

**Vaccines**
- BCG, DTP, TT/Td, OPV
- HepB, HepA, YF, Penta, MCV
- Meningococcal, PCV, IPV, HPV
- JE, OCV, Rota, Typhoid, Malaria, Seasonal Influenza

**Safe Injection Equipment**

**Cold Chain Equipment**

2018

| Vaccines: US$ 1.453 billion | 2.36 billion doses | 2,628 shipments |

For full and partial schedules, information is based on country forecasts to UNICEF for 2019.

This map does not reflect a position by UNICEF on the legal status of any country or territory or the delimitation of any frontiers.
OPV remains the volume driver, but declining (in doses)
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Source: UNICEF Supply Division
Vaccine Procurement Overview
UNICEF’s procurement is focused on achieving Vaccine Security:

*The sustained, uninterrupted supply of affordable, vaccines of assured quality.*

- To achieve value for money and access to vaccines for children in need;
- Achieving healthy markets through the Vaccine Security approach (forecasting, funding and appropriate contracting) and specific vaccine procurement principles;
- Vaccines as biological products – requiring a specific approach for vaccine procurement;
- Quality of vaccines through prequalification by WHO – ensuring acceptability, in principle, as well as quality, safety and efficacy in target population of procured vaccines.
UNICEF Vaccine Procurement Principles

1. A healthy industry is vital to ensure uninterrupted and sustainable supply of vaccines

2. Procurement from multiple suppliers for each vaccine presentation

3. Procurement from manufacturers in developing countries and industrialized countries

4. Paying a price that is affordable to Governments and Donors and a price that reasonably covers manufacturers minimum requirements

5. UNICEF should provide manufacturers with accurate and long-term forecasts; Manufactures should provide UNICEF with accurate and long-term production plans

6. As a public buyer, providing grants to manufacturers is not the most effective method of obtaining capacity increases

7. The option to quote tiered pricing should be given to manufacturers.
UNICEF guiding procurement principles

- Fairness, integrity and transparency through competition
  (clear & appropriate regulations/rules applied to all suppliers, fair process, equal treatment of suppliers, transparent system)

- Economy and effectiveness
  (meet requirement in terms of quantity, quality, timeliness at the right place. Economy=minimize cost, Effectiveness=meet end-user interest)

- Best value for money
  (Consider the optimum combination of factors in meeting the end user needs; BVM does not mean lowest cost but best ROI)

- Promotion of objectives of UNICEF
  (fulfilling the mandate, goals and objectives)

Each UN organization has a different mandate, but all UN organizations share the same procurement principles.
Nearly two decades ago!

United Nations Children’s Fund
Executive Board
First regular session 2002
21-25 January 2002
Item 6 of the provisional agenda*

Vaccine security: ensuring a sustained, uninterrupted supply of affordable vaccines
The broad public health community on Vaccine Security must be focused on:

- Ensuring every child has timely access to vaccines, winning support from decision-makers and the wider public in recognizing the value of vaccines and immunization across the life cycle and in ensuring sufficient resources are earmarked;

- Stimulating manufacturers from both IFPMAC and DCVMN to ensure an uninterrupted supply of quality assured vaccines to all countries, leveraging the power of business and markets;

- Embracing and fostering innovation on vaccine improvements, new platforms and production technologies that enhance vaccine access.
The basic pillars of vaccine security are available funding for vaccines, accurate forecasting and appropriate contracting. This focus needs to be continued but with major shifts foreseen over the next decade:

**Available funding:** Gavi has been the source of secure funding for a major portion of procurement through UNICEF, but as countries transition from Gavi support there will be more uncertainty regarding demand and the timing of demand especially for more expensive vaccines. UNICEF will focus on enhancing its financing options through procurement services, and work with countries to secure sufficient domestic resources for vaccines well ahead of need in order to meet manufacturer deadlines for delivery.

**Accurate forecasting:** Most challenges in meeting demand have been related to unpredictable forecasts especially for the introduction of new vaccines. The next decade should include clear programming in policy planning on specific vaccines to ensure that manufacturers have the needed lead-time to scale up production.

**Contracting:** Longer-term contracts, firm orders, pre-payment and bank guarantees have all been used but innovation is important to be able to effectively respond to country demand, including pull incentives and contracting and stockpiling of vaccine that have not achieved (and may never) regulatory approval.
## Vaccine Market Overview

<table>
<thead>
<tr>
<th>Typology</th>
<th>Risks</th>
<th>Procurement Approaches</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Traditional Vaccines (Routine):</strong> BCG, Td, Hep B, YF, M/MMR</td>
<td>Increasing WAP</td>
<td>Longer term (5+ years) contracting for improved visibility of demand and stability of pricing</td>
</tr>
<tr>
<td>Vaccine Introductions (Routine): Penta/Hexa, PCV, Rota, HPV, IPV, MR JE, TCV, MenA</td>
<td>Product preference; interchangeability of products; First to market price premium; convergence of pipeline suppliers to the market; Country procurement and demand is not aligned with supply/production planning</td>
<td>Longer term demand planning with countries (7-10 years) for improved visibility; Longer term contracting to achieve affordable pricing; Special contracting considerations to achieve procurement objectives</td>
</tr>
<tr>
<td><strong>Global Polio Eradication Initiative:</strong> OPV, mOPV, nOPV</td>
<td>Managing market exit in set timeframe (2023) while maximizing production; Limited bulk suppliers; Response to outbreaks – sufficiency of stockpile and rapid replenishment</td>
<td>Close collaboration (Working Groups) at the global level including suppliers Good faith agreements, acknowledging risk sharing Blend of service and goods contracts</td>
</tr>
<tr>
<td><strong>Emergency Response (stockpiles):</strong> Meningococcal OCV, YF, Ebola</td>
<td>High level of demand uncertainty for preventative and outbreaks requirements; Limited routine program to utilize vaccine (rolling stockpiles) leading to high level of investment to secure quantities for stockpile; Rapid replenishment of stockpiles</td>
<td>Special contracting considerations to achieve procurement objectives UNICEF warehousing of vaccines (exploring)</td>
</tr>
<tr>
<td><strong>Vaccine Development:</strong> Chikungunya, Zika, Shigella, Lassa</td>
<td>Uncertainty of demand Uncertainty of the immunogenicity, efficacy, safety, program recommendations for use</td>
<td>Close collaboration with suppliers (non-competitive) Blend of service and goods contracting UNICEF warehousing of vaccines (exploring)</td>
</tr>
<tr>
<td><strong>Non-Standard Vaccines:</strong> Rabies, Hep A, self-financing MIC demand outside of tenders</td>
<td>Uncertainty of demand Securing supply at affordable, predictable prices</td>
<td>RFQ Development of time-bound supply agreements</td>
</tr>
</tbody>
</table>
Across the need to continue and enhance current actions and introduce new modalities, UNICEF involvement across country, regional and headquarter's offices must address two broad themes related to Vaccine Security going forward:

**Market intelligence**, providing reliability and predictability on global vaccine demand and supply.

**Capacity building** to develop national supply chain systems, including the upstream on procurement and financing, and downstream on vaccine management, delivery, monitoring and evaluation.
Key Market Updates

Visit UNICEF’s website on market updates here: https://www.unicef.org/supply/
Knowledge Sharing and VPPEF

• Launched online forum (http://www.vppnetwork.org/) to support peer-to-peer exchange… The Vaccine Procurement Practitioners Network (VPPN)

• Working with partners (Gavi, BMGF, R4D) to integrate within knowledge sharing platform for Gavi transitioning countries
New Initiatives: Strategic Vaccine Procurement

Vaccine procurement assessment toolbox
- **What:** A standardized methodology for governments to assess national vaccine procurement processes
- **When:** Expected January 2020
- **Who:** National governments

Vaccine procurement e-learning course → Under development (in collaboration with Global partners and Industry)
- **Objective:** Participants to be able to identify & understand the strategic vaccine procurement cycle & its tools and processes to ensure sustainable access to affordable vaccines
- **Collaboration:** BMGF, CHAI, DCVMN, IFPMA, Gavi, MSF, Norwegian IPH, WHO, PAHO, Path, World Bank,
- **Status:** All modules are under development, with most within the peer review stage
Regulatory update

Demand

- Some countries have local licensure requirements for vaccines, including WHO pre-qualified vaccines of assured quality.
- The regulatory requirements of countries that accept WHO PQ vaccines may change without prior notice; clarity of registration pathway and insufficient time for manufacturers to register.

Supply

- There are instances where documented waiver of registration is required from countries where vaccines are not yet registered.

Impact

- Regulatory challenges are a risk to vaccine security, shipments may be cancelled or quarantined on arrival
- Additional costs due to regulatory challenges and investments to register vaccines across several countries.
Regulatory update: Processes to mitigate supply risks

A database of country regulatory requirements and registration status of supplier-specific vaccines in 100+ countries. (Currently 2080 files of vaccines registration data and growing)

Contractual requirements of bidders to share registration status of their products and commitment to continuously share updates on new registrations, variations and renewals.

Advocacy with partners and countries through VPPF, VPPN, annual forecasting exercise for continuous improvement.

Working with countries to secure official confirmations of their NRA requirements from their designated government officials for the MOH.

- Year to date, 22 out of 52 countries that accept WHO PQ have confirmed with an official letter
- These countries also agreed to provide sufficient notice and transition time for any future changes in NRA requirements, including clarity on the pathways for vaccines licensure

*Official letter received from the Minister of Health or a designated official to confirm that WHO PQ is accepted*
ENIRONMENTAL SUSTAINABILITY SHEET

As UNICEF moves towards the implementation of the Sustainable Development Goals, we are keenly interested in the efforts made by the manufacturers and suppliers towards sustainable initiatives and would like to collect information about such initiatives. Hereby you are kindly requested to read and answer below questions and return the filled questionnaire along with your submission in response to UNICEF’s RFP-DAN-2018-502784.

Important: The questionnaire is not a part of the mandatory requirements. Your answers to the questionnaire will not be used in the evaluation of the offers.

1. Does your company have a formal Environmental policy? If yes, please include the copy.
2. Does your company have an Environmental Management System in place e.g. ISO 14 001 or equivalent? If yes, please include the copy.
3. Does your company have an Energy Management System in place comparable to e.g. ISO 50 001 or equivalent? If yes, please include the copy.
4. Please indicate the percentage of your company’s power consumption from non-renewable energy sources and provide information on any plans to convert to renewable energy sources. (Your original question)
5. Does your company monitor CO2 emission from its operations, including production, travel, and transport of goods?
6. Please list the 3 main negative Environmental impacts of your manufacturing facility, and explain how you are working to reduce / prevent those impacts as well as highlight any specific results achieved so far.
7. Does your company have a recycling plan for the waste generated in vaccine production?
8. Does your company have a formal plan to reduce waste generated in vaccine production?
9. Please indicate how your company handles pharmaceutical waste, and attach certificates issued by local authorities or any subcontracted company handling the pharmaceutical waste.
10. Please indicate the percentage of any recycled material used in production?
11. Does your company use any recyclable material for packaging and/or labelling of vaccines, or tries to reduce the environmental impact of packaging of goods?
Environmental Sustainability – Baseline Assessment

- Corporate Environmental Policy: 70%
- Certified Environmental Management System: 43%
- Certified Energy Management System: 35%
- Plan to convert to renewable energy: 39%
- Monitoring CO2 Emission: 48%
- Waste Management: Recycle Plan for Waste: 61%
<table>
<thead>
<tr>
<th>Product</th>
<th>2019</th>
<th>2020</th>
<th>Current Award Period</th>
<th>Next Award Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Papilloma Virus Vaccines (HPV)</td>
<td>Q4</td>
<td>Q1</td>
<td>Q2</td>
<td>Q3</td>
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<tr>
<td>Ebola Vaccine</td>
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<td>Hepatitis B Vaccine - pediatric (Hep B)</td>
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<td>Diphtheria, Tetanus and Pertussis vaccine (DTP)</td>
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<tr>
<td>Pentavalent Vaccine (Penta)</td>
<td>2018-2020</td>
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<tr>
<td>Measles Containing Vaccine</td>
<td></td>
<td>Q4</td>
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<tr>
<td>Yellow Fever Vaccine</td>
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<td>Rotavirus Vaccine</td>
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<td>Pneumococcal Conjugate Vaccine</td>
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<tr>
<td>Typhoid Conjugate Vaccine</td>
<td>2019-2020</td>
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<tr>
<td>Inactivated Polio Vaccine</td>
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<td>Meningococcal Vaccine (Stockpile and Men A)</td>
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<tr>
<td>Oral Cholera Vaccine</td>
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<tr>
<td>Rabies Vaccine</td>
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<tr>
<td>Adult Tetanus Toxoid (TT) and Tetanus-Diphtheria (Td) Vaccines</td>
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<td>Japanese Encephalitis (JE)</td>
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<tr>
<td>Bacillus Calmette-Guerin vaccine (BCG)</td>
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<tr>
<td>Bivalent Oral Polio Vaccine (bOPV)</td>
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Shipping and Logistics – 2018 Summary

- 2629 Shipments
- 2154 POs
- 244 Critical Shipments
- 25 Charter Flights
- 6,640 Tonnes
- 25 Suppliers
- 99 Destination Countries
- 32.8m (USD) Freight $

Measurable achievements - VAR

<table>
<thead>
<tr>
<th>KPI5 - VARs Received Within 3 Working Days - 2018</th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
<th>Grand Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Shipments</td>
<td>627</td>
<td>664</td>
<td>596</td>
<td>742</td>
<td>2629</td>
</tr>
<tr>
<td>Number of VAR Received</td>
<td>627</td>
<td>664</td>
<td>596</td>
<td>742</td>
<td>2629</td>
</tr>
<tr>
<td>% of VAR received</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Number of VARs received within 3 working days</td>
<td>454</td>
<td>460</td>
<td>441</td>
<td>523</td>
<td>1878</td>
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<tr>
<td>% of VAR received within 3 working days</td>
<td>72%</td>
<td>69%</td>
<td>74%</td>
<td>70%</td>
<td>71%</td>
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</tbody>
</table>
Supplier Performance

- Improved Supplier Performance card format
- Qualitative indicators and quantitative metrics
- ScoreCard covers all purchase orders that had deliveries in the current calendar year vs. KPI 4 that monitors the deliveries only under orders issued in the current year
- In context of new SP 2018-2021 focus on scorecards and results monitoring
Supplier Performance
LA Delivery Date – Statistical Delivery Date

KPI 12 performance

<table>
<thead>
<tr>
<th>Year</th>
<th>Performance</th>
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</thead>
<tbody>
<tr>
<td>2012</td>
<td>59%</td>
</tr>
<tr>
<td>2013</td>
<td>64%</td>
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<tr>
<td>2014</td>
<td>59%</td>
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<tr>
<td>2015</td>
<td>63%</td>
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<tr>
<td>2016</td>
<td>69%</td>
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<tr>
<td>2017</td>
<td>70%</td>
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<tr>
<td>2018</td>
<td>89%</td>
</tr>
<tr>
<td>2019 May</td>
<td>92%</td>
</tr>
</tbody>
</table>
THANK YOU!