UNICEF Vaccine Supply Overview: Priorities, status and way forward

Vaccine Industry Consultation
1 October 2018
UNICEF Supply Division, Copenhagen

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UNICEF procures vaccines & vaccine related supplies for around 100 countries annually

Immunization Supplies:

Vaccines
- BCG, DTP, TT/Td, OPV, HepB, YF, Penta, MCV, Meningococcal, PCV, IPV, HPV, JE, OCV, Rota, TCV, Hep A, Rabies

Safe Injection equipment

Cold Chain Equipment

This map does not reflect a position by UNICEF on the legal status of any country or territory or the delimitation of any frontiers.
UNICEF Annual Vaccine Procurement $
OPV Remains Main Volume Driver (in doses)

Source: UNICEF Supply Division
Emerging Market Country Manufacturers

2017: 1.3 billion doses with a value of $400m sourced from developing countries

Source: UNICEF Supply Division
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
UN Supplier Code of Conduct

All UN and UNICEF registered suppliers acknowledge the UN Code of Conduct. (rev. Sept 2013).

- Based on the UN charter, the principles of the Global Compact and ILO standards;
  - The UN expects that these principles apply to suppliers and their employees, parent, subsidiary or affiliate entities, and subcontractors; that they are seen as minimum standards that suppliers strive to meet and exceed them.

- The code addresses:
  - **Labour conditions**: Freedom of Association, no force or compulsory, no child labour, discrimination, standards for working conditions.
  - **Human Rights**: No Harassment, Harsh or Inhumane Treatment, no manufacture or sale of mines.
  - **Environment**: Compliance with regulations, manage chemical and hazardous materials; waste and air emissions, Minimize Waste, Maximize Recycling.
  - **Ethical conduct**: No corruption, conflict of interest declaration, no gift and hospitality, post employment restrictions.
UNICEF’s GTCs: Ethical standards overview

UNICEF’s General Terms and Conditions (GTC) of Contract

Article 7 (Ethical Standards)

• Anti-fraud
• Anti-corruption
• Sexual Exploitation and Abuse
• Post-employment restrictions
• Conflict of Interest Disclosure
• Sanctions and suspension

UNICEF may terminate a contract with immediate effect and no liability in case of breach of Article 7 of the GTC
7.2 (b) The Supplier represents and warrants that the following requirements with regard to former UNICEF officials have been complied with and will be complied with:

I. During the one (1) year period after an official has separated from UNICEF, the Supplier may not make a direct or indirect offer of employment to that former UNICEF official if that former UNICEF official was, during the three years prior to separating from UNICEF, involved in any aspect of a UNICEF procurement process in which the Supplier has participated.

II. During the two (2) year period after an official has separated from UNICEF, that former official may not, directly or indirectly on behalf of the Supplier, communicate with UNICEF, or present to UNICEF, about any matters that were within such former official's responsibilities while at UNICEF.
7.2 (c) The Supplier represents that, in respect of all aspects of the Contract (including the award of the Contract by UNICEF to the Supplier and the selection and awarding of sub-contracts by the Supplier), it has disclosed to UNICEF any situation that may constitute an actual or potential conflict of interest or could reasonably be perceived as a conflict of interest.
7.7 The Supplier represents and warrants that it has taken and will take all appropriate measures to prevent sexual exploitation or abuse of anyone by its Personnel including its employees or any persons engaged by the Supplier to perform any services under the Contract. For these purposes, sexual activity with any person less than eighteen years of age, regardless of any laws relating to consent, will constitute the sexual exploitation and abuse of such person. In addition, the Supplier represents and warrants that it has taken and will take all appropriate measures to prohibit its Personnel including its employees or other persons engaged by the Supplier, from exchanging any money, goods, services, or other things of value, for sexual favours or activities or from engaging in any sexual activities that are exploitive or degrading to any person. This provision constitutes an essential term of the Contract and any breach of this representation and warranty will entitle UNICEF to terminate the Contract immediately upon notice to the Supplier, without any liability for termination charges or any other liability of any kind.
UNICEF’s Policy on Conduct Promoting the Protection and Safeguarding of Children

• UNICEF’s Policy on Conduct Promoting the Protection and Safeguarding of Children re-affirms UNICEF’s long-standing commitment to promote the protection and safeguarding of all children, and to promote the universal understanding that the best interests of the child must be a paramount consideration in all actions affecting children.

• The policy is available at UNICEF’s procurement policies webpage: https://www.unicef.org/supply/index(procurement_policies).html
<table>
<thead>
<tr>
<th>Avoid Conflicts of Interest</th>
<th>Conduct business during working hours</th>
<th>Make an agenda and minutes for all meetings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zero-Tolerance Policy towards unethical behaviour</td>
<td>Bring a colleague to all meetings</td>
<td>Ensure sufficient distance – especially if relationship of many years</td>
</tr>
<tr>
<td>Do not accept gifts and gratuities</td>
<td>Use a meeting room, not your office</td>
<td><strong>Intention: Protect the supplier and staff!</strong></td>
</tr>
</tbody>
</table>
UNICEF’s procurement policies webpage

- Webpage address: [https://www.unicef.org/supply/index_procurement_policies.html](https://www.unicef.org/supply/index_procurement_policies.html)


- Provides information/links to all the key UNICEF (and UN) policy documents including the UN Supplier Code of Conduct, the Global Compact, UNICEF’s Policy Prohibiting and Combatting Fraud and Corruption, UNICEF’s Policy on Conduct Promoting the Protection and Safeguarding of Children, UNICEF’s Information Disclosure Policy and UNICEF Procedure on Sustainable Procurement.

- Supplier feedback/complaints: Your views are important to us and your feedback and complaints are taken seriously in Supply Division. If you have any complaint, please contact Quality Assurance Centre: [sd.complaints@unicef.org](mailto:sd.complaints@unicef.org)
UNICEF’s standard contractual texts

UNICEF standard contracts, Long Term Agreements (LTA) & solicitation documents are made up of various elements, notably:

• Description of goods or Terms of Reference for services
• Contractual provisions
• Invoicing & shipping (in the case of goods) instructions
• General Terms and Conditions (GTCs)
  • (including information on delivery; inspection; risk of loss; price; invoicing; insurance; confidentiality; termination; etc.)
Opening and publication of elements of proposal

- Due to the nature of the RFP, there typically is no public opening of proposals.

- Supplier name, vaccine, price, quantity, duration of award, and total award value.

- Annual awarded **Weighted Average Prices** for each vaccine presentation.
Confidentiality

• Except for the elements specifically mentioned to become publicly accessible, information in proposals will be treated as confidential.

• WHO technical assessor will have access to technical aspects of the proposal.

• UNICEF will share aggregate information related to proposals and award recommendations with a Procurement Advisory Group under confidentiality and provided declaration of any conflicts of interests.

• UNICEF will share general principles offered for supply risk mitigation and related costs, including special contracting terms requiring financial backing.
Proposals for Products not yet pre-qualified

Detailed plan on timeline to obtain WHO pre-qualification, product and plans for manufacturing and licensing required

- Product Development: Status and plans, including source of bulk antigens to be used;
- Clinical Trials: Trials conducted so far and planned, with timelines;
- National Regulatory Registration: Status and plans for registration, including NRA that would be responsible for release of finished product and planned product presentations; and
- File submission to WHO: Status and plans
Does UNICEF procure vaccines without WHO pre-qualification?

**Availability of quality assured vaccines:**
UNICEF procures WHO prequalified vaccine.

If there is limited or no supply of prequalified vaccine, UNICEF has established criteria to ensure the quality of the product including:

A) The manufacturer must be WHO pre-qualified for supply of at least one other vaccine.
B) The vaccine must be licensed by the NRA in the country of origin, and this NRA must be functional (as assessed by WHO/RSS)
C) The vaccine must be registered in at least two additional countries with functional NRAs (as assessed by WHO/RSS).

In emergency situation where there are no options that meet the criteria, we will procure with the approval of the recipient country and WHO endorsement

**Product registration in country:**
Approval is required by country to permit the vaccine into country if there are no other options available; we must respect the NRAs; support from WHO if/as needed
Vaccine Procurement: Priorities
UNICEF Tenders will focus on multiple elements crossing the 3 pillars (Environmental, Economic, Social) of sustainable procurement and extending along the supply chain, including:

- **Influencing Industry’s Sustainable Procurement (SP) Policy**: Continue driving for green manufacturing (QMS) and address social SP elements through requiring industry to report on such

- **Implementing Sustainable Procurement Criteria**: Implementation within the Tender activity, including SP elements in the tender evaluation (Weight, Volume, Local manufacturing); GTC requirements

- **Internal process**: Introduce step one of e-tendering through switching from paper based to electronic bid submissions

- **Leveraging procurement functions**: Reducing the resultant waste generated

UNICEF shipped over 30,000m³ (5,500 tons) of Safe Injection Equipment in 2016, generating contaminated waste, requiring disposal.
ENVIRONMENTAL 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. Herewith 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-

Important: The questionnaire is not a part of the tender 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 recycled material for packaging and/or labelling of vaccines, or tries to reduce the environmental impact of packaging of goods?
Vaccine Introductions

**Global PCV Introduction Status 2018**
- Introduced into National Program: 142 countries (73%)
- No Decision: 35 countries (18%)
- Planning Introduction: 17 countries (9%)

**Global HPV Introduction Status 2018**
- Introduced into National Program: 90 countries (46%)
- Planning Introduction by end of 2021: 34 countries (18%)
- No decision: 71 countries (36%)

Source: IVAC Global Vaccine and Introduction March 2018
Source: PATH August 2018
Supporting Countries

**Forecasting and shipment planning**

- Annual forecasting with all countries, review and analysis of forecast submissions from countries with inputs from SD (historical forecast, existing stock levels, etc) (MSDEU)
- Regular communications and guidance to country offices on shipment plans, stock levels and CEs
- ViVa support, mobile VAR

**Gavi co-financing support**

- Co-financing monitoring and identification of countries at risk
- Cost Estimates issuance and coordination of procurement
- Financing support through VII or other pre-financing options (PSC)

**Procurement capacity building**

- Procurement TA through:
  - Vaccine Procurement Practitioners Exchange Forum (VPPEF) – both global and regional
  - Vaccine Procurement Practitioners Network (VPPN)
  - Ad-hoc in-country missions

**Knowledge management**

- Market Notes / Market Dashboard
- Pricing tool / Gavi Product Menu and Gavi Shipment Plan (monthly) / Stockpile Visibility
- ViVa – online tool for EPI managers to assess stock levels
Regulatory Systems Strengthening

- Favorable regulatory environment e.g. advance notice on imminent changes in requirements
- Provision of temporary waivers of licensure requirements to allow transition period for registration
- Acceptance of collaborative procedure
- Clarity on regulatory requirement for vaccines at country level
- Improved coordination between Country Office, UNICEF SD and in-country coordination between EPI/MOH and NRA
UNICEF's role in vaccines for emergency response

Scientific leadership
- WHO
- CEPI
- Supported by scientific community (KOLs)

Push funders
- CEPI
- BMGF
- BARDA
- NIH
- EU
- Welcome Trust
- Venture capital
- Industry (+ merger & acquisition)

Vaccine developers
- Universities
- Institutes
- Small & Midsized Entities (SMEs)
- MNC
- Developing Country Vaccine Manufacturers (DCVMN)

Vaccine Manufacturers
- Small & Midsized Entities (SMEs)
- MNC
- Developing Country Vaccine Manufacturers (DCVMN)
- …

Emergency response funders
- Governments
- GAVI
- WB
- …

Experimental phase
- Preclinical testing
- Phase I safety/ POC
- Phase II Dose/ safety
- Phase III Efficacy/ Safety
- Regulatory approval
- Bulk production filling
- Packaging/ batch release

QC/ cGMP Scale up manufacturing

Emergency response
- Prelicensure
- Post licensure

NOTE: Certain emergency vaccines may be never licensed, while access is required
# Key Market Updates

Visit UNICEF’s website on market updates here: [https://www.unicef.org/supply/](https://www.unicef.org/supply/)

### SUPPLIED BY UNICEF FOR GAVI, THE VACCINE ALLIANCE

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Product Availability</th>
<th>Weighted Average Price per Calendar Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphtheria, Pertussis &amp; Tetanus (DPT) Vaccine</td>
<td>Available</td>
<td>$1.00</td>
</tr>
<tr>
<td>Measles Vaccine</td>
<td>Available</td>
<td>$1.00</td>
</tr>
<tr>
<td>Polio Vaccine</td>
<td>Available</td>
<td>$1.00</td>
</tr>
<tr>
<td>Tetanus Vaccine</td>
<td>Available</td>
<td>$1.00</td>
</tr>
<tr>
<td>Haemophilus Influenza B (Hib) Vaccine</td>
<td>Available</td>
<td>$1.00</td>
</tr>
<tr>
<td>Bacille Calmette-Guerin (BCG) Vaccine</td>
<td>Available</td>
<td>$1.00</td>
</tr>
<tr>
<td>Influenza Vaccine</td>
<td>Available</td>
<td>$1.00</td>
</tr>
<tr>
<td>Hepatitis B Vaccine</td>
<td>Available</td>
<td>$1.00</td>
</tr>
<tr>
<td>Meningococcal Conjugate Vaccine</td>
<td>Available</td>
<td>$1.00</td>
</tr>
<tr>
<td>Pneumococcal Conjugate Vaccine</td>
<td>Available</td>
<td>$1.00</td>
</tr>
</tbody>
</table>

Data shows the weighted price per course of AED per supplier per calendar year. The values are based on actual prices paid to UNICEF by the Government of Thailand in 2015. The data is subject to change as new agreements are signed.
Transparency Prices

Visit UNICEF’s webpage on vaccine price data:
https://www.unicef.org/supply/index_102225.html

Source: UNICEF Supply Division
Visibility on Stockpile Levels: Vaccines in Constrained Supply

https://www.unicef.org/supply/index_94563.html
Operations
<table>
<thead>
<tr>
<th>Product</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>Current Award Period</th>
<th>Next Award Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bivalent Oral Polio Vaccine (bOPV)</td>
<td></td>
<td></td>
<td></td>
<td>2018-to cessation</td>
<td></td>
</tr>
<tr>
<td>Rabies Vaccine</td>
<td></td>
<td></td>
<td>Q3</td>
<td>2017-2019</td>
<td>TBD</td>
</tr>
<tr>
<td>Seasonal Flu</td>
<td></td>
<td></td>
<td></td>
<td>No LTAs, PO basis</td>
<td>No LTAs, PO basis</td>
</tr>
<tr>
<td>Pneumococcal conjugate vaccine (PCV)</td>
<td></td>
<td></td>
<td></td>
<td>2018-2027</td>
<td>2018-2027</td>
</tr>
<tr>
<td>PCV for MICS</td>
<td></td>
<td></td>
<td></td>
<td>TBD</td>
<td>TBD</td>
</tr>
<tr>
<td>Measles Containing Vaccine (MCV)</td>
<td></td>
<td></td>
<td></td>
<td>2018-2020</td>
<td>TBD</td>
</tr>
<tr>
<td>Yellow Fever Vaccine (YFV)</td>
<td></td>
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<td></td>
<td>2018-2021</td>
<td>TBD</td>
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<tr>
<td>Meningococcal emergency stockpile</td>
<td></td>
<td></td>
<td></td>
<td>2018-2019</td>
<td>TBD</td>
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<tr>
<td>Diphtheria and Tetanus toxicoid (DT) vaccines</td>
<td></td>
<td></td>
<td></td>
<td>2018-2019</td>
<td>TBD</td>
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<tr>
<td>Meningococcal A Vaccine (MenA)</td>
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<td>2019-2022</td>
<td>TBD</td>
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<tr>
<td>Hepatitis B Vaccine - pediatric (Hep B)</td>
<td></td>
<td></td>
<td></td>
<td>2016-2018</td>
<td>2019-2021</td>
</tr>
<tr>
<td>Japanese Encephalitis (JE)</td>
<td></td>
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<td></td>
<td>2019-2022</td>
<td>TBD</td>
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<tr>
<td>Human Papilloma Virus Vaccines (HPV)</td>
<td></td>
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<td>2013-2019</td>
<td>TBD</td>
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<tr>
<td>Rota Vaccine for India (RV)</td>
<td></td>
<td></td>
<td></td>
<td>2017-2021</td>
<td></td>
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<tr>
<td>Oral Cholera Vaccine (OCV)</td>
<td></td>
<td></td>
<td></td>
<td>2019</td>
<td>TBD</td>
</tr>
<tr>
<td>Diphtheria, Tetanus and Pertussis vaccine (DTP)</td>
<td></td>
<td></td>
<td></td>
<td>2016-2018</td>
<td>2019-2021</td>
</tr>
<tr>
<td>Bacillus Calmette-Guerin vaccine (BCG)</td>
<td></td>
<td></td>
<td></td>
<td>2016-2018</td>
<td>2019-2023</td>
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<tr>
<td>Adult Tetanus Toxoid (TT) and Tetanus-Diphtheria (Td) Vaccines</td>
<td></td>
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<td>TBD</td>
<td>TBD</td>
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<tr>
<td>Pentavalent vaccine (Penta)</td>
<td></td>
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<td>2017-2019</td>
<td>TBD</td>
</tr>
<tr>
<td>Typhoid Conjugate Vaccine</td>
<td></td>
<td></td>
<td></td>
<td>2019-2020</td>
<td>TBD</td>
</tr>
</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
Shipping and Logistics

592 shipments
455 POs
50 critical shipments
6 charter flights
1,590 MT
25 suppliers
78 destination countries
6.5m (USD) freight $
THANK YOU