Safe Injection Equipment: Supply and Demand Update

UNICEF Supply Division

November 2018
Safe Injection Equipment
Supply & Demand Update – November 2018

This update provides information on safe injection equipment supply and demand through UNICEF for 2018-2019. It highlights market developments and key focus areas and priorities for UNICEF, including applying a sustainable procurement framework approach and developing local markets.

1. Summary

- Safe injection equipment (SIE), including auto-disable (AD) syringes, re-use prevention (RUP) syringes, and safety boxes, are indispensable products used in immunization activities, reducing the risk of blood borne disease transmission through syringe reuse and needle stick injuries.
- UNICEF procures SIE on behalf of 80-100 countries annually, including for UNICEF and Gavi, the Vaccine Alliance (Gavi) supported country programmes and partners. For 2018-2019, UNICEF forecasts demand to reach 1.3 billion AD syringes, representing 93 per cent of its total SIE procurement volume.
- UNICEF shipped 30,000 cubic meters (m³) of SIE in 2016, representing associated carbon dioxide (CO₂) emissions and a sizeable volume that would end up as contaminated waste material requiring proper and appropriate disposal. Appropriate healthcare waste management, including the proper disposal of SIE waste material from immunization activities, remains a concern in many UNICEF programme countries.
- UNICEF is applying a sustainable procurement and a local market development framework to its SIE procurement. UNICEF will reduce the amount of SIE waste generated through reductions in volumes per unit it transports by applying sustainable procurement criteria across its supply and logistics management chain. UNICEF sets a target to ensure 20 per cent of its tendered awards target new suppliers from UNICEF programme countries, and to source 80 per cent of its SIE supplies from suppliers that are able to source and bundle products together. Together, they will increase procurement and delivery efficiency, effectiveness, and value for money, while reducing CO₂ emissions and waste generation, as well nurture and promote local market economic development.

2. General Brief and Background

Country immunization programmes require a combination of SIE devices, including AD syringes, disposable and RUP syringes for vaccine reconstitution, as well as safety boxes for safe sharps waste disposal. They constitute indispensable and critical products used in immunization activities to reduce the risk of blood borne disease transmission through syringe reuse and needle stick injuries.

UNICEF only procures World Health Organization (WHO) prequalified AD and RUP syringes and safety boxes that meet WHO performance, quality, and safety (POS) standards, in addition to UNICEF technical and quality requirements (Figure 1). The list of WHO prequalified syringes and safe injection devices is accessible here.¹

UNICEF considers these products strategic due to their role in immunization programmes and in emergency response activities in both immunization and curative settings, as well as part of the interagency emergency health kits (IEHK). UNICEF procures SIEs for immunization programmes on behalf of 80 to 100 countries annually, reaching a sizeable volume of approximately 30,000 m³ a year.

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3. **Product Innovation**

Several new and innovative vaccine delivery mechanisms are on the market or currently under development, including needle-free mucosal delivery such as nasal and inhalation sprays, transdermal patches, microneedle patches, and jet injectors. UNICEF monitors product development and progress in areas of particular interest, including assessing possible solutions for sharp injury protection features for AD syringes, as well as the development of novel pain-free and safe injection technologies.

4. **Current Market Situation**

Reports from WHO estimate that approximately 16 billion injections are administered globally per year.\(^2\) Over 90 per cent are for therapeutic purposes and only five per cent are for immunization purposes for both children and adults. In 2016, the global syringe market was estimated to value USD 10.56 billion, which market researchers anticipate will grow at an 8.7 per cent compound annual growth rate (CAGR) to reach approximately USD 16 billion by 2021.\(^3\) Key drivers of this growth include the high global prevalence of chronic diseases, a growing aged population, rapid urbanization, as well as the advancement of technology, expanding immunization programmes, and growth in vaccine demand and safety syringes.\(^4\) UNICEF annually procures approximately 730 million syringes for immunization programmes, reaching a value of more than USD 30 million in 2017. Even though it only equates to 0.2 per cent of the global syringe market value, ninety-three per cent of UNICEF’s procurement is exclusively for AD syringes, which accounts for approximately 40 per cent of the world’s total AD syringe volume.

In terms of USD value, AD syringes represent 81 per cent of UNICEF’s annual SIE procurement (USD 24 million), and safety boxes account for 12 per cent (USD 3.4 million).\(^5\) As such, these two product categories drive UNICEF’s procurement strategy, with the 0.5ml AD syringes being the key driver, as nearly all administered injectable vaccines require this syringe, and it accounts for 97 per cent, of UNICEF’s AD syringe volume share. Over the past 20 years, UNICEF and partners have undertaken several critical actions to influence the AD syringe market (Figure 2).

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\(^4\) Ibid.

\(^5\) Based on UNICEF 2016 procurement.
Figure 2 UNICEF 0.5ml Auto-Disable Syringe Market Overview 1997-2019 and Region of Origin

4.1 Demand

In 1999, WHO established the Safe Injection Global Network (SIGN). It is a voluntary coalition bringing together partners, including UNICEF, that are focused on promoting and achieving, amongst other aspects: the safe and appropriate use of quality injection devices; standards for AD syringes; performance specifications and standards for syringes and needles; and the prequalification of injection equipment. In 1999, UNICEF, WHO and the United Nations Population Fund (UNFPA) issued a joint statement on the use of AD syringes, which set a target to ensure that all countries only use AD syringes for immunization by the end of 2003. In 2000, WHO issued a product information sheet (PIS) for AD injection devices, which has since been replaced by WHO’s POS system, and lists all prequalified equipment and devices that are based on the performance characteristics that meet the relevant specification standards, quality, reliability for field conditions, and the life-cycle safety characteristics for patients.

Several initiatives since 1999 drove injection safety and AD syringe introduction with donor support providing funding security and enabling UNICEF and partners to bring the AD market to scale. In 1999, UNICEF, UNFPA, and WHO launched the Maternal and Neonatal Tetanus Elimination (MNTE) initiative. In 2001, the American Red Cross, the United Nations Foundation, the US Centers for Disease Control and Prevention (CDC), UNICEF and WHO launched the Measles Initiative (since renamed the Measles and Rubella Initiative), and again, in 2001, Gavi launched their injection safety support (INS) and new vaccine support (NVS).

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As a consequence of these major efforts, AD syringe procurement through UNICEF grew from just under 100 million syringes a year to over 500 million from 1999 to 2003. It also enabled UNICEF to consolidate demand through using multi-year long-term arrangements (LTAs) to source supply where WHO prequalified suppliers existed, mainly from European and US markets.

In 2004, UNICEF encouraged greater geographic diversity and a wider supply base, while pursuing further improvements to injection safety, expressing a preference for syringes with early enabling activation features. UNICEF was able to nurture and improve market health and growth by fostering greater international competition with new market entrants, and by publishing its LTA pricing awards, which decreased product weighted average prices (WAP) (see also 7 Pricing).

Countries’ demand for SIE through UNICEF has now reached approximately 730 million units a year for both immunization and curative settings, including emergency response health kits, of which 90 per cent is for AD syringes (Table 1). All SIE products are interdependent and based on country programme needs. Any increase or decrease in AD syringe demand creates a similar increase or decrease in other products.

Table 1 UNICEF’s SIE Commodity Forecast 2018-2019

<table>
<thead>
<tr>
<th>Commodity Grouping</th>
<th>Programme Focus Areas</th>
<th>Use / Application</th>
<th>Forecast Quantities in Units – Two Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>AD Syringes</td>
<td>Immunization</td>
<td>To administer vaccines / in immunization programmes / during campaigns</td>
<td>1,312,500,000</td>
</tr>
<tr>
<td>Disposable Syringes</td>
<td>Immunization/ Curative</td>
<td>To reconstitute lyophilised vaccines / Part of health kits</td>
<td>65,900,000</td>
</tr>
<tr>
<td>RUP Syringes</td>
<td>Immunization/ Curative</td>
<td>To reconstitute lyophilised vaccines / Part of health kits</td>
<td>51,130,000</td>
</tr>
<tr>
<td>Needles</td>
<td>Curative</td>
<td>Part of health kits</td>
<td>22,600,000</td>
</tr>
<tr>
<td>Safety Boxes</td>
<td>Immunization/ Curative</td>
<td>Safe collection of used syringes and sharps</td>
<td>14,050,000</td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division

### 4.2 Supply

UNICEF currently has seven target (volume) bound LTAs with suppliers as a result of its tender in 2017, providing a suite of product offerings as well as consolidated product bundles over 2018-2019 (Table 2).

The current global supply of quality assured, technically acceptable, SIE products far outweighs demand, with the exception of 0.1ml AD syringe availability, which may be subject to possible delays, should demand unexpectedly exceed forecast quantities. As such, UNICEF considers the SIE market to be generally in a very good state of health. However, UNICEF seeks further improvements by leveraging its share of the global AD syringe market to further SIE supply chain efficiencies and effectiveness by promoting sustainable procurement and engaging industry.12

Table 2 Current UNICEF SIE LTA Awards for AD and RUP Syringes and Safety Boxes for 2018-2019 — continued overleaf

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<table>
<thead>
<tr>
<th>Supplier</th>
<th>LTA Period</th>
<th>Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Helm Medical (Germany)</td>
<td>2 years</td>
<td>0.05ml AD syringes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.1ml AD syringes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.5ml AD syringes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2ml RUP syringes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5ml RUP syringes</td>
</tr>
<tr>
<td>Hindustan Syringes &amp; Medical Devices (India)</td>
<td>2 years</td>
<td>0.5ml AD syringes + 5l safety boxes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2ml RUP syringes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5ml RUP syringes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10ml RUP syringes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5lt safety boxes</td>
</tr>
<tr>
<td>KD Medical GmbH Hospital Products (Germany)</td>
<td>2 years</td>
<td>0.05ml AD syringes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.1ml AD syringes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.5ml AD syringes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.5ml AD syringes + 5l safety boxes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2ml RUP syringes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5ml RUP syringes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5lt safety boxes</td>
</tr>
<tr>
<td>Smurfit Kappa Lagamill (Sweden)</td>
<td>2 years</td>
<td>5lt safety boxes</td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division

5. **Sustainable Procurement**

Sustainable procurement (SP) is an approach to procurement that incorporates sustainable social, economic, and environmental impact considerations. It goes beyond the more familiar “green” public procurement, to ensure that all products and services procured support local economic development with the least environmental and most positive social impact, and the best value for money (VfM).

In February 2018, UNICEF released its Procedure on SP [SUPPLY/PROCEDURE/2018/001](#). The procedure constitutes UNICEF’s policy on SP and is applicable across all UNICEF offices engaged in supply planning and procurement, wherever feasible and applicable, whether for goods or services, or for programmes or office assets, read more [here](#).  

UNICEF identified SIE as one of the procurement categories where it can leverage its procurement to influence and advance SP. In 2016, UNICEF shipped over 30,000 m² of SIE, most of which would end up as contaminated waste requiring disposal. UNICEF sourced and shipped products from suppliers located in Europe, Asia, and the Middle East, with more than two thirds of it delivered to countries in sub-Saharan Africa, together with the associated CO₂ emissions generated during transport, waste management concerns, as well as overlooking opportunities to improve delivery efficiency and reduce associated CO₂ emissions.

In 2015, UNICEF started to merge the different tenders for SIE categories into one, encouraging suppliers to offer product bundles. Product bundling allows suppliers to offer several products for sale as one combined offering or service package. By tendering for bundled awards, UNICEF allows suppliers to offer the full range of SIE as a package, as they are already indispensable from each other. As such, UNICEF allows suppliers to consolidate supplies, reducing the number of transactions, shipments, as well as the overall cost.

Building on the gains from 2016-2017, UNICEF revised its procurement approach for its 2018-2019 SIE tender, to include a greater focus on sustainability, delivery efficiency, and local market development, notably by:

- Influencing industry’s SP policy by calling for the inclusion of green manufacturing Quality Management Systems (QMS) and social considerations, as well as requiring industry to report on such;

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- Switching from a paper-based submission to an electronic bid system, with a revised response template to increase efficiency, reducing requirements for hard copy prints;
- Implementing SP criteria in tenders to make up 30 per cent of the commercial evaluation based on comparative product weight and volumes across technically acceptable offers;
- Including specific supply targets to develop local industry capacity in UNICEF programme countries, setting a target to award 20 per cent of supply to new local suppliers by 2021. This target is to incentivise current WHO prequalified suppliers in UNICEF programme countries to meet all UNICEF technical requirements; increase local production; and reduce environmental emissions, by reducing shipments of finished goods. UNICEF considers the focus on sustainability as complementing support for a healthy market framework. It prioritises this target over other product objectives that meet:
  - Mandatory and technical requirements.
  - Preference for early disabling mechanism activation.

6. Tender Outcomes and Comparisons

Between 2013 and 2017, procurement volumes through UNICEF increased by 12 per cent against a procurement value that only increased by six per cent, reflecting the price gains achieved over this period.

6.1 Electronic Tender System

For its 2018-2019 tender, UNICEF switched from a paper-based tender process to an electronic process and automated data extraction that reduced the evaluation timeline by 50 per cent, even though the tender timeline was delayed due to changes in the tender document.

6.2 Product Bundling

Figure 3. UNICEF Product Weight and Volume Comparative Analysis of AD 0.5 ml Syringe Tender Awards

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Awarded Quantity</td>
<td>1,310,000,000</td>
<td>1,210,000,000</td>
</tr>
<tr>
<td>Shipping Volume (m³)</td>
<td>51,585.71</td>
<td>44,960.49</td>
</tr>
<tr>
<td>Shipping Weight (kg)</td>
<td>6,784,545.9</td>
<td>5,525,397.22</td>
</tr>
<tr>
<td>Volume per Unit</td>
<td>0.00003938</td>
<td>0.00003716</td>
</tr>
<tr>
<td>Variance -6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight per Unit</td>
<td>0.00517904</td>
<td>0.00456644</td>
</tr>
<tr>
<td>Variance -12%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division

UNICEF’s product bundle awards for AD syringes, safety boxes and reconstitution syringes for 2016-2017, represented 40 per cent of total demand through UNICEF. Compared to levels in 2015, it enabled UNICEF to consolidate orders and shipments, reducing the number of orders placed by 16 per cent, and the number of shipments by 21 per cent.

UNICEF’s 2018-2019 tender outcome resulted in generating 12 per cent less contaminated waste and reducing the volumes to be transported by six per cent (Figure 3), against an overall WAP increase of only one per cent.

For 2018-2019, 62 per cent of UNICEF’s AD syringe and safety boxes awards were for product bundles, which will further contribute to achieving UNICEF’s 2021 SP target and improve UNICEF procurement and delivery efficiency. UNICEF
anticipates further efficiencies can be gained by increasing the awards for product bundling across all suppliers and has set a target to allocate 80 per cent of its supply awards for product bundles by 2021, to gain greater delivery efficiency and CO₂ emission reductions.

6.3 Transactional Workload Efficiencies

UNICEF’s transactional workload for the procurement of SIE was the same as its transactional workload to procure vaccines, even though its SIE procurement represents only two per cent of the value of vaccines, which can reach USD 1.4 billion. Following streamlining of operations between UNICEF and Gavi, UNICEF gained overall 16 per cent greater transactional efficiency, and 11 per cent on delivery efficiency when comparing reductions in the number of procurement requests and the number shipments (Figure 4), when compared to a slightly higher volume delivered (Figure 2).

UNICEF achieved this by increasing product bundling awards across commodities, introduced in 2017, as well as by collaborating with Gavi to consolidate SIE orders under a single approval per country. UNICEF anticipates further transactional and delivery efficiency gains from increases in product bundled awards over 2018 and 2019.

Figure 4: Gains in Transactional Efficiency for Gavi Funded SIE Procurement in 2016-2017

7. Pricing

The cost of SIE compared to the costs of vaccines in immunization programmes is low, and in SIE, the cost of some products, such as reconstitution syringes is only a fraction of the total SIE cost required for immunization programmes. Over the past nine years, the WAP for AD syringes has dropped significantly, from just under USD 0.050 in 2011 to reach USD 0.036 in 2018, representing a nearly 30 per cent decrease (Figure 2). UNICEF considers the price of SIE to be very affordable. The cost of SIE to fully immunize a child, based on using a lyophilised vaccine, requiring a three-dose schedule, does not exceed USD 0.3, representing a fraction of the costs required to administer a vaccine in immunization programmes.

Since 2011, UNICEF has published its LTA SIE pricing as part of its influencing markets strategy, and broader commitments to information and price transparency, recognizing that the free flow of information and correcting information asymmetry is critical to underpin an efficient market. Pricing on AD and RUP syringes, as well as safety boxes and bundled awards is accessible here,¹⁰ and at: https://www.unicef.org/supply/index_67309.html.

8. Issues and Challenges

Several challenges exist in the SIE market, which UNICEF considers important to address to further improve the health of the SIE market globally (Figure 5).

Figure 5 Issues Requiring Consideration

- **INJECTION SAFETY**
  - **Consideration**
    AD and RUP syringe safety is at the forefront of UNICEF’s SIE supply considerations, promoting their exclusive use for vaccine administration and reconstitution (respectively) for all immunization activities. Countries have already successfully implemented the use of AD syringes with early disabling feature activation in their programmes. However, some still use regular disposable syringes to reconstitute lyophilized vaccines.
    UNICEF strongly recommends countries to only use AD syringes for vaccine administration, systematically and exclusively, and RUP syringes to reconstitute lyophilized vaccines. WHO, UNICEF, and UNFPA will be issuing an update of their 1999 joint statement on the use of AD syringes in immunization, scheduled for later this year. It will aim to reinforce the recommendation that countries exclusively use RUP syringes for the reconstitution of lyophilized vaccines.

- **SUSTAINABLE PROCUREMENT**
  - **Consideration**
    In implementing SP, UNICEF will seek to include green manufacturing QMS and social considerations, SP criteria in tender commercial evaluations, and specific supply targets to develop local industry capacity in programme countries.
    In applying SP, many UNICEF procurement decisions will face trade-offs between SP’s three (economic, social, and environmental) pillars, and present key operational challenges, especially between environmental and social considerations, with the latter often being more difficult to quantify. The absence of evidence to make any informed trade-off decisions will be part of the challenge. The other challenge will be the difficulty to make value judgments to prioritize one pillar over the other. However, solutions will be situation specific and priorities based on readiness, market influence, and targeted objectives.
    Some SP elements, notably under the social pillar, may put some pressure on short-term costs that generate longer-term savings, such as investments in fairer employment working conditions, or health and safety, which would be offset by increased motivation, productivity, and reductions in work-related injury and absenteeism. To achieve higher tangible economic benefits and VFM, UNICEF and industry will strive to manage procurement decisions based on longer-term perspectives, considering the advantages of environmentally, socially sound products and services, and better performing staff, bring in the long-term.

Source: Supply Division

9. Steps Forward

- UNICEF will continue to apply its approach to SP to products across all sectors, including SIE, where feasible and applicable, including a focus on developing local markets, notably in Africa, and reducing waste. Some SP approaches will need gradual introduction in a phased manner to ensure suppliers can comply and remain competitive. UNICEF will give due consideration to market health and long-term competition, among other market objectives.

- In pursuing local market development, UNICEF and industry may have to make decisions and will have to make trade-offs between the three SP pillars, most notably between the environmental and social pillars. Where most of the focus to date globally has been on economic and environmental pillars, UNICEF will increasingly include a focus on social considerations, considering the countries and communities UNICEF serves through developing local and regional markets for acceptable products.

- Waste management in health programmes in most UNICEF programme countries constitutes an issue as yet unresolved. UNICEF will look at expanding its product range to create a portfolio of environmentally friendly waste disposal solutions available to UNICEF programme countries.

- UNICEF will continue to monitor progress in innovative new SIE device product development and assess potential areas of engagement to support products of interest.
For further questions or additional information, please contact:

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Other UNICEF information notes are found at http://www.unicef.org/supply/index_54214.html.