Immunization Safe Injection Supplies: Market & Supply Update

UNICEF Supply Division

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1. Summary

- UNICEF procures a variety of safe injection devices, including auto-disable (AD) syringes, syringes for the reconstitution of vaccines and safety boxes for immunization activities.

- The markets are considered healthy; UNICEF currently has thirteen long-term arrangements (LTAs) for different injection-related supplies.

- The implementation of a landed cost evaluation for the 2014-2015 tender period provided a more realistic assessment of the actual cost to countries. The weighted average price (WAP) for AD syringes and safety boxes decreased by ~11% from the previous tender, saving an estimated $5 million on AD syringes alone.

- A revised approach to operations, consolidating shipments, resulted in a 15% reduction in the overall number of shipments to countries in 2014, reducing the burden of receipt of goods and customs clearance, and consolidating receipt of the various commodities in a reduced time span.

- In 2014, collaborative planning across partners enabled optimization of shipments, i.e., packed and shipped based on micro planning, reducing the overall lead-time and resource requirements specifically for campaigns.

- The timely receipt of funds, shipment delivery lead times, forecast accuracy and effective bundling of the required injection devices are key challenges affecting injection device supply and delivery.

- The 2016-2017 tender will encourage further industry engagement in addressing the challenges faced. An industry consultation is scheduled for early 2015.

- The use of safe injection devices for the reconstitution of vaccines remains an issue. Higher priced re-use prevention (RUP) syringes and the absence of a clear policy recommendation for RUP syringe use impedes improvements to injection safety.

2. General Brief and Background

UNICEF procures safe injection devices for immunization programmes, including AD syringes, reconstitution syringes and safety boxes on behalf of approximately 80 countries annually. AD syringes are used in routine and supplementary immunization programmes and are designed to overcome the challenges of unsafe injection administration with a built-in auto-disabling mechanism inhibiting syringe re-use to avoid the transmission of HIV/AIDS, Hepatitis B, C and other possible blood borne pathogens. WHO estimates that unsafe injections cause 32% of Hepatitis B, 40% of Hepatitis C and 5% of new HIV infections annually\(^1\), though it is unclear how much is relates specifically related to unsafe immunization practices. WHO, UNICEF and the UN Population Fund (UNFPA) recommend AD syringes to be used for vaccine administration.\(^2\)

A variety of AD syringe technologies exist and are categorised as either ‘passive’ or ‘active’ devices. ‘Passive’ device technologies do not require any additional effort by health care workers and administer vaccines according to normal procedure. ‘Active’ devices require an additional effort made by healthcare workers to activate the disabling mechanism. AD syringe technologies differ principally according to the location of the disabling mechanism.

UNICEF prefers AD syringes that have the disabling mechanism initiated at the onset of the administration of the injection to ensure re-use prevention. Other syringes exist with re-use

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prevention (RUP) features and fulfil a similar disabling function to AD syringes. Even though the use of RUP syringes is recommended to reconstitute vaccines, policy guidance is yet to be issued. Without a policy in place to influence decision makers and with price levels currently 50% higher than regular disposable syringes ($0.045 vs. $0.03 per syringe), RUP syringes are unlikely to fully replace the demand for disposable syringes for vaccine reconstitution.

Further developments in injection safety products include Sharps Injury Protection (SIP) features, which reduce the risk of needle stick injuries by covering the needle tip. Syringes could have both RUP and SIP features, and some of such technologies do exist today. Although RUP syringes with SIP features reduce the risk of reuse as well as needle stick injury, they come at a higher cost. UNICEF is monitoring the progress of a number of innovative new safe injection devices recent come to market and under development, including anticipated needle-free devices, jet injectors, micro needles, aerosols and intradermal patches. WHO-leads a working group that has been established for new vaccine delivery mechanisms, tracking the development of new technologies.

UNICEF only procures WHO prequalified AD syringes (ISO 7886-3:2005), RUP syringes (ISO 7886-4:2006) and safety boxes (E10/SB01-VP.1) that meet WHO performance, quality and safety (PQS) standards, in addition to UNICEF technical and quality requirements. The list of WHO prequalified syringes and safe injection devices is accessible [here](#).

3. Current Market Situation

3.1. Injection Devices Demand and Forecast

Country immunization programmes require a combination of injection-related devices, including 0.05ml and 0.5ml AD syringes, 2ml, 5ml, and potentially 10ml syringes for vaccine reconstitution, as well as 5 litre safety boxes for safe sharps waste disposal. The demand forecast for injection devices is generated from an annual 5-year immunization forecast exercise that is reviewed with partners.

Figure 1 UNICEF Procurement of Different Syringes and Safety Boxes 2005-2013

Source: UNICEF Supply Division.

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Over 90% of UNICEF’s syringe procurement is for AD syringes (Figure 1). All injectable vaccines require a 0.5ml AD syringe, with the exception of BCG which requires a 0.05ml AD syringe, for administration. Procurement reflects programme requirements which are mostly for vaccines in liquid form, and which do not require reconstitution. Reconstitution syringes (RUP and disposable syringes) are only required for lyophilized vaccines, which are mostly in 10 dose vials. Safety boxes can hold a minimum of 100 syringes and therefore reflect proportionally lower demand levels.

0.5ml AD syringe procurement has varied significantly over the past 15 years (Figure 2). The GAVI Alliance (GAVI) supported new vaccine introductions, GAVI Injection Safety Support (ISS) and the scale-up of measles and maternal/neonatal tetanus (MNT) campaigns have contributed to UNICEF’s increased procurement through 2002-2007. In addition, the Government of India procured through UNICEF in 2006. The Government of India’s decision in 2007 to return to self-procurement reduced UNICEF levels of procurement, leading to a modest increase in WAP. GAVI’s support for new vaccine introductions and increased immunization campaign activities since 2009 have increased demand to reach ~630 million syringes during 2013. UNICEF expects similar demand levels to continue through 2015.

Figure 2 AD Syringe Procurement Volume, WAP and Forecast through UNICEF 2001-2015

![Graph showing AD Syringe Procurement Volume, WAP and Forecast through UNICEF 2001-2015](source: UNICEF Supply Division)

3.2. Syringe Demand Through UNICEF

UNICEF is one of the largest buyers of AD syringes globally, procuring on behalf of ~80 countries annually and currently representing ~70% of the 0.5ml AD syringe global market and ~54% of the market for BCG AD syringes. 4

The top 20 countries account for ~80% of the total demand in volume and include DR Congo, Ethiopia, Nigeria, Pakistan and Tanzania. The largest purchasing countries also have the greatest variance and volatility between forecasted and procured volumes with forecast accuracy being a significant challenge in the management of injection device supply. Supplementary (campaign) requirements often result in large orders subjected to short lead times for delivery, due to delayed

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funding approval or release. These late, large orders negatively impact on supply availability. Over the past three years, forecast accuracy has ranged from -34% to +28% overall, and -69% to +71% for supplementary campaign activities.

Variances in measles-containing vaccine demand account for the largest differences. Increased demand against original forecasts show a similar trend during 2014 year-to-date and has required UNICEF to increase awards to suppliers to meet the demand. Other safe injection devices echo similar fluctuations but to a lesser degree. UNICEF has developed a strategy to address the issue of forecast accuracy and is working closely with partners to implement this during 2015.

The demand for vaccine reconstitution syringes is gradually transitioning from disposable syringes to RUP syringes, even though there is increased volatility per product specific for forecast accuracy (Figure 3). A clear policy recommendation from WHO in support of using RUP syringes for vaccine reconstitution would accelerate the transition process.

Figure 3 Reconstitution Syringe Procurement and Transition 2005-2013

Source: UNICEF Supply Division.

3.3. Supply

UNICEF sources the different safe injection devices from different suppliers over a wide geographic spread covering Europe, Asia and the Middle East (Figure 4). While there is good geographic spread in the supply base, the delivery lead times (in combination with delayed funds release) remain a challenge as most of UNICEF’s country demand (72%) is in Sub-Saharan Africa (Figure 4).

A market development overview of AD syringe is available in the 2013 UNICEF Supply Division Annual Report. 5

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3.4. Price Trends

UNICEF’s recent 2014-2015 tender introduced a landed cost evaluation methodology which takes the freight charges, based on the individual product weights and volumes and geographic location of the supplier into consideration. It provides for a more accurate assessment of the true procurement costs to country programmes. An overview of the approach and the basis of evaluation was provided to Industry during the Industry Consultation prior to the tender issuance, available on the internet here. The LTAs awarded to suppliers focused on maintaining a healthy, quality assured market with a reduction in the WAP and a more sustainable approach to procurement. The 2014-2015 tender results registered a WAP reduction of 11% for AD syringes and 10.5% for safety boxes, as well as a healthier and more balanced supply base. The WAP for AD syringes has been reducing since 2008 (Figure 2). UNICEF publishes the prices for different injection devices, which is accessible here.

4. Issues and Challenges

A number of challenges affect injection devices supply and delivery as highlighted above. A key element behind the challenges relates to the focus on vaccines rather than the associated injection devices with regards to immunization supplies due to (i) the limited availability, (ii) long production lead times, (iii) limited shelf life (2 years), (iv) considerably higher cost and (v) temperature controlled (cold chain) storage requirements of vaccines. The aspect that is often overlooked is that vaccines are shipped by air and devices by sea, with the average transit times being 2.5 days and 36 days respectively. This is further exacerbated by the fact that the various injection devices are often sourced from various suppliers requiring that the longest lead time of the components becoming the principal constraint. Including order lead times, freight forwarder planning and a realistic shipment lead time, countries should allow for 3 months (on average) for delivery. Country-specific order lead times can be provided by UNICEF on request.

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6 UNICEF 2013 average shipment durations for vaccines and injection devices.
Table 2 describes some of the key challenges affecting injection devices supply and delivery, as well as potential solutions that are under active consideration.

Table 2: Challenges Affecting Safe Injection Equipment Delivery

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<th>Challenge</th>
<th>Possible Considerations</th>
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| Long lead delivery shipment times.                                        | - Increased awareness, timely receipt of funding and early order process initiation could reduce lead times for delivery.  
- Switching from an invitation to bid (ITB) to a request for proposal (RFP) tender modality, including the consolidation of all injection-related commodities in one tender would provide the opportunity for industry’s engagement is finding solutions to the challenges including the potential consideration of establishing regional distribution hubs and stock prepositioning closer to the end-user points. |
| Multiple country shipment deliveries and high demands placed on country customs, clearance and storage facilities. | - Containerised packing based on campaign regional distribution plans prior to order placement allows for improved country delivery performance beyond port of entry and eases pressure on central port of entry storage facilities.  
- Facilitate the possibility for suppliers to offer a range of injection devices in support of bundled deliveries to countries in addition to individual items.  
- Consolidate individual requests into consolidated, single shipments. |
| Delays in the timely receipt of funds.                                    | - As GAVI represents ~50% of AD syringe procurement, there is opportunity to jointly explore alternative injection devices financing mechanisms to allow for early order placements.  
- Increased injection device lead times awareness for delivery requirements. |
| Forecast inaccuracy, delayed notification of vaccination campaigns.       | - Increased UNICEF engagement in early planning with large countries and key partners for large-scale campaigns.  
- Increased advocacy with partners and key countries on the importance of accurate forecasting and early receipt of funds for injection devices. |
| No policy on RUP syringes.                                                | - UNICEF will follow-up and advocate with programme partners for the need for a policy recommending the use of RUPs for reconstitution of vaccines.                                                                                                                                                                                      |
| Multiple shipments from different suppliers                              | - UNICEF will explore different tender modalities to encourage industry to expand the range of injection safety-related supplies offered, enabling consolidation and reducing the overall number of deliveries further.                                                                                                                     |

Source: UNICEF Supply Division.

5. Opportunities

UNICEF will continue to optimise supply delivery and logistics by analysing, planning and engaging collaboratively with all stakeholders. Through collaborative planning in 2014, the number of shipments was reduced by 15% though consolidation of orders, reducing the number of shipments and associated customs and clearance charges to countries. UNICEF will expand the early engagement in country campaign planning, including the receipt of regional distribution plans, prior to injection device order placements, enabling packaged, labelled and containerised deliveries for regional distribution in country to simplify the complexity of in-country logistics.

6. Steps Forward

- UNICEF is considering a single tender to cover all immunization safe injection devices as opposed to separate tenders, as well as a switch from an ITB to RFP tender modality. The change would allow bidders to submit proposals for individual items or bundled safe injection equipment and to explore the options to establish regional hubs to reduce the lead times for delivery. Establishing regional hubs may improve delivery efficiency by reducing the overall number of shipments, and the burden of clearance and logistics. An industry consultation will be scheduled in early 2015.
UNICEF will engage with key partners to explore options to ensure the timely release of funds and explore alternative funding mechanisms for injection devices to improve supply security and to allow for earlier order placements.

UNICEF will follow-up with programme partners and advocate for a policy statement for the use of RUPs for the reconstitution of vaccines.

UNICEF will monitor the progress and developments on pipeline safe injection device products.

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