Vitamin A Supplementation
Market and Supply Update – June 2018

This update provides information for the period 2018-2019 on vitamin A supply. It highlights new developments in UNICEF’s efforts to address recent vitamin A supply interruptions, as well as price increases by global manufacturers.

1. Vitamin A Brief and Background

Vitamin A deficiency (VAD) is a form of undernutrition that increases the risk of disease and mortality from severe infections, including diarrhoeal disease and measles.\(^1\) VAD is also the leading cause of child blindness, and can cause night blindness in pregnant women, especially during the last trimester when demand by the unborn child is at its highest, and which may increase the risk of maternal mortality. VAD is a concern in many countries, notably in Africa and South-East Asia. A third of young children and pregnant women in low-income countries experience VAD.\(^2\)

To eliminate VAD and its consequences, the World Health Organization (WHO) recommends breastfeeding, as breast milk is a natural source of vitamin A, as well as vitamin A supplementation, combined with a vitamin A-rich diet and food fortification.\(^3\) For those already affected by VAD, two rounds a year of high-dose vitamin A supplementation is critical and can significantly reduce mortality and morbidity.\(^4\) WHO includes vitamin A on its **List of Essential Medicines (EML)**.\(^5\) The EML comprises a list of essential medicines that should be available in all functioning health systems.

UNICEF procures vitamin A mostly as retinol, which is the animal form of vitamin A, with a minimum shelf-life of 24 months. It is used as a dietary supplement, and presented in an oral liquid preparation (OLP). An OLP is a solution containing active pharmaceutical ingredients (API) and can come in the form of capsules. UNICEF procures retinol in two OLP-capsule presentations, which are the subject of this Supply Update:

<table>
<thead>
<tr>
<th>Table 1 UNICEF Vitamin A Product Presentations</th>
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<tbody>
<tr>
<td><strong>Product</strong></td>
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<tr>
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<tr>
<td>Retinol 100,000IU soft gelatine capsules</td>
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<td></td>
</tr>
<tr>
<td>Retinol 200,000IU soft gelatine capsules</td>
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</tbody>
</table>

Source: UNICEF Supply Division

At the end of 2017, UNICEF procured retinol 100,000IU and 200,000IU soft gelatine capsules in packs of 100 for the first-time, which will be available in its warehouse in Copenhagen from

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\(^3\) WHO, *Micronutrient Deficiency, Vitamin A Deficiency*.

\(^4\) In cases of measles, the periodic supply of vitamin A has proven to reduce mortality by up to 23% overall, and by up to 50% in acute cases.

June 2018. Even though the cost per capsule will increase, the smaller pack sizes will facilitate use in routine or community settings, as it will reduce wastage rates, and provide an alternative to bulk (hospital) packs, as well as for countries that restrict importation.

2. Current UNICEF supply Situation

UNICEF’s procurement for programme country deliveries only represents a relatively small volume of total vitamin A procurement. Nutrition International (NI), formerly known as the Micronutrient Initiative (MI), 6 is a global health partnership with over 25 years of field experience. It provides technical expertise and programme support addressing micronutrient deficiency in more than 60 countries, reaching millions of people. NI procures more than 75% of the global vitamin A requirements for programme countries (approximately 460 to 530 million capsules a year), which goes through UNICEF as contributions-in-kind (CIK). 7 UNICEF only procures vitamin A for country offices and partner programmes that are not served by NI, for example programmes treating women postpartum (immediately following childbirth), and for countries that have graduated from NI support and use UNICEF’s Procurement Services. 8 Since 2007, UNICEF has procured on average approximately 70 million vitamin A capsules a year (corresponding to 140,000 bottles of 500 capsules), most have been for UNICEF’s warehouse in Copenhagen (Figure 1). The large difference in warehouse orders in 2017 was due to additional replenishment orders to cover a supply gap created by low procurement volumes in 2016.

Figure 1 UNICEF Vitamin A Procurement 2007 – 2017

Source: UNICEF Supply Division

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7 In addition to the two presentations procured by UNICEF, NI procures and delivers through UNICEF retinol 100,000IU soft gelatine capsules in packs of 100 capsules.
8 UNICEF’s Procurement Services is a transitional development mechanism that provides access to UNICEF’s supply network, experience, and expertise to procure strategic and essential products for children. For further details see here: UNICEF, Procurement Services, UNICEF, Copenhagen, 2017.
UNICEF bases its procurement volumes of vitamin A on several factors, including stock level analysis, buffer requirements, purchase orders, and stocks reserved for packing sets. Annual volume fluctuations represent the quantities procured and delivered to replenish UNICEF’s warehouse (in part following response to emergencies). The current lead-time for vitamin A deliveries against UNICEF’s warehouse purchase orders is between three and five months.

Figure 2 UNICEF Vitamin A Country Deliveries 2007 – 2017

![Graph showing vitamin A capsules in millions from 2007 to 2017.](image)

Source: UNICEF Supply Division

By comparison to UNICEF procurement data, yearly aggregation of UNICEF deliveries to programme countries (Figure 2), mostly from UNICEF’s warehouse stocks, has been more stable, although declining in recent years. The data excludes vitamin A CIK from NI. This product is used in emergencies and included in UNICEF’s Emergency Supply List (ESL), as an emergency pre-positioned item. In 2017, UNICEF supplied vitamin A to approximately 40 countries. Four countries accounted for 60% of the supplied volume, notably Angola, Egypt, Morocco, and Sierra Leone, of which Egypt was the single largest recipient, accounting for 32% alone. 24% was for use in emergency response, notably for the Central African Republic, the Democratic Republic of the Congo, Somalia, and South Sudan.

The declining volumes is in part related to changes in guidelines on use. Specifically, in 2013 WHO updated its guidelines on the management of severe acute malnutrition (SAM) in infants and children. The revised guidelines strongly recommend that children suffering from SAM do not require high vitamin A dose supplementation if they receive F-75 or F-100 therapeutic milk.

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9 It excludes quantities delivered to countries as part of a kit. For instance, UNICEF includes retinol 200,000IU soft gelatine capsules, as part of its Inter-Agency Emergency Health Kit - supplementary medicines kit 1 (material number S9901006), as well as in several country-specific kits.


or ready-to-use therapeutic food (RUTF)\textsuperscript{12} that comply with WHO specifications, as these already contain sufficient levels of vitamin A.\textsuperscript{13} As more and more countries adopt the WHO guidelines, UNICEF anticipates further decreases in demand for vitamin A capsules for treating SAM.

Figure 3 presents the weighted average price (WAP) for retinol procured through UNICEF for both presentations, and excludes the costs of handling, warehousing, transport, and delivery. The trend in WAP reflects the impact of vitamin A API on the world market price, as most vitamin A API is destined for other uses in human and animal nutrition. In addition, other factors such as global exchange rate fluctuations, the difficulty of producing vitamin A for VAD, as well as the limited supplier base for this product contribute to the WAP trends.

![Figure 3 UNICEF Vitamin A Procurement Weighted Average Price in USD 2007 – 2017](image)

Source: UNICEF Supply Division

3. Issues and Challenges

Retinol soft gelatine capsules in OLP are a niche product, and not produced by many manufacturers. UNICEF’s procurement volumes are also relatively modest.

In 2017 UNICEF awarded two suppliers long-term arrangements (LTA) to supply retinol through January 2019 (Table 2). The issuance of these new LTAs sought to secure supply availability and timely deliveries to countries.

Table 2 UNICEF Supplier Long-Term Arrangements

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Product</th>
<th>LTA start date</th>
<th>LTA end date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catalent, Canada</td>
<td>Retinol 100,000IU soft gel.caps/PAC-500</td>
<td>08/2017</td>
<td>01/2019</td>
</tr>
<tr>
<td></td>
<td>Retinol 200,000IU soft gel.caps/PAC-500</td>
<td>08/2017</td>
<td>01/2019</td>
</tr>
<tr>
<td>NutriCorp, Canada</td>
<td>Retinol 100,000IU soft gel.caps/PAC-500</td>
<td>07/2017</td>
<td>01/2019</td>
</tr>
<tr>
<td></td>
<td>Retinol 200,000IU soft gel.caps/PAC-500</td>
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Source: UNICEF Supply Division


\textsuperscript{13} WHO, \textit{Updates on the Management of Severe Acute Malnutrition in Infants and Children Guideline}, p. 4.
In addition, UNICEF is working with potential new sources to develop products compliant with UNICEF’s requirements. This can help expanding the supplier base for UNICEF, potentially NI, and ultimately other development partners and governments.

Unfortunately, the number of API manufacturers that can offer validated vitamin A (retinol) API bulk are limited. DSM and BASF are the two main global sources for human vitamin A API. What’s more, a fire at BASF’s production plant in October 2017 significantly reduced global API bulk production capacity. A concurrent increase in the cost of API led the two UNICEF vitamin A approved suppliers (Catalent and NutriCorp) to increase the price of the finished product for 2018. UNICEF did not reflect price increases in Figure 3. However, UNICEF anticipates price increases could range from 13% to 52% on procurement orders placed in 2018. Both suppliers reported to procure their API from DSM. It appears BASF will not be able to restore their bulk production capacity until 2Q 2018, at the earliest. As such, UNICEF anticipates bulk API global shortages will nevertheless continue through much of 2018.

4. Steps Forward

• UNICEF will advocate with DSM to minimize the impact of constrained API availability on prices of final products. The increased procurement cost of retinol has a direct effect on the programme coverage.
• To avoid a recurrence of the supply shortages experienced in 2016, and to minimize the risk of dependency on a limited number of validated sources, UNICEF and NI will continue to collaborate to expand the supplier base and work with potential suppliers to expand their capacity and maintain regular replenishment of warehouse stocks.
• UNICEF will warehouse retinol 100,000IU and 200,000 IU soft gelatine capsules in packs of 100 capsules, and make them available to countries from June 2018. Smaller pack sizes will reduce wastage rates for supplementation in routine or community settings (outside of campaigns) and provide an alternative for countries restricting importation and use of bulk (hospital) packs.

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