Shelf-life recommendations for importation of health commodities

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Supply chain shelf-life regulations for health commodities

Background:

• Countries regulate the importation of medical products (pharmaceuticals, vaccines and medical devices, including in-vitro diagnostics) by limiting the shelf-life (SL) of incoming goods to a minimum amount.

• Many countries require a minimum percentage of the remaining shelf-life (RSL) at the time of importation.
Supply chain shelf-life regulations for health commodities

Problem Description:

• In many instances current regulations have proven to hinder importation of life saving medical products and adversely impact patient access.
• Consumption patterns in many countries often times require far less SL than the those mandated by regulations requiring a minimum percentage SL (ex. 75% RSL).
• Many countries have made significant improvements in forecasting and supply chain management.
• Rejection of products due to the requirement of a minimum percentage of RSL may contribute to stockouts.
Supply chain shelf-life regulations for health commodities

<table>
<thead>
<tr>
<th>Maximum SL</th>
<th>75% RSL</th>
<th>80% RSL</th>
<th>85% RSL</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 months</td>
<td>18 months</td>
<td>19.2 months</td>
<td>20.4 months</td>
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<tr>
<td>36 months</td>
<td>27 months</td>
<td>28.8 months</td>
<td>30.6 months</td>
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<tr>
<td>48 months</td>
<td>36 months</td>
<td>38.4 months</td>
<td>40.8 months</td>
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<tr>
<td>60 months</td>
<td>45 months</td>
<td>48 months</td>
<td>51 months</td>
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Supply chain shelf-life regulations for health commodities

Problem Description – Challenges for 90/90/90:

- Lack of patient access will not allow:
  - 90% of people living with HIV to know their status
  - 90% of to enroll in Antiretroviral Treatment (ART)
  - 90% of to have viral suppression
- Significant impediment to reaching global HIV targets
CASE STUDY:
ANTIRETROVIRALS (ARVs)
The need for flexibility in shelf life due to limited availability

- USAID maintains stock at regional distribution centers (RDCs)
  - Lopinavir/Ritonavir (48 month SL) & Tenofovir/Lamivudine/Dolutegravir (24 month SL)
    - Limited availability in global market & access remains challenge at national level
    - Significant value in holding stock
    - Manufacturing and shipping would require a minimum of 6-9 months additional lead-time
      - In case of LPV/r upwards of 20 months due to supply constraints
  - Products with 50% shelf life can significantly increase access and prevent stockouts
    - LPV/r = 24 months provides significant time for consumption
    - TLD = 12 months; 1st line treatment in many countries
The need for flexibility in shelf life to incentivize introduction of products with longer shelf life

- Current regulations do not incentivize products with longer shelf life
  - Atazanavir + Ritonavir 300/100mg Tab
  - Multiple eligible products with varying SL (24 and 36 months)

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The need for flexibility in shelf life to incentivize introduction of products with longer shelf life

- The 36 month SL product will be rejected in countries with a requirement of 75% RSL at importation for having anywhere in the range of 18-27 months of RSL.
- The competitor product that has a 24 month SL can easily import their product while having 18 months RSL.
- Incentivizes procurement of products that will not face importation barriers, rather than the products that give the supply chain more actual months of stock to move the product through to patients.
CASE STUDY: HIV Rapid Diagnostic Test Kits (RTKs) and Viral Load (VL) Reagents
The need for flexibility in shelf life to incentivize introduction of products with longer shelf life

- Brand A” & “Brand B” are picked up from the manufacturer for shipment with 15 months SL
- “Brand A” = 92% RSL
- “Brand B” = 74% RSL

The need to reduce reliance on exceptions

- 53% of most commonly delivered VL products would **not** meet 75% RSL requirement
- Potential inconsistencies in granting exceptions, which may hinder patient access

Source: GHSC-PSM Memo issued to USAID OHA
“Diagnostics Shelf Life Background and Recommendations”
WHO Policy on Remaining Shelf-life of Medical Products & Recommendations
USAID is collaborating with WHO to develop a recommendation on importation requirements

- Scope includes pharmaceuticals, vaccines and medical devices (including in vitro diagnostics and reagents/components).
  - Excludes “kits” (ex: VMMC kits)
- Recommends shift from requiring a minimum percentage of RSL to a months-based RSL importation policy.
- Expected to be reviewed by WHO ECSPP in Oct 2019.

The policy allows for flexibility dependent upon consumption rates

<table>
<thead>
<tr>
<th>Expiry date</th>
<th>RSL at time of dispatch from Manufacturer’s premises</th>
<th>RSL at time of delivery at port of entry of country</th>
<th>RSL at time of delivery at point, after customs clearance</th>
<th>RSL at time of delivery at end-user level</th>
</tr>
</thead>
<tbody>
<tr>
<td>48 months &lt; RSL &lt; 60 months</td>
<td>40 months</td>
<td>30 months</td>
<td>18 months</td>
<td>12 months</td>
</tr>
<tr>
<td>36 months &lt; RSL &lt; 48 months</td>
<td>30 months</td>
<td>24 months</td>
<td>18 months</td>
<td>12 months</td>
</tr>
<tr>
<td>24 months &lt; RSL &lt; 36 months</td>
<td>20 months</td>
<td>15 months</td>
<td>10 months</td>
<td>6 months</td>
</tr>
<tr>
<td>12 to 24 months</td>
<td>9 months</td>
<td>7 months</td>
<td>5 months</td>
<td>3 months</td>
</tr>
<tr>
<td>Less than 12 months</td>
<td>Special arrangements and conditions apply</td>
<td></td>
<td></td>
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Benefits of a Months-Based RSL Importation Policy include the following

1. Increases the efficiency of global public health supply chains to help ensure patients do not receive expired products
   - Incentivizes manufacturers to file for longer SL
   - Removes potential preferences of procuring lower SL products
   - Aligns practices in supply chain management of (stock on hand in terms of months of supply) with import regulations
   - Decrease use of exceptions and allow for more predictable importation process
Benefits of a Months-Based RSL Importation Policy include the following

2. Provide flexibility in importation requirements to improve patient access to life-saving commodities and avoid stockouts
   - Provide products immediately to resolve potential stock issues
   - Through distribution from RDCs or direct from stock available at the manufacturer/vendor
Recommendations

• Follow the issuance of the WHO policy
  - Expected to be reviewed in ECSPP in October
• Advocate for implementation as per the WHO policy
  - National
  - Regional – RECs
  - Continental level via AMRH
• Review regulations and begin process of updating
  - All levels (National and RECs)
Thank you! Questions or comments?

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