World Health Organization

The Optimum Shelf-Life for Modules/Sets/Units of Emergency Health Kits (EHKs)

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TARGET AUDIENCE: HQ, RO, WCO procurement and logistics officers.

PURPOSE: This guidance note outlines the optimum shelf-life for the modules/sets/units of Emergency Health Kits (EHKs)

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1. Background

WHO Emergency Health Kits (EHKs) are highly complex. On the distributor side, challenges include sourcing and assembling multiple items per kit, managing various product shelf lives, and maintaining cold chain requirements for certain items. On WHO side, complexities arise from

occasional surges in demand from concurrent emergencies and from addressing importation requirements for different countries and HUBs.

The WHO TRS 1044 - Annex 8 *Points to consider for setting the remaining shelf life of medical products upon delivery* was published in 2022. It introduces the concept of remaining shelf-life and highlights the specific considerations for EHKs in Addendum 2[1]. Despite efforts to standardize, some countries and HUBs are not adhering to WHO guidance, which defines the minimum remaining shelf-life. When requesting EHKs from suppliers, there have been instances of unreasonable demands regarding the expected shelf-life.

2. What defines a kit module/set/unit shelf-life

The total shelf-life

The total shelf-life of a product depends on its nature. A product's shelf-life is determined by its active ingredient: the stability of this ingredient defines the shelf-life of the product. Some products are not stable and have a reduced shelf-life. Typically, the shelf-life of medicines ranges from 18 to 48 months, depending on the stability of their active ingredient.

Once manufactured, a product needs to undergo a series of tests to check its quality. These tests are necessary for the manufacturer to issue the Certificate of Analysis (CoA), which is attached to a batch. During the testing period, the product is placed in quarantine. By the time the product is ready for dispatch from the manufacturer, it has already lost 1 or 2 months of its total shelf-life. The total shelf-life of one product cannot be changed or influenced.

The total shelf-life of a set/unit/module of an EHK is determined by the product in the set/unit/module with the lowest total shelf-life. Among the 100 products composing the set/unit/module, it could be only one product with a short shelf-life that will define the overall shelf-life of the set/unit/module.

The remaining shelf-life

The remaining shelf-life of a set/unit/module is influenced by several logistical factors, including transport time from the manufacturer to the supplier's premises, the quality check of

[1] WHO TRS 1044 - Annex 8: "Points to consider for setting the remaining shelf-life of medical products upon delivery" published in 2022. Available at: https://www.who.int/publications/m/item/trs-1044-annex-8-shelf-life-medical-products-delivery

goods at the supplier's facility, and the complexity of the kit (how many items need to be assembled for a given set/module/unit). Once the set/unit/module is assembled, it may be stored or prepared for dispatch if an order has been placed. During this period, the shelf-life continues to decrease as it progresses through the supply chain (awaiting green light, pickup, transportation, customs clearance, storage, and ultimately, handover to the end user).

It's important to note that a supplier managing multiple kits/modules/units cannot assemble them all simultaneously. Suppliers schedule assemblies, prioritizing kits with longer shelf-lives to be assembled in advance, while those containing items with shorter shelf-lives are assembled more often. Assembly capacity at supplier level is also dependent on the number of production lines available.

Like the total shelf-life, **the remaining shelf-life of a set/unit/module is determined by the product with the shortest remaining shelf-life.** Among 100 products composing the set/unit/module, there could be just a single product with a short shelf-life that will determine the remaining shelf-life. Short shelf-life items are often critical, life-saving products, such as antibiotics or adrenaline (epinephrine). For logistical simplicity, items with the shortest shelf-lives are all consolidated in BOX 1/X of the set/unit/module.

It is important to note that the expiry dates of medicines are listed in months/years and always refer to the last day of the specified month.

Since the remaining shelf life cannot be extended, it is the responsibility of the requestor to assess the actual need and consumption rate and estimate the required order quantity to ensure the product is used within the available shelf life. Making informed decisions regarding the type and quantity of set/ unit/ module requested will facilitate the acceptance of the remaining shelf life and help avoid wastage.

3. How to positively influence the remaining shelf-life

Some key actions can make an optimum remaining shelf-life possible, thereby preventing short expiry, rework, and wastage.

The Emergency Health Kit Prioritization and Allocation Working Group, established in 2022, aims to streamline the kit allocation process. The working group is composed of WHO staff from the Procurement and Supply Services Department and the Operations Support and Logistics team

from the WHO Emergencies Programme. The working group has implemented an allocation mechanism to optimize the use of WHO emergency kit stockpiles and suppliers' production capacity, ensuring the best possible shelf-life for countries and HUBs while also informing suppliers to adjust their production schedules thereby enhancing program implementation at the country level and improving planning functions for both WHO and suppliers.

The allocation decisions are guided by criteria such as the urgency of the emergency, supplier stock availability, expiry dates, and stock location affecting overall costs, shipping lead times, and carbon footprint, as well as the results of the Invitation to Bid (ITB) that established the associated Long-Term Agreement (LTA). To facilitate the allocation process, suppliers are required to share with the working group their stock and production plans monthly. The allocation mechanism outcomes are communicated to suppliers via purchase orders and ensure equitable distribution of EHKs among all Member States and donors.

Annual country planning is essential for the Emergency Health Kit Prioritization and Allocation Working Group and suppliers to plan fresh production batches with the longest possible shelf-life items. Country planning also allows shipping teams to identify the most cost-effective transport mode and route, for a more efficient supply chain, and prevents rejection or rejuvenation of EHKs. It also allows country offices to prepare for the receiving of the EHKs, by informing relevant national authorities of the content specificities (dangerous goods, cold chain, etc), to prepare the green light processes, assess the storage space and ensure that the distribution plans are developed and approved.

A distribution plan logically follows the development of annual procurement planning. Having a distribution plan in place streamlines the in-country supply chain, preventing EHKs from being stuck at the central level while shelf-life decreases, and avoiding expiry and wastage. The distribution should be agreed upon before the EHKs reach the country, aiding the planning of both shipping and in-country transport.

Staggered delivery of large requests of units/kits/modules with short shelf-life is recommended. The country focal point should assess the absorption capacity of the port and warehouse to ensure that shipments are not delayed, avoiding demurrage fees and further reduction of shelf-life. Splitting large shipments allows for receiving items with different remaining shelf-life. Although placing multiple orders may increase the workload for green light

approval, shipment monitoring, and customs clearance processes, staggered deliveries help ensure that the items have sufficient remaining shelf-life to be used before expiry.

Close monitoring of shipments is recommended. The country focal person should follow the status of their shipments through the Transport Management System (TMS) and implement stringent tracking of shipments. This improves inventory management practices, minimizing delays in the green light and customs clearance processes.

Building EHK knowledge: country focal points must have a comprehensive understanding of the EHKs, including their composition, target population, intended use, and characteristics[2]. This knowledge is crucial for effectively informing and supporting national authorities in their decision-making processes. By sharing relevant information about the medicines with short shelf-lives, their respective quantities, the rationale behind their shelf-life settings, and the importance of these life-saving items, the country focal points can facilitate a smoother green light process and acceptance by the MoH, and customs authorities of the unit/module/kit proposed remaining shelf life.

4. The "Optimum" acceptable remaining shelf-life for EHKs

The "optimum" remaining shelf-life given by the supplier or HUB refers to the moment when the distribution is finalized and the request to the Supplier/Hub is acknowledged. It does NOT reflect the remaining shelf-life at the port of entry or upon arrival at the warehouse in-country.

1. When a registration is submitted in GSM, the Emergency Health Kit Prioritization and Allocation Working Group will allocate it to a supplier or HUB, which will propose an "optimum" remaining shelf-life based on the total shelf-life of the requested module, as outlined in the table below.

   The figures in the table represent the "optimum" remaining shelf-life proposed by the supplier or HUB when the procurement team contacts them to confirm the expiry date.

   If the supplier's proposed expiry dates match or exceed those in the table, the procurement team will proceed with ordering without seeking further confirmation from the requesting country.

[2] Information about EHKs https://www.who.int/emergencies/emergency-health-kits

However, if the proposed shelf-life, for any valid reason, is shorter than the those in the table, the procurement team will contact the country, which has up to 5 working days to confirm its acceptance. If no confirmation is received within this period, suppliers may reallocate the "reserved" unit/kit/module to other countries. This measure ensures timely allocation and prevents delays that reduce the shelf-life or demands to suppliers to rejuvenate the kit.

2. If the request is planned, meaning the registration (REG/#) is placed in the system at least 5 months in advance, with a clear note to the procurement team indicating the preferred delivery schedule, the Emergency Health Kit Prioritization and Allocation Working Group can inform the supplier in time for them to assemble the EHKs from new production. Depending on the situation, a longer shelf-life than that indicated in the table below might then be possible.

Optimum remaining shelf-life for the different EHK set/module/unit

Total shelf-life of the unit/module/set as part of an EHKs	**FROM STOCK** – immediate availability, shelf-life at the time of request confirmation to supplier, NOT at the time of arrival in the country.
18 -16 months	Best shelf-life 13 months (for laboratory reagents)
24 months	Best shelf-life 15 months
30 months	Best shelf-life 20 months
36 months	Best shelf-life 23 months
48 months and above	Best shelf-life 31 months

Acceptance and accountability

Please note that for requests where the stock is available, packed and ready at the supplier warehouse, once the agreed-upon shelf-life is established, the stock is reserved, and labelling and shipping documents are prepared according to the consignee's specifications. At this stage, the country cannot request changes to their order. It is therefore crucial for the country to assess the green light and transport time before ordering. If the supplier or the HUB needs to rejuvenate the kit due to delays in response from the country (e.g. not responding to WHO, supplier or freight forwarder emails) the associated costs, if any, will be borne by the country.

Annex: Journey of a medicine through the supply chain from the manufacturer to assembly of an EHK