# ASSISTIVE PRODUCT SPECIFICATION FOR PROCUREMENT

## Medication organizers

### Objective:

The objective of this specification is to help organizations in procuring good quality medication organizers that are durable and which assist individuals to organize medication.

World Health Organization

# 1. Product description

| The purpose of this section is to provide specific key details relevant to the assistive product so that it is easily identifiable. | |
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| Purpose of 1.1 | Name of product as per WHO priority APL and/or commonly used names. |
| 1.1 Name of product | Medication organizers |
| Purpose of 1.2 | As per ISO 9999 classification and terminology document (refer https://www.iso.org/standard/60547.html). |
| 1.2 ISO 9999 code | 04 19 04 *Assistive products for measuring, dispensing or modifying medication to ensure its proper use.*<br>Devices to enable a person to measure the correct dosage of medicine, taken orally or injected; to dispense the correct dosage of a medicine; to modify a tablet, capsule or pill to obtain a lower dose of the active ingredient; or to modify the form of a medication to facilitate its proper administration or consumption. Included are, e.g. pill crushers, pill splitters, assistive products for measuring the volume of liquid medicine.<br><br>22 27 *Assistive products for alarming, indicating, reminding and signaling*<br><br>22 27 16 *Memory support products*<br>Devices for notifying or reminding a person about people, important activities or events of daily life. Included are, e.g. medication reminders, timed reminder systems. |
| Purpose of 1.3 | Describes the product type in clear, simple, easily understood language and the intended use in addressing functional needs. |
| 1.3 Description and intended use | The purpose of these products is to support individuals to take their medications in the correct dosages at the correct time and to prevent adverse drug events (e.g. missed doses, overdoses). These products are intended to keep the individual's prescribed medications, to notify the individual when the prescribed medications are due to be taken, and to monitor whether the individual took the medication. |
| Purpose of 1.4 | Refers to general characteristics of the assistive product that describes its appearance and components. |
| 1.4 General features | Grid-shaped square box or fan-shaped round box. Square box takes out medicine by flip, button, and moving slider, while round box takes out medicine by rotating and dumping. Usually made of transparent plastic for easy identification of drugs, with different colors or printed marks used to distinguish time (hour/time period/day/month). Able to organize multiple drugs for the user.<br><br>Some medication organizers have time prompts or alarms. Some medication organizers have a lock function. Some medication organizers have the function of prompt/alarm/remote monitoring and management.<br><br>The size of the medication organizers vary and are usually lightweight and portable. |
| Purpose of 1.5 | Refers to product models that are included in the specific APS. |

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| 1.5 Inclusion | • Grid-shaped square medication organizer (pill organizer), which opens the organizer with a lid, button, etc.<br>• Fan-shaped round medication organizer (pill dispenser), usually by rotating the lid and pouring it through the small hole in the lid<br>• A medication organizer that displays time and timed reminders (the timed reminder mode may be alarm, vibration, flash or voice)<br>• Medication organizer with locking function<br>• Medication organizer for mobile phone drug reminder management software<br>• Medication organizer for functional services such as reminders, alerts, remote monitoring and management, and communications<br>• Monthly rental medication organizers for reminders, alerts, remote monitoring and management, and communications |
| Purpose of 1.6 | Refers to product models that are excluded in the specific APS. |
| 1.6 Exclusion | • Suppositories<br>• Liquids<br>• Injections<br>• Inhalers<br>• Single use medication organizers |
| Purpose of 1.7 | Important, searchable words that relate to the specific assistive product. |
| 1.7 Keywords | Grid-shaped square medication organizer (pill organizer); fan-shaped round medication organizer (pill dispenser); timed reminder medication organizer; medication organizer with sound and light vibration timing prompt function; medication organizer with lock function, medication organizer with timed reminding medication software; medication organizer with timed reminder, alarm, remote monitoring and communication functions; monthly rented medication organizer with timed reminder, alarm, remote monitoring and communication functions |

# 2. Product requirements

The purpose of this section is to provide details of all applicable requirements relative to the specific assistive product. A requirement is mandatory and typically describes what a product should be able to do, how it should appear (product and packaging) etc. Only supply and service requirements considered applicable in procurement of medication organizers.

## 2.1 Functional requirements

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| Purpose of 2.1 | | A functional requirement refers to technical details and other specific functionality that define what a product variation is supposed to accomplish. Per product variation, the requirement should describe the typical user, specific characteristics of the product (in addition to the general features above) as well as the requirements for standard configuration of the product. It is important to focus on performance requirements rather than form factors. It is important to have a clear and specific description of the typical users including e.g. health condition, functional limitation or demographics (range of age, body weight, height, etc). If applicable, specific context of use (e.g. indoor/outdoor, in noisy environment, etc) should be specified in the product variations. | | |
| **Item** | **Product variations** | **Typical user** | **Specific characteristics** | **Requirements for standard configuration** |

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| 1 | Grid-shaped square medication organizer | Any medication user | These products are usually rectangular in shape and come in a variety of forms. Such as a separate flip-top box, grids inside the box, a small box inside the box. These products taking out medication by flipping the lid | Square medication organizer, usually in different colors or printed marks for different times, are easy to carry. |
| 2 | Fan-shaped round medication organizer | Mostly used for health care users | Usually a disc-shaped box with a rotatable, fan-shaped disc-shaped container, by rotating the lid to pour out the tablets. Among them, there are types with time reminder function, usually can automatically rotate the storage compartment for pouring out the medicine. There are also cylindrical organizers that have independent grids in the container. The cylindrical medication organizer usually does not have a timed reminder device, and the medicine lid is turned by hand to pour the medicine. | Disc or cylindrical medication organizer. The round box type often has a timed reminder and an automatic rotating device for the medicine storage part, which is convenient to carry. |
| 3 | Medication organizer with timed reminder function | Medication users who need to be prompted or reminded about medication compliance | The small grid has other sensory information for prompting time management | Square or disc-shaped medication organizer with timed reminder device, easy to carry with battery. |
| 4 | Medication organizer with sound and light vibration timed reminder function | Medication users who need sensory input prompts or remind medication compliance | Alarm function can emit tactile, audible and/or visual alarms | Light, vibration, sound or voice reminder, easy to carry. |
| 5 | Medication organizer with timed reminder and alarm function | Benefit for controlling dosage for medication users | Ability to set the accessibility of small cells to determine when the medication is released | There are timed reminders and alarm devices. Multiple alarm times can be set, and alarms through sound, light, vibration, etc., which can be alarmed throughout the medication period and automatically turn off the alarm when the medication is removed. |

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| 6 | Medication organizer with lock function | Users who need to pay attention to the safe taking or storage of medication. | The organizer can be locked or open with a key | Medication organizer with a lock attached to it and a matching key. |
| 7 | Medication organizer with timed reminder medication software | Medication users who need medication reminders, medication management, and can use mobile phones | Medication organizer with supporting software | The software has the function of timed reminder, which can be downloaded and installed from the manufacturer's website, and the merchant provides instructions for use. |
| 8 | Medication organizer with timed reminder, alarm, remote monitoring and communication functions | Medication users who agree and benefit from product usage record data. Others can view this data directly or through communication lines. | Data logging and sharing capabilities help the medical team's smart health management, self-management, and personal decision making | Can access the internet, can be reminded regularly, can issue an alarm during the medication period until the medication is taken out, can remotely monitor the medication taking situation, can be remotely communicated, there are two types of monthly rent and one purchase for long-term use. |

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| Purpose of 2.2 | Brief and clear description of general product performance requirements and overall qualities (e.g. stability, strength, durability, waterproof, etc). |
| 2.2 General design requirements | Made from food grade plastic, no BPA. The material is durable and not easily damaged. The lid is easy to open, but it does not open automatically due to carrying and vibration. The lid can be tightly closed to prevent moisture and ensure the health and safety of the medicine. Can be used in a variety of everyday environments. Color or print mark can be used to distinguish the time to take medication in each compartment. Clear printed mark with 3,000 (5000) times of erasure resistance. Optional braille mark. |
| Purpose of 2.3 | Details of existing or in-progress national or international standards should be provided here, whether freely or commercially available. |

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| 2.3 Standards | The organizer design should comply with relevant international, national and industry standards.<br><br>*No current product standards for medication organizers exist.* Relevant Standards may include:<br>Standards governing the safe handling of medications out of packaging; and standards for the automated dispensing of foodstuffs such as pet food.<br>IEC 60335-2-75 Ed. 3.1 Household and similar electrical appliances - Safety Part 2-75: Particular requirements for commercial dispensing appliances and vending machines.<br>ISO/IEEE 11073-10471:2010 Health informatics --Personal health device communication. Part 10471: Device specialization - Independent living activity hub.<br>ISO/IEEE 11073-10472:2012 Health Informatics - Personal health device communication. Part 10472: Device specialization - Medication monitor.<br>EN 15823:2010 Packaging. Braille on packaging for medicinal products<br><br>All documentation should be in the official language or in English (other languages could be specified too). |
| Purpose of 2.4 | A certificate of conformity confirms that a product conforms to applicable national and/or international regulations. If a certificate is required for the specific assistive product, this information should be requested, e.g., CE (Europe), COC (Japan), GCC (USA). |
| 2.4 Certificate of conformity | A certificate that the product conforms with applicable national or international regulations and standards should be provided (for example, a declaration of conformity with the medical device directive or the medical device regulation of the European Union).<br><br>If the product does not conform with applicable national or international regulations and standards, the supplier should provide a certificate that the product complies with the requirements in this call for tender and is safe and effective for use by the typical user.<br><br>The certificate should specify the product, all applied standards, if any, and the name and contact information of the supplier and be provided with the tender. The certificate of conformity is a legal document and should be signed by an authorized person at the supplier.<br><br>The certificate of conformity should be supplied in the official language or in English (other languages could be specified too). |
| Purpose of 2.5 | Lists the relevant scope of information required to identify the appropriate size and weight of the assistive product in its standard configuration (specific dimensions may be given if appropriate). |
| 2.5 Size and weight | Size is variable. Selection can be guided by usage factors such as portability within and outside the home and duration (how many doses contained within). Information about the overall width, length, height and weight of the pill organizers should be provided. Dimensions of operable compartments and lids should be provided. |
| Purpose of 2.6 | Lists the relevant scope of information that should be provided to service providers (e.g. how to select, assemble, fit, adapt, follow up, maintain, repair, refurbish the assistive product). The desired language(s) in which the technical information should be provided should be stated. |

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| 2.6 Technical information (for service providers) | Information on how to assemble and adapt the medication organizer should be provided.<br><br>Instructions on how to maintain, service, repair, refurbish and clean the medication organizer should be provided.<br><br>The technical information should be provided in the official language or in English (other languages could be specified too). |
| Purpose of 2.7 | Lists the scope of information, and its format, that should be provided to end-users to show how to safely use the assistive product. |
| 2.7 Instructions for use | A user manual with instructions for use of the medication organizer should be provided by the supplier. It should provide instructions on how to safely and effectively use the product, and how to maintain and clean it. It is intended for the user and/or care-giver.<br><br>The user manual may be provided in print or electronic format. The user manual should summarize, in plain language, any technical information (2.6) regarding medication-specific design features (temperature control; light; airtight environment; storage with other drugs) stating clearly which types of medications are CONTRA-INDICATED for storage in the medication organizer.<br><br>The user manual should be provided in the official languages, and if applicable, in English (other languages could be specified too). |
| Purpose of 2.8 | Refers to the various weather and other environmental conditions, e.g., temperatures, humidity, rain, snow, sunshine, that the assistive product should be able to withstand. |
| 2.8 Environment of use | Guidance should be provided from manufacturers on environmental situations of non-safe use (e.g. do not place in direct sunlight, situations of extreme heat etc.). Manufacturers should advise the user to adhere to medication temperature tolerances. |
| Purpose of 2.9 | Refers to the duration of the warranty period and the details of the warranty the manufacturer/supplier should provide within the specified period. |
| 2.9 Warranty | Provided normal heedful use, the supplier should, during the warranty period and without extra expenses, repair parts which break on the products delivered. This comprises all spare parts and labour, except for normal wear and tear of the product.<br><br>The warranty period should be at least 12 months after delivery of the medication management system. The same should apply for spare parts and accessories.<br><br>The supplier should cover all transport when repairing a medication management system.<br><br>Following a written complaint, the supplier should repair or replace the product within 10 working days and no more than 30 working days or other specified. |
| Purpose of 2.10 | Refers to the expected duration, in years, of the assistive product. Documents describing how this is ensured must be provided. |
| 2.10 Lifespan | Given the purpose of use by typical users, the medication management system should be designed for a lifetime of at least 2 years. |
| Purpose of 2.11 | Lists the scope of information required in packaging and labeling the assistive product. Explains the state of assembly the assistive product should be in when received by the end-user. |

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| 2.11 Packaging, labelling, and state of assembly | Each medication organizer should be delivered in an individual package with a label clearly stating details of the product. All necessary parts should be included in the package. The package should withstand handling during transport.<br><br>The medication management system should be delivered fully assembled or assembled to such an extent that the remaining assembly can be carried out with the use of commonly available screwdrivers or wrenches. If any special tool is required, it should be included with the delivery. |
| Purpose of 2.12 | Refers to additional product requirements, depending on the specific assistive product, e.g., material, corrosion-resistance, adjustability, foldability, etc. |
| 2.12 Other product requirements | Not applicable in this call for tender. |

## 3. Supply and service requirements

From the information provided below, only those supply and service requirements considered applicable may be used in a procurement bid.

| The purpose of this section is to describe key supply and service requirements that are needed in order to ensure that the assistive product is received in due time, operational, being maintained/repaired and refurbished. | |
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| Purpose of 3.1 | Lists the scope of information to be requested on how the assistive product will be transported to the place of delivery. |
| 3.1 Transportation | Information on how the medication organizers will be transported should be provided and who should pay for the transportation. |
| Purpose of 3.2 | Specifies the time between placing an order and receiving delivery of the assistive product (e.g. that it should not exceed 30 calendar days). |
| 3.2 Delivery time | The time between placing an order of up to 120 medication organizers and receiving delivery of them should not exceed 30 working days. |
| Purpose of 3.3 | Refers to the specific details of the various accessories and spare parts available for the assistive product, including pricing and availability. |
| 3.3 Accessories and spare parts | The supplier should offer the following accessories and spares:<br>• Moving or removeable parts of the medication organizer (e.g. lids, compartments, dividers etc.) which may be replaced at some stage, should be offered as spare parts.<br><br>The supplier should state which variations of medication organizer the accessories and spare parts are meant for. When an accessory consists of one part, the same part should not be offered both as an accessory and a spare part, but only as an accessory. When an accessory consists of several parts that can be replaced, all replaceable parts should be offered as spare parts.<br><br>Spare parts should be made available for a period of at least 12 months after the last order of a medication organizer. The price of the spare parts should be offered per part and not per set or pair. |
| Purpose of 3.4 | Provides information regarding required maintenance services the supplier will provide, including the timeframe and frequency. |

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| 3.4 Maintenance | Not applicable in this call for tender. |
| Purpose of 3.5 | Provides information regarding required repairment services the supplier will provide, including the timeframe and frequency. |
| 3.5 Repair | Information about the costs of the repair, postal address and who should pay for postage and packing. Timescales for the item repair should not exceed 21 calendar days. Information about payment per hour, including definitions of when a job starts and finishes; travel expenses, from – to, fee per km, rules when several repair jobs are done on the same route; hotel bills; who should provide the spare parts; in cases the job is done by a sub-supplier, the invoice should be sent by the supplier with the contract. The prices should be according to the contract. (More information may be requested to be provided.) |
| Purpose of 3.6 | Provides information regarding required refurbishment services the supplier will provide, including the timeframe and frequency. |
| 3.6 Refurbishing | Not applicable in this call for tender. |
| Purpose of 3.7 | Specifies if training service providers is required by suppliers, and the key elements included in the training (e.g. selection, assembly, fit, maintenance and repair of the assistive product). Refers to detailed training contents or materials, if available and applicable. |
| 3.7 Training of service providers | Training manuals or videos to be provided with the products. |
| Purpose of 3.8 | Specifies if training users is required by suppliers, and the key elements included in the training (e.g. training to users should include fit, use, maintenance and cleaning of the assistive product). Refers to detailed training contents or materials, if available and applicable. |
| 3.8 Training of users | Training manuals or videos to be provided with the products. |
| Purpose of 3.9 | Provides information regarding other supply and service requirements. |
| 3.9 Other supply and service requirements | Not applicable in this call for tender. |