World Health Organization

POLICY ON REMAINING SHELF LIFE OF MEDICAL PRODUCTS

(March 2019)

DRAFT FOR COMMENTS

Please send any comments you may have to Dr S. Kopp, Group Lead, Medicines Quality Assurance, Technologies Standards and Norms (kopps@who.int), with a copy to Ms Sinéad Jones (jonessi@who.int) **by 5 May 2019**.

Medicines Quality Assurance working documents will be sent out electronically only. They will also be placed on the Medicines website for comment under "Current projects". If you have not already received our draft working documents, please send your email address (to jonessi@who.int) and we will add you to our electronic mailing list.

SCHEDULE FOR DRAFT WORKING DOCUMENT QAS/19.788:

POLICY ON REMAINING SHELF LIFE OF MEDICAL PRODUCTS

Description of Activity	**Date**
Informal discussion at The Global Fund to Fight AIDS, Tuberculosis and Malaria offices in Geneva, Switzerland.	February 2019
Preparation of the document.	February 2019
Circulation of document, inviting comments.	March and April 2019
Review of comments received. Preparation of discussion document.	May 2019
Discussion at the informal Consultation on Good Practices for Health Products Manufacture and Inspection, Geneva, Switzerland.	June – July 2019
Preparation of revised text by a working group in close collaboration with the IPC.	August 2019
Circulation of revised working document for public consultation.	August – September 2019
Consolidation of comments received and review of feedback.	October 2019
Presentation to the Fifty-fourth meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations in Geneva, Switzerland.	October 2019

POLICY ON REMAINING SHELF LIFE OF MEDICAL PRODUCTS

1. INTRODUCTION

Following discussions relating to establishing policy for shelf life of medical products, including the discussion between the Interagency Pharmaceutical Coordination (IPC) group representatives, it was decided to initiate a project to have a policy on remaining shelf life for procurement and supply of medical products.

The concept and project to establish such a policy was also discussed during the meeting of the Fifty-third Expert Committee on Specifications for Pharmaceutical Products (ECSPP) in October 2018. It was noted that some guidance documents were available from different procurement agencies. It was agreed that the World Health Organization (WHO) will initiate the discussion and preparation of a policy whilst following the WHO process for the establishment of a policy paper.

The information and policy on remaining shelf life was collected from different agencies and interested parties and a first draft document was prepared after an informal discussion meeting at the offices of The Global Fund to Fight AIDS, Tuberculosis and Malaria, in Geneva, Switzerland, in January 2019.

It was agreed that the policy should not cover only pharmaceutical products but should be extended to also cover other products, including but not limited to, diagnostics, reagents, and kits.

The draft document will be circulated to IPC members and through other channels to invite comments. The comments will be reviewed during informal discussion meetings before being tabled at the meeting of the Fifty-fourth ECSPP in October 2019.

The policy contained in this document is intended to address remaining shelf life of medical products and should be implemented by all stakeholders in the supply chain of medical

products. It is also recommended that the policy be considered in the national policy of countries.

The aims of this policy document include:

- to ensure that there is a balance between enforcing the remaining shelf life policy and ensuring availability of product;
- to facilitate the national authorization of importation of stock where applicable;
- to assist in ensuring that there is sufficient stock of medical products, with acceptable remaining shelf life, in-country;
- to prevent dumping of medical products;
- to ensure that barriers to access and supply are addressed;
- to prevent stock-outs;
- to prevent receiving donations of medical products that are not appropriate; and
- to prevent having expired stock.

2. SCOPE

The principles contained in this document should be applied to medical products in the supply chain, including pharmaceutical products, medical devices, diagnostics, reagents and others.

Policy on remaining shelf life should be realistic. It should be defined for medical products and the detail may vary for different categories of products, depending on the type of product, storage condition, resources in-country and others.

This document presents policy on shelf life and does not address details contained in other guidelines, guides and agreements between different parties in the supply chain.

(***Note from Secretariat***: *it is suggested to add references to those relating to Donations, Public Health Emergencies and Products needed in exceptional circumstances. Proposals for references are welcome).*

Manufacturers, suppliers, donors and recipients should take note of the shelf life policy contained in this document.

3. THE NEED FOR POLICY

As there was no harmonized policy on shelf life for medical products amongst procurers and donors, it was agreed that it will be beneficial to have a harmonized approach on policy for shelf life. This will assist suppliers, donors, procurers and distribution points in managing medical products throughout the supply chain, ensuring the availability of quality products within the remaining shelf life, in reaching the end user.

The authorization of importation of medical products by national regulatory authorities (NRA) sometimes further delay access to medical products. A harmonized approach may facilitate authorization.

This policy document is not a standalone document. It should be read with other documents and guidelines, including but not limited to, WHO Guidelines on Stability Testing, Good Storage and Distribution Practices, Donations, Model Quality Assurance System for Procurement Agencies (MQAS), Pharmacopoeia, ICH guidelines, and other related guides and recommendations.

4. POLICY ON SHELF LIFE: MANUFACTURERS, SUPPLIERS, DONORS AND RECIPIENTS

The manufacturing date of a product should be defined by the manufacturer and be provided upon request by the recipient. This will help to ensure that an accurate shelf life can be calculated and verified.

Products, such as pharmaceutical products, should have an expiry date allocated by the manufacturer. The expiry date should be established based on stability testing results obtained in the relevant packaging (primary and secondary packaging where appropriate) and required stability conditions. (*See WHO Guideline: Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Technical Report Series 1010, Annex 10, 2018.*)

Products with an expiry date should not be subjected to re-testing by the purchaser or recipient for the purpose of extension of shelf life.

Where a manufacturer or supplier has obtained approval from an NRA, where applicable - for a new or extended shelf life - this should be applied to batches of product to be delivered. Only in exceptional cases, such as product shortages, should a recipient consider to extend the expiry date of received batches subject to certain conditions, such as availability of scientific data. (*See Annex.*)

Products with a re-test date allocated by a manufacturer or supplier should have at least one year of shelf life remaining (from the date of delivery to the labelled re-test date) on the date of delivery.

Products with a re-test date allocated by a manufacturer, e.g. chemicals and reagents, may be re-tested and used if the quality parameters are met.

Products with an “Install by” date should be installed prior to the date specified by the supplier.

The principles contained in this policy document should be applied to managing donated products. (*See WHO Guidelines on Donations.*)

Products received should be scrutinised to be able to identify possible substandard and falsified products. It should be ensured that, for example, the expiry date is not falsified. (*See Guidelines on Substandard and Falsified Products, WHO Guidance on Testing of "suspect" falsified medicines.*)

Products should be appropriately labelled. The label should include the expiry, re-test or install by date, as appropriate.

Products should be transported, received, stored and distributed in accordance with *Good Storage and Distribution Practices*. Special attention should be given to temperature sensitive products. (*Ref: WHO GSP, GDP, Temperature Sensitive materials*.)

Products supplied by the manufacturer or supplier should meet the policy requirements in terms of remaining shelf life prescribed by the recipient. Compliance with this requirement should be verified by the appropriate means, such as a pre-shipment inspection.

Where different periods for remaining shelf life have been defined for products, recipients should ensure that the products meet the remaining shelf life requirement for the intended destination, e.g. central warehouse, regional warehouse or user point.

National authorization for importation, where required, should be obtained based on the available information, including the supplier specified remaining shelf life, to assist in expediting approval.

Recipients should regularly verify that products in stock are rotated or used within their remaining shelf life.

There should be an agreement between the supplier and purchaser covering the relevant responsibilities of each party and policies relating to, for example, remaining shelf life, transport conditions and returns.

The policies should be applicable to all products including emergency supplies. Where so justified, suppliers, recipients and national authorities may negotiate deviations from the remaining shelf life policy provided that:

(a) the product quality will be ensured, and

(b) where the shelf life is shorter than stipulated in the policy, it is ensured that the stock will be consumed prior to expiry of the batch.

Examples of considerations and recommended remaining shelf life of products are given in the Annexure.

GLOSSARY

(Note: Definitions will be taken from existing WHO guidelines where possible. Alternatively, from other recognised guidelines. In case specific definitions are required, comments will be welcomed and considered)

Expiry date

Install by date

Manufacturing date

Medical product

Pharmaceutical product

Remaining shelf life

Re-test date

ANNEXURE

EXAMPLES OF CONSIDERATIONS AND RECOMMENDED REMAINING SHELF LIFE OF PRODUCTS

Examples of considerations in determining the remaining shelf life:

- existing shelf life;
- required storage conditions;
- risk management;
- type of product;
- frequency of order;
- need and emergency;
- warehouse; and
- supply chain and resources.

Recommended remaining shelf life of products

Table 1. Classification depending on the expiry date

Expiry date *	Remaining shelf life at time of delivery
3 to 5 years	2 years
2 to 3 years	18 months
1 to 2 years	8 months

*Based on stability testing, as stipulated on the label. Presented in number of years, based on the calculation from the date of manufacture.

Table 2. Classification depending on storage conditions

Storage condition	Remaining shelf life at time of delivery *(See Table 3, unless there are opinions that the remaining shelf life should be considered purely on storage conditions)*
Below 30 ºC	
Below 25 ºC	
2 to 8 ºC	
Below 0 ºC	

Table 3. Recommended remaining shelf life (alternative to Table 1 and 2)*

	Expiry date → Less than 2 years	2 – 3 years	3 – 4 years	4 – 5 years
Storage condition ↓				
Below 0	8 months	1 year	1 year	1 year
2 to 8 ºC	8 months	1 year	1 year	1 year
< 25 ºC	8 months	18 months	24 months	2 years
<30 ºC	8 months	18 months	24 months	2 years
	Remaining shelf life →			

*The remaining shelf is calculated, based on expiry date, storage conditions and risks.

***