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2 **POLICY ON REMAINING SHELF LIFE**
3 **OF MEDICAL PRODUCTS**

4 (March 2019)

5 *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.

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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

45 **POLICY ON REMAINING SHELF LIFE**
46 **OF MEDICAL PRODUCTS**
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48 **1. INTRODUCTION**
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50 Following discussions relating to establishing policy for shelf life of medical products,
51 including the discussion between the Interagency Pharmaceutical Coordination (IPC) group
52 representatives, it was decided to initiate a project to have a policy on remaining shelf life for
53 procurement and supply of medical products.
54

55 The concept and project to establish such a policy was also discussed during the meeting of the
56 Fifty-third Expert Committee on Specifications for Pharmaceutical Products (ECSPP) in
57 October 2018. It was noted that some guidance documents were available from different
58 procurement agencies. It was agreed that the World Health Organization (WHO) will initiate
59 the discussion and preparation of a policy whilst following the WHO process for the
60 establishment of a policy paper.
61

62 The information and policy on remaining shelf life was collected from different agencies and
63 interested parties and a first draft document was prepared after an informal discussion meeting
64 at the offices of The Global Fund to Fight AIDS, Tuberculosis and Malaria, in Geneva,
65 Switzerland, in January 2019.
66

67 It was agreed that the policy should not cover only pharmaceutical products but should be
68 extended to also cover other products, including but not limited to, diagnostics, reagents, and
69 kits.
70

71 The draft document will be circulated to IPC members and through other channels to invite
72 comments. The comments will be reviewed during informal discussion meetings before being
73 tabled at the meeting of the Fifty-fourth ECSPP in October 2019.
74

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

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

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80 The aims of this policy document include:

81

82 • to ensure that there is a balance between enforcing the remaining shelf life policy and
83 ensuring availability of product;

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85 • to facilitate the national authorization of importation of stock where applicable;

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87 • to assist in ensuring that there is sufficient stock of medical products, with acceptable
88 remaining shelf life, in-country;

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90 • to prevent dumping of medical products;

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92 • to ensure that barriers to access and supply are addressed;

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94 • to prevent stock-outs;

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96 • to prevent receiving donations of medical products that are not appropriate; and

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98 • to prevent having expired stock.

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100 **2. SCOPE**

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

104

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

108

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

111

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

115

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

118

119 **3. THE NEED FOR POLICY**

120

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

126

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

130

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

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

142

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

146

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

153

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

156

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

162

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

166

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

169

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

171

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

174

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

179

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

182

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

186

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

190

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

194

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

198

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

201

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

205

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

209

210 (a) the product quality will be ensured, and

211

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

214

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

217

218 **GLOSSARY**

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

223

224 *Expiry date*

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226 *Install by date*

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228 *Manufacturing date*

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230 *Medical product*

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232 *Pharmaceutical product*

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234 *Remaining shelf life*

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236 *Re-test date*

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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.

270 **Recommended remaining shelf life of products**

271

272 Table 1. Classification depending on the expiry date

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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

274

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

277

278 Table 2. Classification depending on storage conditions

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

280

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

282

	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 °C	8 months	1 year	1 year	1 year
< 25 °C	8 months	18 months	24 months	2 years
<30 °C	8 months	18 months	24 months	2 years
	Remaining shelf life →			

283

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

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