

 World Health Organization	REGULATION AND PREQUALIFICATION DEPARTMENT	
	VACCINES ASSESSMENT TEAM	
TEMPLATE		
Standard letter B - notification of major specification changes		
Doc No: IMD/TP/02b	Version No: 2	Revise before: 15 Jun 2027
Effective date: 15 Jun 2024	Replaces: Annex 2	Page 1 of 1
Approved by:	TL-VAX, date: 8 May 2024	UH-PQT, date: 31 May 2024
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Standard letter B - Notification of major specification changes

Dear Sir/Madam,

Proposed changes to IMD-PQS performance specification

We refer to the WHO IMD-PQS performance specification <reference, title and date>.

Your company currently has prequalified product(s) conforming to this specification listed on the IMD-PQS database. As a matter of courtesy, we write to inform you that we intend to make significant changes to the document. The nature and purpose of these changes is summarised below:

<i>Proposed change</i>	<i>Reason for change</i>
<list>	<list>

If you have any comments on the proposed alterations please contact the writer by post, fax or email no later than <dd.mm.yy>. In preparing the revised document we will take full account of your comments and those of other prequalified manufacturers and we may wish to discuss them with you in detail before finalising the revisions.

Our intention is to publish the revised specification in <mm.yy> and we will expect all existing prequalified manufacturers to comply with the new requirements no later than <mm.yy>.

Yours faithfully,