

 <b>World Health Organization</b>	<b>REGULATION AND PREQUALIFICATION DEPARTMENT</b>	
	<b>VACCINES ASSESSMENT TEAM</b>	
<b>TEMPLATE</b>		
<b>STANDARD LETTER B -NOTIFICATION OF MAJOR CHANGES TO VERIFICATION PROTOCOL</b>		
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## Standard letter B -Notification of major changes to verification protocol

Dear Sir/Madam,

**Proposed changes to IMD-PQS product verification protocol**

We refer to the WHO IMD-PQS product verification protocol <reference, title and date>.

Your company currently has prequalified product(s) conforming to this protocol listed on the 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><sup>1</sup>. 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 verification protocol in <mm.yy> and we will expect all existing prequalified manufacturers to re-verify their products in accordance with the new requirements by no later than <mm.yy><sup>2</sup>.

Yours faithfully,

<sup>1</sup> Allow a minimum of two months.

<sup>2</sup> Allow a minimum of one year after the publication date in the first instance.