



**Steps for Completing Global Fund's Round 8 Proposal for
Requesting funds for Pharmacovigilance**

Locations where Pharmacovigilance Information should be included and suggestions for content:

Excerpts from R8 GF Proposal Form: Section/Sub-section	Comments and Suggestions						
<p>3 PROPOSAL SUMMARY</p> <p>3.5 Summary of Round 8 HIV-TB-Malaria Proposal</p> <p>Provide a summary of the HIV-TB-Malaria proposal described in detail in section 4. <i>Prepare after completing s.4</i></p>	<p>Indicate that a pharmacovigilance system will be setup to monitor drug safety as part of the HIV-TB-Malaria program.</p>						
<p>4 PROGRAM DESCRIPTION</p> <p>4.1 National prevention, treatment, care, and support strategies</p> <p>(a) Briefly summarize:</p> <ul style="list-style-type: none"> ▪ the current HIV-TB-Malaria national prevention, treatment, and support strategies; ▪ how these strategies respond comprehensively to current epidemiological situation in the country; and ▪ the improved HIV-TB-Malaria outcomes expected from implementation of these strategies. <p>(b) From the list below, attach* only those documents that are directly relevant to the focus of this proposal (or, *identify the specific Annex number from a Round 7 proposal when the document was last submitted, and the Global Fund will obtain this document from our Round 7 files). <i>Also identify the specific page(s) (in these documents) that support the descriptions in s.4.1. above.</i></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;">Document</th> <th style="width: 30%;">Proposal Annex Number</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> </tbody> </table>	Document	Proposal Annex Number					<p>Include a sentence on Pharmacovigilance, if part of the national policy.</p> <p>Attach:</p> <ul style="list-style-type: none"> • National Pharmacovigilance Policy (if any). • GF Policy on Pharmacovigilance [Refer to GF Policy on pharmacovigilance: Guide to the Global Fund's Policies on Procurement and Supply Management (available at http://www.theglobalfund.org/pdf/guidelines/pp_guidelines_procurement_supplymanagement_en.pdf)].
Document	Proposal Annex Number						
4.3. Major constraints and gaps							



<p><i>(For the questions below, consider government, non-government and community level weaknesses and gaps, and also any key affected populations¹ who may have disproportionately low access to malaria prevention, treatment, and care and support services, including women, girls, and sexual minorities.)</i></p>	
<p>4.3.1. HIV-TB-Malaria program</p> <p>Describe:</p> <ul style="list-style-type: none"> • the main weaknesses in the implementation of current HIV-TB-Malaria strategies; ▪ how these weaknesses affect achievement of planned national HIV-TB-Malaria outcomes; and ▪ existing gaps in the delivery of services to specific at-risk populations. 	<p>Indicate Pharmacovigilance/drug safety monitoring is a program component & briefly describe implementation weaknesses; and how this impacts the implementation of your program</p>
<p>4.3.2. Health System</p> <p>Describe the main weaknesses of and/or gaps in the health system that affect HIV-TB-Malaria outcomes. The description can include discussion of issues that are common to malaria, tuberculosis and HIV programming and service delivery; and issues that are relevant to the health system and HIV-TB-Malaria outcomes [e.g.: delivery of ITNs or IRS, or provision of intermittent preventive treatment to pregnant women (IPTp) OR PMTCT services OR PAL services], but perhaps not also HIV and tuberculosis (Or malaria and tuberculosis Or HIV and tuberculosis programming and service delivery).</p>	<p>Describe main weaknesses in Health system relating to Pharmacovigilance (refer to WHO, Uppsala Monitoring Centre documents (www.who-umc.org) on Pharmacovigilance).</p>
<p>4.3.3. Efforts to resolve health system weaknesses and gaps</p> <p>Describe what is being done, and by whom, to respond to health system weaknesses and gaps that affect malaria outcomes.</p>	<p>Describe current activities on Pharmacovigilance being conducted to overcome weaknesses and gaps.</p>
<p>4.5 Implementation strategy</p> <p>4.5.1. Round 8 interventions</p>	



<p>Explain: (i) who will be undertaking each area of activity (which Principal Recipient, which Sub-Recipient or other implementer); and (ii) the targeted population(s). <i>Ensure that the explanation follows the order of each objective, program work area (or, "service delivery area (SDA)"), and indicator in the 'Performance Framework' (Attachment A). The Global Fund recommends that the work plan and budget follow this same order.</i></p> <p><i>Where there are planned activities that benefit the health system that can easily be included in the HIV-TB-Malaria program description (because they predominantly contribute to malaria outcomes), include them in this section only of the Round 8 proposal.</i></p> <p><i>Note: If there are other activities that benefit, together, HIV, tuberculosis and malaria outcomes (and health outcomes beyond the three diseases), and these are not easily included in a 'disease program' strategy, they can be included in s.4B in one disease proposal in Round 8. The applicant will need to decide which disease to include s.4B (but only once). → Refer to the Round 8 Guidelines (s.4.5.1.) for information on this choice.</i></p>	<p>Indicate Pharmacovigilance activity will be implemented through country program or National Drug Regulatory Authority.</p> <p>Indicate a work plan with salient steps/activities for Pharmacovigilance; some examples are included below (also refer to WHO documents on Pharmacovigilance):</p> <ol style="list-style-type: none"> 1. Assess country's overall pharmacovigilance capacity, and specifically assess pharmacovigilance capacity in public health programs of HIV-TB-Malaria 2. Assess and develop policies, framework, strategy and approach for establishing/strengthening pharmacovigilance in the country (developed jointly with country and global experts) 3. Assess human resource capacity and conduct workshops in strengthening pharmacovigilance capacity 4. Post-workshop, continue off-site and on-going technical support for duration of grant period 5. Establish new systems and/or support the strengthening of existing systems for passive pharmacovigilance (spontaneous reporting) 6. Develop protocols for conducting drug specific active pharmacovigilance in country. Conducted jointly with other stakeholders in country and internationally. 7. Conduct product specific active surveillance of key first line drugs (phase 1). 8. Conduct product specific active surveillance of key first line drugs (phase 2). 9. Any other. <p>The details are not to be included in the proposal. However, this should be provided in a detailed PSM plan after the approval of the proposal by GF.</p>
4.9 Implementation capacity	



<p>4.9.6. Strengthening implementation capacity</p> <p>The Global Fund encourages in-country efforts to strengthen government, non-government and community-based implementation capacity.</p> <p>If this proposal is requesting funding for management and/ or technical assistance to ensure strong program performance, summarize:</p> <ul style="list-style-type: none"> (a) the assistance that is planned;** (b) the process used to identify needs within the various sectors; (c) how the assistance will be obtained on competitive, transparent terms; and (d) the process that will be used to evaluate the effectiveness of that assistance, and make adjustments to maintain a high standard of support. <p><i>** (e.g., where the applicant has nominated a second Principal Recipient which requires capacity development to fulfill its role; <u>or</u> where community systems strengthening is identified as a "gap" in achieving national targets, and organizational/management assistance is required to support increased service delivery.)</i></p>	<p>Indicate in short the technical/management assistance planned for proposed Pharmacovigilance activities so as to fulfill the needs; how the assistance will be obtained; and effectiveness of this assistance, viz., strengthening of national Pharmacovigilance programme, etc. You may contact RBM or WHO/ Uppsala who will provide you with specific support in this area.</p>
<p>4.10 Management of pharmaceutical and health products</p> <p>4.10.2 Table of roles and responsibilities</p> <p>Provide as complete details as possible. <i>(e.g., the Ministry of Health may be the organization responsible for the 'Coordination' activity, and their 'role' is Principal Recipient in this proposal). If a function will be outsourced, identify this in the second column and provide the name of the planned outsourced provider.</i></p>	



Activity	Which organizations and/or departments are responsible for this function? <i>(Identify if Ministry of Health, or Department of Disease Control, or Ministry of Finance, or non-governmental partner, or technical partner.)</i>	In this proposal what is the <u>role</u> of the organization responsible for this function? <i>(Identify if Principal Recipient, sub-recipient, Procurement Agent, Storage Agent, Supply Management Agent, etc.)</i>	Does this proposal request funding for additional staff or technical assistance	
Ensuring rational use and patient safety (pharmacovigilance)	National Drug Regulatory Authority, National HIV-TB-Malaria Control Program		<input type="checkbox"/> Yes <input type="checkbox"/> No	Fill up this row on Pharmacovigilance. Mention about the technical assistance proposed to be provided by the Technical Partners of WHO-RBM for Pharmacovigilance activity.
<p>4.10.4. Alignment with existing systems</p> <p>Describe the extent to which this proposal uses existing country systems for the management of the additional pharmaceutical and health product activities that are planned, including pharmacovigilance systems. If existing systems are not used, explain why.</p>			Describe in detail current operations/activities of Pharmacovigilance in country and additional support to be provided by the WHO-RBM and its partners.	

5 FUNDING REQUEST

5.2 Detailed Budget

Suggested steps in budget completion:

1. **Submit a detailed proposal budget in Microsoft Excel format as a clearly numbered annex.** Wherever possible, use the same numbering for budget line items as the program description.
 - **FOR GUIDANCE ON THE LEVEL OF DETAIL REQUIRED** (or to use a template if there is no existing in-country detailed budgeting framework) **refer to the budget information available at the following link:** <http://www.theglobalfund.org/en/apply/call8/single/#budget>
2. Ensure the detailed budget is consistent with the detailed work plan of program activities.
3. From that detailed budget, prepare a 'Summary by Objective and Service Delivery Area' (s.5.3.)
4. From the same detailed budget, prepare a 'Summary by Cost Category' (s.5.4.)

Do not include any CCM or Sub-CCM operating costs in Round 8. This support is now available through a separate application for funding made direct to the Global Fund (and not funded through grant funds).

The application is available at: <http://www.theglobalfund.org/en/apply/mechanisms/guidelines/>

Adapt and modify the following table based on program needs. Indicative steps and activities are given below which need to be adapted into objective and Service Delivery Areas. Modify format to ensure consistency with Table 5.2, 5.3, 5.4.

Budgeting and Timeline for Establishing/Strengthening Pharmacovigilance programme are given below).			
Steps and Activities	Estimated Cost		
1. Assess country's overall pharmacovigilance capacity, and specifically assess pharmacovigilance capacity in public health programs of HIV-TB-Malaria			
2. Assess and develop policies, framework, strategy and approach for establishing/strengthening pharmacovigilance in the country (developed jointly with country and global experts)			
3. Assess human resource capacity and conduct workshops in strengthening pharmacovigilance capacity			
4. Post-workshop, continue off-site and on-going technical support for duration of grant period			
5. Establish new systems and/or support the strengthening of existing systems for passive pharmacovigilance (spontaneous			



								reporting). Hiring of staff should be budgeted separately.			
								6. Develop protocols for conducting drug specific active pharmacovigilance in country. Conducted jointly with other stakeholders in country and internationally.			
								7. Conduct product specific active surveillance of key first line drugs (phase 1)			
								8. Conduct product specific active surveillance of key first line drugs (phase 2)			
								Based on the budget table, prepare a 'Summary by Objective and Service Delivery Area'			
5.3 Summary of detailed budget by objective and service delivery area											
Objective Number	Service delivery area (Use the same numbering as in program description in s.4.5.1.)	Year 1	Year 2	Year 3	Year 4	Year 5	Total				
[use "Add Extra Row Below" from "Table" menu in Microsoft Word menu bar to add as many additional rows as required]											
Round 8 malaria funding request:											

5.4 Summary of <u>detailed budget</u> by cost category (<i>Summary information in this table should be further explained in sections 5.4.1 – 5.4.3 below.</i>)							Based on the budget table, prepare a 'Summary by Cost Category' (Most of the Pharmacovigilance activities will fit into 'Human Resources', 'Training', 'Communication Materials' and 'Technical and Management Assistance' categories)
<i>Avoid using the "other" category unless necessary – read the Round 8 Guidelines .</i>	<i>(same currency as on cover sheet of Proposal Form)</i>						
	Year 1	Year 2	Year 3	Year 4	Year 5	Total	
Human resources*							
Technical and Management Assistance							
Training*							
Health products and health equipment							
Pharmaceutical products (medicines)							
Procurement and supply management costs							
Infrastructure and other equipment							
Communication Materials*							
Monitoring & Evaluation							
Living Support to Clients/Target Populations							
Planning and administration							
Overheads							
Other: (<i>Use to meet national budget planning categories, if required</i>)							
Round 8 malaria funding request <i>(Should be the same annual totals as table 5.2)</i>							
5.4.1. Overall budget context							



<p>Briefly explain any significant variations in cost categories by year, or significant five year totals for those categories.</p> <p>5.4.2. Human resources In cases where 'human resources' represents an important share of the budget, summarize: (i) the basis for the budget calculation over the initial two years; (ii) the method of calculating the anticipated costs over years three to five; and (iii) to what extent human resources spending will strengthen service delivery. <i>(Useful information to support the assumptions to be set out in the detailed budget includes: a list of the proposed positions that is consistent with assumptions on hours, salary etc included in the detailed budget; and the proportion (in percentage terms) of time that will be allocated to the work under this proposal.</i> → Attach supporting information as a clearly named and numbered annex</p> <p>5.4.3. Other large expenditure items If other 'cost categories' represent important amounts in the summary in table 5.4, (i) explain the basis for the budget calculation of those amounts. Also explain how this contribution is important to implementation of the national HIV-TB-malaria program. → Attach supporting information as a clearly named and numbered annex</p>	<p>Based on the Budget Table, indicate only if major variation/s in costs by year, etc.</p> <p>Indicate HR budget for building/establishing dedicated personnel for Pharmacovigilance</p> <p>Indicate if any for building/establishing dedicated team for Pharmacovigilance, & its importance in strengthening the Pharmacovigilance programme.</p>
<p><i>Annex Attachment A: Indicators and Targets Table</i></p>	<p>Needs to be completed.</p> <p>Include a few indicators (e.g. number of people trained; number of protocols developed; number of sentinel sites established; number of Adverse Drug Reactions reports collected, analyzed; etc.)</p>

**For additional information, please contact:
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