



Rapid Pharmacovigilance Implementation in Developing Countries

Assessing Pharmacovigilance (PV) Capacity in Public Health Programs

Malaria Programs

Country: _____

Date : _____

I.	Respondent: Background Information	
	Name	
	Designation	
	Department, Ministry	
	Address	
	Email	
	Phone; Mobile; Fax	

II.	Country and Public Health Information	
	Country Population	
	Estimated number of malarial episodes in country 1. total cases 2. indicate peak seasons for malaria (months)	

III.	Malaria Treatment Information				
		List ACT's Registered and Available on the market (public and private sector)			
		Adults	Adolescents	Children	Infants
	Drug name(s) (use generic names)				
	Drug name(s) (use generic names)				



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	Drug name(s) (use generic names)				
	<p>What is the estimated number and type of ACTs purchased by MoH in the past year?</p> <p>What is the projected ACT procurement for current year?</p>	<p><i>Indicate ACT Name</i></p> <p>Adults</p> <p>Adolescents</p> <p>Children</p> <p>Infants</p>	<p>Last year</p>	<p>Current year</p>	
		<p><i>Indicate ACT Name</i></p> <p>Adults</p> <p>Adolescents</p> <p>Children</p> <p>Infants</p>	<p>Last year</p>	<p>Current year</p>	
	<p>Through which channel are the ACTs being distributed?</p> <p style="text-align: center;">Public sector</p> <p style="text-align: center;">Private sector</p> <p style="text-align: center;">NGO sector</p> <p>Is the public sector distributing ACTs through the private sector pharmacies/drug shops? Get details of these shops – number, distribution, etc.</p>				
	<p>How do patients get the ACTs for malaria in the public sector? In the private sector? For example, do they need prescriptions? Are they tested before receiving them? Any other special process?</p>				
	<p>Which international organizations are working in ACT procurement and /or distribution in the country?</p>				



IV.	PV Process for Malaria	
	<p>Is there a nationally approved ADR form?</p> <p>If yes, is the same form being used in the malaria program?</p>	
	<p>What system of PV is used for malaria?</p>	<p>Circle one or more:</p> <p>Passive PV</p> <p>Active research (e.g. Cohort event Monitoring)</p> <p>Prescription event monitoring</p> <p>Case control studies (phase IV)</p> <p>Any other</p>
	<p>Is reporting mandatory or voluntary or both?</p> <p>If mandatory, as part of which health program?</p>	
	<p>Who fills out the reports – Doctor/Nurse/Pharmacist/other?</p>	
	<p>Is data being processed?</p> <p>What method is used? (Manual, computerized)</p> <p>What software? (E.g. Vigiflow, Aris G, other?)</p> <p>Is there any outside source involved in data processing?</p>	
	<p>Is there a pharmacist working in the malaria program (even if the person is not involved with pharmacovigilance).</p>	
	<p>What pharmacovigilance specific training has this pharmacist received? By whom?</p>	
	<p>Are there specific target population in malaria program for PV - pregnant women, children, elderly, and patients with concomitant</p>	



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	infections, e.g. HIV/AIDS, TB, other?	
	<p>What is the commonly used language(s) by patients, health workers?</p> <p>In what language are the ADRs/AE completed?</p> <p>Is there an English version of the same ADRs/AE reports available?</p>	

V.	PV Efficiency and Outcomes for Malaria/ ACTs	
	<p>How many malaria specific ADR/AE reports have been collected during the past 12 months?</p> <p>What are the total number of reports that you have?</p> <p>How many have been analyzed?</p> <p>Is there any outside source involved in data analysis, causality assessment/signal detection?</p>	
	For ACTs, have any ADR problem/s been detected? Any other drug related problem/s?	
	How would you rate the quality of the final reports? [Completeness of forms, quality of reporting]	
	<p>How is ADR information disseminated to policy makers, doctors, pharmacists, nurses and other paramedics, health system, institutions, other – confidential letters/conferences/mass media?</p> <p>How soon and how often?</p>	
	Is there any policy decision as a result of Pharmacovigilance?	



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VI.	Challenges and Future Scale Up	
	What are the challenges in implementation of Pharmacovigilance including capacity constraints for data entry/processing, assessing events, severity, causal relationship, etc, responding to signals of ADRs	
	Suggestions for improving and scaling up Pharmacovigilance Type/s of assistance required to establish an efficient and effective Pharmacovigilance system	

VII.	Other Contacts/Information		
		Name	Contact (email / telephone)
	Name of Head of National Malaria Program		
	Name of Head of National Drug Authority		
	Name of Head of Pharmacovigilance		
	Name of WHO Officer in charge of Pharmacovigilance		

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