



Rapid Pharmacovigilance Implementation in Developing Countries

Assessing Pharmacovigilance (PV) Capacity in Public Health Programs

TB Program

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 TB cases in country	
	Estimated number of TB patients taking treatment (first line/second line)	
	Percent pediatric patients taking treatment (first line/second line)	
	Estimated number of MDR TB patients taking treatment	
	Estimated number of XDR TB patients taking treatment	

III.	TB Treatment Information				
	Drug name(s) (include generic names)	First Line		Second Line	
		Adults	Pediatrics	Adults	Pediatrics
	High Intensity phase				
	Continuation (consolidation) phase				



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	<p>Compliance:</p> <p>What is the estimated Drop Out Rates of the Patients: (if possible, distinguish between pediatric vs. adult drop out rates)</p>			
	<p>Number of DOTS centers in the country</p> <p>In Public sector</p> <p>In NGO sector</p> <p>In Private sector</p>			
	<p>What is the estimated number of DAILY visits to the DOTS centers in:</p> <p>- Large and busy centers</p> <p>- Small and less busy centers</p>			
	<p>What are the operating hours of the DOTS centers?</p> <p>- Which days of the week?</p> <p>- Typical hours of work each day?</p>			
	<p>Human Resources for Treatment Delivery at DOTS centers:</p> <p>- How many staff is usually present in DOTS centers? (large vs. small ones)</p> <p>- What types of staff are operating the DOTS centers? (large vs. small ones) [Admin, IT, nurses, pharmacists, doctors, etc.]</p> <p>- Estimated percent of posts that is vacant</p>			
	<p>- What is the estimated number and type of drugs purchased by MoH in the past year?</p> <p>- What is the projected drug procurement for current year?</p>	<p><i>Indicate Name</i></p>	<p>Last year</p>	<p>Current year</p>
<p>Adults:</p> <p>First line</p> <p>Second line</p>				
<p>Pediatric</p> <p>First line</p> <p>Second line</p>				



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IV.	PV Process for TB	
	<p>Is there a nationally approved ADR form?</p> <p>If yes, is the same form being used in the TB program?</p>	
	<p>What system of PV is used for TB?</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 DOTS center (even if the person is not involved with pharmacovigilance).</p>	
	<p>What pharmacovigilance specific training has this pharmacist received? By whom?</p>	



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	<p>Are there specific target population in TB program for pregnant women, children, and patients with concomitant infections, e.g. HIV/AIDS, other?</p>	
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V.	PV Efficiency and Outcomes for TB drugs	
	<p>How many TB specific ADR/AE reports have been collected during the past 12 months?</p> <p>What is 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>	
	<p>For first line/second line drugs, have any ADR problem/s been detected? Any other drug related problem/s?</p>	
	<p>How would you rate the quality of the final reports? [Completeness of forms, quality of reporting]</p>	
	<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>	
	<p>Is there any policy decision as a result of Pharmacovigilance?</p>	



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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 of Head of National TB 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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