MOZAMBIQUE MALARIA VACCINE DECISION-MAKING FRAMEWORK-DATA

Pre-licensure 5 years before licensure				Available data - Phase 3				Licensure 2 years after licensure	Post-licensure 5 years after licensure		
Malaria disease burden	Reported malaria cases (inpatient data) (critical data) Reported Severe malaria group and by due to of province, with special attention to pregnant women (critical data) (critical data) Reported Cases by age group and by due to of malaria malaria special attention to pregnant women (critical data)							MALARIA VACCINE INTRODU	Cases by age group and by province, with special attention to pregnant women (critical data) Cases by age malaria cases ported due to of malaria malaria malaria malaria malaria in HIV + (critical data)		
Other malaria interventions	Impact of malaria interventions estimates of separate malaria interventions (ITNs, IRS, IPT, health educ.) malaria interventions (critical data) (critical data)			Updated cost-effectiveness estimates of separate malaria interventions (ITNs, IRS, IPT, health educ)				Changes in impact of malaria interventions			
Malaria vaccine impact	Impact in different age groups			Interaction with other EPI vacc	Absolute impact (specific to Moz)	Marginal impact with other malaria interventions	Impact on epidemiology and morbidity in older age groups (on rebound effect)		Immunization coverage		
Economical and financial issues	price estimate estima vaccin	effectiveness r ates of malaria ne (regional or	teturn on investment neasured in terms of: DALYs impact on GDP impact on health budget	Subregional cost- effectiveness data of malaria vaccine (critical data)	National affordability	Public-sector vaccine price (critical data)	Donor subsidy of malaria vaccine (critical data)	Sustainable ity of donor subsidy commitment	Updated malaria vaccine cost- effectiveness data	Return on investment	
Malaria vaccine efficacy, quality and safety	Safety Adverse events			Efficacy, including impact on: • clinical disease • severe disease • # of deaths due to malaria • parasitemia • HIV + pop. (critical data) Efficacy against intestinal parasitosis • parasitemia • HIV + pop. (critical data)					fectiveness including impact on: clinical disease (lab confirmed) severe disease anemia parasitemia		
Programmatic considerations	Vaccine presentation (critical data) Evidence of estat policy, regulatory institutional path support intervent		nd schedule ys to	duration of protection		:	arget popln critical data)	Supply availability (critical data) Policy, regulatory, and institutional pathways to support intervention	Evidence of established policy, regulatory, and institutional pathways to support intervention	Supply availability (critical data)	
Socio-cultural environment	Knowledge, attitudes, and practices of expectations of communities towards vaccines and malaria interventions Community expectations of vaccine efficacy vaccines in clinical trial areas						IEC policy to address vaccine efficacy				

MOZAMBIQUE MALARIA VACCINE DECISION-MAKING FRAMEWORK-PROCESSES

	Pre-licensure 5 years before licensure		Licensure 2 years after licensure							Post-licensure 5 years after licensure		
	AVAILABLE DATA - PHASE 3			MALARIA	MALARIA VACCINE INTRODUCTION DECISION							
National processes		Countries signal interest (1-3 years before)	National regulatory authority reviews and makes a decision based on scientific evidence, incl checking opinion of expert groups at any level (within 1 yr of licensure)	MOH consults with key stakeholders - scientists, WHO (key lobbying group for implementation), communities (critical processes)	Countries consider incorporating new malaria vaccine in multi-year strategic plans for EPI/NMCP (4-5 years before) (critical processes)	Countries issue special Put in plat programmatic initiatives guidelines for implementation (within 1 year of licensure)		ce training	National regulatory authority will monitor vaccine performance and evaluate	Pharmaco- vigilance	Put in place training initiatives	
			Advocacy with decision makers	Countries develop communications package about malaria vaccine (1 year before)	MoH will make a decision about integration of vaccine into EPI	Countries consider incorporating new malaria vaccine in multi-year strategic plans for health sec (critical processes)	and educ for comm tor partially e vaccine (v	develop cations package ation campaign unities about Efficacious within 1 year of ion decisions)	evaluate impact			
Global processes	Integrate country requirements whenever scientifically justified into product development plans (approximately 5 years before)	WHO and other international agencies submit cost estimates and production capacity of manufacturers	WHO publishes vaccine management guidelines (licensure)	Donors provide funding to support vaccine (critical processes)	International community improve mechanisms to support countries in introduction of vaccines	policy recommending use of vaccine (critical processes)	International agencies plan for procurement (within 1 year of licensure)	WHO pre- qualification (within 1 year of licensure)	Monitoring vaccine performance at the global level including evaluation of the impact			

Key: National process Global process