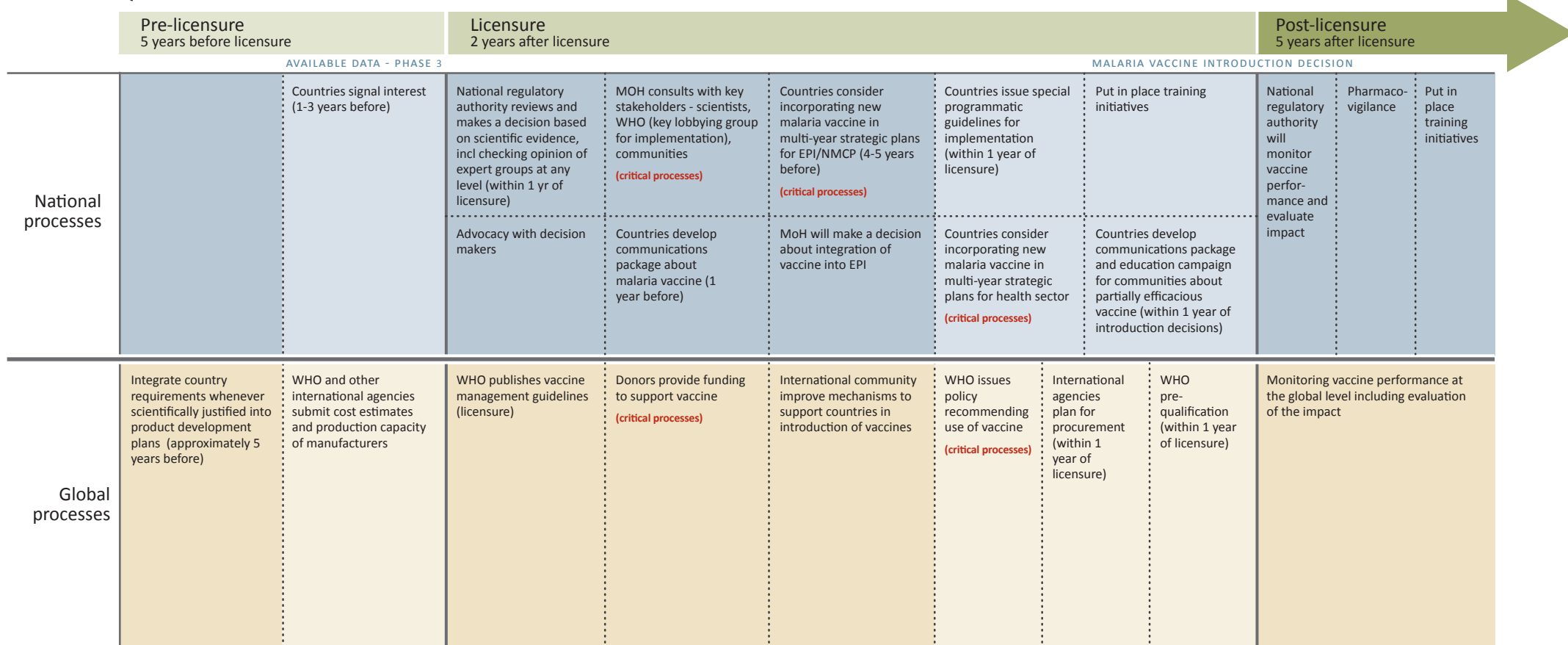


MOZAMBIQUE MALARIA VACCINE DECISION-MAKING FRAMEWORK–DATA

	Pre-licensure 5 years before licensure						Available data - Phase 3				Licensure 2 years after licensure		Post-licensure 5 years after licensure						
MALARIA VACCINE INTRODUCTION DECISION																			
Malaria disease burden	Reported malaria cases <i>(critical data)</i>	Severe cases (inpatient or hospitalized)	Reported malaria deaths <i>(critical data)</i>	Cases by age group and by province, with special attention to pregnant women <i>(critical data)</i>	Disability due to malaria	Burden of malaria in HIV +							Cases by age group and by province, with special attention to pregnant women <i>(critical data)</i>	Reported malaria cases <i>(critical data)</i>	Severe cases (inpatient or hospitalized)	Re-reported malaria deaths <i>(critical data)</i>	Disability due to malaria	Burden of malaria in HIV +	
Other malaria interventions	Impact of malaria interventions		Cost-effectiveness estimates of separate malaria interventions (ITNs, IRS, IPT, health educ.) malaria interventions <i>(critical data)</i>		Cost-effectiveness estimates of malaria interventions used in combination <i>(critical data)</i>		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	Credible public-sector price estimate	Preliminary cost-effectiveness estimates of malaria vaccine (regional or subregional results)		Return on investment measured in terms of: • DALYs • impact on GDP • impact on health budget		Subregional cost-effectiveness data of malaria vaccine <i>(critical data)</i>	National affordability	Public-sector vaccine price <i>(critical data)</i>	Donor subsidy of malaria vaccine <i>(critical data)</i>		Sustainability of donor subsidy	Sustainable national 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 • anemia • parasitemia • HIV + pop. <i>(critical data)</i>		Efficacy against intestinal parasitosis	Duration of protection <i>(critical data)</i>	Adverse events <i>(critical data)</i>	Safety <i>(critical data)</i>	Effectiveness including impact on: • clinical disease (lab confirmed) • severe disease • anemia • parasitemia				Post-licensure safety data (pharmacovigilance)		
Programmatic considerations	Vaccine presentation <i>(critical data)</i>		Evidence of established policy, regulatory, and institutional pathways to support intervention			Vaccine schedule		Administration and duration of protection <i>(critical data)</i>		Supply availability <i>(critical data)</i>	Target popln <i>(critical data)</i>		Supply availability <i>(critical data)</i>	Evidence of established policy, regulatory, and institutional pathways to support intervention		Evidence of established policy, regulatory, and institutional pathways to support intervention			
Socio-cultural environment	Knowledge, attitudes, and practices of communities towards vaccines and malaria interventions		Community expectations of malaria vaccines in clinical trial areas		IEC policy to address vaccine efficacy						IEC policy to address vaccine efficacy								

Key: National data Global data

MOZAMBIQUE MALARIA VACCINE DECISION-MAKING FRAMEWORK—PROCESSES



Key: ■ National process ■ Global process