East and Southern Africa Malaria Vaccine Decision-Making Framework – Data Needs

Malaria Efficacy, Other Malaria **Economic & Programmatic** Sociocultural Malaria Vaccine Quality, & Disease Burden Interventions **Financial Issues Considerations Environment** Safety **Impact PRE-LICENSURE (5 years)** Credible publicmpact of existing Projected impact Knowledge, Anticipated vaccine confirmed clinical and severe malaria malaria interventions sector price estimate on mortality and characteristics and attitudes, and morbidity in presentation Adverse events practices of ses by age group different age communities aroups Preliminary cost towards vaccines Interaction with stablished policy, egulatory, and nstitutional and malaria effectiveness álaria : interventions elated deaths by terventions malaria vaccine ge group athways to Community Coverage of current malaria support ntervention Public health return expectations of on investment in terms of DALYs, malaria vaccines in clinical trial areas pidemiology and nterventions impact on health budget, impact on GDP ransmission at province level Cost-effectiveness stimates of alaria cases in existing malaria regnant women nd HIV + nterventions Economic burden of malaria **AVAILABLE DATA - PHASE III** Efficacy, including mpact on: clinical disease Absolute impact Public sector Supply availability vaccine price Demand forecast Marginal impact Donor subsidy of severe disease interventions malaria vaccine anemia IS capacity to ccommodate a parasitemia HIV + of subsidy epidemiology and morbidity by age Duration of effica affordability group of the vaccine **LICENSURE AND DECISION (2 years)** Sustainability of Changes in impact efined targeted donor subsidy groups and a and costeffectiveness of ommunication other malaria Sustainable interventions ational ommitment stablished policy, egulatory and nstitutional athways to nterventions MALARIA VACCINE INTRODUCTION DECISION **POST-LICENSURE (5 years)** Reported and lalaria vaccine Public health return vidence of supply fety data on investment ittitudes, and nd severe malaria ases by age group nalaria vaccines. Effectiveness Updated malaria specially cceptability and ncluding impact effectiveness data eported malariaclinical disease mpliance elated deaths by severe disease anemia ecurrent and parasitemia mortality cluding marketing nd surveillance Required data National data point Global data point

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Global Level Processes National Level Processes PRE-LICENSURE (5 years) Integrate country requirements into product development plans (5 years before) Assess and strengthen regulatory, ethics and data management processes in-country Integrate the malaria vaccine in the multiyear strategic plan (4-5 years before) Signal vaccine demand (1-3 years before) **AVAILABLE DATA - PHASE III** Engage pharmaceutical companies Share information on vaccine research Develop communication plan on the malaria Conduct global advocacy to leverage funding vaccine (1 year before) **LICENSURE AND DECISION (2 years)** WHO issues policy recommending use of vaccine Donors provide funding to support vaccine National expert group/technical working group WHO publishes vaccine management and introduction guidelines (licensure) issues recommendation regarding vaccine introduction MOH makes a decision about integration of vaccine into EPI Incorporate malaria vaccine into national budgeting processes Engage local private-sector partners and pharmaceutical companies MALARIA VACCINE INTRODUCTION DECISION WHO pre-qualification (within 1 year of licensure) Issue programmatic guidelines for implementation of a malaria vaccine (within 1 International agencies plan for procurement Examine sustainability of existing funding and how to encourage in-country financing evaluation of vaccine impact, safety, and Update the communication plan for implementation (one year after introduction) pharmacovigilance **POST-LICENSURE (5 years)** Monitoring of vaccine performance, including evaluation of vaccine impact, safety, and pharmacovigilance Monitor implementation of the vaccine and evaluate impact on health system infrastructure