World Health Organization

REGIONAL OFFICE FOR Africa

Regulatory consideration for introduction of RTS, S in SMC countries

MVIP Meeting
Tuitai Lydia
WHO AFRO

Preparatory meeting towards joint review of RTS,S – June 2022

- A total of 17 countries participated in the preparatory meeting towards joint review of the RTS,S malaria vaccine
- Joint regulatory review of the vaccine will be conducted by a team of experts convened under AVAREF
- The experts from marketing authorization, pharmacovigilance, clinical trial authorization
- Aim of joint review - NRAs finalizing the assessment, using the reliance, for issuance of a marketing authorization
- Experts from EMA, WHO PQ to support the joint review by providing their expert advice

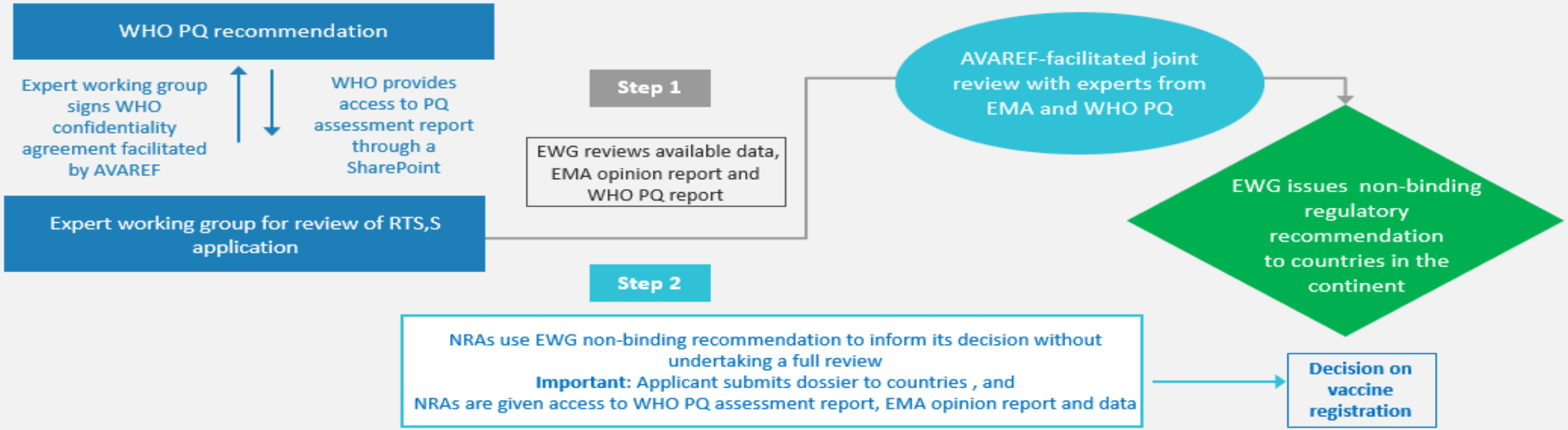
Preparatory meeting towards joint review of RTS,S – June 2022

- A team of experts representing the Regional Economic Communities (RECs) to constitute an Expert Working Group (EWG), to review reports and data and come out with non-binding recommendations
- The Non-binding recommendation endorsed by AVAREF Steering committee on 23-24th June 2022
- Mechanisms in place for regulatory pathways for registration of vaccines, and timelines after vaccine prequalification
- Agreements to use reliance method for decision making and approval of the vaccines with country specific timelines - 5 working days, 10 days, 30 working days, 90 working days, quarterly, Quarterly, 180 days & Not specific

World Health Organization
REGIONAL OFFICE FOR Africa

Agreed Action Plan

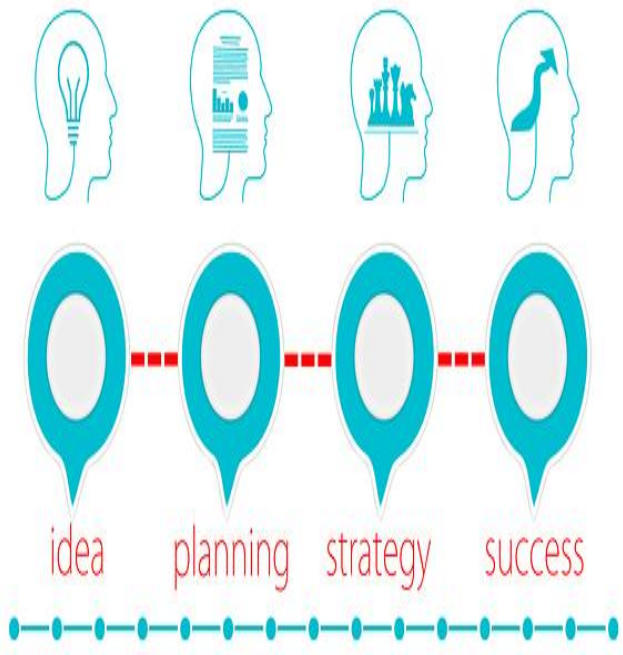
Facilitated Registration of RTS,S malaria vaccine



Timeline for step 1: 30 working days from AVAREF facilitated joint review meeting to non-binding recommendation

Timeline for step 2: 30 working days from submission of dossier to NRA + access to reports and data, to registration decision

REGULATORY PATHWAY



- Joint review for the registration of the RTS,S using AVAREF Platform with decisions based on the EMA and WHO PQ assessment reports
- Convergence in common approach and regulatory requirements application to facilitate the process.
- WHO to contact the heads of NRAs and heads of RECs for nominations of the members of EWG to participate in the joint review for facilitated registration of the RTSS,S vaccine
- The EWG, to review reports and data and come out with non-binding recommendations
- Availability of full dossiers to the regulators and compliance to administrative requirements from each country

REGULATORY PATHWAY

- The same data in the dossiers that was submitted for PQ and EMA to be submitted to the regulators
- Dossiers submitted at least 30 days ahead of the joint review date
- After joint review the authorities to use the non-binding recommendation and assessment reports to make the decision.
- Countries with no legal basis for reliance to use the best practice in the regions i.e accepting decisions from other SRA sand joint review reports from EMA, WHO, AVAREF etc) to facilitate access of the vaccines to their populations
- Efforts to be put in place to revise the regulations to mandate the regulatory authorities to accept reliance as part of the decision-making process for registration of prequalified products

REGULATORY PATHWAY

- Countries to share their annual **calendar schedule of advisory committee meetings** to AVAREF and sponsors to ensure that when a joint review to avoid delays in approval processes
- Countries to access the publicly available reports from WHO and EMA on RTS,S vaccine from the websites
- Countries with hot climate issues to ensure they assess and increase capacity in storage and handling of vaccines for maintenance of cold chain before vaccinations commence.
- The meeting report should be shared with the countries that did not participate in this preparatory meeting so that they are informed on the action plans and agreed recommendations.
- The procedure for the joint review of the vaccine should be transparent and visible so that all NRAs should be informed to facilitate country decisions.
- Virtual meeting with the regulators to discuss arrangements for the joint review meeting

ACTIONS TAKEN & NEXT STEPS

- CTD dossier dispatched to the pilot countries - Ghana, Malawi and Kenya
- Status of NRA submission:
  a) Ghana – dossier under finalization locally. Letter received from FDA Ghana with guidance on submission process
  b) Kenya - dossier under finalization locally with successful call with MOH in Dec 2022
  c) Malawi - dossier under finalization locally – awaiting NRA feedback
- Current target submission date to NRAs – end Jan 2023
- Next Steps:
  a) Confidentiality form to be sent to NRAs for electronic access of the dossier
  b) Pre-submission meeting through AVAREF platform
  c) Joint review meeting with feedback on dossier evaluation
  d) Country final decision
- WHO PQ to be part of the joint review process for technical support

World Health Organization

REGIONAL OFFICE FOR Africa

Thank you!