Ending disease in Africa

Bringing Alignment and Harmonization on Regulatory Requirements for Vaccine Developers for Priority Disease Areas - AVAREF's Role

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World Health Organization
African Region

UHC/UCN
Universal Health Coverage/Communicable and noncommunicable Diseases

AVAREF Objectives

- To increase the efficiency and quality of reviews and inspections
- To promote Patient Safety
- To increase the timeliness and transparency of regulatory decisions for all interventional trials conducted in Africa
- To accelerate the African Medicines Regulatory Harmonization (AMRH) process, linking all Regional Economic Communities (RECs)
- To stimulate Innovation and Research in Africa
- To enhance emergency preparedness on the continent, in RECs and in individual countries

Regulatory pathways for Emergency Use Authorization (1)

The AVAREF platform has been leveraged **to facilitate national regulatory approval process and strengthen reliance mechanism** for Mpox Vaccines regulatory authorisation:

- Facilitate information sharing between African countries through joint sessions for Vaccines with WHO EUL and approval from Stringent Regulatory Authorities
- Coordinate a joint assessment of applications facilitated by AVAREF

Guidelines: African Vaccine Regulatory Forum (AVAREF)

Strategy and Guidance for Emergency Preparedness together with WHO Guidelines on regulatory preparedness for the oversight of pandemic or other emergency use vaccines in importing countries (2024)

To facilitate access to Mpox vaccines, from lessons learnt during Covid-19 vaccines manufacturers will not be able to submit dossiers in all the countries globally and therefore AVAREF will facilitate registration by requesting access to the dossiers and assessment reports from the stringent regulatory authorities that have granted EUL/Registration as well as WHO sharepoint once vaccines are EU Listed.

3 scenarios for the Expedited Regulatory Authorisation process

Scenario 1

Vaccines with WHO EUL/PQ[1] approval

Note: This option is **currently not** available for Mpox vaccines until EUL begins

- For vaccines with WHO EUL/PQ approval, AVAREF to organise an explanatory familiarization session with all NRAs
- During the session, WHO PQ representatives to explain their findings and AFRO representatives in the WHO EUL process to share their experience

Scenario 2

Vaccines with SRAs/WLA[2] approval

- For vaccines with approval of one or several SRAs, AVAREF to organise an explanatory familiarization session with all African NRAs, should that vaccine be submitted for a marketing authorisation in any African country
- RECs and representatives from the relevant SRA to present findings and answer queries from NRAs

Scenario 3

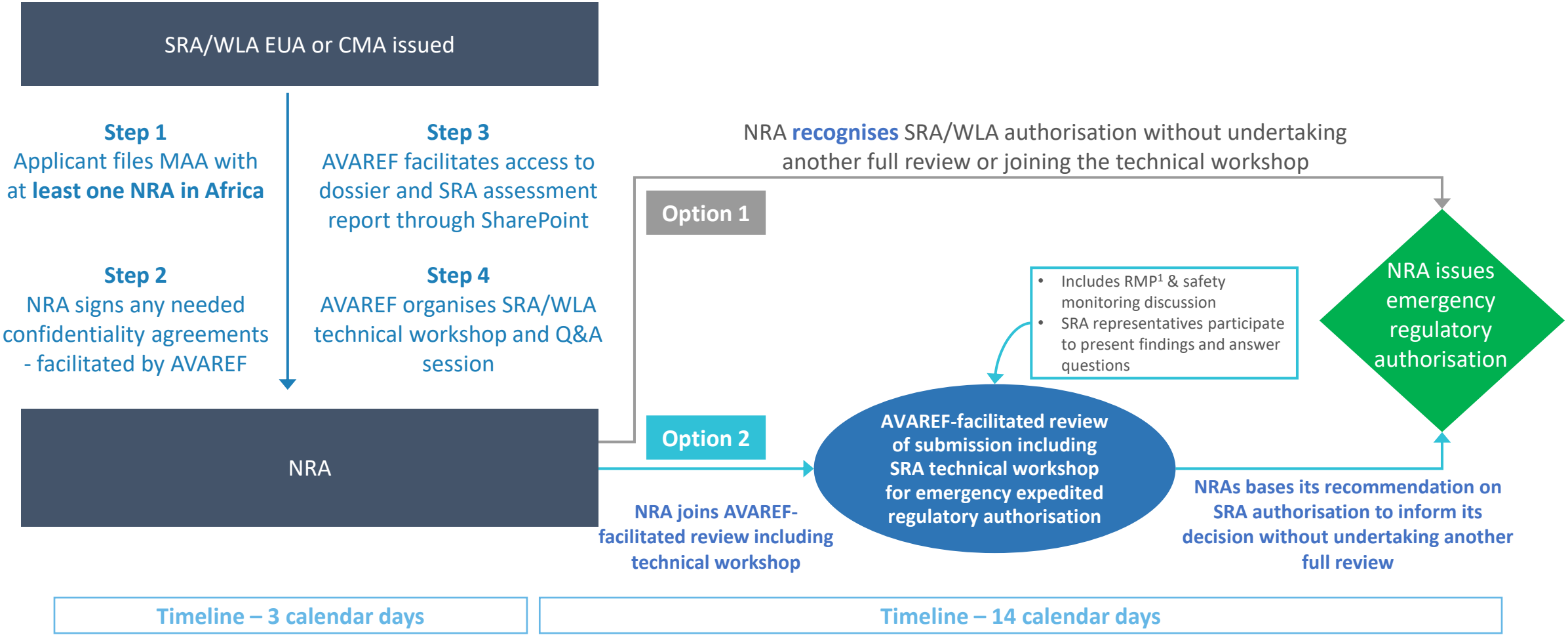
Vaccines without WHO EUL/PQ nor SRA approvals

- For other vaccines with a MAA[3] in any African country, AVAREF to organise a joint review of the application with the purpose of delivering a non-binding recommendation on the regulatory aspects with a final product utilisation policy provided by an Expert advisory group
- Details on the following slides

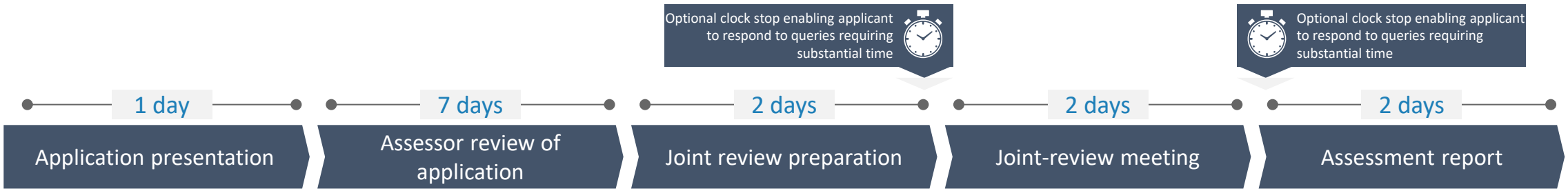
1. Emergency Use Listing, Pre-Qualification 2. Stringent Regulatory Authority/who Listed Authority 3. Marketing Authorisation Application
Note: Stringent Regulatory Authorities identified are EU – EMA, United Kingdom – MHRA, United States of America-USFDA….etc

Scenario 2: Vaccines with SRA authorization

(Applicable to current situation on Mpox as of August 2024)



14 working days timeline to finalise the joint - review process



Description
Applicant provides detailed explanation of application to assessors with NRAs joining as observers

Timeline for entire joint review is agreed and scheduled

Description
Assessors conduct review of application and post queries while Applicant responds

Description
Assessors align on queries to address in the joint review meeting with their assessment teams taking into consideration the Applicant's responses

NRAs familiarize themselves with the queries that have been posted and the associated responses from the Applicant

Applicant responds to any unanswered queries

Description
2-day joint review

- Day 1: Closed session to align on queries to address and optional meeting with NRA from manufacturing country
- Day 1 & 2: Open session with Applicant to discuss queries
- Day 2: Closed session to address query responses

An additional meeting to resolve outstanding queries is scheduled if needed

Description
Assessors develop report and present findings to NRAs with opportunity for NRAs to pose queries

Key Messages

- Effective Coordination and Collaboration required for ecosystem partners such as WHO, ACDC, AUDA-NEPAD, US-FDA, USP, BMGF, etc. need to harness the benefits for the biopharmaceutical sector, including local vaccine production.
- A need for all parties to enhance (ramp-up) its activities (approaches) to ensure that locally producing vaccines meet internationally acceptable standards of safety, quality, and effectiveness.
- Significant regulatory considerations prior to pre-qualification should be addressed collaboratively by both manufacturers and regulators.
- Continued efforts required to address regulatory hurdles including lengthy clinical trial approval times and human resource (expertise) limitations
- WHO (AVAREF) committed to use its network approach, experience, and ability to bring multiple stakeholders together to strengthen the technical capacity for this initiative.

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THANK YOU

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