Africa Vaccine Manufacturers Webinar

Understanding Africa's Evolving Regulatory Landscape:
An Interactive Dialogue with the African Medicines Agency

Consolidated Questions from AVMI African Vaccine Manufacturers

1. Continental Regulatory Harmonisation and Market Authorisation
    - How does AMA plan to implement regulatory harmonisation and reliance across African countries to reduce duplication of product assessments and enable vaccines or biologics assessed or registered in one African market to achieve accelerated market authorisation in other Member States?
    - What is AMA's roadmap and expected timeline for achieving greater regulatory harmonisation at continental level?

    ***Themes raised by**: Gennex Egypt, AfriVax Nigeria, Aspen South Africa, IPD Senegal and Vaccine Access Initiative Uganda.*

2. AMA's Relationship with National Regulatory Authorities (NRAs) and Regulatory Reliance
    - How will AMA work with NRAs at different levels of regulatory maturity, including ML3 authorities, and what regional or continental mechanisms will be used to facilitate regulatory reliance, mutual recognition and accelerated registration?
      In particular, manufacturers would welcome clarity on how reliance could reduce the need for repeated assessments where a product has already undergone review by a recognised NRA.

    ***Themes raised by**: VBC Egypt, Aspen South Africa, Gennex Egypt and IPD Senegal*

3. GMP Inspections, Certification, Quality Control and Vaccine Lot Release
    - What is AMA's approach to harmonising GMP inspections, certification, quality-control and vaccine lot-release requirements across Africa?
    - Will AMA promote reliance on, or mutual recognition of GMP inspections, certifications and lot-release certificates issued by competent African NRAs?
    - Manufacturers would also welcome clarity on AMA's roadmap and anticipated milestones towards a continentally recognised GMP inspection and certification system.

    ***Themes raised by:** Kenya Biovac, AfriVax Nigeria and Vaccine Access Initiative Uganda.*

4. AMA and WHO Prequalification
    - How will AMA collaborate with the WHO Prequalification Programme, and to what extent could AMA's harmonised regulatory processes, assessments and GMP certification support African manufacturers working towards WHO Prequalification and broader regional or international market access?
    - Manufacturers are particularly interested in understanding whether increased continental regulatory harmonisation could reduce duplication between African regulatory processes and international requirements.

    ***Themes raised by:** Kenya Biovac, VBC Egypt and AfriVax Nigeria.*

5. Practical Regulatory Support for Emerging African Manufacturers
    - What practical regulatory support and pathways will AMA provide to emerging African vaccine and biologics manufacturers, from early product development and manufacturing readiness through regulatory compliance and market authorisation?
    - How and at what stage should manufacturers engage with AMA to ensure that regulatory requirements are considered early in product development?

    ***Themes raised by:** Kenya Biovac, AfriVax Nigeria and Vaccine Access Initiative Uganda.*

6. Vaccine Manufacturing Facility Development and Regulatory Readiness
    - What role or capacity will AMA have in providing regulatory guidance or technical support during vaccine manufacturing facility development, including areas such as User Requirement Specifications (URS), facility design, Fill & Finish facilities and overall regulatory readiness?

    Theme raised by: *Kenya Biovac.*

7. Stability Data and Shelf-Life Requirements
    - Is AMA considering a harmonised or reliance-based approach to stability-data requirements that would allow accelerated stability data, together with available long-term data and prior regulatory assessments, to support an initial shelf-life while additional real-time stability data are being generated?
    - Such an approach could potentially help reduce time to market while maintaining appropriate requirements for product quality, safety and efficacy.

    Theme raised by: *Gennex Egypt.*

8. Clinical Development and Multi-Country Clinical Trials
    - How does AMA plan to harmonise and streamline regulatory and ethics approval processes for multi-country clinical trials involving vaccines and biologics, while maintaining high standards of participant safety and scientific integrity?
    - Manufacturers would also welcome AMA's perspective on how a more coordinated approach could strengthen Africa's competitiveness as a location for vaccine and biologics clinical research.

    Theme raised by: *AfriVax Nigeria.*

9. Localisation and Regulatory Definitions
    - From a regulatory perspective, how will localisation be defined, including which product categories will be considered for purposes of defining locally manufactured products?

    Theme raised by: *Aspen South Africa.*

10. Implementation and Sustainability of Continental Regulatory Harmonisation
    - What are the key milestones and timelines for implementing AMA's continental regulatory harmonisation strategy, and how will the implementation of this strategy be funded and sustained?

    Theme raised by: *IPD Senegal.*

Particular areas of interest include:

- Avoiding duplicate GMP inspections and regulatory reviews;
- Accelerated market authorisation across multiple African countries;
- Practical application of regulatory reliance;
- Stability-data requirements and shelf-life assignment; and
- Early regulatory engagement with African vaccine manufacturers.

Where possible, it was requested that practical examples are shared during the webinar as would assist manufacturers in understanding how AMA's evolving regulatory framework may operate in practice.