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Improving Regulatory capacity in Africa through joint reviews: Experiences from the African Vaccine Regulatory Forum (AVAREF)

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KEY Regulatory Challenges in LMICs

Clinical development

- Processes confusing for product developers involving regulatory agencies and ethics committees, Example
  - Lack of clarity of roles between regulatory authorities and ethics committees
  - Lack-of/disparate application requirements
  - Overall lack of capacity / capabilities and transparency

Registration & Licensure

- Rx/Vx: well-established “3-step” process, but slow and Redundant retarding timely Country introduction of needed Health products
- Dx: Unpredictable processes, lack of agreed-upon standards, multiple quality assurance mechanisms, slow registration and uptake of novel life-saving technologies

Post-licensure / Surveillance

- Limited pharmacovigilance Capacity in increasing number of vaccines and Drugs
- Increased inflow of counterfeit and falsified Substandard products due to low surveillance and enforcement
Why AVAREF?

- Growing public health needs and limited resources, demand faster, cheaper, and better treatments and vaccines.

- Mosaic of regulations govern product development and oversight, creating inefficiency and adding to costs of safe, innovative, and effective vaccines and therapies.

- Duplication due to overlapping reviews and inspections of clinical/ manufacturing sites for similar purposes.
What is the African Vaccine Regulatory Forum (AVAREF)

• ALL National Regulatory Authorities of African Region and national Ethics Committees (ECs)

• Established by WHO in 2006 to build capacity for vaccine clinical trials in 19 African countries
African Vaccine Regulatory Forum (AVAREF) HISTORY

Jan. '05: Network approach to regulation of clinical trials proposed at NRA workshop organized by WHO

2006: Joint reviews of CTAs, joint GCP inspection of phase II trial of Men. A. conjugate vaccine using model procedure

2005/2006: Dev. of model reg. procedures for countries to adapt/adopt

2007: Joint reviews of CTAs, joint GCP inspection of phase II trial of Men. A. conjugate vaccine using model procedure

2007-2014: Annual meetings with review of RTS,S, TB vaccines, and others

2006: Birth of AVAREF (Accra), managed by WHO-HQ/AFRO

2015: New AVAREF strategy developed

2014/15: Joint reviews of CTAs for Ebola interventions

2015: New AVAREF strategy launched

Nov. 16: New AVAREF strategy launched
African Vaccine Regulatory Forum (AVAREF)

- Arab Maghreb Union (UMA)
- SADC
- East African Community (EAC)
- Economic Community of Central African States (ECCAS)
- Economic Community of West African States (ECOWAS)
- Intergovernmental Authority on Development (IGAD)

FROM VACCINES TO ALL PRODUCTS

54 countries → 6(8) regions → 1 continent

Adapted AMRH © Bill & Melinda Gates Foundation
Core Values and Guiding Principles

• Values –
  – Transparency & integrity,
  – responsiveness, & innovativeness
  – Ownership & collaboration

• Guiding Principles
  – Strong Partnerships and alignment with AMRH and other initiatives
  – National ownership, stewardship and leadership
  – Reliance on competent work and decisions of functional ethics committees and regulatory authorities
  – Upholding confidentiality
  – Efficiency and sustainability
What is a Joint Review?

• Review whether for approval of products or clinical trials carried out by NRAs with or without ECs to provide outcomes in a short time without sacrificing the quality of assessment.
  • Multi-country/multi-site
  • One country assisted by others
  • Clinical trial applications/marketing authorization
  • Face-to-face sessions and closed sessions
Joint Reviews

- 2006: Joint reviews of CTAs, joint GCP inspection of phase II trial of Men. A. conjugate vaccine using model procedure
- 2008: Joint review of malaria vaccine, RTS,S,
- 2011: Joint review of CTA of candidate TB vaccine
- Joint reviews for MenAfriVac
- December 2014: CTA of vaccine against Ebola
- February 2015:
  - March 2015: Assisted Reviews
  - 2016: Assisted review of therapy against eumycetoma, Neglected disease
- Joint review of combination treatment for leishmaniasis
Joint/Assisted Reviews and GCP Inspections

“Process has been widely viewed as successful, improving the capacity and coordination and encouraging the use of defined review timelines and common documentation” -

Source: Safer, Faster, Cheaper Improving Clinical Trials and Regulatory Pathways to Fight Neglected Diseases - Report of the Center for Global Development’s Working Group on Clinical Trials and Regulatory Pathways
Upcoming Review

• Special Approval of malaria vaccine Mosquirix
• Three countries – Ghana, Kenya and Malawi
• Issue special limited authorization for a pilot of the new vaccine.
• Implement pharmacovigilance readiness
• Jointly receive and review safety data for 3 countries
Challenges and Opportunities

• From decision to import permit
  – Advocacy & leadership training
• Secure electronic platform
• Sequential to parallel submissions
• Addressing Epidemics
  – CEPI & BMGF supporting Table Top exercise to develop framework by AVAREF
• Sustainability
  – Funding from WHO to countries and RECs.
  – Common formats for use in RECs and countries
Conclusion

• Joint reviews, improve worksharing, promote harmonization, efficiency and transparency
• Effective in emergencies/outbreaks - Ebola
• Limitations
• Further improvements required