THE PAN AFRICAN HARMONIZATION WORKING PARTY (PAHWP).

2nd African Regulatory Forum on Medical Devices and Diagnostics
Cape Town; 21st – 23rd January, 2014
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[Ministry of Health, Uganda], **outgoing chair.**

HISTORY of PAHWP

- The PAWHP was conceived in 2012 following stakeholder meetings in East Africa, with an interim secretariat within the East African Community (EAC).
- A baseline survey of regulation of medical devices and medical diagnostics in EAC Partner States was undertaken in October 2012.
- The survey found several weaknesses in the regulatory process [limited or none regulation of medical devices & diagnostics, inadequate capacity of NRAs, most of the validation is done by specific country programs].

- The formation of PAHWP was announced in a satellite symposium at the African Society for Laboratory Medicine Conference on 3rd December 2012 in Cape Town.

- The EAC Regional Task Force on Regulation of Medical Devices and Diagnostics meeting was held in April 2013 in Dar-es –Salaam (attended by Nigeria, South Africa, LSHTM, ASLM), approved the vision and structure of PAHWP; which was presented to the 1st African Regulatory forum in Nairobi, July 2013.

History

- The 1st African Regulatory Forum on Medical devices and Diagnostics was attended by > 90 people from 21 countries (SADC was represented).
- Earlier on; the AU/NEPAD Agency-African Medicines Regulatory Harmonization Advisory Committee (AMRH-AC) meeting held in Nairobi, Kenya, June 2013 also endorsed PAHWP structure, mission & vision.

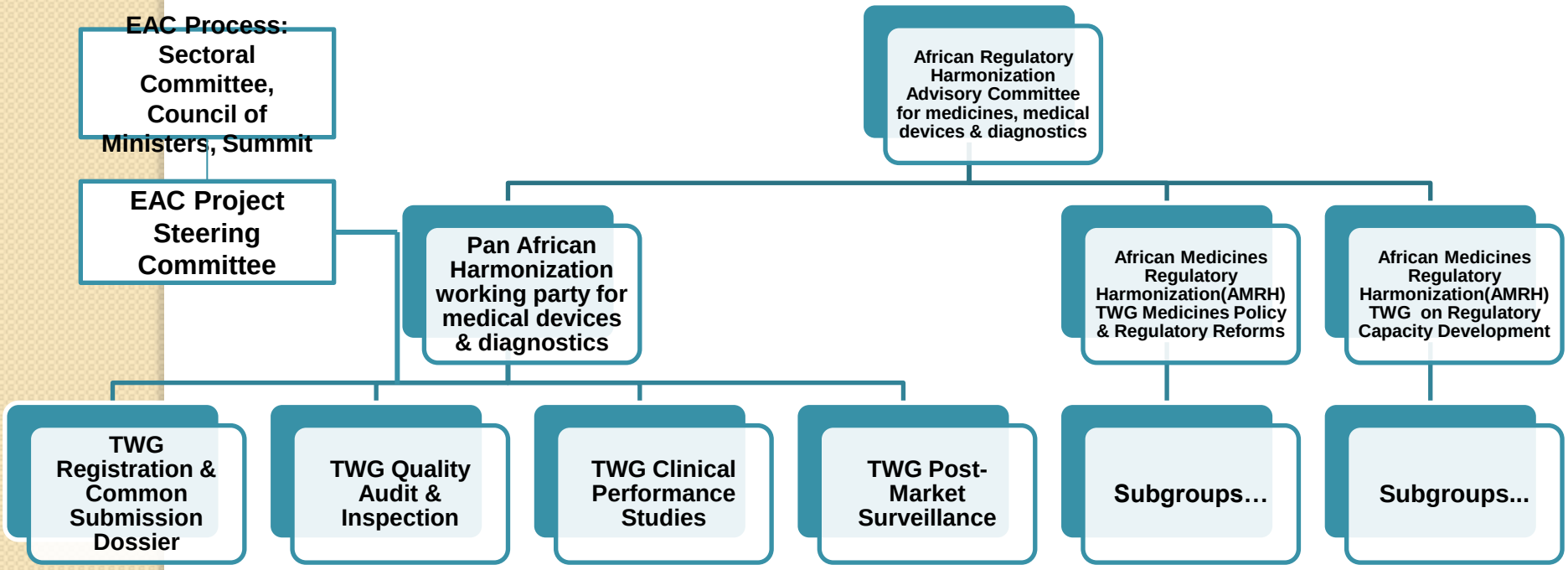
MISSION, VISION, GOAL

- The **mission** of Pan African Harmonization Party is to protect public health.
- **Vision:** is that valuable, quality assured, safe medical devices and diagnostics are made available where needed.
- **Goal:** is to study and recommend ways to harmonize medical devices and diagnostics regulation in Africa, working in coordination with Global Harmonization Task Force/International Medical Device Regulators forum (GHTF/IMDRF), AHWP, WHO, RECs, ASLM, other Regional and International organizations.
- Current priority is ***in-vitro*** diagnostic medical devices (point of care CD4, Viral Load, EID of HIV).

STRUCTURE

- PAHWP is a voluntary body housed within the AU-NEPAD, under the African Regulatory Harmonization Advisory Committee for Medicines, Medical Devices & Diagnostics.
- Secretariat: Chair: current EAC Chair (Kenya).
- Vice Chair: Nigeria (NAFDAC)
- Secretary: South Africa (NHLS)

Structure of the Pan African Harmonization Working Party (PAHWP) for Medical Devices &Diagnostics



Current Advisory committee for AMRH is anchored within the AU/NEPAD Agency, can it be expanded to include medical devices & diagnostics

COMPOSITION

- Ministries of Health, Regulatory Authorities, Medical devices & diagnostic Industry, Regional Economic Communities, WHO, NEPAD, London School of Hygiene and Tropical Medicine (LSHTM), African Society for Laboratory Medicine (ASLM), German International Cooperation (EAC-GIZ).
- Members co-opted as recommended and approved in PAHWP meetings
- Observers: interested organizations

TECHNICAL WORKING GROUPS

1. **Common Registration File**

Goal: A Common Registration file for IVD Medical Devices using point- of – care tests for CD4, viral load and early infant diagnostics as examples.

2. **Quality Systems Audit**

Goal: To reduce duplication, costs and delays associated with regulatory audits of manufacturer's quality management systems.

3. **Clinical Evidence**

Goal: Reduced duplication of clinical trials for regulatory approval in African countries.

4. **Post Market Surveillance**

Goal: Safe, reliable diagnostic products from Africa.

5. **Risk Classification**

Goal: Standardized rules for classifying IVD for their regulation based on risk to individual and public health.

More Information

Visit: www.pahwp.org