PAN-AFRICAN HARMONIZATION WORKING PARTY (PAHWP)

1st African Regulatory Forum on
Medical Devices & Diagnostics;
Nairobi, Kenya, 24th-26th July, 2013.

Dr. Isaac Kadowa ;

(MOH-UGANDA)- [Interim Chair, PAHWP]

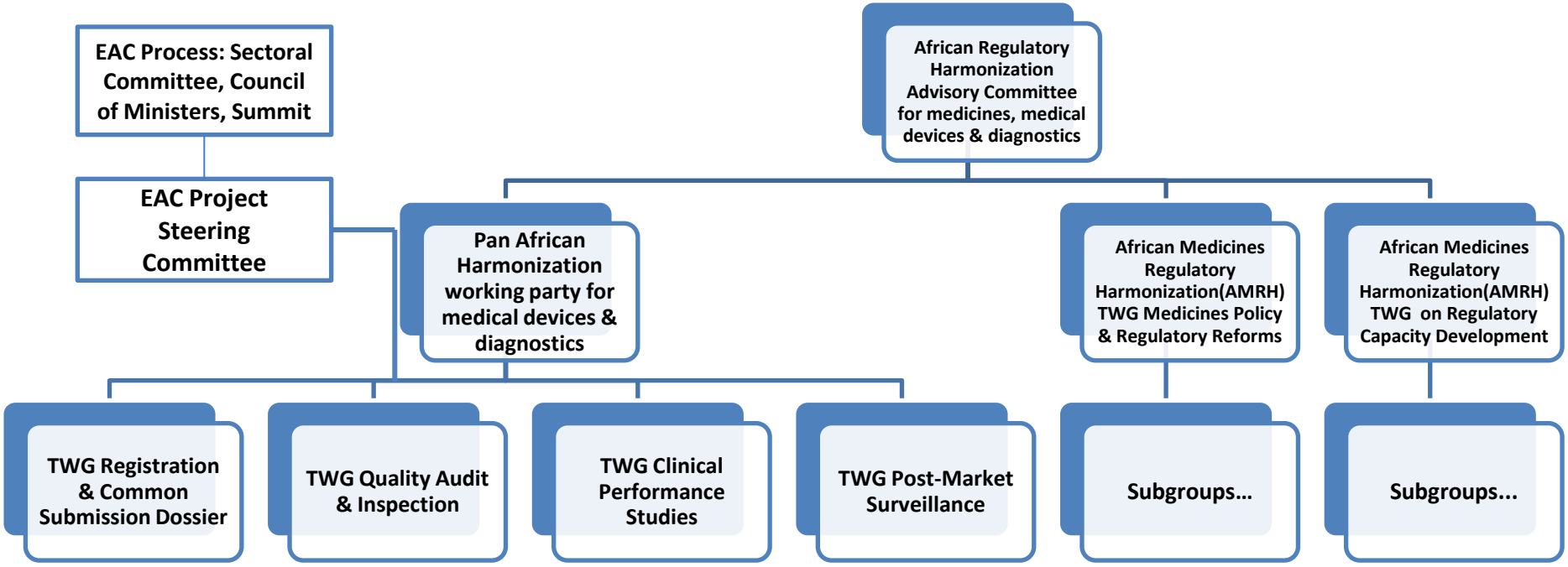
PAHWP: Background

- The **Pan-African Harmonization Working Party (PAHWP)** was conceived in 2012 following stakeholder meetings in the East Africa, with an interim Secretariat within the East African Community (EAC).
- A baseline survey of regulation in EAC Partner States was completed.
- The 1st meeting of the EAC Regional Task Force on Regulation of Medical Devices and Diagnostics held in April in Dar-Es-Salaam approved the proposed structure of PAHWP.

Background

- The structure was presented to the AU/NEPAD Agency African Medicines Regulatory Harmonization Advisory Committee meeting in June 2013, held here in Nairobi.
- It was further agreed that the structure should be presented to this forum for approval.

Proposed structure for Pan African Harmonization Working Party (PAHWP) for Medical Devices &Diagnostics



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

Vision, Mission and Goal of PAHWP

Vision: Protect Public Health

Mission: valuable, quality-assured, safe, medical devices and diagnostics are made available where needed

Main goal: to study and recommend ways to harmonize medical devices and diagnostics regulation in Africa and other regions and to work in coordination with the Global Harmonization Task Force/International Medical Device Regulators Forum (GHTF/IMDRF) , Asian Harmonization Working Party (AHWP), WHO, Regional Economic Communities (RECs) such as EAC, and other international organizations aiming at establishing harmonized requirements, procedures and standards.

- Regulation of IVDs shall be the priority.

PAHWP

- **Composition:** Regulatory Authorities, Medical device & diagnostics industry representatives, RECs, WHO, NEPAD, LSHTM, ASLM, ECSA-HC…
- Members co-opted as recommended and approved in PAHWP meetings
- Observers: Other interested organizations

Interim officials proposed by the Task Force Meeting:

- Chair: Uganda
- Vice-Chair: Nigeria (NAFDAC)
- Secretary: South Africa (NHLS)
- Nominees from Member States will be on rotational basis (annual).

Advisory Committee

- Advisory Committee shall be responsible for providing strategic and policy advice on medical devices and diagnostics regulatory issues in Africa
- The technical work to be delegated to Technical Working Groups to be composed on ad-hoc basis based on identified needs
- Proposed composition: AU bodies, RECs, WHO, Industry representation, ASLM, Regulatory Authority representatives, LSHTM

Why harmonization and why now?

Why harmonization?

- **Duplication** in facility inspections and clinical trials results in increased cost of goods, making products less affordable
- **Approval processes in some countries are lengthy and not transparent**, leads to costly delay in patient access
- **Costly and lengthy regulatory approval are significant disincentive to innovation**

Why now?

- **Substantial investment** in point-of-care diagnostics due to the recognition that inequity of access to diagnostics is a barrier to good health
- **Rapid technological advances** such as nanotechnology, microarrays is driving innovation
- Recognition that **regulatory barriers can stifle innovation**
- **Favourable environment** for harmonization, e.g. harmonization for registration of medicines in EAC, Asia Harmonization Working Party (AHWP), Pacific Health Summit, President Obama's directive to US FDA

Harmonization efforts

Global Harmonization Task Force (GHTF) A voluntary group of representatives from national medical device regulatory authorities and industry (Australia, Canada, EU, Japan, USA). GHTF published and disseminated harmonized documents on basic regulatory practices and served as an information exchange forum. GHTF is transitioning to the International Medical Devices Regulatory Federation (IMDRF) a purely regulatory body which will continue to promote the principles of harmonization.


GHTF

FINAL DOCUMENT

Global Harmonization Task Force

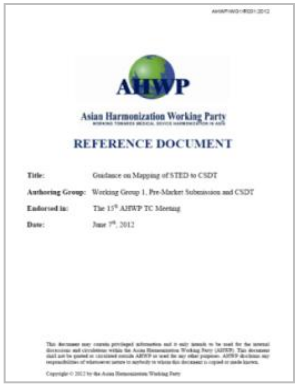
Title: Medical Devices: Post-Market Surveillance: National Competent Authority Report Exchange Criteria

Authoring Group: Study Group 2

Date: 21 May 2002

Rita MacLachlan, GHTF Chair

Asia Harmonization Working Party (AHWP) A non-profit organization of experts from medical device regulatory authorities and the medical device industry (23 member economies). Goals are to study and recommend ways to harmonize medical device regulations in the region in coordination with the GHTF, APEC and other related international organizations.


AHWP

Asian Harmonization Working Party

REFERENCE DOCUMENT

Title: Guidance on Mapping of STED to CSDT

Authoring Group: Working Group 1. Pre-Market Submission and CSDT

Endorsed in: The 15th AHWP TC Meeting

Date: June 3rd, 2012

The Latin American IVD Association (ALADDIV) Created in 2012 as a forum for regulators and other stakeholders to promote the convergence of regulatory standards and procedures in the region, consistent with efforts in other regions.

Next Steps

- Baseline studies in other RECs: ECOWAS, SADC, ECCAS…
- Project proposals for other RECs mainly drawing from successes in the EAC Project and learning from its challenges
- Mobilise resources for implementation stages
- For purposes of regulatory harmonization a few countries in a REC or across RECs may work together to achieve specific objectives of harmonization
- **Medical diagnostics to be prioritized**

Planned meetings with funding from Grand Challenges Canada though a grant to the London School of Hygiene & Tropical Medicine and from ASLM.

2013 24-26 July	**1st African Regulatory Forum for Medical Diagnostics**	To share consensus PAHWP vision and workplan with major stakeholders, including industry; develop a communications plan with all stakeholders; workshops on 4 areas of harmonization for the TWGs
2014 Jan.	**2nd African Regulatory Forum for Medical Diagnostics**	To review the vision of PAHWP with major stakeholders and industry; present progress and achievements of PAHWP; identify gaps and challenges; discuss the way forward; hold workshops on 4 areas of harmonization for the TWGs
2014 May	**3rd African Regulatory Forum for Medical Diagnostics**	To review PAHWP progress against its objectives and deliverables with major stakeholders and industry; identify gaps, challenges and the need for resource mobilization to continue its work; discuss the way forward and its vision for the future; hold workshops on four areas of harmonization for the TWGs