PAHWP

The 20th AHWP Annual Meeting Program

2nd to 6th November 2015

UPDATES ON PAN AFRICAN HARMONIZATION WORKING PARTY (PAHWP)

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Background

- PAHWP = Pan African Harmonization Working Party
- is a voluntary body that aims to improve access to safe and affordable medical devices and diagnostics in Africa though harmonized regulation.
- Members : 15 Countries.
- Tanzania, Zanzibar, Nigeria, South Africa, Burundi, Kenya, Ethiopia, Ghana, Malawi, Mozambique, Senegal, Sierra Leone, Uganda, Zimbabwe and Zambia.

Background.....

Conceived in 2012 following stakeholder meetings in East Africa with an interim secretariat within the East African Community.

- Activities of PAHWP are based on **awareness raising and advocacy**
- **Focus areas:**
  - Regulatory frameworks
  - Common Registration File
  - Reducing duplication in clinical performance studies
  - Post Market Surveillance

PAHWP Vision, Mission & Goal

- The vision of PAHWP is that valuable, quality assured, safe medical devices and diagnostics are made available where needed.

- The mission of the PAHWP is to protect public health.

- Goal of PAHWP is to study and recommend ways to harmonize medical devices and diagnostics regulation in Africa.

PAHWP priority areas for harmonization:

- **Common Registration File**
- **Quality Systems Audit**
- **Clinical Evidence**
- Post Market Surveillance (including AEs)
- Risk Classification (GHTF model)

PAHWP Leadership

- **Chair:** United Republic of Tanzania, Tanzania Food & Drugs Authority (TFDA)

- **Vice chair:** Nigeria; National Agency for Food and Drug Administration Control (NAFDAC)

- **Secretary:** South Africa; National Health Laboratory Service (NHLS)

Activities /updates

1. Attended the first AMRH Advisory Committee meeting.

2. 1st African Regulatory Forum on Medical Diagnostics held July 2013 (Nairobi)

- ***Key issue:*** Discussed promotion and facilitation of linkages with AU-NEPAD, WHO and other regional harmonization working groups; inter-regional cooperation among African regional economic communities and regional healthcare organizations.

3. Joint workshop with Asian Harmonization Working Party sub group on *in vitro* diagnostics held September 2013 in Taiwan.

Activities/updates……

4. AMRH Advisory Committee meeting in June 2013 (Nairobi, Kenya):
   Key issue: *PAHWP accepted as a member of the Advisory Committee; consequently the scope of the Advisory Committee expanded to include medical devices and IVDs.*

5. 2nd African Regulatory Forum on Medical Diagnostics held in January 2014 (Cape Town).
   Key issue: invitation from ISO TC 212 . Technical Committee on Clinical laboratory testing and in vitro diagnostic test systems *and Introduction of new working group namely "Regulatory Framework Working Group".*

Activities/updates……

6. March 2014 (Durban, South Africa): PAHWP updated the AMRH Advisory Committee on progress made; PAHWP Report was adopted.

7. 3rd African Regulatory Forum on Medical Diagnostics - November 2014 (Cape Town). Resolutions of the meeting.

8. Two training in good review practice for clinical performance data Basic workshop, Arusha, Tanzania, July 2014
   - Advanced workshop, Dar es Salaam, Tanzania, October 2014
   - Training materials (www.pahwp.org). (supported by LSHTM)

Activities/updates……

6. PAHWP attended AMRH Advisory Committee meeting in Durban on 26th March 2015 where the following were the outcome:

- ✓The Advisory Committee accepted the recommendation to be incorporated into the AMRH platform with amendments on utilizing the AMRH Governance structure.

- ✓The Advisory Committee recommended that the AMRH explore the feasibility of establishing a TWG on medical Devices and Diagnostics within the AMRH implementation structures.

Future Plans (1)

- Expanding the reach of PAHWP: more member states to join in 2015:-
  - *Application form for joining PAHWP and ToRs will be finalized* in May 2015 and sent out to regulators to formally join.

- Continue working with WHO, AHWP and any other partner on issues of regulation of medical devices and diagnostics in Africa.

- Expects countries to adopt a stepwise approach to harmonized regulation of medical devices and *in vitro* diagnostics and identify 1-3 key priority areas for implementation in 2015. (*lesson from AHWP Playbook)*

Future (2)

- Counties to review their laws and adopt the model law for Medical Products prepared In collaboration with AU NEPAD Agency so as to address the issue of multiple institutions doing similar work (reduce duplication, confusion and delays).

- PAHWP is evolving and need to tap into global efforts underway e.g. AHWP, ALADDIV, GHTF-IMDRF, WHO-PQ.

- Realities of capacity limitations: financial, lack of human technical capital and weak or absence of regulatory and legal frameworks for medical devices and diagnostics need to be addressed.

Conclusion

PAHWP has a significant role in promoting harmonization and strengthening regulation of medical devices and diagnostics in Africa and therefore need all kind of support for its vision to be realized and that is

"valuable, quality assured, safe medical devices and diagnostics are made available where needed".

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