13th AHWP Annual Meeting

MITEC

Kuala Lumpur, Malaysia

22-25 October, 2018

Grace M. Shimwela
Tanzania Food and Drugs Authority

Update on the Pan African Harmonization Working Party (PAHWP)

(Progress on alignment of PAHWP with African Medicines Regulatory Harmonization, AMRH)

About PAHWP

- Pan Africa Harmonization Working Party is a voluntary body that aims to improve access to safe and affordable medical devices and diagnostics in Africa through harmonized regulation.

- Activities of PAHWP are based on awareness raising and advocacy.

- Mission is to study and recommend ways to harmonize medical devices and diagnostics regulation in Africa.

About PAHWP…

- PAHWP initiatives started back in 2012.

- Its priority was initially on harmonized regulation for *in vitro diagnostics* (whose regulation in most of African countries is not optimal).

- Current members: 18 countries namely: Burkina Faso, Burundi, Ethiopia, Ghana, Kenya, Malawi, Mozambique, Nigeria, Rwanda, Senegal, Sierra Leone, South Africa, Uganda, Tanzania, Togo, Zambia, Zanzibar and Zimbabwe.

Rationale for harmonization

Why harmonization?? Why now??

- Regulation of medical devices and diagnostics is as important as pharmaceuticals. Poor quality medical devices and diagnostics has significant impact in the health care system

Wrong diagnosis → **Wrong medication**

- Incidences of poor quality medical devices and diagnostics in Africa (*Quality of medical devices and in vitro diagnostics in resource-limited settings by Marcella Mori1,4, Raffaella Ravinetto2 and Jan Jacobs1,3)*

Absence of regulation → **inadequate information about extent of the problem.**

Rationale for harmonization…

- Duplication in facility inspections and clinical trials results in increased costs, 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.

Rationale for harmonization...

- Favourable environment for harmonization e.g. IMDRF, AHWP, ALADDIV and AMRH Programme coordinated by AU – NEPAD Agency.

- Most important is the need from the African Regulators to have a harmonized system for regulation of these products as more and more products are pouring into our countries and have no capacity to verify their safety & performance (range is from simple to complicated products).

PAHWP vision of a streamlined future

Today

- ~ 54 regulatory regimes governing medical device regulation across Africa, at different levels of development and efficiency
- Regulators capacity highly variable, some with almost no capacity at all
- Different requirements and formats, lack of clear guidelines
- Minimal transparency, No clear timelines
- Global regulatory efforts underleveraged

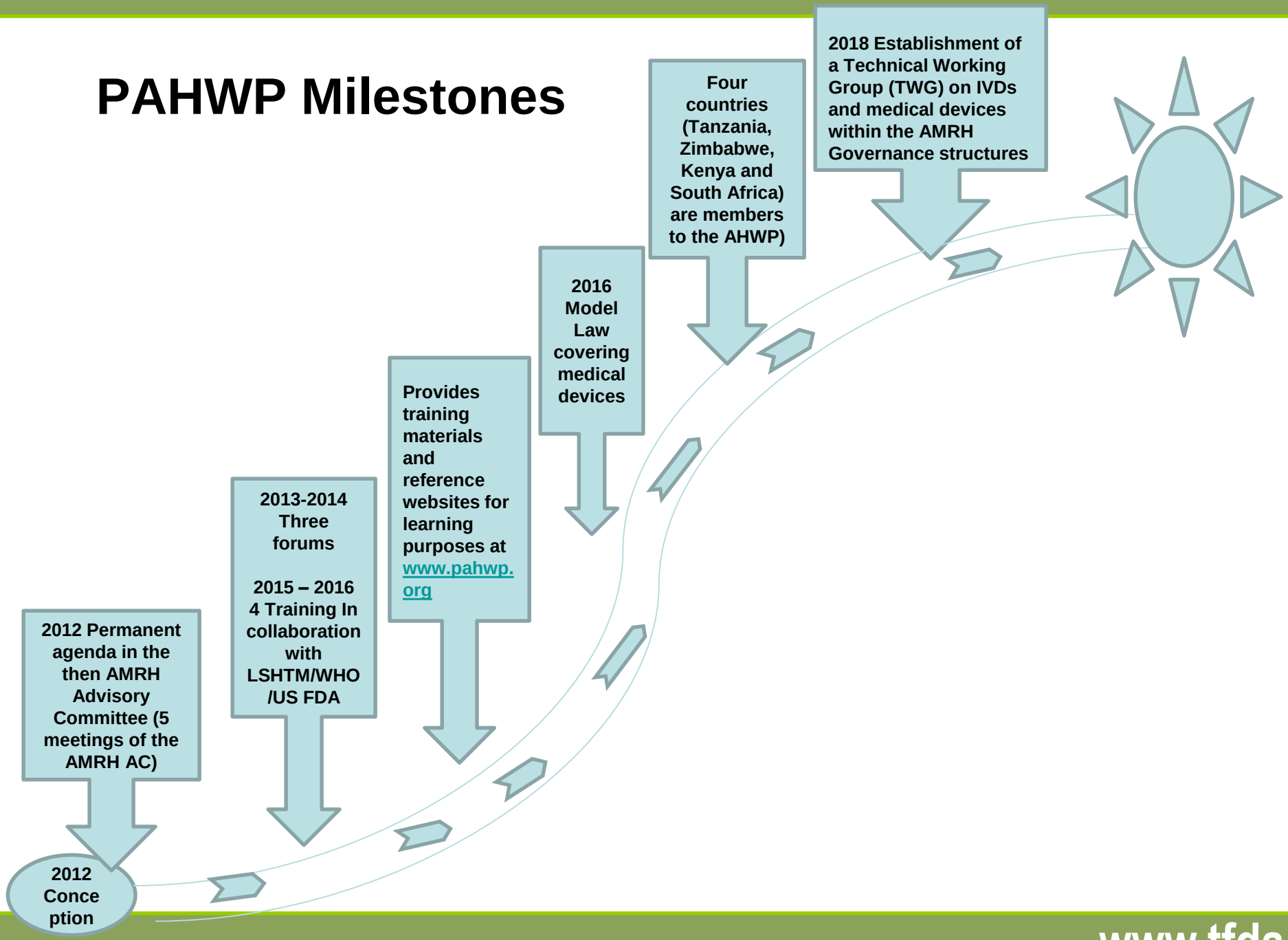
Streamlined (harmonized) future

- Between 5-7 regional economic communities (RECs) covering the entire African continent
- Stronger, institutionalized regulatory capacity building programmes
- Clear guidelines, harmonized requirements, procedures and standards
- Transparent regulatory processes with clear timelines
- Resource pooling and information sharing

Earlier approval of medical devices and diagnostics

Access to quality and safe medical devices and diagnostics

PAHWP Milestones

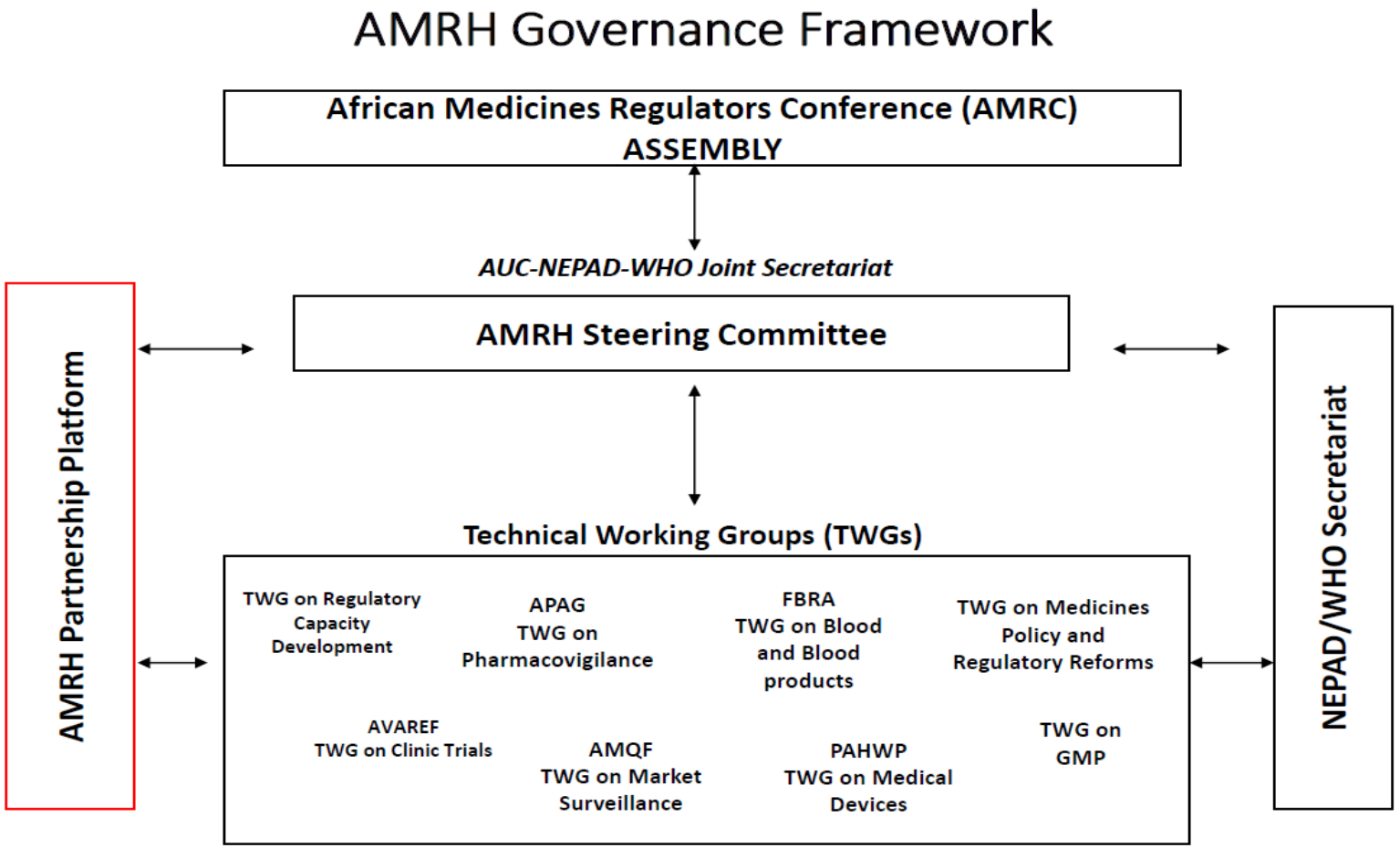


Current status

- PAHWP has been transitioned as a continental TWG on medical devices and diagnostics under the new AMRH Governance structure (recommended at 18th International Conference of Drug Regulatory Authorities as way of establishing regulatory capacity for medical devices and diagnostics in Africa).

- The work and guidelines already developed or adopted under the PAHWP will be carried forwards and institutionalized as part of ongoing expert and technical work of AMRH and ultimate constitute as a key scientific pillar of the AMA.

AMRH Governance Framework with PAHWP



Plan for 2018

AMRH week (Kigali 10-14 December 2018)

- Finalize and endorse governance structures and operating model for PAHWP.

- Finalize TORs for PAHWP based on the new structure.

- Develop work programme for the next two years include conduct a baseline survey through RECs to determine the capacity of each regulator so that appropriate interventions are recommended.

Plan for 2018…

- Establish sub-TWGs made up of experts to work on specific areas as periodically needed.

- Elect officials to serve in the PAHWP TWG as provided in the TORs.

❑ Proposed participants: current 18 member countries and other invited guests.

Further steps

- Sensitize Regulators in Africa to adopt a stepwise approach to harmonized regulation of medical devices and *diagnostics based on the WHO Model Regulatory Framework for Medical Devices and IVDs, 2016.*

- Continue to work with interested partners to ensure harmonization and collaboration across Africa.

- Continue to participate in the AMRH SC as a technical partner in the area of medical devices and diagnostics.

- Continue to promote information sharing and reliance.

Asante, Merci, Thank you

15