Harmonizing the regulation of in vitro diagnostic (IVD) medical devices in developing countries

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Regulating *in vitro* diagnostic tests in DC

- Baseline surveys of regulatory landscape have revealed regulation of IVDs is neglected area
- Most, but not all, East African Community (EAC) Member States have a legal framework but lack capacity for regulating diagnostics and there is little activity, except through disease control programs (HIV/AIDS, TB, malaria)
- In some countries there is confusion between role of laboratory organisations and National Regulatory Authorities (NRAs)
- There is no platform for sharing information between countries
- There is enthusiasm for harmonization and convergence amongst regulators and industry
Why harmonization and why now?

Why harmonization?

- **Confusing, costly and lengthy** pre-market registration reduces access to new products, and is disincentive to innovation
- **Duplication** in inspections and clinical performance studies results in increased cost of goods, making products less affordable
- **Lengthy approval** processes lead to delayed patient access to new tests

Why now?

- **Substantial investment in point-of-care** diagnostics because of the inequity of access to laboratories, especially in rural or remote settings
- **Technological advances** such as nanotechnology, microfluidics, and discovery of new biomarkers leading to innovation
- **Recognition** that regulatory barriers can stifle innovation
- **Favourable environment** for harmonization
  - e.g. African Medicines Regulatory Harmonization (AMRH) Programme;
  - Asia Harmonization Working Party (AHWP);
  - GHTF/IMDRF
LSHTM through a grant from Grand Challenges Canada is working with regulatory authorities, ministries of health and the diagnostics community to improve access to medical diagnostics in the developing world through harmonised regulatory approaches.

Through a grant from UNITAID we shall be using new point of care tests for CD4, viral load and early infant diagnosis of HIV as examples.

Partners include the Asian Harmonization Working Party (AHWP) IVD sub group; the Latin American IVD Association (ALADDIV); the Pan African Harmonization Working Party and the African Society for Laboratory Medicine.
Pan African Harmonization Working Party on Medical Devices and Diagnostics (PAHWP)

PAHWP is a voluntary body whose main goal is to study and recommend ways to harmonize medical devices and diagnostics regulation in Africa and other regions.

Established late 2012 with EAC, Nigeria (NAFDAC) & South Africa (NHLS), now expanding.

Currently transitioning to AU-NEPAD where it shall fall within the African Regulatory Harmonization Advisory Committee for Medicines, Medical Devices & Diagnostics.

To work in coordination with the Asian Harmonization Working Party (AHWP), WHO, Regional Economic Communities (RECs) and other international organizations aiming at establishing harmonized requirements, procedures and standards, including the International Medical Device Regulators Forum (GHTF/IMDRF)

The first priority is *in vitro* diagnostic medical devices
It is the mandate of national regulatory authorities to ensure the safety and effectiveness of diagnostic devices for health. Streamlining the regulatory process could reduce the regulatory burden, lower costs and remove unnecessary delays.

Priority activities:

Convergence on
Product risk classification rules
Pre market registration (common documentation)
Auditing manufacturing quality management

Reduced duplication in clinical performance studies:
joint review of data from accredited labs, using agreed protocols

Build capacity and communications for post market surveillance

Awareness and advocacy
2nd African Forum on Regulation of Medical Diagnostics

22\textsuperscript{nd} & 23\textsuperscript{rd} January 2014. Cape Town, South Africa

To review the vision of PAHWP with major stakeholders and industry; present progress and achievements of PAHWP; identify gaps and challenges; and discuss the way forward.

www.pahwp.org
In vitro diagnostic (IVD) medical device

A device, whether used alone or in combination, intended for the *in-vitro* examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

AHWP SG1/N045:2008 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification