African and interregional harmonization activities to improve access to affordable IVD

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Background

The London School of Hygiene & Tropical Medicine 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.

We are working with regional bodies

AHWP: Asian Harmonization Working Party IVD sub group
ALADDIV: Latin American Alliance for development of IVDs
PAHWP: Pan African Harmonization Working Party

and regional economic communities e.g. East African Community
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), IMDRF etc
Guiding principles
Partnership
Partnership

do not reinvent the wheel...
Regulating *in vitro* diagnostic tests in DC

- Baseline surveys of regulatory landscape in developing countries have revealed IVDs is neglected area
- Most often countries have a legal framework but lack capacity for regulating IVD 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
PAHWP: Pan African Harmonization Working Party on Medical Devices and Diagnostics

Established late 2012 with the East African Community, Nigeria (NAFDAC), South Africa (NHLS) & Ethiopia, quickly expanded.

A voluntary body whose main goal is to study and recommend ways to harmonize medical devices and diagnostics regulation.

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 IMDRF.

Three technical working groups and forum meetings that are open to all stakeholders.

The first priority is *in vitro* diagnostic medical devices
PAHWP sits alongside the medicines initiative within the African Union-NEPAD Planning and Coordinating Agency.
Priorities

Streamlining could reduce the regulatory burden, lower costs and remove unnecessary delays.

Priorities:

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

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

Build capacity and communications for post market surveillance

Advocacy and awareness raising
PAHWP activities

Awareness raising and advocacy

**Regulatory Framework:** to consider GHTF Classification, Conformity Assessment, Essential Principles of Safety and Performance, and Common Submission Dossier and the IMDRF single audit program. To consider establishing an expert classification panel housed in AU-NEPAD to decide on the classification of products that do not fit into existing classification rules.

**Reducing duplication in clinical performance studies:** Pilot project on point-of-care tests for CD4/viral load and early infant diagnosis (UNITAID). Training on good review practice.

**Post Market Surveillance**
Communications platform to be established for reporting problems. Protocol in development for a pilot project on rapid HIV tests.

**Standards** To work with ISO TC 212 on standards for IVD & POCT
Post market surveillance

Sub-standard, fake and IVD of unknown quality are marketed in Africa

Challenges

- Lack of post market surveillance or batch testing of products
- Lack of platform for sharing information
- Lack of corrective and recall mechanisms

Response

- Establish an African communication portal and work towards a common information management system
- Pilot project on feasibility of active surveillance for rapid tests for HIV
Pilot on rapid tests for HIV

PAHWP technical working group includes regulators, labs, medical stores, industry, MoH, academia and ASLM with representation from Ethiopia, Ghana, Kenya, Nigeria, South Africa and Tanzania

Building on work already done by Tanzania and WHO

Post market surveillance

To look at the feasibility of PMS

Pilot on rapid tests for HIV

July
- Collect and collate protocols/guidelines* (Tanzania & others)
- Create check list to assess suitability for participation (capacity, ethics requirement etc)
- Country consultations

Aug

Sept
- PAHWP PMS WG to decide pilot countries by conference call and/or email

Oct
- Six weeks

Nov
- Report findings at PAHWP meeting November 29th in Cape Town.
Pilot project on point-of-care tests for CD4/viral load and early infant diagnosis. International collaboration led by LSHTM. Funded by UNITAID.

Goal: Increased access to beneficial new IVD. Reducing unnecessary duplication will reduce the cost and delay in products reaching the market.

- Protocols agreed by panel of international experts
- Selection of sites (criteria: quality indicators, GLP/GCP, access to samples, IRB approval etc.)
- Manufacturers contract sites
- Independent monitoring of studies
- Training in good review practice
- Joint review of data

www.idc-dx.org
## Inter-regional harmonization activities for regulating IVD

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Acknowledgements

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Invitation

3rd African Regulatory Forum on Medical Diagnostics

30th November 2014, Cape Town, South Africa

Contact Ruth.Mcnerney@lshtm.ac.uk or visit http://www.pahwp.org/7.html

Organised with financial support from Grand Challenge Canada
National Regulatory Authorities have a responsibility to protect their population from unsafe products while facilitating timely access to new products of benefit that are affordable.

How can your organisation assist building capacity for harmonized regulation of medical devices and IVD?