Networks in Diagnostics: The Global Experience

ALADDIV Vth International Workshop: Accessible and Quality Assured In Vitro Diagnostic Tests for Public Health Programs

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To be Covered

Regional networking efforts

Global networking efforts

REGIONAL EFFORTS

The State of Global IVD Regulation

- Relatively few countries regulate medical devices, fewer regulate IVDs
- Serious concerns about duplication of effort for IVD industry from country to country
  - Need to repeat clinical performance studies
- Formation of regional efforts to bring countries together

LATIN AMERICA


ALADDiV

AFRICA

PAHWP: What it is

- Formed in 2012 in an effort to harmonize the regulation of medical devices in Africa, with a particular focus on IVDs
- Initiated by the London School of Hygiene and Tropical Medicine
- Administered by East African Community (EAC)

PAHWP: What it is

- Five priority areas for harmonization:
  - Common Registration File
  - Quality Systems Audits – reduce duplication
  - Clinical Evidence – reduce duplication
  - PMS – to improve the safety and reliability of IVDs across Africa
  - Risk Classification – to set standards for classifying IVDs so that they are regulated based on individual and public risk

PAHWP: What it has done

PAHWP: What it has done

- Meets on a periodic basis to discuss progress toward its goals
- Promoting events and trainings together with the African Society for Laboratory Medicine
  - ASLM 2020 goal for regulatory “harmonization”

Rugera et al. BMC Health Services Research 2014, 14:524
http://www.biomedcentral.com/1472-6963/14/524

BMC Health Services Research

RESEARCH ARTICLE Open Access

Regulation of medical diagnostics and medical devices in the East African community partner states

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Abstract

Background: Medical devices and *in vitro* diagnostic tests (IVD) are vital components of health delivery systems but access to these important tools is often limited in Africa. The regulation of health commodities by National Regulatory Authorities is intended to ensure their safety and quality whilst ensuring timely access to beneficial new products. Streamlining and harmonizing regulatory processes may reduce delays and unnecessary expense and improve access to new products. Whereas pharmaceutical products are widely regulated less attention has been placed on the regulation of other health products. A study was undertaken to assess regulation of medical diagnostics and medical devices across Partner States of the East African Community (EAC).

Methods: Data was collected during October 2012 through desk based review of documents and field research, including face to face interviews with the assistance of a structured questionnaire with closed and open ended questions. Key areas addressed were (i) existence and role of National Regulatory Authorities; (ii) policy and legal framework for regulation; (iii) premarket control; (iv) marketing controls; (v) post-marketing control and vigilance; (vi) country capacity for regulation; (vii) country capacity for evaluation studies for IVD and (viii) priorities and capacity building for harmonization in EAC Partner States.

Results: Control of medical devices and IVDs in EAC Partner States is largely confined to national disease programmes such as tuberculosis, HIV and malaria. National Regulatory Authorities for pharmaceutical products do not have the capacity to regulate medical devices and in some countries laboratory based organisations are mandated to ensure quality of products used. Some activities to evaluate IVDs are performed in research laboratories but post market surveillance is rare. Training in key areas is considered essential to strengthening regulatory capacity for IVDs and other medical devices.

Conclusions: Regulation of medical devices and *in vitro* diagnostics has been neglected in EAC Partner States. Regulation is weak across the region, and although the majority of States have a legal mandate to regulate medical devices there is limited capacity to do so. Streamlining regulation in the EAC is seen as a positive aspiration with diagnostic tests considered a priority area for harmonisation.

Keywords: Regulation, IVD, Diagnostic test, Medical device, East African community

ASIA

AHWP: What it is

- Formed in 1996 by a group of experts from medical device regulatory authorities and medical device manufacturers
- Uses as its basis recommendations from GHTF and IMDRF, and other international organizations

AHWP Membership

Geographical Region	Country	
Asia	Brunei Darussalam	Malaysia
	Cambodia	Myanmar
	Chinese Taipei	Pakistan
	Hong Kong SAR, China	People's Republic of China
	India	Philippines
	Indonesia	Singapore
	Republic of Korea	Thailand
	Laos	Vietnam
Middle East	Abu Dhabi	State of Kuwait
	Jordan	Yemen
	Kingdom of Saudi Arabia	
Africa	South Africa	
South America	Chile	

AHWP: What is does

- Generation of documents that represent what the group considers to be best practice for its members
- Recommends ways to harmonize the regulation of medical devices, including IVDs, across Asia

AHWP: What it does

- Work plan:
  - Revision of GHTF documents
  - Drafting implementation guidelines for AHWP member economies
  - Training AHWP member economies on the guidelines
  - Setting up an adverse event reporting system, development of a QMS and regulatory training program
  - Development of an auditing guidance
  - Adoption of a common system for nomenclature.

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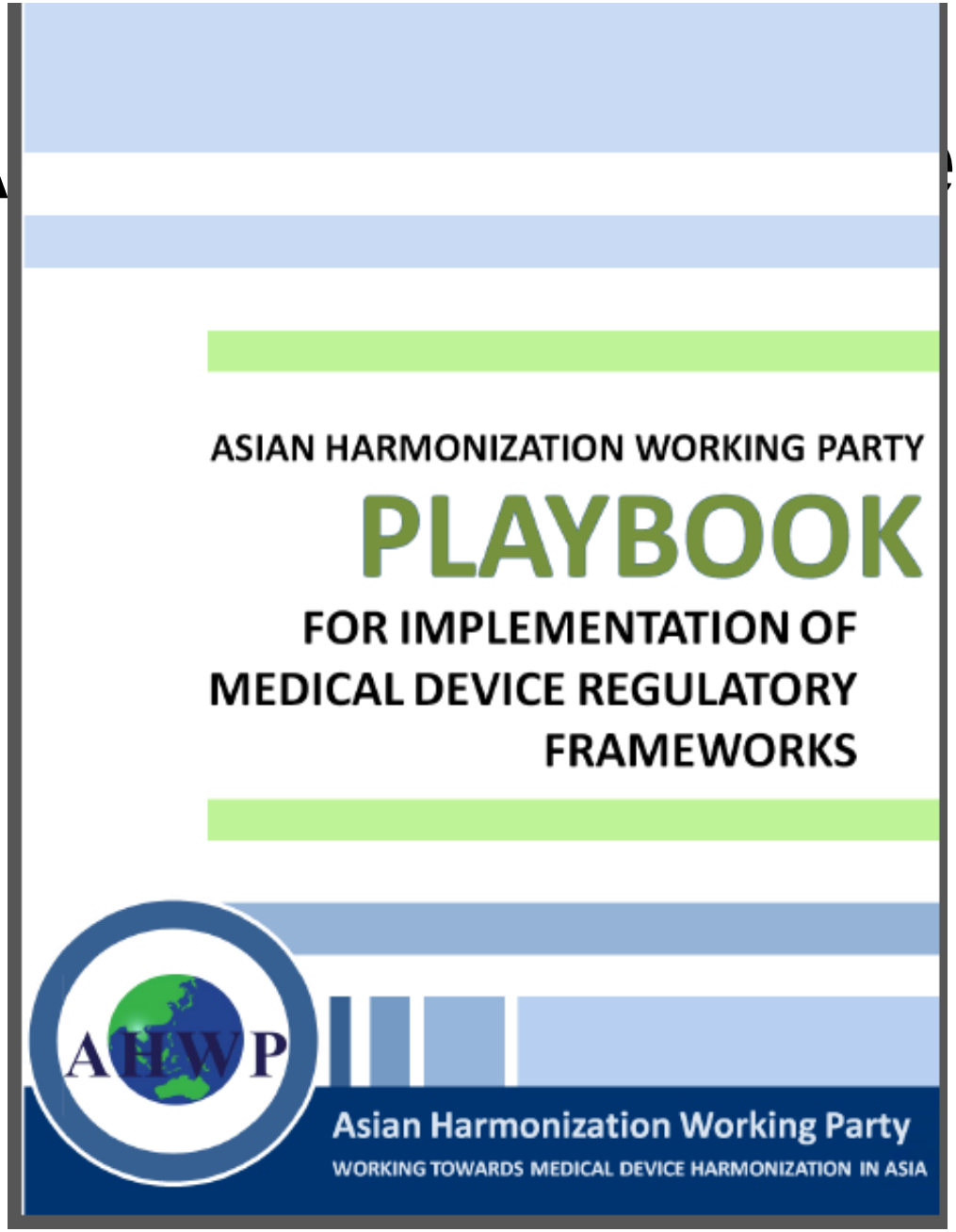
ASIAN HARMONIZATION WORKING PARTY
PLAYBOOK
FOR IMPLEMENTATION OF
MEDICAL DEVICE REGULATORY
FRAMEWORKS
AHWP
Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

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GLOBAL EFFORTS

Global Health Diagnostics: What it is

- An online resource to encourage and support research into improving diagnostics in Global Health through the sharing of knowledge, methods and tools and by enabling the creation of diverse research collaborations.
- Registering is free and open to anyone working in Global Health
- https://globalhealthdiagnostics.tghn.org

Global Health Diagnostics: What it has done

- The objectives of Global Health Diagnostics are to:
  - Provide resources and best practice
  - Create and facilitate an interactive community for sharing of knowledge and experience
  - Facilitate time limited, topical discussions with experts
  - Facilitate e-learning

Global Diagnostics Working Group: What it is

- Group formed to provide a forum to share information and to align actions and communications to its respective constituencies
- Formed in 2013
- Goal
  - To improve the provision of quality-assured HIV related *in vitro* diagnostics (IVDs) to patient.

Global Diagnostics Working Group: What it is

Members:

- African Society for Laboratory Medicine
- Centers for Disease Control and Prevention
- The Clinton Health Access Initiative
- The Global Fund to Fight AIDS, Tuberculosis and Malaria
- Médecins sans Frontières
- UNICEF
- UNITAID
- USAID
- President's Emergency Plan AIDS Relief
- World Health Organization PQDx

Global Diagnostics Working Group: What it does

5 Objectives

- To **strengthen communication, collaboration & coordination** towards the optimal selection and use of quality-assured products
- To effectively **respond in a timely and coordinated manner to urgent quality-related issues**
- To provide **aligned messages to global, regional, and country level users on quality assurance for product selection and testing implementation**
- To provide **aligned messages to manufacturers**
- To advocate for diagnostic tests that are **appropriate and affordable**

CONCLUDING THOUGHTS

A Proposal and a Challenge

- Political will
- Commitment

- Openness
- Flexibility
- Patience

PLAHWP!

MUCHAS GRACIAS!