Baseline Survey On Regulation In The East African Community Partner States, Ethiopia, Nigeria and South Africa

Background

A brainstorming meeting on harmonizing diagnostics held in July 2012 in Nairobi was attended by representatives from each EAC partner state, Ethiopia, Nigeria and South Africa.

The meeting deliberations/recommendations were discussed by the EAC Sectoral committee on health and subsequently the EAC Sectoral Council of Ministers of Health

A survey in EAC partner states was commissioned after approval by 8th Ordinary Meeting of the EAC Sectoral Council of Ministers of Health (Sept 2012)

A regional consultant was engaged to undertake visits to EAC Partner States. National representative collected data in Ethiopia, Nigeria and South Africa.

The questionnaire addressed *in vitro* diagnostic devices and medical devices

A medical device (MD) is an instrument, apparatus, implant, in vitro reagent, or other similar or related article, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or any function of the body and which does not achieve any of its primary intended purposes through chemical action within or on the body.

An 'in vitro diagnostic device' (IVD) is a medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information concerning a physiological or pathological state.

Methodology

Data was collected October-November 2012 by

- A structured questionnaire containing both closed and open ended questions.
- Through desk based review of policy and legislative documents
- and in EAC Partner States by field research, including face to face interviews

Information was collected about medical devices and IVD medical devices

Key areas addressed included

(i) Existence and role of National Regulatory Authorities
(ii) Policy and legal framework for regulation
(iii) Premarket registration
(iv) Marketing controls
(v) Post-marketing control and vigilance
(vi) Country capacity for regulation
(vii) Capacity for evaluation studies for IVD
(viii) Priorities and capacity building for harmonization.

Country	Documents	Organisations interviewed (persons)
Burundi	1	i. Ministry of Health ii. Department of Pharmacy, Medicines and Laboratory
Kenya	17	i. Pharmacy and Poisons Board (3) ii. National Quality Control and Medical Devices Laboratory iii. Kenya Medical Laboratory Technicians and Technologists Board (2)
Rwanda	4	Rwanda Biomedical Centre
Tanzania (Mainland)	11	i. Tanzania Food and Drugs Authority (2) ii. Private Health Laboratories Board
Tanzania (Zanzibar)	6	i. Zanzibar Food and Drugs Board (2) ii. Central Medical Stores, Ministry of Health and Social Welfare iii. Chief Pharmacist, Ministry of Health and Social Welfare
Uganda	8	i. National Drug Authority (3) ii. Pharmacy Division, Ministry of Health iii. Uganda National Bureau of Standards (2) iv. Allied Health Professionals Council v. Medilab (Laboratory supplies company) vi. Central Public Health Laboratories
Total	**47**	**16 (24)**

	Legislation	National Health Policy	National Health Lab Policy	Guidelines	National Regulatory Authority
Burundi	Yes	na	na	na	Directorate of Pharmacies, Medicines and Laboratories
Kenya	Yes	Yes	Yes	Yes	Kenya Medical Laboratory Technicians and Technologist Board / Pharmacy and Poisons Board
Rwanda	Yes	Yes	na	Yes	Task force to set up FDA, but diagnostics not yet included
Tanzania Mainland	Yes	Yes	P	Yes	Tanzania Food and Drug Authority / Private Health Lab Board
Tanzania Zanzibar	Yes	Yes	na	Yes	Zanzibar Food and Drugs Board
Uganda	No	Yes	Yes	Yes	National Drug Authority / Allied Health Professionals Council of Uganda
Ethiopia	Yes	Yes	Yes	Yes	Food, Medicine and Health Care Administration and Control Authority of Ethiopia
Nigeria	Yes	Yes		In development	National Agency for Food and Drug Administration and Control (NAFDAC)
South Africa	In developme	Yes	Yes	In development	In development

Key observations

- Regulation of diagnostics has previously been neglected Regulation is weak, and although the majority of States have a legal mandate to regulate medical devices there is limited capacity to do so.
- There is uneven progress towards regulation
- MoH departments are involved in regulation in some countries
- Some countries have different NRAs carrying out parallel regulation (duplication)
- Existing NRAs have limited capacity (human and quality evaluation) to regulate medical devices and diagnostics
- Some NRAs lack some guidelines

Key observations cont.

- Control of medical devices and IVDs is largely confined to those used by national disease programmes such as TB, 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.

Responses received suggest that harmonization and streamlining regulation in the EAC is seen as a positive aspiration.

A limitation of the study is that due to restraints of time and finance the list of stakeholders consulted was not exhaustive and it is possible that those who were not available for comment would be less enthusiastic about the regulation of IVD and medical devices.

Several respondents indicated that policy reviews are being undertaken and at least one State (Tanzania) is proposing changes to the current regulatory framework and process. The collaboration between the NRAs in United Republic of Tanzania is fertile ground for regulatory harmonisation process in the region

RECOMMENDATIONS

- Diagnostic products should be considered a priority
- Each Partner State should have a legal and policy framework for medical diagnostics and devices suitable for harmonisation. The EAC should collaborate with EAC partner states to expedite IVDs and medical devices legislation and policy framework where it does not exist; and to identify refinement areas to existing ones where it is already in the law system.
- Common nomenclature and product classifications should be used across the EAC
- Partner States should develop mechanisms and capacity for regulation that would feed into EAC harmonised regulation
- EAC and Partner States should establish a communication platform to enable the necessary exchange of information relating to medical diagnostics and medical devices in order to provide prompt safety information for the nations to safeguard patients.

There is need for donor support with regard to medical diagnostics for:

i. Facilitating appropriate legal frame work in each partner states as a matter of urgency
ii. Capacity building and training needs support for NRA;
iii. Facilitating harmonisation in the EAC partner states
iv. Facilitating formation of PAHWP

- Technical Working Groups should be established to pursue harmonization activities.
- An EAC Regional Task Force on Harmonization and Regulation of Medical Diagnostics and Medical Devices should be established
- The task force should lead to the establishment of a PAHWP
- Harmonization activities should be undertaken with consideration to guidelines issued by the Global Harmonization Task Force and activities of other regional bodies such as the Asian Harmonization Working Party.

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Thank You