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A Medical Device Regulatory Framework - Case Study: South Africa

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Abstract—**The regulation of medical devices is well-established in industrialized countries, with increasing global standardization and harmonization. In developing and resource-poor countries, however, there is a much greater degree of variability and implementation. For such countries, this paper suggests a comprehensive and integrated regulatory framework approach using the South African health technology policy framework as a basis for comparison and benchmarking. It is hoped that this compact model, which covers a wide range of HTM-related aspects, will be useful to governments and their partners, amongst other role-players.**

I. Introduction

The broad definition (used by WHO and others) of health technologies includes information and support systems - by implication this includes decision-support tools and instruments used as an integral part of Healthcare Technology Management (HTM) practice.

While an array of HTM decision support tools are available, it is prudent to apply the criteria of **access**, **appropriateness**, **affordabilit**y and **usability** in assessing what is available, which of these lend themselves to implementation in resource-poor environments and, most importantly, are likely to be sustainable. This also applies to conceptual models, frameworks and even policies used to guide and support HTM-related interventions, processes and activities.

II. Background

Regulation often focuses on specific aspects of the medical device life-cycle, from development and manufacture to acquisition and utilisation. In many cases there is an imbalance in that some aspects may be dealt with comprehensively whilst others are downplayed or even ignored. This results in significant imbalances in implementation and impacts negatively on both the strategic and operational environments.

A. Regulatory Systems

Some ten years ago, Nobel [1] observed that ..“no two regulatory systems are the same”. He went further to state that there is “no evidence available yet to suggest that one system is superior to others (in preventing medical device related adverse effects) or that very costly and complex approaches produce superior results to relatively simple and inexpensive approaches”. This may still be true for many countries, and especially those that are seen as resource-poor.

Nevertheless, there is increasing global uniformity and especially in industrialized countries, driven chiefly by the Global Harmonization Task Force [2][3]. The GHTF has as its mission the harmonized implementation of medical device regulations across the globe, and sees its role as encouraging convergence in regulatory practices related to ensuring the safety, effectiveness / performance and quality of medical devices, promoting technological innovation and facilitating international trade.

The GHTF framework integrates the regulatory systems of the countries / regions with the most advanced medical device regulations. This framework identifies safety as a risk management issue and sees ideal conditions for ensuring the optimum safety and performance of medical devices as requiring the cooperation and shared responsibility amongst all involved over the lifespan of a medical device, i.e. manufacturers, vendors, governments, users and the public/patients. To this end it has prepared a checklist outlining the responsibilities of the various stakeholders (this of course presumes that these stakeholders are able to exercise their rights and responsibilities).

The framework recognizes the profound effect of usage (including lack of, or inappropriate, calibration and maintenance) on the safety and effective performance of medical devices.

The GHTF has also provided guidelines for establishing basic regulatory programmes and drafting a national policy on medical device regulation. The GHTF framework serves as a “best-practice” model, but does assume a well-developed and resourced infrastructure.

At the regional level, the Pan American Health Organization (PAHO) has formulated a regulatory model with associated guidelines [4], against a challenging background: in 2002, of 43 Latin American and Caribbean countries, 21 had no medical device legislation; of the 22 countries which had legislation, only 7 effectively enforced it, and 27 countries had no import requirements.

The PAHO guide lists 8 guiding principles, highlights essential features of medical device regulatory programmes and provides a modular model for a regulatory program with critical elements. These elements are as follows:

- Market entry notification
- Post-market vigilance

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- Manufacturing Controls and Inspections
- Safety and Efficacy/Performance Assessment

The PAHO guide also provides a legislative model template for use by health agencies and legislative bodies. In addition, it importantly addresses the reuse of medical devices.

Finally, at the national level, a regulatory framework proposed for South Africa [6] identifies three levels of regulation:

I Market (focusing on GHTF criteria of safety and performance
II Selection (focusing on Technology Assessment and Needs Assessment)
III Utilization (focusing on Good Management Practice) [7].

A. Supporting Instruments

It is suggested – by the GHTF and others – that medical device regulation not be seen in isolation but as part of the health technology management system. It is equally important to link up with healthcare delivery processes, especially with the increasing attention being paid to quality of service delivery and performance. In this regard, tools developed by the WHO for health service performance measurement have been adapted for use by us in an HTM-context. These include the following measures of service provision:

- *Coverage* (the probability of receiving an effective intervention when needed). Coverage has the elements of: **access** (comprising availability, accessibility, affordability and acceptability), **utilisation** and **effectiveness**).
- *Effective coverage* (the ratio of actual gain from interventions to maximum potential gain achievable from the same interventions).

It is proposed that these concepts also be used in measuring the performance of regulatory interventions and associated activities. In addition, sustainability can be considered to include elements of appropriateness, affordability and continuity of resources.

B. Quality

It is equally important to link up with the current drive towards quality of healthcare, defined [8] as "the degree to which services for individuals and populations increase the likelihood of desired outcomes and are consistent with current knowledge". Quality service delivery should be:

- effective
- efficient
- equitable
- patient (client)-centered
- safe and
- timely

It is proposed that these concepts be incorporated into a medical device regulatory framework.

C. Regional and National Policies

Medical device regulation needs to be considered against the backdrop of national policy relating to health technologies in general, and medical devices in particular.

The Eastern Mediterranean Regional Office (EMRO) of the WHO has published a Health Technology Policy Framework [9]. The framework contains the following extracts (*emphasis by author*):

> " Policy should address and promote mechanisms at *all levels of health care delivery* which encourage the effective provision of health care through establishing scientific, technical, (clinical) health and economic criteria for assessment, and evaluation and selection of technologies *appropriate to national health priorities*.
>
> A *national health care technology management system* should be established for proper *integration of health technology resources and processes*, including the supportive and organizational infrastructure within which health care technology is applied.
>
> The *organizational structures* should address the interrelationship of quality, quantity, and economics in support of the stated health care objectives, and should ensure *optimal distribution of the limited health care technology resources*, facilitate equity in access, improve the quality of health services and enhance positive health outcomes.
>
> These organizational structures should be *adequately supported* in terms of political support, budgetary allocations and supporting infrastructure to ensure they can fulfill their mandate."

The WHO Regional Office for the African Region has also published a strategy for the African Region [10]. This poses similar challenges to its member states as that posed by EMRO.

D. South African Health Technology Policy Framework

This framework was published [11] as part of an international trend showing increasing focus on the regulation and management of health technologies, driven by guiding principles such as the WHO's "Health For All" strategy. The Framework makes the following strategic commitments:

- *Mission*: To ensure that Health Technology is harnessed to its fullest extent as one of the tools to improve the delivery of health services. A strategy that facilitates the appropriate utilisation of health technology for the South African health system shall be devised.
- *Outcome*: To create a unified and harmonious Health Technology system that ensures optimal distribution of the limited health technology resources and to facilitate equity in access, with the ultimate aim of improving the

quality of health services and enhancing positive health outcomes.

The proposed *Health Technology System* refers to the proper integration of health technology resources and processes, including the supportive and organizational infrastructure within which health technology is applied, to address the interrelationship of quality, quantity, and economics, in support of the stated health care objectives.

Four constituent (sub-)systems have been proposed, addressing the following processes:

- Health Technology Acquisition and Procurement
- Health Technology Assessment
- Health Technology Planning
- Health Technology Utilisation

The situation analysis - which served to inform the policy framework - included a problem statement indicating lack of systematic planning, resulting in high levels of inappropriate utilisation of health technology as well as unnecessary expenditure. It also showed the lack of a coherent system of regulation and assessment of health technology, within both the public and private sectors.

III. Framework / Discussion

The Medical Device Regulatory Framework is shown in **Figure 1** below. The framework covers the three levels of regulation (market / international; regional / national and local / institutional). At each level are shown the main HTM activities, regulatory criteria and associated instruments. Superimposed on these elements are the sub-systems of the proposed South African Health Technology Management System.

The proposed regulatory framework offers benefits of integration and modularity in a compact, concise format. It straddles all three levels of regulation and provides links between the levels, rather than considering them in isolation or sequentially but independently. It is clear that these activities and processes are conducted at a number of levels in the health system.

It is suggested that a resource-poor country adopt a practical framework that is scaleable in terms of both focus and implementation, but preserves the links between those implemented and those not, and indicates the "big picture" that serves a medium- or long-term goal.

Clearly not all processes and activities need to – or should be – regulated. What is important is that the links between all HTM processes and activities are preserved, so that when regulations are drafted and promulgated their area of influence – relative to the total national needs – can be identified. This is illustrated by means of Figure 2, which indicates the role of HTM- and Clinical Engineering in support of regulatory activities.

IV. Conclusion

The framework presented here serves to support resource-poor countries and their partners in assessing their status quo with regard to a national healthcare technology management system, focus areas for medical device regulation, and the links between HTN-related processes, activities and instruments with associated criteria used in a regulatory context.

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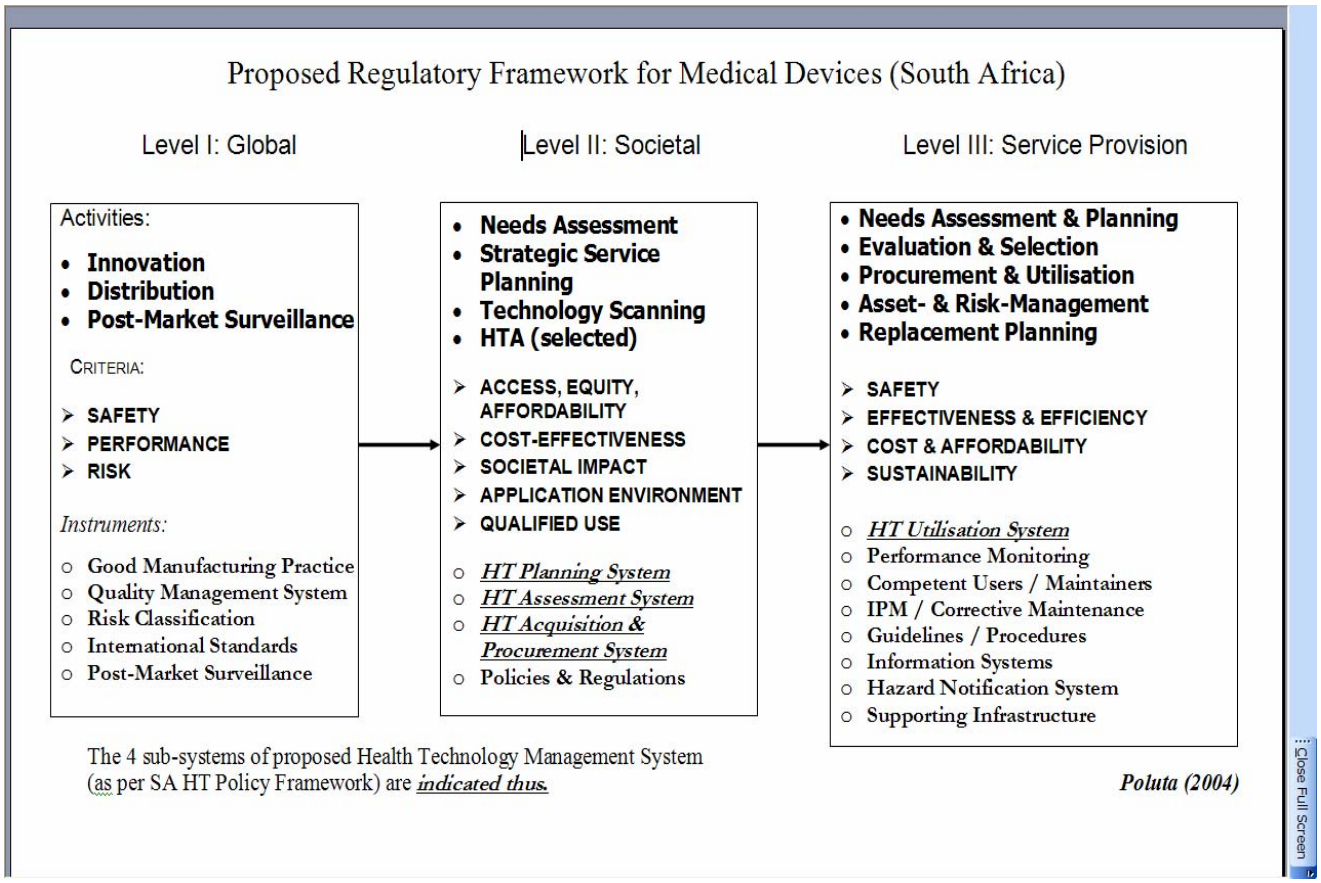
Proposed Regulatory Framework for Medical Devices (South Africa)
Level I: Global
Level II: Societal
Level III: Service Provision
Activities:
• Innovation
• Distribution
• Post-Market Surveillance
CRITERIA:
➢ SAFETY
➢ PERFORMANCE
➢ RISK
Instruments:
○ Good Manufacturing Practice
○ Quality Management System
○ Risk Classification
○ International Standards
○ Post-Market Surveillance
• Needs Assessment
• Strategic Service Planning
• Technology Scanning
• HTA (selected)
➢ ACCESS, EQUITY, AFFORDABILITY
➢ COST-EFFECTIVENESS
➢ SOCIETAL IMPACT
➢ APPLICATION ENVIRONMENT
➢ QUALIFIED USE
○ HT Planning System
○ HT Assessment System
○ HT Acquisition & Procurement System
○ Policies & Regulations
• Needs Assessment & Planning
• Evaluation & Selection
• Procurement & Utilisation
• Asset- & Risk-Management
• Replacement Planning
➢ SAFETY
➢ EFFECTIVENESS & EFFICIENCY
➢ COST & AFFORDABILITY
➢ SUSTAINABILITY
○ HT Utilisation System
○ Performance Monitoring
○ Competent Users / Maintainers
○ IPM / Corrective Maintenance
○ Guidelines / Procedures
○ Information Systems
○ Hazard Notification System
○ Supporting Infrastructure
The 4 sub-systems of proposed Health Technology Management System (as per SA HT Policy Framework) are indicated thus.
Poluta (2004)