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REGULATION AND STANDARDS OF MEDICAL DEVICES IN UGANDA

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INTRODUCTION

The term “medical devices” includes everything from highly sophisticated computerized medical equipment down to simple wooden tongue depressors (WHO, 2003). The regulation of medical devices is a vast and rapidly evolving field that is often complicated by legal technicalities. Recently it has been observed that improvements on biomedical devices and systems used in diagnosis and treatment of illnesses have progressed parallel to the technological developments. However, the tendency to calibrate, regulate and set standards for health equipment and other biomedical devices is still a puzzle in developing countries like Uganda. Although the consciousness and importance of calibration have reached to a remarkable point in some other national sectors such as industry and trade in the past twenty years, the issue of calibration, regulation and setting of standards has started to be discussed in the past five years for the biomedical devices which are directly related to the health of human beings mainly in East Africa (Rugera, McNerney et al. 2014).

The Global Harmonization Task Force and the international medical devices regulator forum (IMDRF) have proposed the following harmonized definition for medical devices which may be of help in setting standards and regulations i.e. a Medical device means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of: diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury, investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life, control of conception, disinfection of medical devices, providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

To better understand medical devices it's necessary to know the different four regulatory classes on the basis of its risk and the evaluation necessary to demonstrate safety and effectiveness. Most class I devices (e.g., stethoscopes) are low-risk and subject only to “general controls,” such as tests of sterility. Class II devices (e.g., computed tomographic scanners) meet general controls as well as “special controls,” such as additional labelling requirements. Class III products (e.g., deep-brain stimulators and implantable cardioverter–defibrillators) require clinical studies evaluating the safety and effectiveness of the device. Class IV are of high risk and require design/clinical trial reviews, product certification, and an assessed quality system involving clinical trials.

The first requirement of the “Essential principles of safety and performance of medical devices” recommended by the Global Harmonization Task Force GHTF (SG1-N020R5) states that; Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety (WHO, 2003; WHO, 2010). This further emphasises the critical importance of biomedical devices since most of them are patient related.

Streamlining and harmonizing regulatory processes may reduce delays and unnecessary expense and improve access to new medical products inclusive of biomedical equipment. Whereas pharmaceutical products are widely and highly regulated in Uganda and internationally, less attention has been placed on the regulation of medical devices (Rugera, McNeerney et al. 2014). Therefore as a result this paper concentrates on the need of calibration, regulation and setting of standards for medical equipment in Uganda.

BACKGROUND

According to the Second African Regulatory Forum on Medical Diagnostics that was organized by London School of Hygiene and Tropical Medicines in collaboration with the East African Community Secretariat, Pan African Harmonization Working Party, African Union/NEPAD Planning and Coordinating Agency, African Society for Laboratory Medicine, German International Cooperation and other International Development Partners from 21st to 23rd January 2014, it had a forum that convened to provide a platform for national regulatory authorities (NRAs) in the continent to share best practices and interact with medical diagnostics industry. The EAC Secretariat was represented by Senior Health Officer (Medicines and Food Safety Unit) and National Medicines Regulation Officer from the Republic of Uganda with a major goal of having a harmonized and functioning regional medical devices and diagnostics regulatory system within the East African Community in accordance with national and internationally recognized policies and standards [WHO & Global Harmonization Task Force (GHTF)] so that there is improvement in the access to safe, efficacious and affordable medical devices and diagnostics for diagnosis and management of communicable and non-communicable diseases in the region. This is also in accordance with the mandate provided by Article 118 of the Treaty on the establishment of the East African Community.

Uganda as an active member of the East African community is therefore obliged to abide by the objectives of this recent forum of 2014 which mainly included; development and implementation of regional harmonized regulatory and mutual recognition frameworks and guidelines for regulation of medical devices and diagnostics based on risk classification, building human resource and infrastructural capacity for the regulation of medical devices and diagnostics in the EAC Partner States, implementation of a quality assurance, audit and management system in each of the EAC Partner States national medicines regulatory authorities for regulation of medical devices and diagnostics and implementation of a common information management system for registration and post market surveillance of medical devices and diagnostics in each of the EAC Partner States' NMRAs.

With that access to medical devices and diagnostics for health in Uganda and in the rest of East African Countries is limited by their availability and cost, and there is uncertainty as to the safety and effectiveness of some products. Regulatory control of medical devices and diagnostics is weak in these countries with efforts to control the quality of imported products largely confined to national disease programs for pathogens such as Human Immunodeficiency Virus (HIV) and malaria. Weak regulatory strategies bring about poor quality products to be marketed and delay access to beneficial new products and increases costs to manufacturers, inflating prices for consumers. Through streamlining and harmonizing regulatory processes in Uganda and the rest of other countries, can reduce delay and unnecessary expense, and improve access to new products.

Like other five national regulatory bodies in East Africa, Uganda has the National Drug Authority (NDA) that was first published in 1993 and established by the National Drug Policy and Authority Act Cap 206 of the Laws of Uganda (2000 edition). It was updated in 2002 to include new strategies to guide implementation and reflect legislative changes. The changes in the access to medicines landscape over the past decade have prompted Ministry of Health to revise the policy in 2015 (MOH, 2015). The National Drug Authority, the Uganda National Council for Science and Technology and the National Health Research Organisation form part of the Ministry of Health of Uganda and have the regulatory responsibility

for clinical trials, medicines and medical supplies inclusive of medical devices for the safety of humans in Uganda, both in public & private sectors, though not explicitly mandated by the law (NDPAA, 1993).

Generally, the regulatory landscape for medical devices and diagnostics in Uganda has found to be weak and inefficient. While much effort and resources have been placed in strengthening regulation of medicines, the area of medical devices including *in vitro* diagnostics has been forgotten or very little effort has been made towards their regulation. Weak regulation allows defective or substandard products to be marketed. Inefficiency in regulation causes unnecessary delay and increases costs to manufacturers and consumers. Wrong diagnosis resulting from a defective or substandard device may result in a complete failure of the whole treatment cycle including wrong medication and may result into death. Therefore, the issue of safety and performance of medical devices and diagnostics cannot be underestimated.

According to a report by Mori, the quality of medical devices and In Vitro Diagnostics in resource limited settings showed that there were limited reports and evidence with regards to poor quality medical devices and this was mainly due to; the poor regulatory oversight of medical devices and *in vitro* diagnostics in resource-limited settings, a general lack of awareness of the problem of poor-quality medical devices and *in vitro* diagnostics amongst the scientific community and decision-makers; and poor quality assurance in diagnostic laboratories in resource-poor settings, precluding tracing quality problems of IVDs from the other potential causes of diagnostic inaccuracy. (Mori M, Ravinetto R, Jacobs J et al, 2011).

The Government's role in medical devices regulation

A regulatory authority in this context is a government agency or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements. The government has the responsibility to oversee the efforts of manufacturers and vendors and ensure that medical devices sold or made available in the country are safe and effective. It provides leadership in creating healthy cooperation among stakeholders in establishing policies and regulations that are fair and clear to all. Policies and regulations should be reviewed periodically to respond to changes in technologies by incorporating appropriate amendments.

In Uganda the government has been able to set up different bodies that are responsible for the regulation and setting of standards for medical devices in Uganda. Some of these bodies include; Uganda National Bureau of Standards, Uganda National Drug Authority, National Medical Stores, Uganda Revenue Authority, among others. These bodies are able to set standards and regulate medical devices and other medical supplies in the country in accordance with the international standards and to what is fit for the standards of Uganda.

The safety and performance of medical devices depend on two critical elements; Pre market review contributes to product control, and post-market surveillance ensures that medical devices in use continue to be safe and effective.(10) There is an important third element, which is the representation of the product to the user. This is controlled through labelling (during the pre-market stage) and advertising of the product. Another aspect of product representation, however, is verbal presentation by the vendor. User/public education is key in guarding against misrepresentation. (10)

Regulatory systems for medical devices are less developed than those for other health products such as medicines or vaccines. According to the 2013 WHO Baseline Country Survey on Medical Devices, only 69% of 175 responding countries have a national authority responsible for implementing and enforcing medical device regulations. Many of those governments that have drafted regulations have made little progress in implementing them. WHO has a clear role and mandate in building regulatory capacity through training and harmonization and is committed to this important work, with the support of all stakeholders.

Ugandan standards and International Organisation for Standardisation of medical devices

The International Organisation for Standardisation (ISO) is a federation of national standards bodies that works with the International Electrotechnical Commission (IEC) on standards and terminology in the areas of electrical, electronic and related technologies. Uganda, like Kenya, Rwanda, and Tanzania, has Membership to ISO through its national standards and regulatory bodies like the Uganda National Bureau of Standards.

The market dynamics for medical devices and diagnostic products for health are distinct from those for pharmaceutical products and their regulation requires a different approach to that for medicines. Medical devices present a wide range of technologies, ranging from the simple band aid to very complex machinery. With that, access to medical devices in developing countries like Uganda is currently limited by their availability and cost and in addition many diagnostic tests require laboratory facilities and trained personnel that are not readily available in these countries (Rugera, Mc Nerney et al. 2014). A new generation of devices are being developed for diagnosing important diseases that promise significant benefit to public health.

Regulation of medical devices in developing countries is weak and this is particularly a problem with diagnostic tests. In countries that do not regulate medical devices and in vitro diagnostic tests, these may be sold with little or no evidence of their efficacy (Rugera, Mc Nerney et al. 2014). Where controls do occur they can act as a barrier to products entering the country (Peeling and Mc Nerney 2011).

According to WHO on the Medical device regulation 2003, it points out that many countries lack access to high-quality devices and equipment that are appropriate for their specific epidemiological needs. This is particularly true in developing countries, where health technology assessments are rare and where little regulatory controls exist to prevent the importation or use of substandard devices. With the vast majority of devices in developing countries being imported, this leaves them prey to unscrupulous market influences and puts patients' lives at risk (WHO, 2003).

It further points out that governments need to put in place policies that will address all elements related to medical devices, ranging from access to high quality, affordable products, through to their safe and appropriate use and disposal. However, these policies will be unsuccessful unless they are translated into national regulations that are enforced by legislation and correlating sanctions, and that form an integral part of the overall national health system.

Surprisingly, regulatory controls for medical devices are scarce in Uganda and in majority of developing countries, even though implementation of national medical device regulations will often address the very issues raised in countries as major concerns for patient safety. Examples of these issues include the illegal re-processing and re-packaging of second hand machines for re-sale; the availability on the market of equipment that fails minimum quality and safety standards; or simply no trace of what devices are being sold in the country among other issues. Such a listing is essential to enable Ugandan government to issue alerts or recalls for unsafe or ineffective medical devices.

Through the Global Harmonization Task Force (GHTF) that was founded in 1993 by the governments and industry representatives of Australia, Canada, Japan, the European Union, and the United States of America to address issues on medicines and medical devices in the world, WHO was able to work with it on the purpose to encourage a convergence in standards and regulatory practices related to the safety, performance and quality of medical devices. The GHTF also promotes technological innovation and facilitates international trade. The primary means by which its goals are accomplished is via the publication and dissemination of harmonized guidance documents for basic regulatory practices.

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