

Chapter 19

Medical Device Regulation in Africa

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Introduction

Medical devices facilitate the diagnosis and treatment of diseases to improve patients' health and quality of life. They range from simple but essential items to sophisticated equipment. The use of medical devices for patient care occurs in different settings such as the bedside, rural health clinics, or large, specialised hospitals (Cheng, 2003). Due to the nature of their use in the health sector, the manufacture and subsequent entry of medical devices into the market is held to a higher standard than for any other product (McAllister & Jeswiet, 2003). It is therefore imperative to define the requirements for the design, development and manufacture of medical devices to ensure that products that reach the market are safe, effective and of good quality, while restricting entry of products that pose risks.

Various countries across the world have established regulatory bodies that guide the medical device industry. For example, medical devices in the USA are regulated under the Medical Device Amendments of 1976, which stipulate the requirements for ensuring safety and effectiveness in the production, registration and marketing of devices (Gottlieb, 2011; Kramer, Xu & Kesselheim, 2012). According to these regulations, manufacturers of high-risk devices such as heart valves are required to demonstrate safety and effectiveness before they can be marketed (Kramer, Xu & Kesselheim, 2012; Sorenson & Drummond, 2014). In the Europe Union, the Medical Device Regulation of 2017 sets the required standards for design, safety and performance for medical devices (EU, 2017). However, the regulation of medical devices is still rudimentary in many developing countries, where regulatory controls are not yet well established to prevent the importation or use of sub-standard devices (Lamph, 2012). It is against this background that this chapter explores medical device regulation in Africa.

The chapter is based on a review of literature extracted using keywords linked to medical device regulation in selected African countries. The documents include reports from the World Health Organisation, journal articles and newspapers. We draw heavily on grey literature because the regulation of medical devices is evolving and relevant documents often appear in the form of reports and communications by government agencies and national and international coordinating bodies. The chapter commences with an overview of international regulations and standards for medical devices. Since the medical device industry is capital intensive, costing governments a substantial amount of money (Cheng, 2003; Moorthy, 2016), we focus on the ten African countries with the highest GDP – Kenya, Nigeria, Egypt, Sudan, Morocco, Angola, Algeria, Tanzania, Ethiopia

and South Africa (World Bank, 2017). An overview is provided of the medical device regulations of these countries, and the implications for the development of their domestic medical device industries are considered.

International regulations and standards

The World Health Organisation promotes the regulation of medical devices across the world. In 2007, it adopted World Health Assembly Resolution 60.29, which encourages the promulgation of national or regional guidelines for good manufacturing and regulatory practices and establishment of surveillance systems and other measures aimed at ensuring quality, safety and efficacy of medical devices (WHO, 2011). The regulatory system is anchored in medical device classification focusing on perceived hazards.

Countries across the world use different classification schemes for medical devices and these depend on design complexity, use characteristics, and potential for harm if misused. Topics such as the degree of invasiveness, the duration of contact, and the body system affected are given attention (Cheng, 2003). In support of World Health Organisation initiatives to minimise regulatory barriers, the Global Harmonisation Task Force proposed regulatory classes for medical devices (GHTF, 2007). These classes determine the level of assessment required; Class 1 applies to medical devices that pose the lowest potential risk and may not need a licence, and Class II demands the manufacturer's declaration of device safety and effectiveness, while devices presenting a greater potential risk that calls for a rigorous assessment, fall under Class III and Class IV. The drive was towards standardisation of regulations as the founding members of GHTF namely Australia, Canada, Japan, the European Union and the USA used different classification systems (Cheng, 2003). For example, the USA categorises medical devices into three classes while Canada and Japan assign four classes (Altenstetter, 2012). The European Union classifies medical devices into three classes with Class II being subdivided into IIa and IIb (Cheng, 2003; Greenspan, 2013). The Global Harmonisation Task Force was disbanded in 2012 and replaced by the International Medical Device Regulators Forum which is aimed at accelerating harmonisation and convergence to achieve greater uniformity between national regulatory systems (Tamura & Kutsumi, 2014). The World Health Organisation in 2014 adopted a resolution (WHA 67.20) for strengthening the regulatory system for medical products (WHO, 2017).

Quality standards are applied to the design, manufacturing and distribution of medical devices. Such standards are aimed at ensuring that customers receive products that meet both regulations and safety expectations (Cheng, 2003; Mitra, 2016). For example, compliance with the ISO 13485 quality management system, which prioritises risk reduction and safety, is a requirement for producing medical devices with a risk classification above Class I (Brown et al., 2008; Mitra, 2016). ISO 9001 specifies a quality management system for consistent provision of products and services that meet

customer and regulatory requirements (Schlickman, 2003). Donors and purchasing organisations, such as the United Nations and the Global Fund, commonly require medical devices to be manufactured at a site compliant with ISO 13485 or ISO 9001 (UNFPA, 2015). With the procurement of medical devices being driven by conformity to regulations, manufacturers who are in possession of ISO 13485 and/or ISO 9001 have an edge in the market over those who do not (Cheng, 2003; Hoyle, 2017).

Regulation of medical devices in Africa

In Kenya, the regulation of medical devices is the responsibility of the Pharmacy and Poisons Board which is a regulatory authority established under the Pharmacy and Poisons Act, Chapter 244 (WHO, 2017). Its core mandate is to regulate the practice of pharmacy and the trade in drugs, poisons, medical products and health technologies (Rugera et al., 2014; WHO, 2017). All imported medical devices are subject to pre-export verification of conformity to standards through a programme implemented by the Kenya Bureau of Standards (KEBS, 2017). It is mandatory for importers of medical devices in Kenya to obtain certificates of conformity for their cargo prior to applying for import permits from the Pharmacy and Poisons Board through the Kenya National Single Window Electronic System (Technofreight, 2017). The regulation of imports in Kenya is important as the country relies heavily on products brought from other countries (Lilech, 2014).

In Nigeria, the regulation of medical devices is the responsibility of the National Agency for Food and Drug Administration and Control under the provisions of Act CAP F33 LFN 2004 and the accompanying guidelines (NAFDAC, 2005). According to NAFDAC, medical devices must be registered first before they are manufactured, imported, exported, advertised, sold or distributed in Nigeria (WHO, 2017). The regulations are aimed at controlling unscrupulous entry of imported products into the country. Foreign manufacturers are required to provide evidence that they are licensed to manufacture medical devices for sale in the country of origin and that the imported medical devices do not contravene the laws of the country of origin (NAFDAC, 2005). With regard to the import of a new medical device, evidence is needed to the effect that the product is registered in the exporting country and the ingredients are approved. To facilitate monitoring and evaluation of the medical devices that are imported to Nigeria, the regulations require representation of foreign manufacturers by a duly registered company or individual with facilities to effect recall of imported products when necessary (Erhun, Babalola & Erhun, 2001). In addition, a trademark registration is a required before a medical device is licensed.

With regard to Egypt, the registration and approval of medical devices require compliance with the Central Administration of Pharmaceutical Affairs, a division of the Egyptian Ministry of Health that oversees the country's medical device market (Gad et al., 2016). A specialised committee for the study of manufactured and imported medical

devices and equipment has the mandate of controlling the registration process. The committee is made up of experts with a medical background from different specialities such as ophthalmology, orthopaedics, surgery, cardiology, pharmacy and biomedical engineering (US. Department of Commerce, 2006). The key task of the committee is to review and approve applications for the manufacture and/or importation of medical devices. Evaluation of applications includes particular attention to the intended use of the medical device and establishing whether there is a real need and benefit for patients (Gad et al., 2016). The Medical Device Safety Department within the Central Administration of Pharmaceutical Affairs is a separate entity tasked with regulating the medical device market in Egypt (WHO, 2017). The importation of used and refurbished medical devices is banned in Egypt and an importer is required to present an original certificate from the manufacturer indicating the production year of the equipment and that it is new and safe (US. Department of Commerce, 2006). Although medical device market access in Egypt is uncomplicated if there is proof of authorisation to sell a product in a reference country, the system has shortfalls in terms of ensuring patient safety and enabling fast access to innovations; for example, the interim nature of medical device legislation, lack of transparency, and poor management of electronic databases, combined with pervasive corruption, present formidable barriers in the regulation of medical devices in Egypt (Gad et al., 2016).

In Sudan, the regulation of medical devices is undertaken by the National Medicines and Poisons Board (WHO, 2017). This regulatory body is responsible for the implementation of medical device regulations in collaboration with the Department of National Health Technology Management and Assessment (FMoH, 2011; Omer, 2016). Medical devices are regulated under the Pharmacy, Poisons, Cosmetic and Medical Devices Act 2001, which controls the sale, distribution and supply of medical devices (Ali & Omer, 2012). The regulation of medical devices stretches from pre-market approval to post-market surveillance. The regulation of medical devices in Sudan is similar to that for medicines, food, and other medical products (Omer, 2016). The regulation makes provisions for donated medical devices which are issued a temporary import license and are required to meet general criteria covering equipment quality, safety, compliance with specifications and standards, non-obsolescence, and appropriateness of the medical device for the user environment (FMoH, 2011). There is emphasis on safeguarding quality with respect to donations, and when the quality is unacceptable in the donor country, the device is also considered inappropriate as a donation.

The importation and registration of medical devices in Morocco is the responsibility of the Moroccan Ministry of Health through the Medical Devices Advisory Committee (Samadi, 2015). Medical devices other than radiation equipment require approval from the Ministry of Health showing compliance with Moroccan health standards. The country recognises certifications provided by the FDA. About 20 percent of imported medical equipment in Morocco is used or reconditioned. Importers of used medical devices are required to provide Moroccan buyers with FDA authorisation, technical documentation

and directions for use of the product, electro-technical and radiation safety certification, and documentation on previous maintenance (Harper, 2003). Prior to 2015, registration was compulsory for all second-hand medical equipment within 12 months of purchase. There is a new law under consideration which calls for banning the purchase of used medical devices and equipment in the country (Berrami, 2016). The regulations for medical devices lack a risk-based classification (MD24, 2015). Instead, they are classified by function according to the duration of use, degree of invasiveness, means of use (surgical or not), activity, and use on the body (WHO, 2014).

Angola has developed regulations for medicines and other pharmaceutical products which apply across the public and private sector, but the country does not have a comprehensive regulatory system that is specific to medical devices (Thumm et al., 2013). Medical devices are regulated by the National Pharmaceutical Policy of 2010, which stipulates the registration, roles and responsibilities of different actors and requirements for quality assurance (Thumm et al., 2013). The National Directorate for Pharmaceuticals and Equipment, which falls under the Ministry of Health in Angola, is the regulatory body that sets the criteria for the entry of pharmaceuticals and medical equipment in the country (Nogueira, 2017). The Health Inspection Office of the Ministry of Health ensures that the medical devices imported into the country meet required norms and standards.

Medical devices in Algeria are regulated by the Directorate of Pharmacy in collaboration with the National Laboratory for the Control of Pharmaceutical Products, which falls under the supervision of the Ministry of Health and Population (Samadi, 2015). The classification system of medical devices is similar to the EU system (Classes I, IIa, IIb and III). It is a requirement that medical devices be registered and manufacturers with no local presence are required to appoint a local authorised representative responsible for the registration process and submission of the documentation to the Directorate of Pharmacy (THEMA-MED, 2015). Medical devices require approval before being placed on the market and imports must meet conformity requirements (WHO, 2017).

In Tanzania, the Food and Drugs Authority regulates the quality, safety and performance of medical device (Lissel et al., 2016). The regulatory provisions for medical devices in Tanzania are stipulated in the Food, Drugs and Cosmetics (Control of Medical Devices) Act of 2015 which controls the registration of medical products. According to the Act, no person shall sell, manufacture, import or export, distribute, provide as a grant or gift or offer for sale any medical device unless it is registered by the authority (TFDA, 2016). Medical devices in Tanzania are classified into class A, B, C and D depending on the level of risk, which is in line with the principles of medical device classification as stipulated by the Global Harmonisation Task Force on medical devices (WHO, 2016a). The approval of a medical device for registration is on condition that its availability is in the public interest, it is safe, efficacious and of acceptable quality, and its manufacturing premises and operations comply with good manufacturing practices (Ndamugoba, 2017).

Medical devices in Ethiopia are regulated by the Food, Medicine and Healthcare Administration and Control Authority of Ethiopia (Gebreab & Wolyei, 2014). Medical devices are classified based on risk to the human body. An agency agreement is required between the manufacturer of a medical device for registration and the agent responsible for the import, distribution, and sale of the product in Ethiopia (FMHACA, 2014). The authorisation process for medical devices in Ethiopia includes inspection of the manufacturing premises, assessment for good manufacturing practice compliance, and conducting laboratory testing where applicable (Suleman et al., 2016). A manufacturer of medical devices in Ethiopia is required to attest that the product complies fully with all applicable essential principles for safety and performance (FMHACA, 2014).

In South Africa, medical devices are regulated by the newly enacted Medicines and Related Substances Amendment Act, 14 of 2015 (Kirby, 2017). The Act provides for the establishment of the South African Health Products Regulatory Authority, a body in charge of regulatory oversight for medicines, medical devices, complementary medicines, foodstuffs, cosmetics, and related substances (Gray & Vawda, 2016). The regulation of medical devices is based on a four-tier, risk-based classification system for obtaining device licences for manufacturers, importers and distributors. The distribution of medical devices and in vitro diagnostic devices (IVDs) in South Africa is subject to regulations depending on the level of risk and the intended use (Eisenhart, 2016). Only registered products are sold in South Africa as the regulation does not allow a manufacturer, wholesaler or distributor of medical or IVD devices to manufacture, act as a wholesaler of, or distribute, any medical device or IVD without a valid licence (Khan, 2017).

Implications for the development of the medical device industry in Africa

The establishment of medical device regulations is an important step towards better health for a country's population. The question then becomes how the regulations are formulated and implemented to support the local medical device industry. An overview of the regulation of medical devices in the ten countries discussed in this chapter reveals some interesting insights which may influence the development of African medical device industries.

The regulations described this chapter have a strong focus on imports. This is not surprising given heavy reliance on medical devices from developed countries. For example, South Africa, Nigeria and Egypt, which are considered to be the largest markets and economies in Africa, continue to be dominated by the supply of orthopaedics, prosthetics, patient aids and consumables from the USA (Nagel, 2017). Few local companies manufacture products for the domestic and export markets. The regulatory approval process for medical devices in Africa is lengthy, not transparent and skewed

towards controlling of entry into the market of substandard imports which are a risk to health (McNerney & Peeling, 2015).

None of the ten African countries discussed have specific regulations or regulatory bodies dedicated to medical devices. Instead, the regulations are presented broadly to cover medicines, foodstuffs, cosmetics, and related substances. Although established regulatory frameworks such as that of the FDA are broad in their approach to regulation, encompassing many types of product, they however have divisions and trained personnel for the regulation of medical devices specifically. This is not the case with the African countries reviewed, as they likely lack the resources and a critical mass of skilled personnel to focus solely on the regulation of medical devices. Under such conditions, the regulatory bodies may fail to cope with registrations of medical devices, which would result in delays and ultimately lack of access to medical devices by the public.

Medical device regulations in Africa are designed along the framework of models used in developed countries. For example, the requirements for importation and exportation of medical devices in South Africa, Algeria, Kenya and Ethiopia are similar to the internationally recognised certification/registration programmes of the European CE Mark, the US FDA and the Australian Hybrid Therapeutic Goods Administration. This is important in that it aligns African countries with a harmonised framework for medical device regulation. The World Health Organisation encourages the harmonisation of medical device regulation, towards standardisation to promote uniformity between national medical device bodies. In an era of globalisation, this facilitates cooperation among regulators and the industry, particularly with regard to audits, submission requirements, use of international standards, and exchange of safety information, and leverages experience gained over time.

Beyond regulations, much could be done to promote the development of medical device industries in African countries. An example is preferential procurement of domestically manufactured medical devices, as part of wider industrial policy (Deloitte & Touche, 2014). This would involve allocating some government spending to domestic manufacturers to increase demand for home-grown products and enhance the level of local content on the market. Furthermore, measures can be put in place to enhance the technology and production capacity of the local industry. In Ethiopia, Ghana, Kenya and Tanzania, a World Health Organization framework for local production and access to essential medical products is being implemented to stimulate innovation and provide appropriate technical assistance, towards establishing a viable and competitive domestic medical device industry (WHO, 2016b). Thus African governments can play a leading role in encouraging the development of their domestic medical device industries, not only by establishing medical device regulations and providing adequate resources for their implementation, but also through broader policy considerations.

References

- Ali, G.K. & Omer, A.M. 2012. Pharmaceuticals in Sudan: development in regulations, governance and implementation of national drug policies. *African Journal of Pharmacy and Pharmacology*. 6(1):1–12.
- Altenstetter, C. 2012. Medical device regulation in the European Union, Japan and the United States. Commonalities, differences and challenges. *Innovation: The European Journal of Social Science Research*. 25(4):362–388.
- Berrami, H. 2016. *Healthcare resource guide: Morocco*. Available: https://2016.export.gov/industry/health/healthcareresourceguide/eg_main_092016.asp. [2019, May 20].
- Brown, A., Eatock, J., Dixon, D., Meenan, B.J. & Anderson, J. 2008. Quality and continuous improvement in medical device manufacturing. *The TQM Journal*. 20(6):541–555.
- Cheng, M. 2003. *Medical device regulations: global overview and guiding principles*. Available: <https://apps.who.int/iris/handle/10665/42744> [2019, May 14].
- Deloitte & Touche. 2014. *Research to guide the development of strategy for the medical devices sector of South Africa*. Available: <http://www.samed.org.za/DynamicData/LibraryDownloads/60.pdf> [2019, May 14].
- Eisenhart, S. 2016. *South African medical device regulatory system set for implementation*. Cape Town. Available: <https://www.emergogroup.com/blog/2016/08/south-african-medical-device-regulatory-system-set-implementation> [2019, May 14].
- Erhun, W., Babalola, O. & Erhun, M. 2001. Drug regulation and control in Nigeria: the challenge of counterfeit drugs. *Journal of Health & Population in Developing Countries*. 4(2):23–34.
- EU. 2017. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. *Official Journal of the European Union*. Available: <https://www.emergogroup.com/sites/default/files/europe-medical-devices-regulation.pdf> [2019, May 14].
- FMHACA. 2014. *Guideline for registration of medical devices*. Available: <http://apps.who.int/medicinedocs/documents/s23057en/s23057en.pdf>. [2019, May 20].
- FMoH. 2011. *Health technology management policy (medical devices)*. Available: [http://www.fmoh.gov.sd/Health-policy/Sudan HTA&M Policy_final.pdf](http://www.fmoh.gov.sd/Health-policy/Sudan%20HTA&M%20Policy_final.pdf) [2019, May 14].
- Gad, M., Kriza, C., Fidler, A. & Kolominsky-Rabas, P. 2016. Accessing the medical devices market in Egypt and Saudi Arabia: a systematic review of policies and regulations. *Expert Review of Medical Devices*. 13(7):683–696.
- Gebreab, S. & Wolyei, A.R. 2014. *Regulatory overview: Ethiopia*. Available: www.idc-dx.org/download/file/470 [2019, May 14].
- GHTF. 2007. *Summary technical documentation for demonstrating conformity to the essential principles of safety and performance of medical devices (STED)*. SG1/N011R17. Global Harmonization Task Force.
- Gottlieb, S. 2011. *How the FDA could cost you your life*. Available: <https://www.wsj.com/articles/SB10001424052970204831304576597200095602270> [2019, May 14].
- Gray, A. & Vawda, Y. 2016. Health policy and legislation. *South African Health Review*. 2016(1): 3–15.

- Greenspan, D.C. 2013. Regulation of medical devices: current status. In *An introduction to bioceramics*. L. L. Hench, Ed. [Singapore]: World Scientific. 549–560.
- Harper, S.R. 2003. *Global import regulations for pre-owned (used and refurbished) medical devices*. Washington, DC.: Office of Microelectronics, Medical Equipment, and Instrumentation, International Trade Administration/Trade Development, US Department of Commerce.
- Hoyle, D. 2017. *ISO 9000 Quality systems handbook – updated for the ISO 9001: 2015 standard: increasing the quality of an organization’s outputs*. London: Routledge.
- KEBS. 2017. *To all importers of medical devices, food supplements, medical cosmetics, herbal products and other allied healthcare borderline products* [Press release]. Available: <http://www.tecnofreight.net/wp-content/uploads/2017/06/13025840R-Final-artwork-KEBS-PPB-Advert.pdf>. [2019, May 20].
- Khan, J. 2017. *Regulation of medical devices in South Africa*. Available: <https://www.linkedin.com/pulse/regulation-medical-devices-south-africa-jesca-khan> [2019, May 14].
- Kirby, N. 2017. *A new regulatory regime for medicines comes into force in SA*. Available: <https://www.timeslive.co.za/news/2017-06-15-a-new-regulatory-br-regime-for-medicines-br-comes-into-force-in-sa/> [2019, May 14].
- Kramer, D.B., Xu, S. & Kesselheim, A.S. 2012. Regulation of medical devices in the United States and European Union. *The New England Journal of Medicine*. 366 (9): 848–855.
- Lamph, S. 2012. Regulation of medical devices outside the European Union. *Journal of the Royal Society of Medicine*. 105(1_suppl):12–21.
- Lilech, H. 2014. *Healthcare resource guide: Kenya*. Available: <https://2016.export.gov/industry/health/healthcareresourceguide/kenya084198.asp> [2019, May 14].
- Lissel, A., Ottenberg, F., Bracio, B.R., Ravizza, A., De Maria, C., Ahluwalia, A., Di Pietro, L. & Trommler, P., 2016, August. Status and solutions to medical device regulations for improving the healthcare landscape in Africa. In *2016 38th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC)* 4329–4332.
- McAllister, P. & Jeswiet, J. 2003. Medical device regulation for manufacturers. *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine*. 217(6):459–467.
- McNerney, R. & Peeling, R.W. 2015. Regulatory in vitro diagnostics landscape in Africa: update on regional activities. *Clinical Infectious Diseases*. 61(suppl 3):S135–S140.
- MD24. 2015. *Registration of medical devices to the moroccan ministry of health*. Available: <http://www.sante.gov.ma/Pages/Accueil.aspx>. [2019, May 20].
- Mitra, A. 2016. *Fundamentals of quality control and improvement*. Portland, OR.: John Wiley & Sons.
- Moorthy, S. 2016. Medical devices manufacturers feel let down by budget. *The Hindu*. Available: <http://www.thehindubusinessline.com/economy/medical-devices-manufacturers-feel-let-down-by-budget/article8305435.ece> [2019, May 14].
- NAFDAC. 2005. *Guidelines for registration of imported drug products in Nigeria* NAFDAC/RR/002/00. Available: <http://digicollection.org/hss/documents/s17115e/s17115e.pdf> [2019, May 14].
- Nagel, F. 2017. *South Africa – medical devices*. Available: <https://www.export.gov/article?id=South-Africa-medical-devices> [2019, May 14].

- Ndamugoba, S. 2017. *Importation of medical drugs and medical devices to Tanzania*. Available: <https://www.abcattorneys.co.tz/importation-medical-drugs-medical-devices-tanzania/> [2019, May 14].
- Nogueira, C. 2017. *Angola – healthcare*. Available: [https://www.export.gov/apex/article2?id=Angola Healthcare](https://www.export.gov/apex/article2?id=Angola+Healthcare). [2019, May 20].
- Omer, A.M. 2016. Evaluation of national drug policy in Sudan: regulatory privatisation, social welfare services and its alternatives. *Pharmaceutical and Biological Evaluations*. 2(6):271–283.
- Rugera, S.P., Mc Nerney, R., Poon, A.K., Akimana, G., Mariki, R.F., Kajumbula, H., Kamau, E., Mpawenimana, S. et al. 2014. Regulation of medical diagnostics and medical devices in the East African community partner states. *BMC Health Services Research*. 14(1):524.
- Samadi, F. 2015. *Regulatory requirements of medical devices in MENA countries*. Available: https://dgra.de/media/pdf/studium/masterthesis/master_samadi_f.pdf [2019, May 14].
- Schlickman, J.J. 2003. *ISO 9001: 2000 quality management system design*. London: Artech House.
- Sorenson, C. & Drummond, M. 2014. Improving medical device regulation: the United States and Europe in perspective. *The Milbank Quarterly*. 92(1):114–150.
- Suleman, S., Woliyi, A., Woldemichael, K., Tushune, K., Duchateau, L., Degroote, A., Vancauwenberghe, R., Bracke, N. et al. 2016. Pharmaceutical regulatory framework in Ethiopia: a critical evaluation of its legal basis and implementation. *Ethiopian Journal of Health Sciences*. 26(3):259–276.
- Tamura, A. & Kutsumi, H. 2014. Multiregional medical device development: regulatory perspective. *Clinical Journal of Gastroenterology*. 7(2):108–116.
- Technofreight. 2017. *Kenya: new regulation on import of medical devices and other products*. Available: <http://www.tecnofreight.net/en/kenya-new-regulation-import-of-medical-devices/> [2019, May 14].
- TFDA. 2016. *The Tanzania Food, Drugs and Cosmetics Regulations, 2015*. Dar Es Salaam: Government of Tanzania. Available: [https://www.tfda.go.tz/index/sites/default/files/GN_315 REGULATIONS.pdf](https://www.tfda.go.tz/index/sites/default/files/GN_315_REGULATIONS.pdf) [2019, May 14].
- THEMA-MED. 2015. *Medical device registration in Algeria*. Available: <http://www.thema-med.com/en/medical-device-registration-algeria/> [2019, May 14].
- Thumm, M., Gaparayi, P., Goredema, W. & Tjipura, D. 2013. *Assessment of the medicines regulatory system in Angola: report. submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program*. Available: <http://apps.who.int/medicinedocs/en/d/Js21700en/> [2019, May 14].
- UNFPA. 2015. *Policy and procedures for regular procurement*. Available: [https://www.unfpa.org/sites/default/files/resource-pdf/Policy and Procedures for Regular Procurement Rev_4 April 2015.pdf](https://www.unfpa.org/sites/default/files/resource-pdf/Policy+and+Procedures+for+Regular+Procurement+Rev_4+April+2015.pdf) [2019, May 14].
- US. Department of Commerce. 2006. *Medical device regulatory requirements for Egypt*. Available: [https://www.trade.gov/td/health/Egypt Medical Devices Regulatory Profile 2007.pdf](https://www.trade.gov/td/health/Egypt+Medical+Devices+Regulatory+Profile+2007.pdf) [2019, May 14].
- WHO. 2011. *First WHO global forum on medical devices: context, outcomes, and future actions*. Available: <https://apps.who.int/iris/handle/10665/70668> [2019, May 14].
- WHO. 2014. *Medical devices regulatory systems at country level: Morocco*. Available: http://www.who.int/medical_devices/countries/mar.pdf. [2019, May 14].
- WHO. 2016a. *Medical devices regulatory systems at country level – Tanzania*. Available: http://www.who.int/medical_devices/countries/regulations/tza.pdf [2019, May 14].

- WHO. 2016b. *Promoting and supporting local manufacturing of quality medical products in developing countries*. Available:
http://www.who.int/phi/publications/1651_phi_brochure_130515.pdf [2019, May 14].
- WHO. 2017. *Global atlas of medical devices: WHO medical devices technical series*. Available:
http://www.who.int/medical_devices/publications/global_atlas_meddev2017/en/ [2019, May 14].
- World Bank. 2017. *Economy and growth: world development indicators*. Available:
<https://data.worldbank.org/data-catalog/GDP-ranking-table> [2019, May 14].