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QUALIFICATION WORK

on the topic: **«INVESTIGATION OF PECULIARITIES OF THE MEDICAL PRODUCTS MARKET DEVELOPMENT IN AFRICAN COUNTRIES IN THE CONDITIONS OF GLOBALIZATION»**

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ANNOTATION

In the qualifying work, an analysis of the features of the development of the medical goods market in African countries was carried out, as well as prospects were analyzed, the main trends in its development were predicted, taking into account national and historical characteristics, recommendations were made regarding the strategic priorities of its further development and effective cooperation in the context of globalization.

The work is presented on 49 pages of printed text and consists of an introduction, three sections, general conclusions, a list of references and appendices. The work is illustrated with 19 figures, and contains 35 sources of scientific literature.

Key words: medical products, medical products market, government regulation, scientific and technical developments, healthcare, African countries.

АНОТАЦІЯ

У кваліфікаційній роботі проведено аналіз особливостей розвитку ринку медичних товарів у країнах Африки, а також проаналізовано перспективи, спрогнозовано основні тенденції у його розвитку з урахуванням національних та історичних особливостей, надано рекомендації щодо стратегічних пріоритетів його подальшого розвитку та ефективної співпраці в умовах глобалізації.

Робота викладена на 49 сторінках друкованого тексту і складається зі вступу, трьох розділів, загальних висновків, списку використаної літератури та додатків. Робота ілюстрована 19 малюнками, містить 35 джерел наукової літератури.

Ключові слова: медичні товари, ринок медичних товарів, державне регулювання, науково-технічні розробки, сфера охорони здоров'я, країни Африки.

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LIST OF ACRONYMS

4IR - 4th Industrial Revolution

AI - Artificial Intelligence

WHO - World Health Organisation

NAFDAC - National Agency for Food and Drug Administration and Control

SA - South Africa

PLM - Product Life-Cycle Management

SAHPRA - South African Health Products Regulatory Authority

SAMED - South African Medical Technology Industry Association

SAMRC - South African Medical Research Council

TIS - Technology Innovation System

MD - Medical Device

MDC - Medical Device Company

MDM - Medical Device Manufacturer

MPM - medical productsmarket

INTRODUCTION

Actuality. 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, specialized hospitals.

The African medical device industry was a previously unregulated industry, unlike most other medical device industries around the world. Africa does not have a comprehensive system of medical device regulation similar to US FDA or European requirements. This lack of regulation and quality control measures contributes to the fact that imported products constitute an unprecedented 95% of all medical devices. To understand why local medical device manufacturers are not starting up in the African industry, the trends in challenges and experiences faced by local medical device manufacturers, and the opinions of key African manufacturers, required investigation. Although the medical device industry is global, many restricting factors were attributed specifically to African regulations and the South African market environment.

Purpose: to analyze the dynamics, structure and trends in the market of medical products in African countries, to analyze the strengths and weaknesses in order to develop strategic directions for its development and improve the efficiency of the healthcare sector.

According to the purpose of the qualification work, the following ***tasks*** are established:

- to characterize the features of the medical goods market, its development trends in the world and in African countries;

- to analyze the historical peculiarities of the medical goods market development, its structure in African countries;

- to consider economic and legal mechanisms for regulating the market of medical goods in African countries and their features;

-on the basis of SWOT analysis, identify strengths and weaknesses, as well as determine strategic prospects in the development of the medical goods market;

- determine development prospects and predict changes in its structure and capacity;

-recommendations for medical goods market development, including research and development management, financing and industry support from the public and private sectors.

The object of the study is the market of medical products in African countries.

Subject of research: countries of the African region, indicators of population health and well-being, socio-economic indicators of African countries, their relationship with indicators of health, provision of medical goods and services.

In the course of the study, the following ***methods*** were used during the qualification work: content analysis, historical, logical, correlation-regression analysis, statistical, graphic.

Approbation of the results of the study and publication: according to the research, a scientific article was published in the collection «The XIV International Scientific and Practical Conference «Prospects for the development of science and the environment», April 10 – 12, Helsinki, Finland. 415 p.

The practical significance of the results obtained: the results of the analysis of the medical products market in African countries, their development opportunities and risks, taking into account the forecasting of its main trends, can become the basis for strategic decisions and the development of this area and the development of effective management decisions to improve the efficiency of the health care sector in the African region .

The structure and scope of the qualification work: introduction, experimental part, conclusion, list of references, Appendixes.

UNIT 1
MEDICAL GOODS MARKET: PECULIARITIES OF FORMATION IN AFRICAN COUNTRIES

1.1. Medical goods market: theoretical and methodological basis of study

The medical devices market includes general purpose products that can be used both by end-users (for example, for the diagnosis, prevention and treatment of any disease at home, as well as for patient care), and public and non-governmental medical institutions that acquire a large number of medical equipment, machinery and various consumables for their activities. Retail trade can be carried out, for example, by individual entrepreneurs who have a license for this type of activity, various medical organizations and their divisions (general medical practice centers, pharmacies, etc.).

The market for medical devices is quite complex in its structure and has characteristic features that should be taken into account when analyzing future prospects. Medical Device Market иу Application Surgical and Infection Control Devices:

- General Medical Devices;
- Cardiovascular Devices;
- Orthopedic Devices;
- Home Healthcare Devices;
- Other Devices.

Medical Device Market By Function Diagnostic and Monitoring:

- Therapeutic;
- Surgical;
- Other Devices.

Medical Device Market By End Use:

- Homecare Medical Devices;
- Hospital and Ambulatory Care Medical Devices.

The segmentation of the medical devices market is as follows:

– ophthalmology and lenses;
– orthopedics;
– gynecology, neonatology and perinatology;
– urology;
– equipment for cardiovascular surgery;
– surgery;
– implants;
– cosmetology and plastic surgery;
– IVL, anesthesia, anesthesia equipment;
– endoscopes;
– functional diagnostics and monitoring;
– laboratory diagnostics (in vitro);
– diagnostic equipment and products with a high degree of visualization;
– general therapy and physiotherapy;
– efferent therapy;
– remote monitoring and warning devices;
– general clinical equipment;
– sterilization and disinfection;
– mobile medical complexes;
– blood service;
– rehabilitation and facilities for the disabled;
– medical devices for self-use by patients and self-testing;
– traumatology;
– dentistry;
– otorhinolaryngology;
– Emergency Medicine;
– oncology, etc.

The global market for general medical products demonstrates high growth rates and today is over $400 billion. According to the estimates of analysts from the consulting company Evaluate, the volume of this market will reach $522 billion by 2022, while the growth rate will gradually increase and by 2022 it will already be 5.1% [1]. According to experts' forecasts, the same positive dynamics will be observed in the next three years, subject to the dynamic development of high technologies in the field of medicine [1]. Such indicators allow us to conclude that the market for general medical goods is developing steadily and is quite promising (Fig. 1.1).

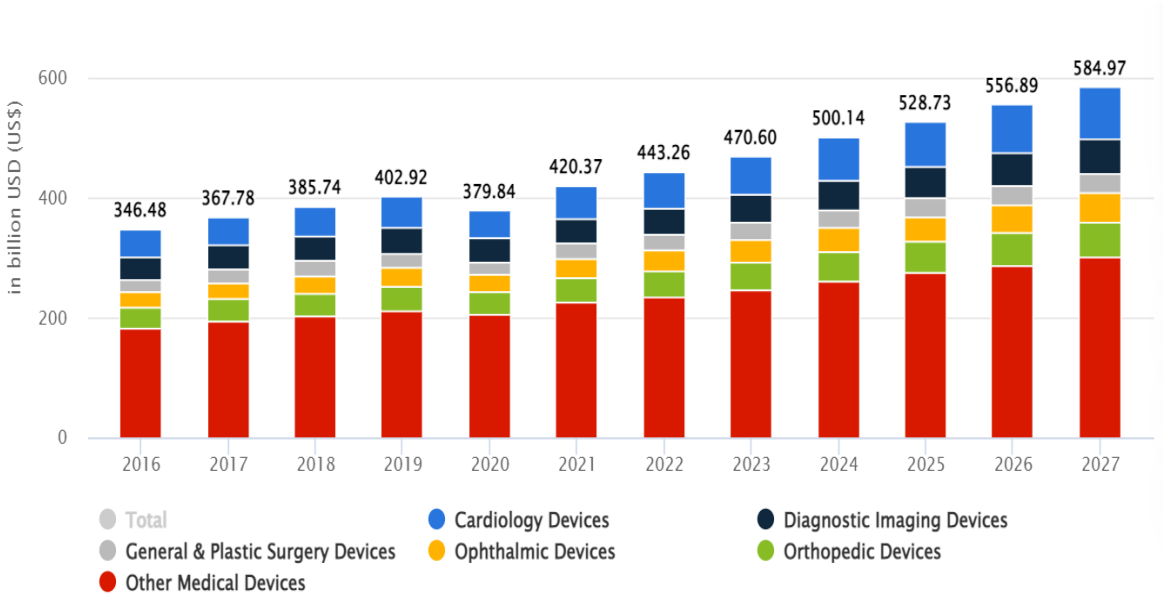

Fig.1.1. Forecast for the development of individual segments of the global market for medical products

1.2. Making Medicines in Africa: historical political Economy overview and modern trends

The South African medical device industry was a previously unregulated industry, unlike most other medical device industries around the world. Features of the MPM in African countries, taking into account the historical features of their

development and integration into the global economic community, are given in Appendix A.

The Medicines and Related Substances Amendment Act 14 of 2015 brought significant changes to the existing regulatory atmosphere in South Africa [16], and creating a new regulatory authority, the South African Health Products Regulatory Authority (SAHPRA). Previously, only electronic medical devices were governed by Medicines Control Council regulations [16]. The fundamental changes brought about by the amendment include the introduction of a new regulatory body, tier-based licensing and registration, and sales and distribution regulations.

The medical devices landscape survey indicated that South Africa has at least 136 medical device manufacturing companies with substantial diversity in terms of size, turnover, products produced and levels of R&D expenditure. The sector is concentrated in three provinces, with most medical device manufacturers being located in Gauteng (60), followed by the Western Cape (WC) (47) and KwaZulu Natal (KZN) (26). The average age of companies that responded to the survey was 20 years, with more than half of the companies older than 20 years.

Most companies that responded to part A of the survey (73%) are classified as small, employing 50 or less permanent staff, with around one third employing 10 permanent staff or less. Most medical device companies fall within the micro (<R10 million) and small (R10-R50 million) enterprise categories in terms of turnover. Only a small percentage (24%) qualify as medium to large enterprises (>R50 million turnover). Around 62% of respondents reported having a BBBEE level of 1-4, while 28% are deemed non-compliant or exempt due to having a turnover of less than R10 million.

The African medical device manufacturing industry is active across a range of fields and device classes. Over half (53%) of MDM respondents operate in the consumables field, followed by orthopedics (27%), other (21%) and hospital furniture (14%). The industry produces and sells a variety of consumable medical device products ranging from medical devices for wound care to diagnostic test kits. More than two thirds (43) of companies that operate in the consumables field sell mostly Class A and/or Class B consumables.

The domestic private sector is the most important market for the companies surveyed, with a quarter of the companies (16) indicating that 75-100% of their revenue is earned from this sector. This is followed by the domestic public sector for which eight (12%) companies indicated that 75-100% of their revenue is attributable to this sector. Slightly more than two thirds (69%) of the respondent companies derive less than 25% of their revenue from exports and fifteen companies focused exclusively on the South African market [20].

Africa, Europe, the Middle East and North America are the most important export markets amongst the respondents. China and India were consistently rated the lowest priority amongst manufacturers. These countries are likely seen as competition rather than markets for South African products. They are also countries where local manufacture of medical devices is prioritized. More than two thirds (68%) of the surveyed companies indicated that they were export ready. Only 10% indicated that they required assistance to become export ready.

Most companies have in-house design (80%), manufacture (82%) and packaging (77%) capabilities. Sterilization is the most frequently outsourced activity, with 25 (38%) companies outsourcing this function. Component assembly was the most frequently cited facility capability, with 58% of the companies indicating this capability. This was followed by mechanical turning (45%), OEM manufacture (41%) and material or component testing (41). The highest number of capabilities related to machining and the lowest to chemicals. In terms of manufacturing, metals and plastics were the materials most frequently used, followed by chemicals and liquids. Forty-four percent of MDM respondents had access to cleanroom facilities, 47% did not and 9% did not comment on this aspect. The following clusters of broadly similar companies can be identified:

- Young, high-tech companies developing and producing sophisticated medical devices for the domestic and export market in fields such as molecular diagnostics, orthopedic implants, diagnostic imaging and audiometers. Companies in this cluster spend a significant portion of their revenue on R&D and in some cases are only now making their first sales. Some of these companies are spin-outs

from STI institutions and many collaborate with local and international STI institutions.

- Medium to large high-tech companies producing sophisticated medical device capital equipment and implants for the domestic and export market. Companies in this cluster also tend to continue to invest in R&D.

- Large commodity producers producing large volumes of commodity products (A and B class)consumables for the domestic market with some exports to neighboring countries. Companies in this cluster do not invest significantly in R&D.

- Small commodity producers producing smaller volumes of specific lower technology products mainly for the local market. Companies in this cluster do not invest significantly in R&D.

A range of companies provide support services to the industry, including technical services, quality improvement and regulatory compliance. The list of support organizations surveyed was not comprehensive and did not include the regulatory consultants. The three public institutions included focus on funding of innovation and commercialization activities.

The medical devices innovation and manufacturing sector has:

- sophisticated processes, tooling, expertise and competent role-players whose needs for optimal value addition are seldom met;

- activities in each of the major product life-cycle stages from basic and applied research through to experimental and product development, manufacture and scale-up, although these are currently not well aligned;

- necessary role-players (idea creators, innovators, pre-clinical and clinical scientists, research engineers, established MDMs, STI institutions, support companies, distributors) required to enable end-to-end MD solutions through the product life-cycle but these are not suitably networked for collaboration and optimal outcomes;

- access to digital collaboration technologies such as Product Life-Cycle Management (PLM) software although these are not optimally used with no common “lingua franca”; andaccess to funding, especially early-stage funding, for

the product life cycle, although only a small fraction of these investments is converted into sustainable products at huge loss to the country.

Consider the features of the supply on the market of medical products in African countries (Appendix B). Manufacturing Africa has limited production capacity for medical devices. The market is therefore largely dependent on import. Fewer than 5% of local industry players manufacture devices, with more than 76% of devices being imported. In terms of market value, 90% is supplied by imports [16]. Africa's manufacturing output of medical devices is estimated to be about US$200 million to US$300 million, of which more than half is exported. Manufacture grew by 9,1% to US211 $million from 2019 to 2022, to account for about 13,5% of the total value. Local manufacture was expected to grow by 8% to US$227.8 million in 2022. Figure 1.2 illustrates trends in domestic manufacture of medical devices which is dominated by products in the other medical devices, consumables and diagnostic imaging product areas[30].

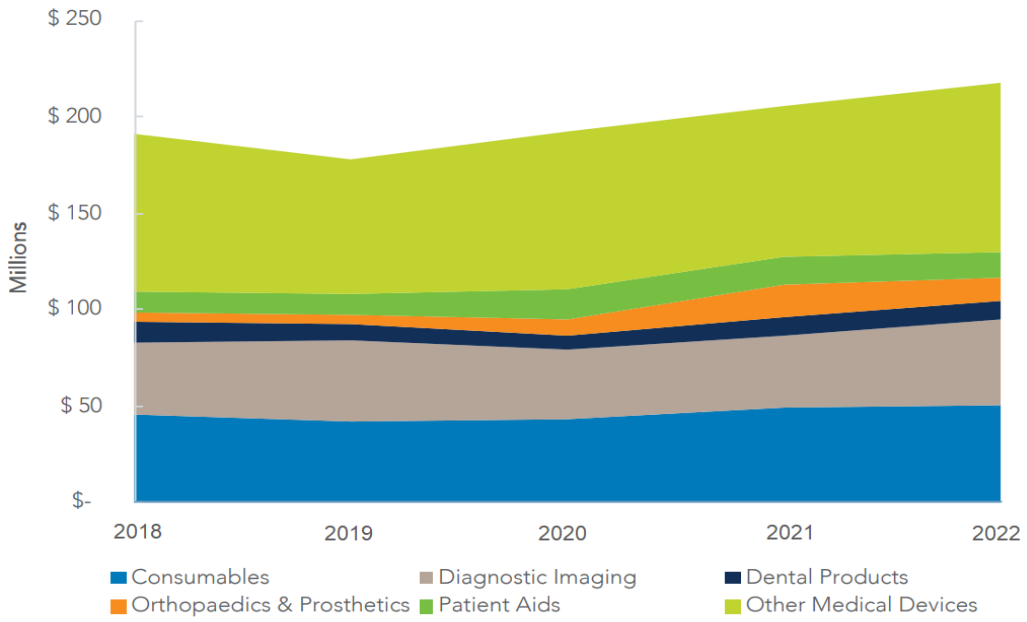

Fig. 1.2. Trends in domestic manufacture of medical devices

South Africa has a large number of industry players with between 350 and 600 suppliers, ranging from companies listed on the JSE to opportunistic agency

traders. The substantial number of suppliers is associated with a high degree of fragmentation, competition and instability. Suppliers range from large multinational subsidiaries, distributors and agents for disposable medical devices to major equipment manufacturers. More than 80% of the industry consists of privately-owned small and medium-sized enterprises (SMMEs) with less than 50 employees who often combine distribution activities with manufacturing. Multinational companies frequently operate in joint ventures with local firms. Most SA manufacturers focus on producing basic medical equipment and supplies[32].

Local manufacturing is focused on the production of low-tech and low-value devices such as surgical goods and disposable needles. There are however several examples of locally developed hi-tech devices including the design and manufacture of advanced breast imaging technology and the development and manufacturer of low radiation full body X-ray machines that are used internationally. According to Who Owns Whom, local manufacturers tend to focus on the export market where SA manufactured devices are well accepted based on high quality and competitive prices.

On average, Africa's sourcing of medical supplies is as concentrated as global sourcing. For certain items, however, Africa finds it harder than other markets to diversify its suppliers. This is true for products above the diagonal 45°- line in Figure 1.3.

The figure suggests that Africa diversifies its suppliers less than average for goods exported by a limited number of countries, such as scintigraphy apparatus, paper masks and garments or hair nets. On the contrary, when many suppliers offer a product, as is the case for stethoscopes or polymerase chain reaction test kits, known as PCR test kits, Africa diversifies its procurement relatively successfully.

In terms of import growth, Germany and China are two of the fastest growing sources of imports, as illustrated in Figure 1.4. Imports from the Netherlands have grown at a rate similar to that of Japan and France.

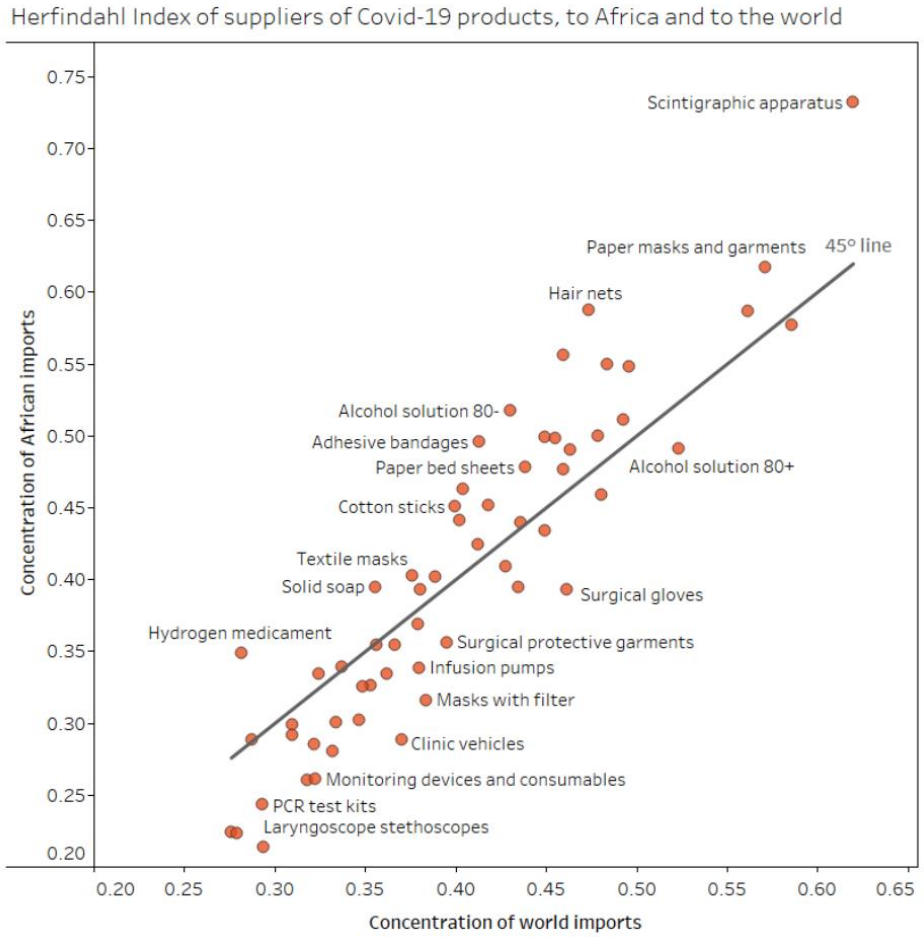

Fig. 1.3. Concentration of supply of African versus world imports, by product

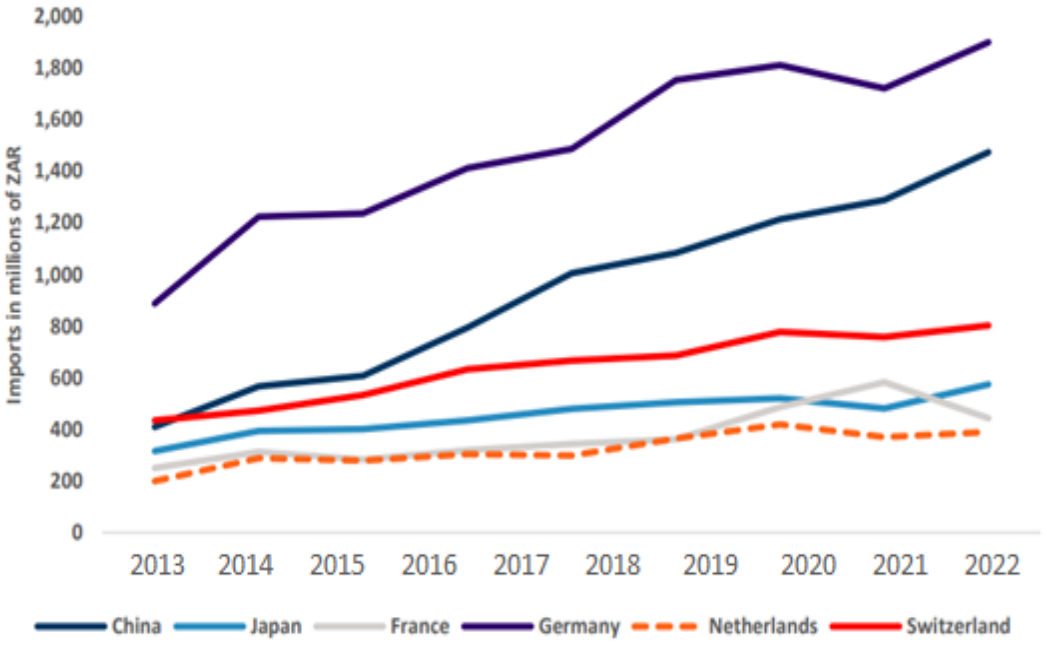

Fig. 1.4. Imports of Medical Technology and Devices 2013-2022

In South Africa, a broad range of health technologies are used, both in the private and public sector. Figure 1.4 below presents the breakdown of imports of medical technology between 2013 and 2022 by type: medical instruments and devices, electronic imaging devices, orthopedic appliances, therapy devices and microscopes.

Figure 1.5 illustrates medical devices exports structure from 2018 to 2022. African medical device exports are dominated by products in the "other" category (46% in 2022) followed by consumables (26% in 2022) and diagnostic imaging (23% in 2022).

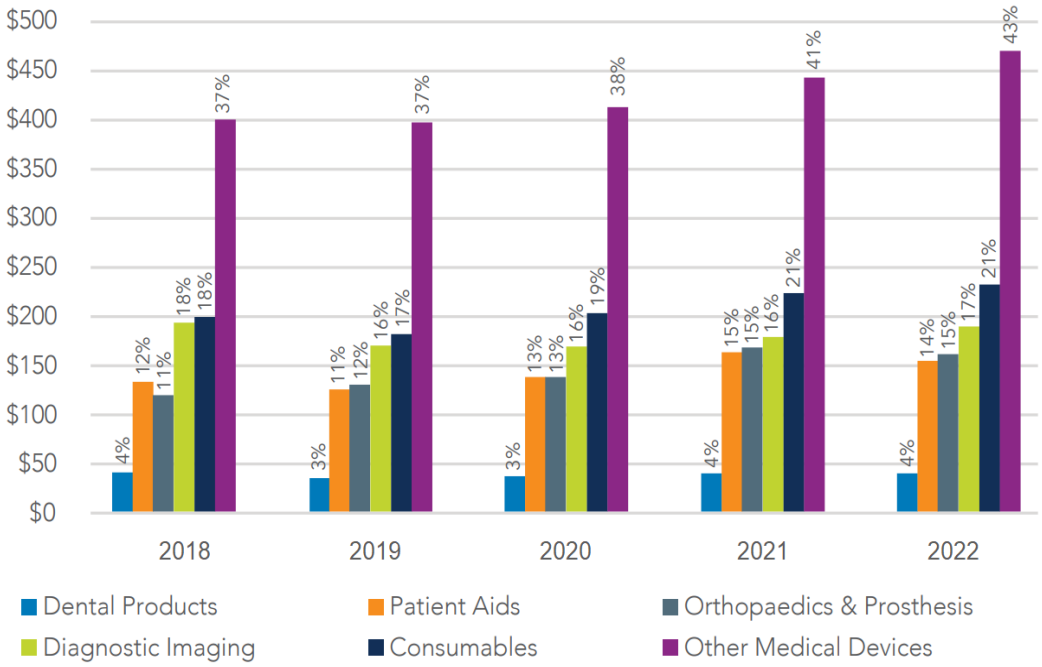

Fig. 1.5. Exports by product area in African countries (2018-2022)

Africa's manufacturing output of medical devices is small (US$ 200 million to US$ 300 million), of which more than half is exported. This output is dominated by low-tech and low-value devices in the other medical devices and consumables product areas, with some hi-tech products for diagnostic imaging.

Medical device R&D expenditure in South Africa is low as a percentage of turnover for the industry in relation to global standards; however, a range of incentives exist to address this and overall industry competitiveness.

The regulation of medical devices in South Africa is still in the process of introduction and significant regulatory hurdles in foreign jurisdictions affect the cost and complexity of compliance.

1.3. Investigation of the of Medical Devices marketregulation in different African countries

Globally, including in South Africa, medical devices have historically been under-regulated, with the sale and use of sub-standard and poorly tested medical devices impacting patients' health, quality of life or even mortality. Most of the reports reviewed were published before theestablishment of the South African Health Products Regulatory Authority (SAHPRA) in 2021. Deloitte reported that the "lack of regulations allow low-quality products to enter the SA market", "the SA medical technology industry is mainly unregulated, except for a few regulated medical technology product categories" [12].

The KPMG (2014) survey found that industry respondents strongly supported the implementation of quality regulation, although most opposed price regulation. Regulations that require role players to be licensed were expected to promote fair competition and contribute towards ensuring safe, high quality products for consumers[17].

New (at the time) Medicines Control Council (MCC) licensing requirements relating to the manufacture, import and distribution of medical devices were expected to "increase compliance for manufacturers of moderate to high-risk devices in line with the move to establish an internationally aligned regulatory system" [5].

Although regulation is mostly viewed in a positive light, lengthy registration processes could adversely affect the salability of medical devices with short life cycles. Although there have until recently been no legislative requirements for the regulation of medical devices in South Africa, electronic products (electromagnetic medical devices or radiation-emitting devices) were required to be registered

before being sold, leased, used, operated or applied in South Africa [8]. Other medical devices were unregulated, leaving advertisers and marketers few legislative formalities with which to comply. However, public procurement of devices generally included a requirement for a CE mark to ensure the requisite levels of safety and quality, again resulting in cost barriers for local companies.

Medicines and Related Substances Amendment Act 14 of 2015 brought about significant changes in the regulation of medical devices. Specifically, the act included the establishment of the South African Health Products Regulatory Authority (SAHPRA) in June 2017 to replace the MCC and provides for implementation of a dedicated regulatory framework for medical devices.

SAHPRA was legally established in February 2017 as a S-schedule 3A Public Entity in terms of the Public Finance Management Act (PFMA, Act 1 of 1999). As a Schedule 3A Public Entity, SAHPRA is a separate juristic person outside of the National Department of Health, mandated to regulate (monitor, evaluate, investigate, inspect and register) all health products. This includes clinical trials, complementary medicines, medical devices and in vitro diagnostics (IVDs). Furthermore, SAHPRA has the added responsibility of overseeing radiation control in South Africa.

SAHPRA's mandate is outlined in the Medicines and Related Substances Act (Act No 101 of 1965 as amended) as well as the Hazardous Substances Act (Act No 15 of 1973). The Medicines and Related Substances Amendment Act 14 (2015) introduced a four-tier, risk-based licensing and registration system, which applies to South Africa-based companies that manufacture, sell, import, export, distribute and wholesale medical devices in the country. The Act also regulates procedures for device registration and requirements relating to advertising and labelling, and the restriction of sampling for the sale of medical devices.SAHPRA is implementing the regulation of medical devices in a phased approach, starting with a call up notice, published in February 2017, requesting all manufacturers and distributors of medical devices to apply for a SAHPRA license within 6 months of publication and wholesalers within 12 months.

Companies that manufacture, pack, label, service, import and export medical devices were required to apply for a medical device establishment license as a manufacturer, those that import, export and distribute as a distributor, and those that are involved in storage, transportation and delivery as a wholesaler.

As part of the application for a SAHPRA medical device establishment license, a company must appoint an Authorized Representative based in South Africa who is responsible for adherence to the law, regulations and guidelines, and must list all the medical devices that it manufactures, distributes or wholesales. The application must also include a declaration on the quality management system in place in the company, which, upon renewal of the SAHPRA license, must include ISO 13485 certification (SAHPRA, 2021b).

ISO 13485:2016 is the latest standard from the International Organization for Standardization that sets out quality management system requirements, rules and guidelines for any company that designs, manufactures, installs, distributes or services medical devices.On 21 May 2021 the proposed “Regulations Relating to Medical Devices” were published in the Government Gazette for comments by interested persons (SAHPRA, 2021c).

The proposed regulations include provisions for the supply of medical devices, the registration of medical devices, licensing of establishments to manufacture, distribute or wholesale medical devices, management of medical devices and investigations, offences and penalties related to the regulations. In terms of registration of medical devices, the proposed regulations specify the classification of medical devices (according to risk), the labelling of medical devices, instructions for use of medical devices which are not in vitro diagnostic devices, instructions for IVDs, application for registration of a medical device, information that must appear in the register for medical devices, application for amendments to the register for medical devices and certificates of registration.

In Kenya, for example, 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. 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. The regulation of imports in Kenya is important as the country relies heavily on products brought from other countries [11].

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. 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. 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. A specialized committee for the study of manufactured and imported medicaldevices and equipment has the mandate of controlling the registration process. The committee is made up of experts with a medical

background from different specialties such as ophthalmology, orthopedics, surgery, cardiology, pharmacy and biomedical engineering. 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. 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 [12]. 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. Although medical device market access in Egypt is uncomplicated if there is proof of authorization 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 [12].

In Sudan, the regulation of medical devices is undertaken by the National Medicines and Poisons Board. This regularity body is responsible for the implementation of medical device regulations in collaboration with the Department of National Health Technology Management and Assessment. Medical devices are regulated under the Pharmacy, Poisons, Cosmetic and Medical Devices Act 2001, which controls the sale, distribution and supply of medical devices[14].

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. 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 [13]. 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 [15]. Medical devices other than radiation equipment require approval from the Ministry of Health showing compliance with Moroccan health standards. The country recognizes 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 authorization, technical documentationand directions for use of the product, electro-technical and radiation safety certification, and documentation on previous maintenance. 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. The regulations for medical devices lack a risk-based classification. 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 [35].

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. 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. 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. 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. The classification system of medical devices is similar to the EU system. It is a requirement that medical devices be registered and manufacturers with no local presence are required to appoint a local authorized 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. In Tanzania, the Food and Drugs Authority regulates the quality, safety and performance of medical device.

The regulatory provisions for medical devices in Tanzania are stipulated in the Food, Drugs and Cosmetics 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. 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 Harmonization Task Force on medical devices. 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.

Medical devices in Ethiopia are regulated by the Food, Medicine and Healthcare Administration and Control Authority of Ethiopia[10]. 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. The authorization process for medical devices in Ethiopia includes inspection of the manufacturing premises, assessment for good manufacturing practice compliance, and conducting laboratory testing where applicable [11]. 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.

In South Africa, medical devices are regulated by the newly enacted Medicines and Related Substances Amendment Act, 14 of 2015. 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 [12]. The regulation of medical devices is based on a four-tier, risk-based classification system for obtaining device licenses 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. Only registered products are sold in South Africa as the regulation does not allow a manufacturer, wholesaler or distributer of medical or IVD devices to manufacture, act as a wholesaler of, or distribute, any medical device or IVD without a valid license [17].

Conclusions to the Part 1

1. The medical devices market in South Africa is one of the largest in the Middle East and Africa region but makes up only 0,3% of the global market. The local industry is dominated by imports, comprising around 90% by value.

2. African countries are rarely among the major suppliers of medical products. For many African countries, tariffs are an important source of government revenue and may be justified to protect emerging industries. Yet, an immediate response to facilitate access to key health products requires open markets.

3. Medical devices facilitate the diagnosis and treatment of diseases to improve patients ‘health and quality of life.Due tothe nature of their use in the health sector, the manufacture and subsequent entry ofmedical devices into the market is held to a higher standard than for any other product.

4. Africa sources most of its medical supplies from a limited number of countries, some of which had restricted their exports to avoid shortages at home. Diversifying procurement may allow the continent to ensure access to these products and increase resilience to future crises.

5. Various countries across the world have established regulatory bodies that guide the medical device industry.In Africa, Angola, Cameroon, Chad, Democratic Republic of the Congo, Niger, Nigeria, Senegal, Togo, United Republic of Tanzania, Zambia and Zimbabwe lifted or reduced import tariffs on medical products.2 Other governments may have decided to follow suit to improve immediate access to essential life-saving goods.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.

PART 2
FEATURES AND TRENDS ANALYSIS OF THE MEDICAL GOODS MARKET DEVELOPMENTIN AFRICAN COUNTRIES

2.1 Analysis of Medical Goods market in Africa

Local manufacturers tend to focus on the export market, with South African manufactured devices valued for their high quality and competitive prices. Africa's top medical device export destinations for 2022. Most of the leading export markets are in Africa, in the Southern African Development Community (SADC) in particular, followed by Europe. It must be borne in mind that the available data does not provide information on value added to exports as it does not distinguish between products imported and re-exported and products manufactured in Africa. At least some exports are reexports of medical devices for which are used as a springboard in Africa (Fig. 2.1).

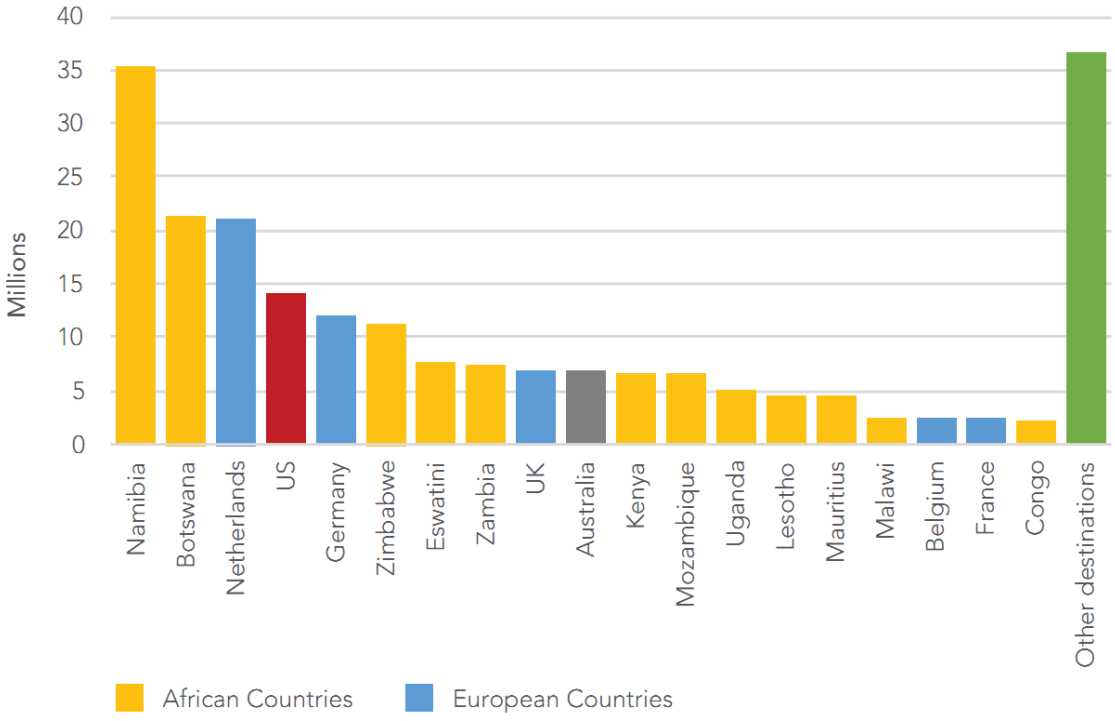

Fig. 2.1. South Africa's top medical device export destinations in 2022

Output by the domestic medical manufacturing industry is estimated to be in the region of USD 200mn-USD 300mn, of which more than half is exported. Production is focused on bandages & dressings, medical furniture and low technology items.

- Akacia Medical
- BeierDrawtex Healthcare
- CapeRay Medical
- CRPM
- Elite Surgical
- Evergreen Latex
- Glycar
- Lifeassay Diagnostics
- Litha Medical
- Lodox
- Medika
- Medi-Safe Surgicals
- Sinapi Biomedical
- Southern Group
- TiTa MED

The industry produces and sells a variety of consumable medical device products ranging from medical devices for wound care to diagnostic test kits. Products are listed in Appendix C.

The global coronavirus pandemic exposed deficiencies in existing global medical device manufacturing supply chains and distribution models, leading initially to shortages of testing reagents, diagnostic test kits, personal protective equipment, and respiratory devices such as non-invasive and invasive ventilators. On the other hand, the crisis revealed the potential of an emergent, collaborative model capable of developing and manufacturing products at short notice. It also saw a flood of new and reallocated funding directed towards expanding health services, product development and roll-out and emergency relief.

Some medical device related activities that were a direct response to the COVID-19 pandemic and are highlighted in the report include the National Ventilator Project, which saw the design, development, manufacture and deployment of 20 000 CPAP ventilators to 69 public hospitals in all nine provinces of South Africa; the South African Solidarity Fund, which supported the National Ventilator Project, COVID-19 testing, vaccine purchase and roll-out and PPE procurement and distribution; the South African Pandemic Intervention and Relief Effort Fund, which supported the purchase of additional essential medical equipment and protective wear and the development of the Inbox to protect hospital workers and critical care patients; and the SAMRC-DSI-TIA investments in local diagnostics for COVID-19 which have to date resulted in 2 locally produced diagnostic tests/kits being approved by SAHPRA.

African countries are rarely among the major suppliers of medical products. Hydrogen medications are the most traded product in Africa, with exports amounting to $340 million, followed by test kits at $150 million and urine bags at $98 million. South Africa, Eswatini and Kenya together account for more than two-thirds of total intra-African exports. Globally, the top five exporters account for 71% of African imports of personal protective equipment, 66% of imports of disinfectants and sterilizers, and 48% of imports of other medical products (Fig. 2.2).

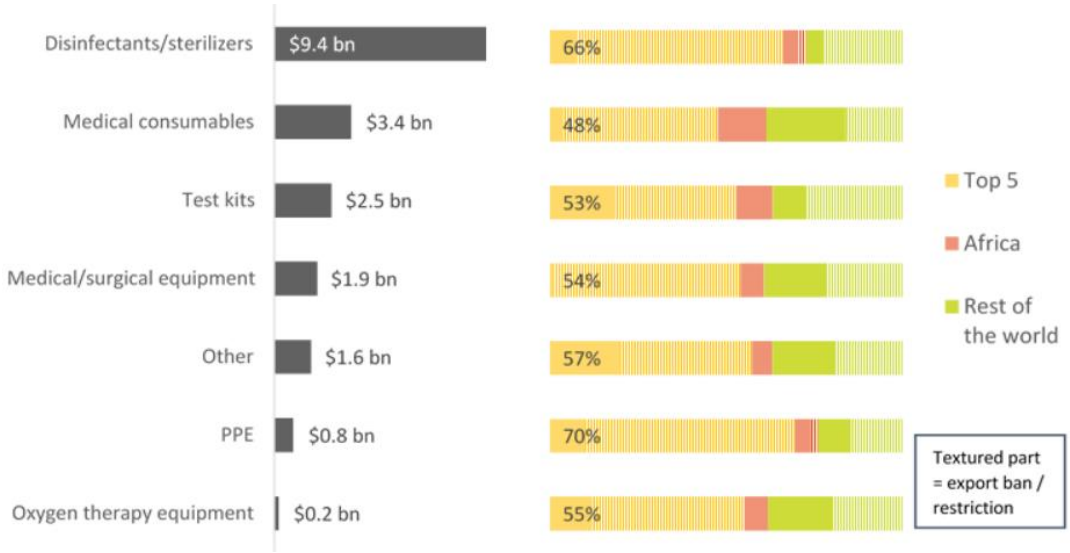

Fig. 2.2. Disinfectants and sterilizers top African medical supply imports

Some of the key suppliers of health products to Africa have restricted exports since the start of the pandemic, complicating the continent's access to these vital materials. On average, 76% of African imports of personal protective equipment and 72% of other medical supplies were subject to temporary trade measures in May 2020. Access to both textile and filtered masks was particularly difficult, with 96% and 90% of African imports, respectively, facing trade restrictions.

In Africa, Angola, Cameroon, Chad, Democratic Republic of the Congo, Niger, Nigeria, Senegal, Togo, United Republic of Tanzania, Zambia and Zimbabwe lifted or reduced import tariffs on medical products.Other governments may have decided to follow suit to improve immediate access to essential life-saving goods.

Alcohols, and in particular 'undenatured, 75% ethyl alcohol', has the highest average tariff, with prohibitive rates in Zimbabwe, Liberia and Angola. Although Angola and Zimbabwe temporarily exempted this product from import duties, Liberia still charged an advisory equivalent tariff of 81% at the time of analysis (Appendix D).

Specific types of protective garments are highly protected as well. Cabo Verde applies rates of 40% on surgical garments, gloves and hair nets, for instance. Finally, soaps face a 37% tariff in Egypt (in bars) and 50% in Cabo Verde (liquid). Interestingly, the preference given to African suppliers is often quite small.

In addition to tariffs, internal taxes add to the price of medical supplies and make them less affordable.

Alcohol solutions in both varieties, with less and with more than 80% ethanol, are most heavily taxed at 46% and 36%, respectively, followed by plastic bags, gloves and garments. Liquid soap, considered essential to follow World Health Organization hand hygiene recommendations, faces significant tariffs and taxes in Africa. Today, only one in six liters of Africa's disinfectant imports comes from regional suppliers. By strengthening regional and global cooperation, this share could grow.

Disinfectants require three inputs: ethanol diluted with distilled water, glycerol and plastic bottles. As Fig. 2.3 shows, Africa already produces ethanol, plastic bottles and caps in sufficient quantities. Providing nearly half a million bottles and caps corresponds to a fraction of Africa's monthly exports of these products (0,2% and 0,1%), with Egypt and South Africa being the main suppliers.

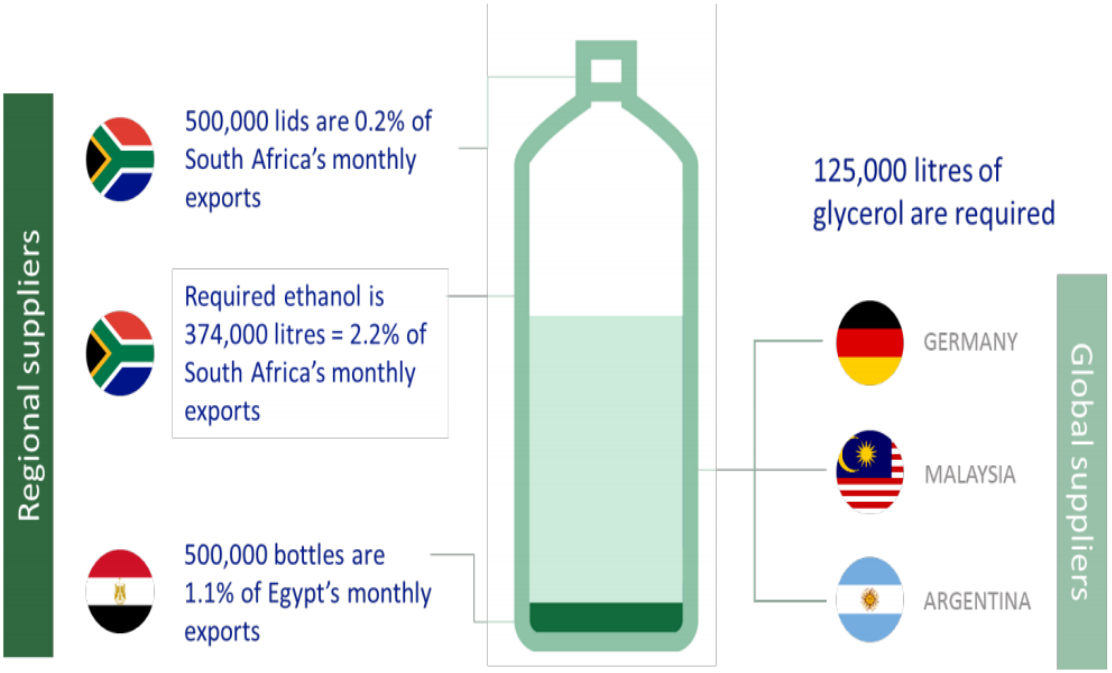

Fig. 2.3. South Africa and Egypt could supply inputs used to make disinfectants (price for ethanol - $0,63 per liter, for glycerol - $2,06 per liter)

Likewise, the required 374,000 liters of ethanol constitute just 1,5% of the continent's (and 2,2% of South Africa's) current monthly exports.

Local glycerol production, however, might be insufficient to meet the requirements to produce disinfectants. This means a global sourcing strategy would be needed. South Africa, the continent's only net exporter of disinfectants, sources glycerol mostly from Malaysia and Argentina. An alternative supplier could be Germany, which has an unrealized export potential for glycerol of $2,9 million to South Africa, and $6,9 million to all of Africa.

2.2. Strengths, Weaknesses, Opportunities and Threats of medical goods market development in Africa

Drivers of growth in medical devices are the rising cost of healthcare, which stimulate development of innovative connected products such as wearable medical devices, growing number of lifestyle diseases, demand for early detection and noninvasive therapies, growing awareness and spread of information technology, and development of user friendly devices. South Africa Consumables: This sector includes bandages and dressings, suturing materials, syringes, needles, catheters, etc. Currently estimated at $240 million [18], this market will grow around 1,7% in 2020.

There is some local manufacturing, but over 90% is imported. Major suppliers are the United States, China, India and Mexico. Diagnostic Imaging: Valued at an estimated $192 million, Germany and the United States are the leading suppliers in this market (20% market share each). Other players include Japan, China, Netherlands and the UK. Despite the underdeveloped nature of this market, there is great need for MRI and PET scanners, radiotherapy products, and other diagnostic imaging products in the public sector. Still, growth will remain muted due to depressed market conditions and unfavorable currency fluctuations. Orthopedics and Prosthetics: Valued at $ 164 million (Fitch Solutions), practically all products in this sector are imported, mainly from the United States (40%) and Switzerland. Dental: Projected growth in this market will be muted, 2,9% in dollar terms from 2019 – 2024. The dental market is currently valued at around $37 million [18]. Although treatment often focuses on the curative, there is recognition that more needs to be done in the area of preventive care [22].

The market is very small for high-end elective procedures due to the associated costs and limited insurance coverage. Over 90% of products in this market are imported, mainly from the United States and Germany (30% each). Smaller suppliers include Switzerland and China. There are some local manufacturers that supply dental instruments, supplies and implants. Patient Aids: Worth approximately $163 million in 2021 (Fitch Solutions), this category

includes portable aids, such as hearing aids and pacemakers, and therapeutic appliances like respiratory apparatus and mechanotherapy. More than 95% of this market is imported. The United States supplies around 25% and other main suppliers include China, Germany, and Switzerland. Growth will be dampened by current economic conditions. Surgical technology: There is a growing market, particularly in the private sector, for advancements in surgical technology, such as robotic-assisted surgery, that positively impact surgical outcomes. Diabetes Technology, equipment and medication: This is a significant health issue in South Africa. Around 15% of the population are either diabetic or pre-diabetic, and diabetes is the second most common cause of death in the country. Medical devices and in vitro diagnostic (IVD) devices are regulated by the SAHPRA.

To determine further prospects for the development of the medical goods market in African countries, we conducted a SWOT analysis, which will allow us to determine the directions for making the right managerial decisions in the field of regulating the economy and healthcare, taking into account global development. The results of the SWOT analysis are presented in the Appendix D.

We have identified major barriers to greater use of technology in healthcare provision, which we set out below. These present more or less significant challenges, depending on the specific subsector in question.

Factors affecting medical device manufacturers and forecast of medical devices market in Africa the lack of local facilities and skills for auditing, laboratory and mechanical testing and the high costs and time taken for independent testing of, for example, electromedical devices, which has to be done overseas. Where there are local testing capabilities, these are expensive.

The second most frequently cited challenge or barrier related to finances. This included access to capital financing, support for product development and growth (especially for small companies) and cash flow issues. Regarding cashflow issues, several respondents complained that Government was slow to pay. The distribution of Government grants and decision making thereon is also slow.

The third most cited issue related to protection of local MDMs from imports and the dominance of multinational corporations. Respondents felt that the lack of import duties exposed them to competition from cheap and low-quality imports. Local companies are often competing with non-compliant manufacturers, many of which are making unbranded, cheap replicas.

Other frequently cited issues related to the lack of preferential procurement for local suppliers (there is no culture of "buy local" in the public and private sectors), insufficient focus on job creation, difficulties in accessing the local public sector market and Government budget constraints (prioritizing price over quality), the way BBBEE regulations were implemented (this has excluded a number of manufacturers with a small number of employees from the public sector market and public incentives), incapacity in Government to properly run and adjudicate tenders, the administrative burden on small enterprises, including value added tax requirements, inefficiencies in importation of components and raw materials (logistical costs for bringing in raw materials and shipping out of the country, especially with exchange rate fluctuations), insufficient championship of the industry by Government, and a lack of access to, coordination within (linkage between Government departments) and responsiveness of Government.

Other issues raised were:

- Tenders needing updating to match the latest Technologies Challenges with medical aid reimbursement and medical funding administration access for product and procedure approvals

- Lack of investment in hospital infrastructure by Government and the private sector.

- Lack of access to information on foreign markets, such as market intelligence, barriers and routes to market and establishing international distribution.

- Difficulties and delays in making international payments, including obtaining the necessary approvals.

- Slow rebates from SARS for exports, which affect cash flow.

- Getting new products into the market and the cashflow issues while waiting for revenues to come in.

- Limited awareness and visibility of local and international business development opportunities.

- Poor policing of compliance.

Based on the 49% in the analysis of Medical Devices Market report which includes data of 136 medical device manufacturers weas identified based on R&D intensity and size. In Figure 2.4 these groupings are plotted on a two by two matrix. Different policy interventions are required for the different quadrants to move the industry towards higher domestic value-add. The rationale for the proposed policy interventions is discussed in more detail in sections 6 and 7.

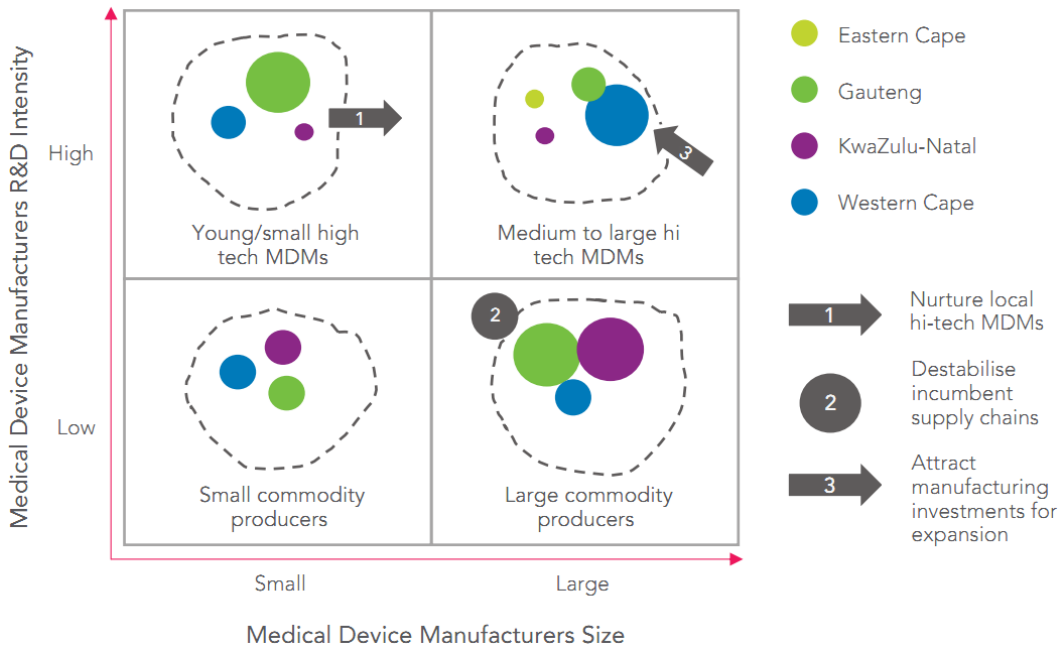

Fig. 2.4. Distribution of MDMs according to province, R&D intensity, and size

Conclusions to the Part 2

1. The medical devices market in South Africa is one of the largest in the Middle East and Africa region but makes up only 0,3% of the global market. However, the market is very sophisticated and it is strongly advisable that the product be approved in another foreign market, or even better, carry the CE marque or be FDA approved. The exception is for electromagnetic medical devices (or radiation emitting devices), which must be registered with the Department of Health, and must have the CE marquee.

2. Medical manufacturing industry in African countries is estimated to be in the region of USD 200mn-USD 300mn, production is focused on bandages & dressings, medical furniture and low technology items.

3. In the context of globalization, the market of medical products in African countries is promising, but it has a number of risks. The prospects for the development of the medical goods market in African countries were studied using a SWOT-analysis, which made it possible to determine the prospects for its development, as well as the threats and risks that need to be taken into account for making strategic management decisions in the field of state regulation of the healthcare sector.

4. The regulation of medical devices in South Africa is still in the process of introduction and significant regulatory hurdles in foreign jurisdictions affect the cost and complexity of compliance. These reports also revealed a number of barriers, threats and weaknesses in the industry as well as strengths and opportunities, with a list of recommendations for improving the sector.

Part 3

RECOMMENDATIONS FOR THE DEVELOPMENT AND IMPROVEMENT OF THE MEDICAL PRODUCTS MARKET IN AFRICAN COUNTRIES

3.1.Development of the medical goods market through our own scientific developments and innovations

STI institutions were asked whether any of their medical device research projects were being conducted collaboratively with medical device companies. Most (60%) STI institutions engage in such partnerships on their medical device projects. Half of the respondents reported having local partners and 30% had international partners, while 20% had both local and international partners (Fig. 3.1). Partnerships are structured around specific objectives, including postgraduate student supervision.

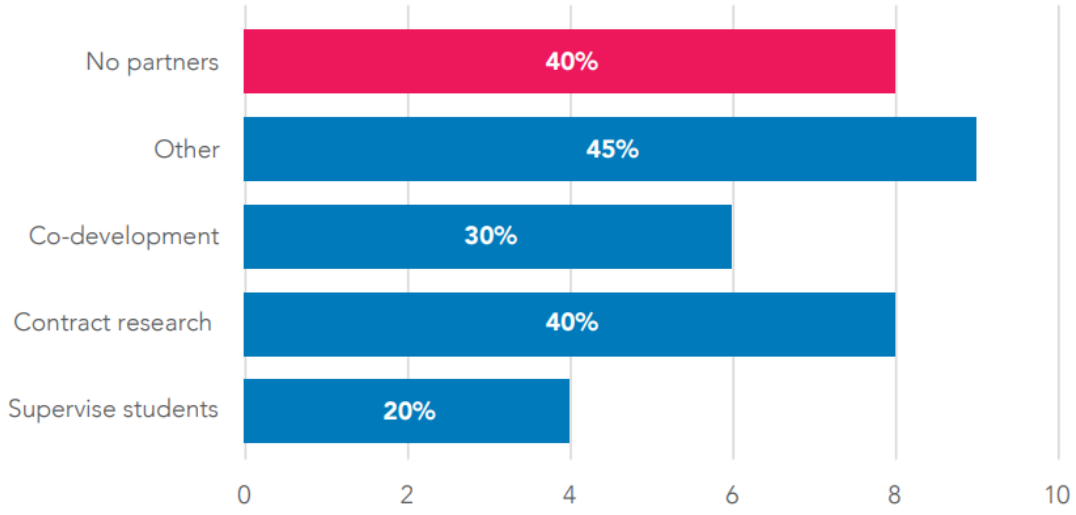

Fig. 3.1. Existing partnership modalities between STI institutions and medical device companies

All twenty respondents indicated an interest in increasing collaboration with the medical device industry. Most (60%) confirmed an interest in joint R&D and in

technology transfer, with a smaller number confirming an interest in experiential training for students. In addition, respondents suggested contract research, advisory and mentoring roles for industry and collaboration on manufacturing (Fig. 3.2).

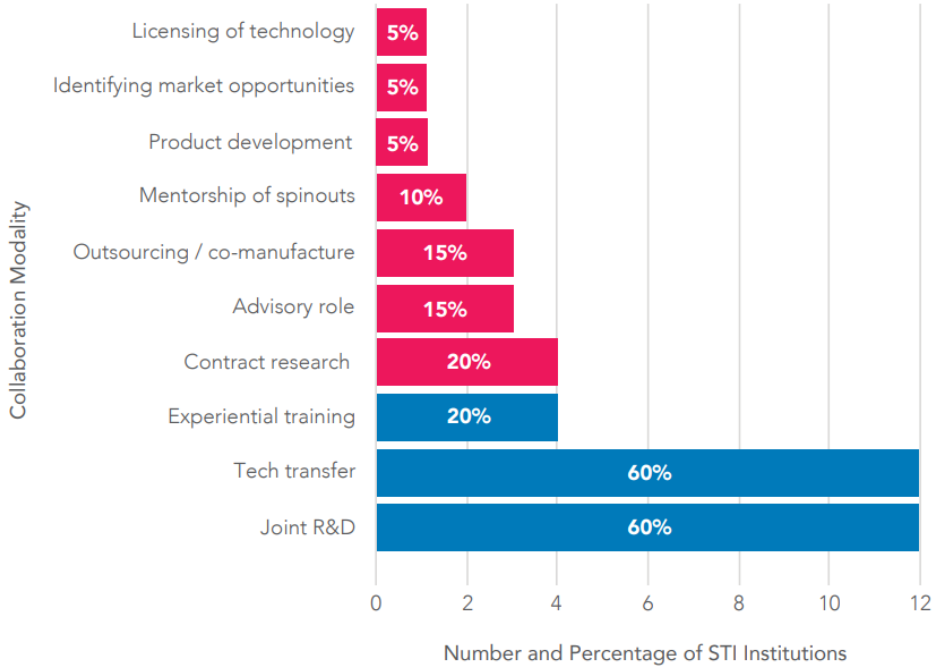

Fig. 3.2. Modalities for increased collaboration with local medical device manufacturing companies

Factors affecting medical device R&D and innovation Innovation barriers The STI institutions were asked to identify, based on their experience, the barriers to the development and commercialization of medical devices in South Africa. Those identified included the need for clearer market guidance and pathways to commercialization, more incentives, clearer guidance on regulation and certification, sufficient funding (also greater funding risk appetite and longer-term funding), industry limitations, a lack of critical mass of R&D capacity, and difficulties related to clinical trials, regulation and scale-up. These inputs were provided in response to an open-ended survey question and represent a combination of causes and consequences that interact with one another and impact on the health of the TIS. Ideally these issues should be further interrogated through interviews and analyzed, supported by analytical tools. A potential approach to do so is presented in De Oliveira et al. (2020) in which

systemic problems and blocking mechanisms are linked to TIS functions through blocking mechanisms as causal mechanisms. Fig. 3.3 presents an example from Oliveira et al. in which the lack of a long term vision negatively impacts on the market creation function in a TIS.

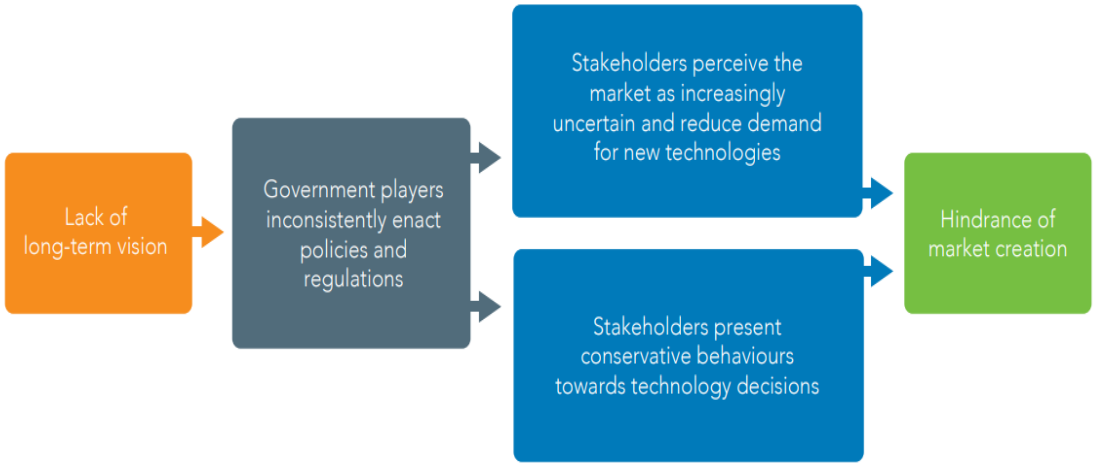

Fig. 3.3. Example of ambiguous behavior by Government as blocking mechanism

Another theme relates to a lack of insight into market requirements by STI institutions. One respondent reported that “research often does not address the needs of the market and in instances where this is the case, the cost of introducing the technology far outweighs the return on investment. The knowledge and capacity to drive the industry-oriented commercial success of technological innovations is not usually available in academic institutions. This includes knowledge regarding Medical Device Regulation, which means that compliance is often sought at great expense after R&D giving rise to innovations, rather than early-on or intrinsic to the process”. Inadequate links between STI institutions and industry may be contributing to R&D innovations from these institutions tending to adopt a technology-push rather than market-pull strategy as well as resulting in both inadequate documentation of early product development, as required for regulatory compliance, and the need for a degree of product redesign when

industry partners do get involved and have to factor in manufacturing considerations and end user requirements. Several institutions also struggled to find industry partners for technology transfer, which is related to the low absorptive capacity of the industry. There is clearly a disconnect and lack of information flows in the sector, as some of the above perceptions are not supported by the results of the MDM survey, which indicate a sizable number of MD manufacturers, at least half of which already have ISO 13485 certification, with a further 24% in process.

77% of MDMs were interested or conditionally interested in manufacturing innovations by South African research institutions. The reasons for the low uptake to date therefore need to be interrogated further and remedied. Lastly, a number of issues were raised regarding deficiencies in the funding regime. Respondents reported that the current approach to funding has focused on a project-by project approach provided by specialized agencies, such as the TIA, SPII and others. The short-term nature of these types of funding prevents STI institutions from building sustainable long-term pipelines for innovation. Several respondents commented that funding is project based which makes it difficult to build critical mass.

To address this problem, investment is required in human and institutional capacity that is focused on market-driven requirements and Government funding instruments should incentivize synchronization with the private sector. Figure 3.4 presents the results of a coding of different responses into different barrier categories. In addition to the themes highlighted above, difficulties with clinical trials and regulatory approval were cited by 43% and 33% of respondents, respectively. Under systemic failures, respondents commented that incentives for higher education did not favor technology outputs as the subsidy system counts publications and graduations only.

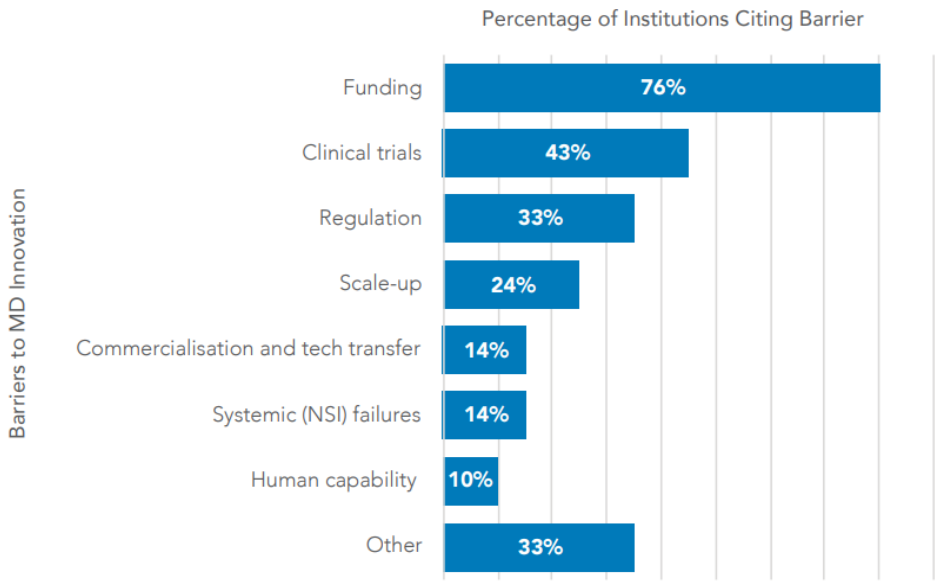

Fig. 3.4.Barriers to medical device innovation cited by STI institutions

Gaps in the development and commercialization of medical devices in African countriesare also requires attention. The gaps in the development and commercialization of medical devices in South Africa cited by respondents overlapped with some of the innovation barriers discussed above and included issues that relate to Government efforts and interventions aimed at stimulating local innovation and technology development, industry related challenges, funding gaps, regulatory challenges, and several other gaps. In terms of Government's role, gaps cited included inadequate support for the medical device sector, including policies or regulation on public procurement that promote local industry competitiveness, challenges with the public procurement process and uncertainty regarding the approval of new technologies for use in State health facilities as well as insufficient or poorly capacitated funding of medical device R&D and initiatives for medical device R&D and manufacture.

We consider that they lacked access to local markets and that there was no uptake by the Department of Health (specifically through preferred local procurement). Respondents reported a gap in the available human capital in the field and the need for more seasoned entrepreneurs to take opportunities forward. Interventions are required for maintaining and building a skilled labor force;

particularly in support of human capacity development of the educators at HEIs who must produce the future crop of innovators.

We indicated a need for funding for the full value chain of R&D, product development, testing and registration. In addition, funding processes needed to be efficient with rapid decision-making as this critically impacts the momentum of medical device manufacturers. As indicated in Figure 3.5, the main factors for commercialization success were attributed to the founder and the team (reported by a third of STI institutions), the funding and funders (a fifth), and entering good markets. This was supported by networks and collaboration, synergies and incubation.

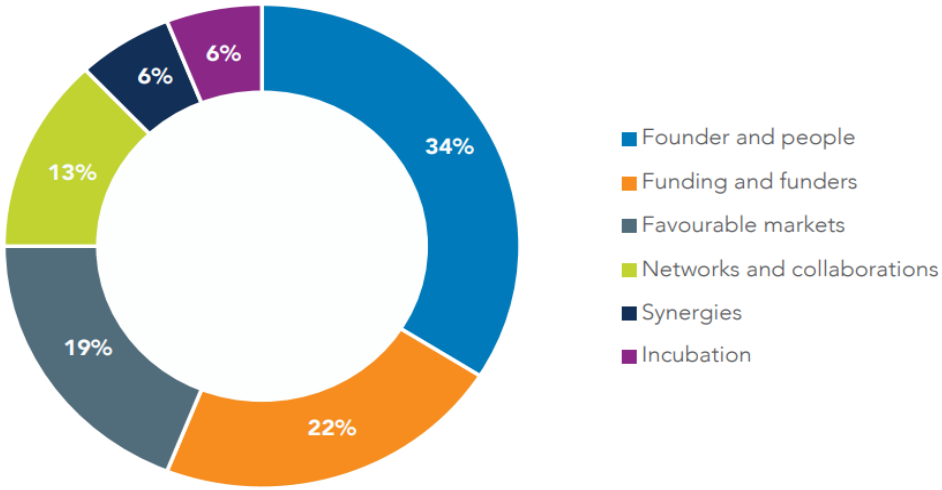

Fig. 3.5.Commercialization success factors

The forecast for the growth of the medical goods market in the countries of Africa is shown in the figure. The analysis was based on data from the South Africa Medical Devices Market Report and The Business of Health in Africa by the International Bank Group. The data was obtained by building a trend in Excel. The product categories being explored are Cardiology Devices, Ophthalmic Devices, Diagnostic Imaging Devices, General & Plastic Surgery Devices, Orthopedic Devices, and Other Medical Devices. According to the reports for the period 2019-2022, trends in the change in the market for these medical products were built (Fig. 3.6).

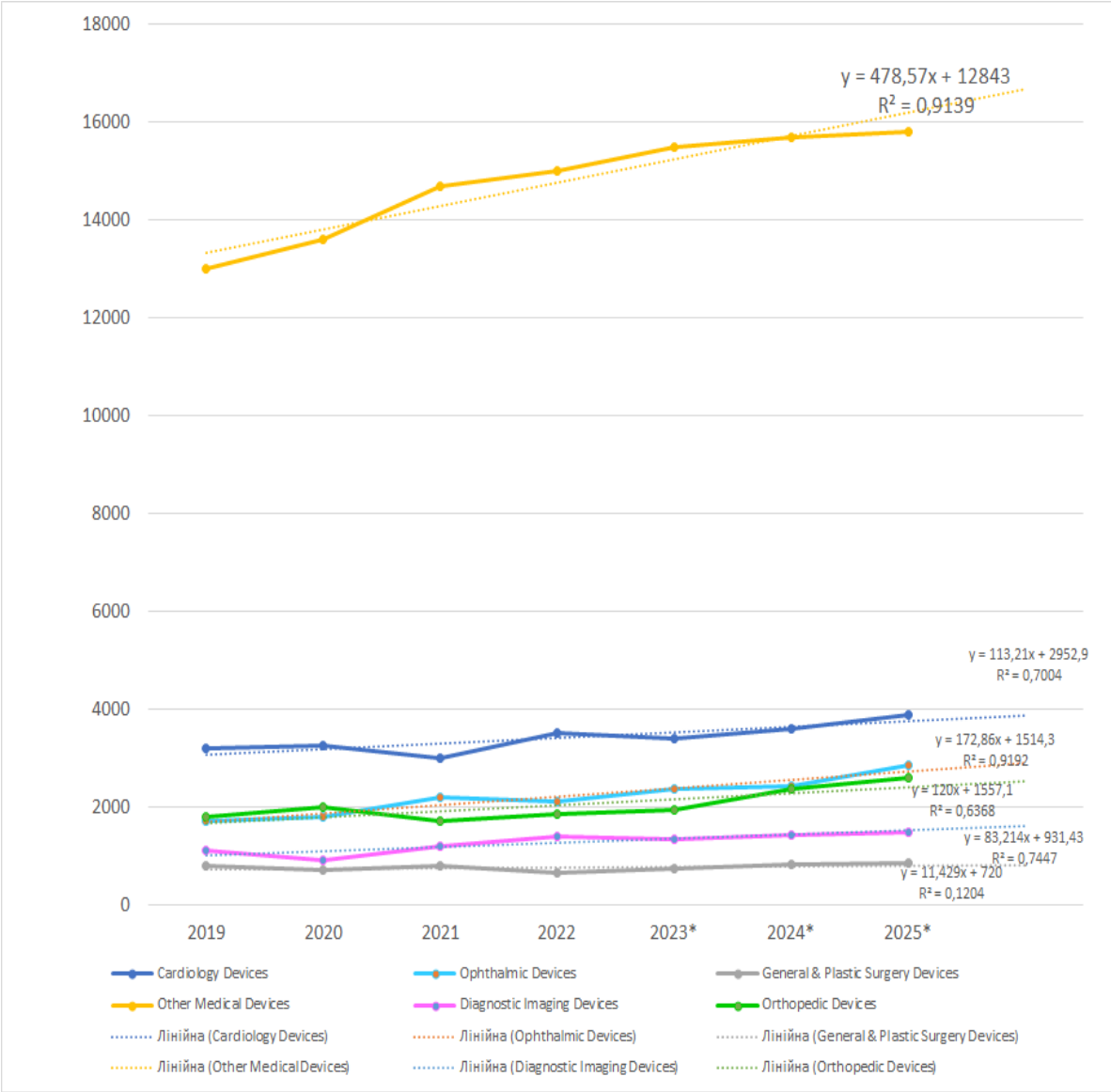

Fig. 3.6. The forecast for the growth of the medical goods market in the countries of Africa to the period of 3 next years

All trends, with the exception of General & Plastic Surgery Devices, have linear patterns of change, which is confirmed by a coefficient R^2 that is in the range of 0,6-0,9 which indicates a fairly high reliability in predicting trends for the period 2023-2025. Thus, the market for medical products in African countries is promising and has good potential, capacity and will increase in the coming years.An important moment in the development of the medical goods market in African countries is the program of support, cooperation and management at the legislative level, social and economic (financial and investment).

3.2.Support Service Organizationsin medical device production

Seven companies and three public institutions that provide support services to medical devices companies and STI institutions were surveyed. The companies surveyed were: BioTech Africa, Skeg Product Development, BMEC Technologies, Steri Solutions, Technimark, TNMC Medical Devices, and CJN Consulting. The public institutions surveyed were the TIA, the SAMRC and the IDC. Six of the organizations were based in the WC (all in Cape Town) and four were from Gauteng (three in Johannesburg and one in Pretoria). Regulatory consultants were not included but form an important component of the support services utilized by the industry. This support component of the survey was not a key focus and therefore has limitations. A more comprehensive analysis of this component of the industry may be valuable in future. While three of the support companies were not able to list their main clients, either due to confidentiality or their client base being too large, most of the others appear to support mainly medical devices companies, with a small number also supporting STI institutions. The main services and support provided to clients was technical consulting. Other services included regulatory advice, product design and development, manufacturing support, R&D and technical services, collaboration and mentoring and support for clinical and field trials. The three public institutions provided largely funding support (Fig. 3.7).

The main barriers to providing services and support, or those faced by clients, were regulations and certifications, and product and market understanding; followed by entrepreneurial barriers (few entrepreneurs and limited business skills, unwilling to consider equity). In addition, lack of expertise or skills, lack of quality management systems, and limited funding; followed by technology failure, high costs and poor feedback and communication were listed (see middle pie chart in Fig. 3.8).

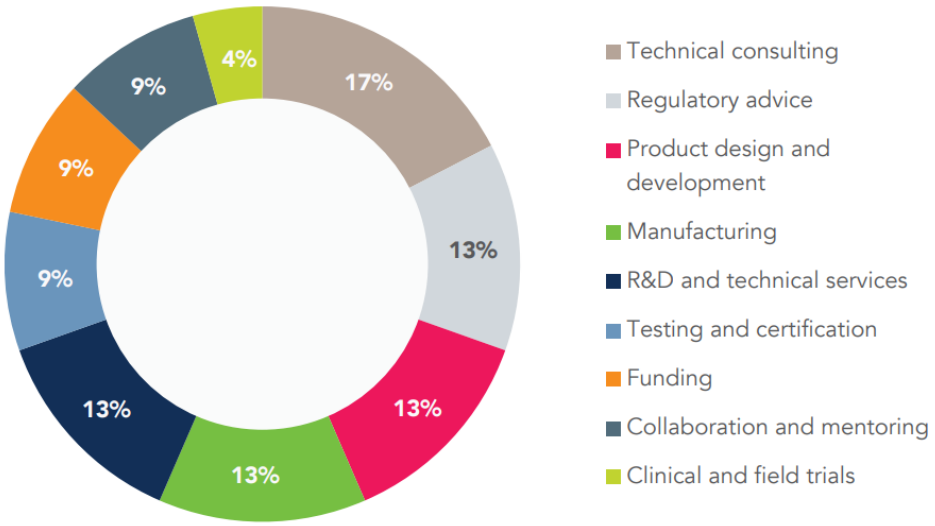

Fig. 3.7. Services provided to medical device developers

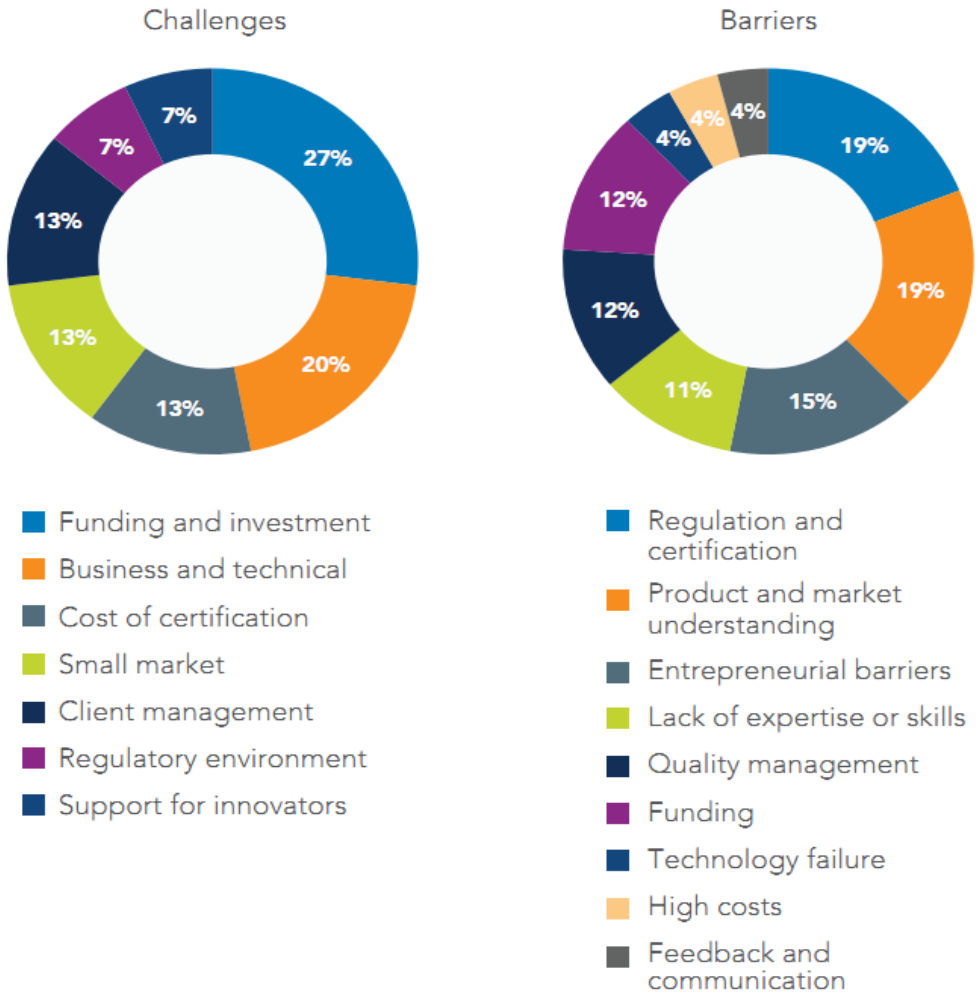

Fig. 3.8. Challenges, barriers and enabling interventions for the medical devices sector as cited by support organizations

The companies supporting medical device development conveyed that the key intervention to benefit the sector was to provide relevant courses, training and workshops, and to champion enterprise development. This was followed by fostering consultation and collaboration, providing regulation and compliance support; then by providing product design support. Other suggested interventions were to provide safe and fit-for-purpose medical devices and to secure sustainable funding.

The development of the medical health technology sector requires synchronization of cross-sectoral policies in industry as well as the health sector. At a supranational level, the African Union and their technical implementing agent, the African Union Development Agency (AUDA-NEPAD), have, since the early 2000s been working with development agencies such as the WHO, GIZ (German development agency), and UNIDO on promoting local pharmaceutical manufacture.

We highlight these supranational policies as well as the regional policies (Fig. 3.9) to show that, for the last two or more decades, there have been voices on the continent calling for more localization of medical health technology manufacturing. However, they have found it difficult to generate the scale or magnitude required to jolt policy makers into action.

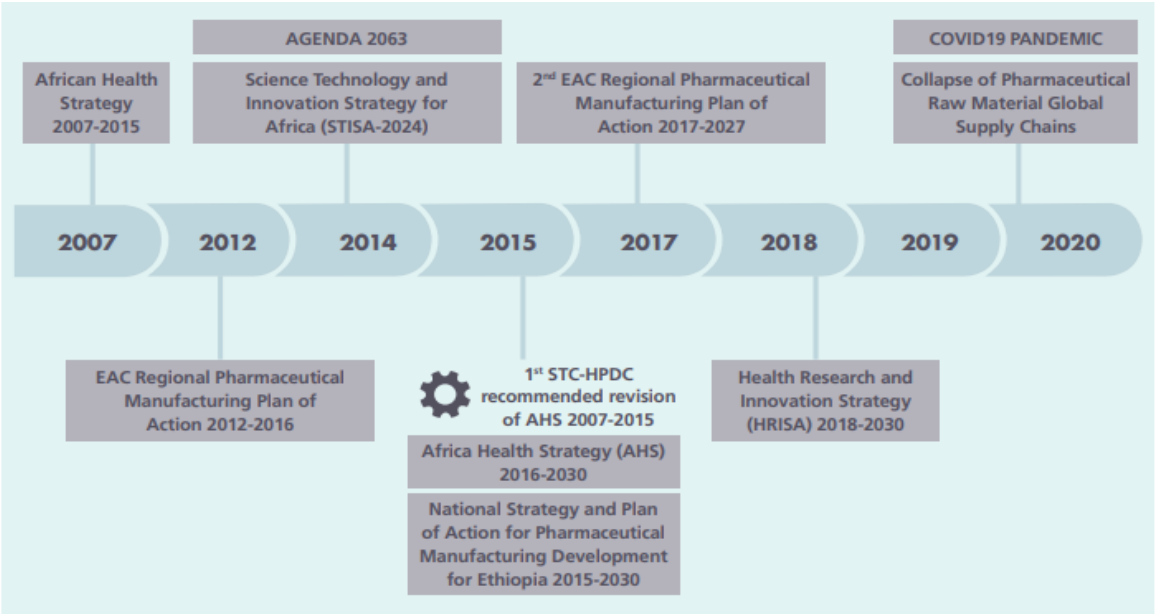

Fig. 3.9. Various continental and regional policies supporting local manufacture

Purposive rebuilding of the medical health technology manufacturing sector requires that governments play multiple roles, including policy formulation, funding and coordination. We have argued elsewhere that medical health technology sectors are not purely technical projects but are political projects, characterized by trade issues and potential backlash at commercial or international relations levels when the interests of incumbent players are threatened. In addition, for some of the particular sub-sectors, there is a need to support entrepreneurship, managerial capabilities and market formation. The public health sector has potency as a purposive industrial policy arena to support the emergence of the sub-sectors and build broad industrial capabilities.

Access to affordable finance for capex and working capital is critical for growth, but entrepreneurs need to carefully consider the source of funds, their motivation, and strategic thrusts. Access to banking finance has the least challenge to vision and strategic thrusts.

The public health system is a potent industrial policy arena that can be used to support building broad industrial capabilities in the medical health technology sector. Procurement and assured markets for locally manufactured products serve as market-signaling mechanisms to entrepreneurship. However, the local industry needs to develop linkages and collaborations with upstream and downstream actors. This requires policy convergence and coherence. Industry associations play an important role in articulating the demands and challenges faced by the sector, and this helps to design policy learning and resolve contestations that may arise.

We show interlinkage between public health systems and industry on Fig. 3.10.

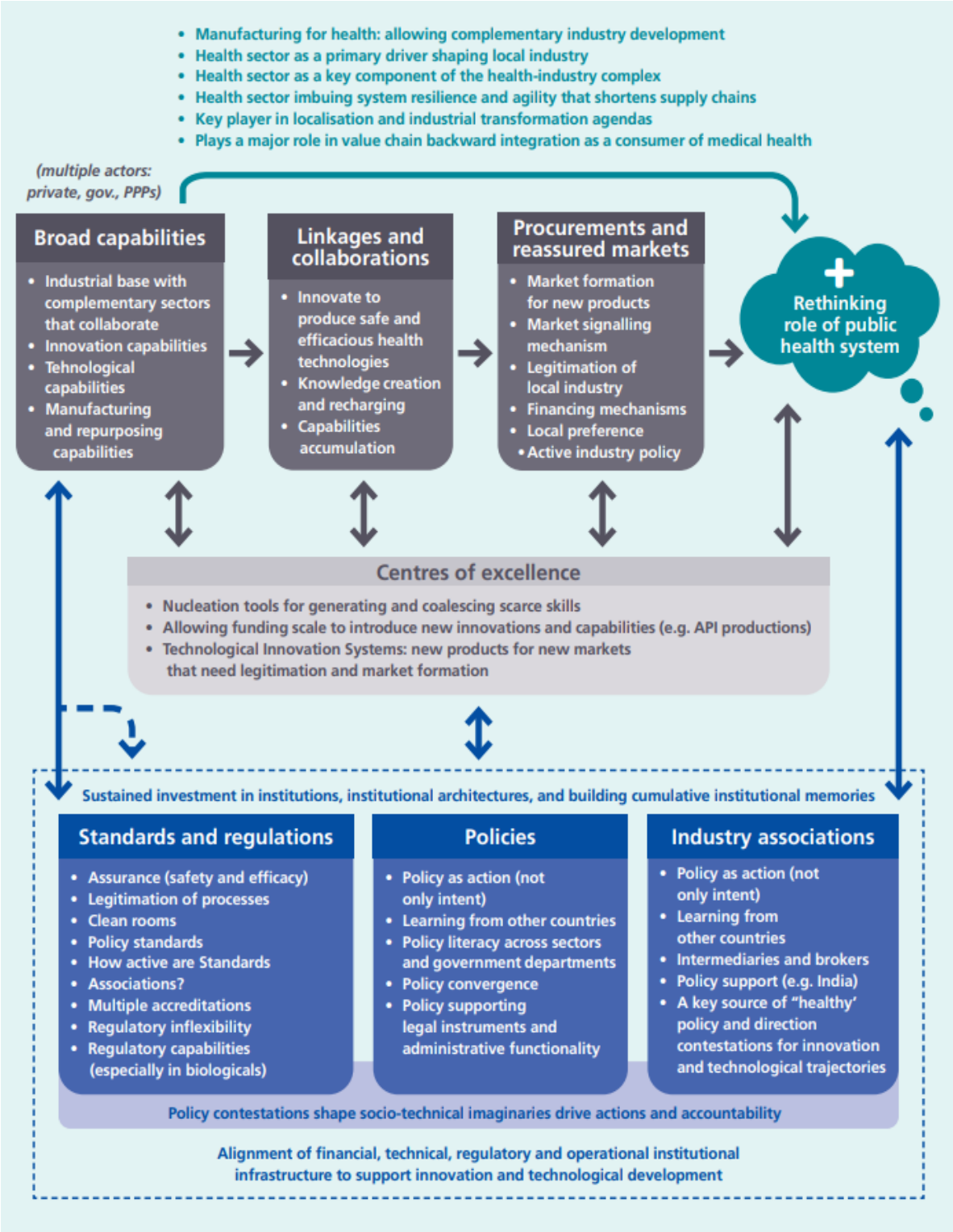

Fig. 3.10. The interlinkage between public health systems and industry

We discussed recommendations to improve access to medicines. See Table 1 for current efforts and challenges-specific recommendations.

Table 3.1

Overview of the current efforts by African governments and other stakeholders and challenges-specific recommendations to strengthen access to medicines in Africa

Challenges facing access to medicines in Africa	Current efforts	Specific recommendations
High burden of infectious and non-infectious diseases	Agencies involved in strengthening healthcare system to effectively respond to diseases and public health emergencies.	1. Improve disease surveillance, health promotion and inter-sectoral collaboration 2. Poverty alleviation programmes
Limited pharmaceutical industries and high costs of raw materials	National Medicines Regulatory Medicines Authorities (NMRAs) focus on regulation of medical products, rather than expanding and strengthening pharmaceutical industries	1. African Medicines Agency (AMA) to establish additional pharmaceutical companies 2. Government should subsidize raw materials including APIs. 3. Research on cost-effective and readily available raw materials 4. Government grants to local drug manufacturers.
Overdependence on countries abroad for medicines	Despite recommendations from researchers, and other stakeholders, government response and political will in this regard is still limited.	1. Invest more in ensuring increase in the presence of more pharmaceutical companies. Private-public partnerships in this regards would be beneficial. 2. The presence of the proposed AMA should also be enhanced across the continent.
Poor supply chains systems	Many African countries have its NMRAs with the role of ensuring effective and efficient drug supply chain systems. However, only 15% of the NMRAs have a legal mandate to perform all critical regulatory functions	1. Revitalization of all the NMRAs. 2. Invest in capacity building of medicines regulatory officers. 3. Developing structural models to address any local barriers, for example, corrupt practices. 4. Strengthening digitalization of supply chain activities

Table 3.1 (continue)

Lack of government investment in pharmaceutical sector	Stakeholders continue to advocate for more investment from the government to revitalize the pharmaceutical sector on the continent	1. Recognition of the pharmaceutical and medical care sectors with direct investment by the government. 2. Increase in political will
Unfavourable manufacturing conditions	High electricity costs, frequent power interruptions, and other infrastructural issues such as poor transportation continue to persist despite all the policy recommendations.	Invest in making the continent conducive for pharmaceutical manufacturing, towards attracting more international investors.
Lack of sustainable health financing mechanism	Effort is seen in advancing health insurance systems on the continent. However, there is still a huge concern regarding coverage.	1. Strengthen health insurance systems. 2. Increase in budgetary allocation to health in African countries 3. Revitalization of primary health care systems remain pertinent.
Lack of infrastructure and technical know-how	Even though more still needs to be done, pharmaceutical companies, with limited support from governments, are involved in strengthening manufacturing capacity through training, and international collaborations.	Invest directly in supporting manufacturing industries through capacity building, improved access to infrastructure, and building local talents.

Conclusions to the Part 3

1. The environment for pharmaceutical production and manufacturing is changing quite rapidly, both in Africa and abroad. Africa may choose a strategic mix of open markets, supply diversification and stronger regional value chains to combat the current health crisis, build the region's resilience against future pandemics and become a competitive supplier of certain healthcare products.

2. Most of the countries with developed industries have used foreign investments and technology in the process of their development.In the long term, to prepare for future health crises and strengthen the African medical industries, government responses may include: Identifying goods for which key inputs are available locally or regionally, making the development of regional value chains feasible, facilitating investments into these sectors to ensure the availability of cost-efficient production technology, leveraging the AfCFTA to ensure a smooth functioning of trade along these regional value chains (i.e. ensuring that these goods trade duty-free within Africa and that other regulations are harmonized), promoting these products in non-African markets that aim to diversify their procurement.

3. The forecast for the growth of the medical goods market in the countries of African 2023-2025 were presented. The main barriers to providing services and support were analyzed.

4. The current status of medical devices, drugs and vaccine manufacturing capabilities is not tenable. Urgent action is needed to build commensurate industrial capabilities. The state is the only actor with the political legitimacy, control of resources and incentives, and ability to exercise immediate agency through public policy, to create the urgency to accelerate rolling out these highly political projects.

CONCLUSIONS

1. Africa faces a double burden of infectious and non-communicable diseases and the need for effective universal access to medicines cannot be deemphasized. However, access to medicines on the continent is not without issues and challenges. Some of which are the high burden of infectious diseases and non-infectious diseases, limited pharmaceutical industries and high costs of raw materials, overdependence on countries abroad for medicines, poor supply chain systems, lack of government investment in the pharmaceutical sector, unfavorable manufacturing conditions, limited health workforce, lack of sustainable health financing mechanisms, lack of infrastructures and technical know-how, low investment on research and development, and circulation of fake and counterfeit medicines among others. Restrictions in access to patents and inability of local manufacturers, researchers and scientists to gain patents is a barrier to accessing medicines in Africa. Pharmaceutical industries in many African countries are not optimally manufacturing new medicines due to low investment in research and development.

2. More so, the emergence of the COVID-19 pandemic has resulted in a shortage of medicines across the continent due to the global travel bans and lockdowns, which affect medicines manufacturing and importation.

3. SWOT-analysis showed that African sub-region relies heavily on the importation of medicines and raw materials for the manufacture of their medications. This could spell serious trouble for rural areas since they are typically the last to get access to any imported medicines or manufactured medicines due to their inaccessibility. This also means that changes to supply chain logistics or policies affecting the importation of the drugs or raw materials could cause scarcity and make medicines inaccessible. The acceptability of medicines correlates with patients' familiarity with medicines and this has implications for a region that is constantly receiving medicines from multiple sources internationally. Patients may refuse certain forms of treatment because they are unfamiliar, or due to religious

and cultural reasons. Similarly, drug distributors and importers (including community pharmacies) may refuse to import or stock certain drugs if they believe that their target population would not accept them. This could place a limit on the number of drugs that can be accessed by people in such an area. Availability of drugs borders on supply chain logistics with respect to demand and supply. The growth of local pharmaceutical industries also relies heavily on the availability of infrastructures such as transportation systems, communication networks, and constant power supply.

3. Many African countries lack proper health financing frameworks needed to achieve UHC, making access to affordable medicines challenging. Despite the 2001 Abuja Declaration in which African leaders agreed to allocate at least 15% of the general government expenditure to health, only five countries (Botswana, Togo, Madagascar, Rwanda, and Zambia) have kept to the commitment.

4. Trends in areas of types of different medical goods were investigated, analysis showed they have linear patterns of change, which is confirmed by a high coefficient R^2 which indicates a fairly high reliability in predicting trends 2023-2025. Thus, medical products market in African countries has good potential, capacity and will increase in future.

5. Global pharmaceutical companies need local business partners to help them navigate Africa’s many markets, which vary widely in consumer preferences, pricing, manufacturing and distribution infrastructure. In the absence of a pan-African pharmacy regulatory body, they also need to invest in local partnerships to understand varying regulatory environments. Leading companies are building partnerships with local manufacturers and distributors to acquire expertise in all these areas and to facilitate market access and expansion in particular countries.

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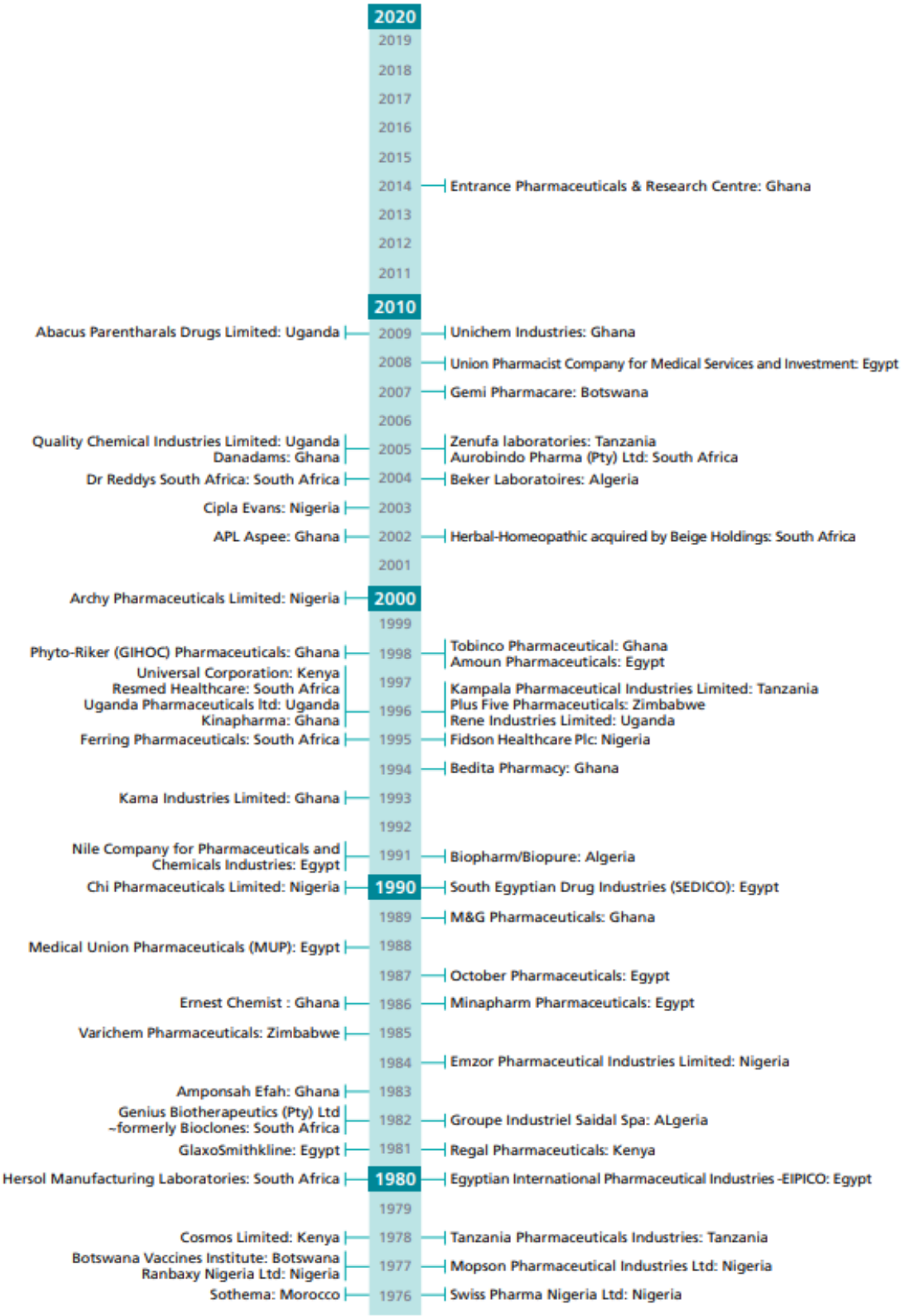
APPENDICES

Appendix A

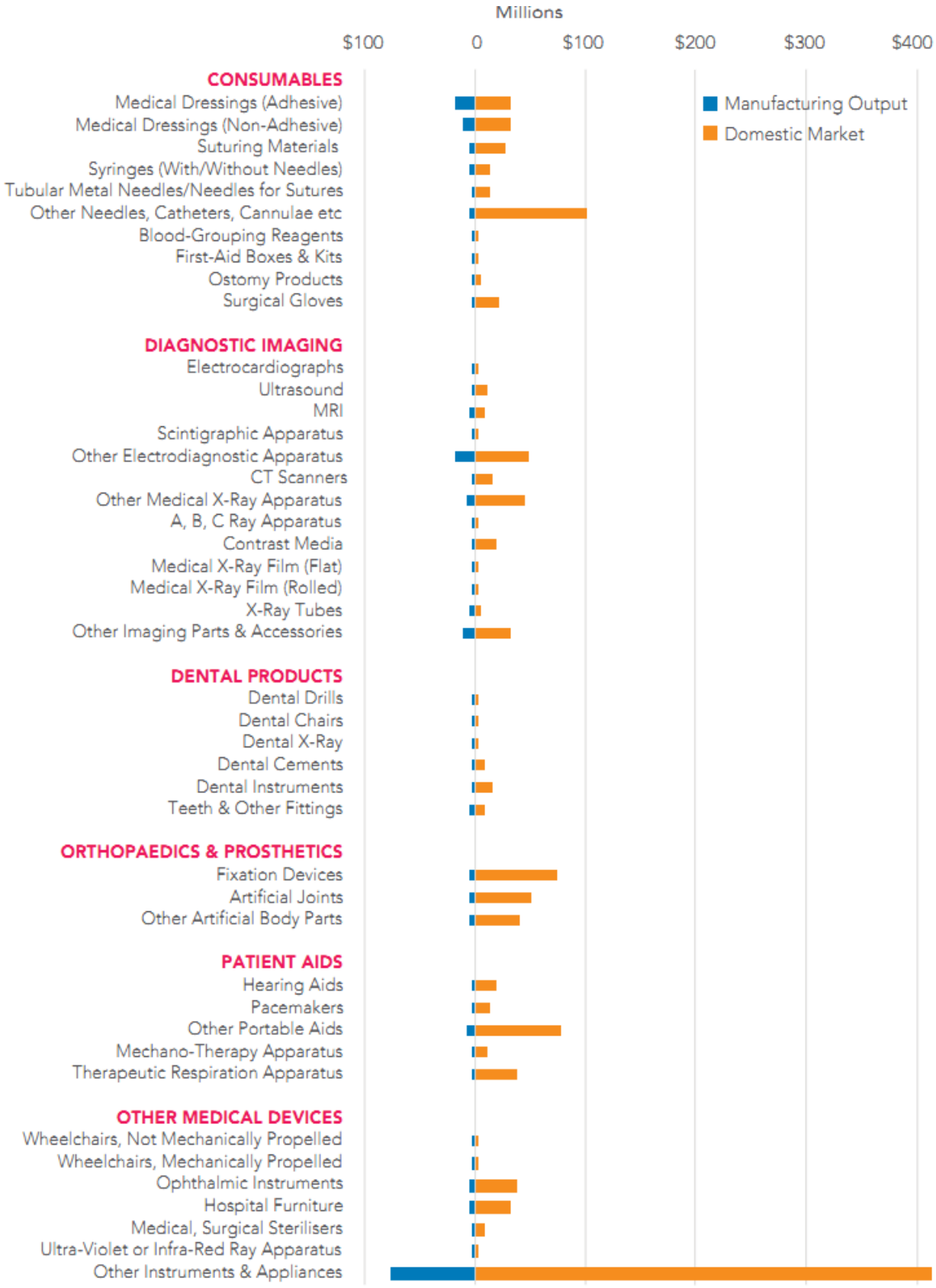
Evolution of major pharmaceutical manufacturing companies in the African continent for selected countries



Appendix B

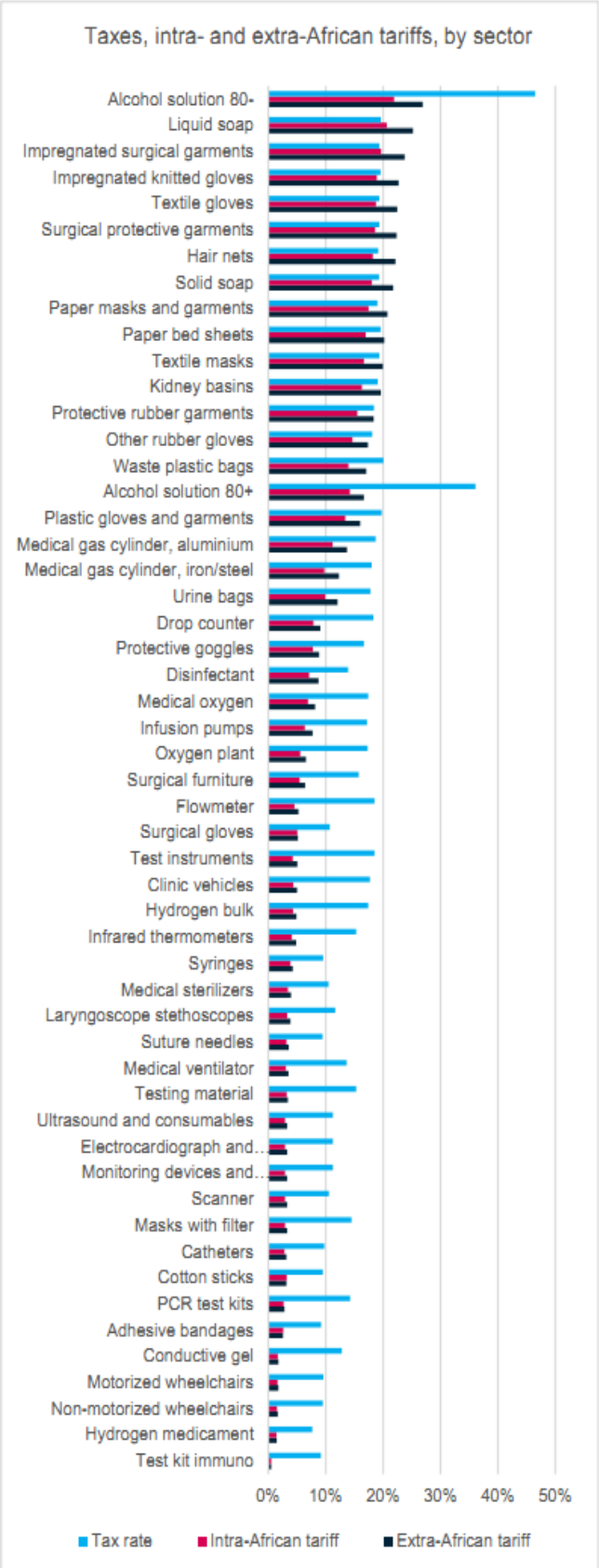
Characteristics of the African Medical Devices Landscape

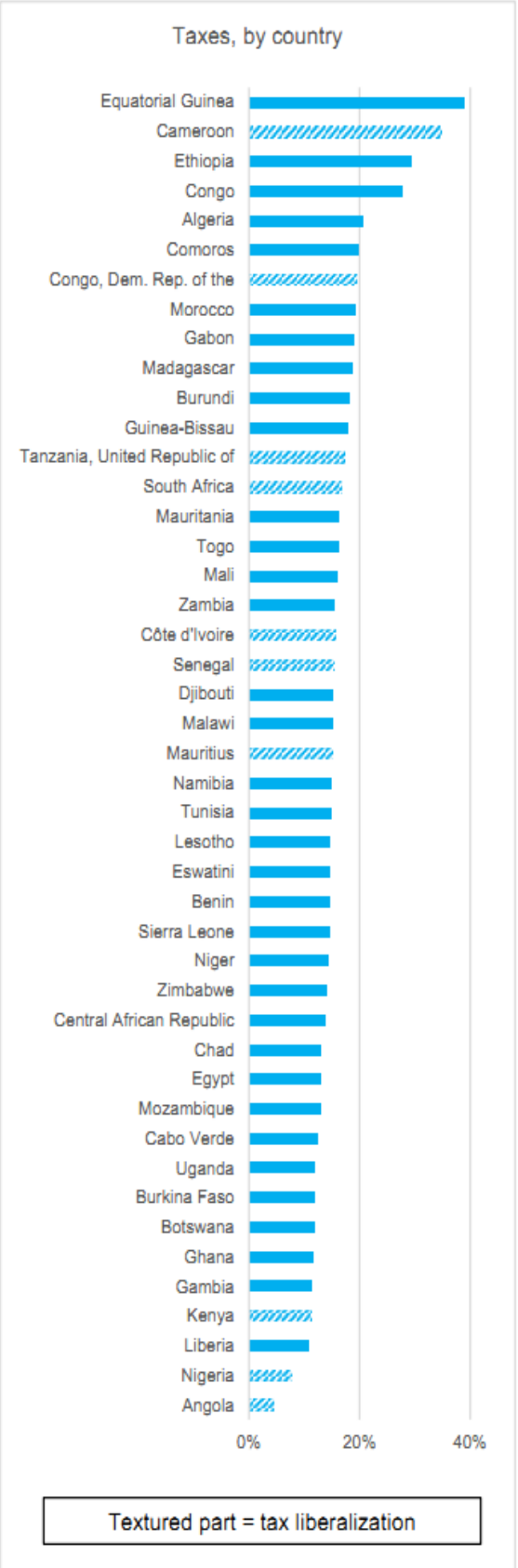
Appendix C


Millions
$100
0
$100
$200
$300
$400
Manufacturing Output
Domestic Market
CONSUMABLES
Medical Dressings (Adhesive)
Medical Dressings (Non-Adhesive)
Suturing Materials
Syringes (With/Without Needles)
Tubular Metal Needles/Needles for Sutures
Other Needles, Catheters, Cannulae etc
Blood-Grouping Reagents
First-Aid Boxes & Kits
Ostomy Products
Surgical Gloves
DIAGNOSTIC IMAGING
Electrocardiographs
Ultrasound
MRI
Scintigraphic Apparatus
Other Electrodiagnostic Apparatus
CT Scanners
Other Medical X-Ray Apparatus
A, B, C Ray Apparatus
Contrast Media
Medical X-Ray Film (Flat)
Medical X-Ray Film (Rolled)
X-Ray Tubes
Other Imaging Parts & Accessories
DENTAL PRODUCTS
Dental Drills
Dental Chairs
Dental X-Ray
Dental Cements
Dental Instruments
Teeth & Other Fittings
ORTHOPAEDICS & PROSTHETICS
Fixation Devices
Artificial Joints
Other Artificial Body Parts
PATIENT AIDS
Hearing Aids
Pacemakers
Other Portable Aids
Mechano-Therapy Apparatus
Therapeutic Respiration Apparatus
OTHER MEDICAL DEVICES
Wheelchairs, Not Mechanically Propelled
Wheelchairs, Mechanically Propelled
Ophthalmic Instruments
Hospital Furniture
Medical, Surgical Sterilisers
Ultra-Violet or Infra-Red Ray Apparatus
Other Instruments & Appliances

Appendix D

Taxes on medical items in African countries in 2022

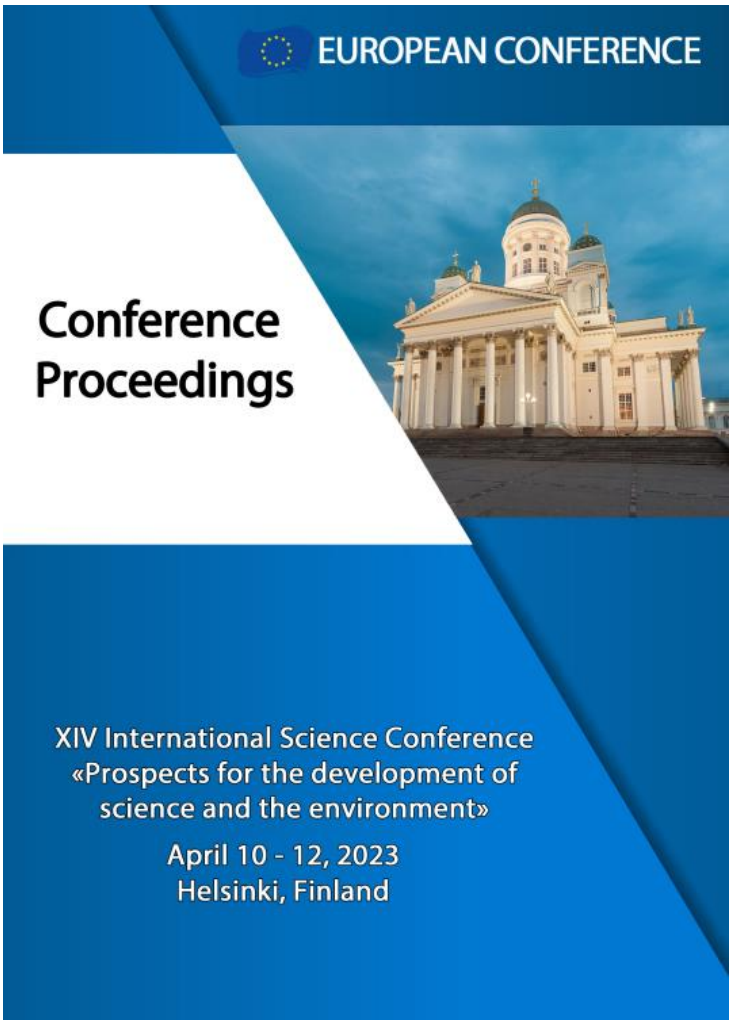




Appendix E

SWOT for the Africancountries medical devices industry

Strengths	Weaknesses
1. Political stability in SA, strong and independent institutions, judiciary and security services 2. Limited threat of terrorism 3. Industrialised economy & rich mineral resources 4. Financial hub & stable banking sector 5. Much of SA public debt is denominated in local currency 6. Observance of contracts and intellectual property rights 7. Quality transport infrastructure 8. Large population 9. Low staff turnover in MD industry 10. Strong private healthcare sector 11. Steady demand for medical devices 12. Licensing requirements promoting compliance and product safety 13. Public funding (DTI and IDC) of the sector 14. Weak Rand a driver for local development and manufacture 15. Increased Government spending on equipment as part of the NHI 16. Recent private equity investment in the sector 17. Government support for exports and innovation in the WC 18. Access to sub-Saharan African markets 19. Established exports of hi-tech, high value MD products	1. High structural unemployment, poverty and political disenfranchisement 2. Corruption 3. Economy over-dependent on primary commodities 4. Currency volatility 5. Labour market rigidities 6. Very high crime rate 7. Lengthy business registration, closing and opening turnarounds 8. Poor healthcare infrastructure, particularly in the rural areas 9. Private healthcare sector out of reach for most of the Black population 10. Many rural facilities under-used or idle due to poor organisation 11. HIV/AIDS overburdening the system 12. Chronic shortage of medical personnel 13. Purchasing procedures complex and fragmented 14. Small size of domestic market and only ~5% of devices used are manufactured locally 15. Low levels of R&D 16. Inconsistent quality of local manufacture 17. Lack of device level licensing/registration 18. Medical device research underfunded 19. Registration of products in overseas markets expensive 20. Medical aid schemes power over pricing of MDs 21. Lack of stakeholder/role-player alignment
Opportunities	**Threats**
1. Emerging party-political diversity 2. Microeconomic reforms, including improved skills training, to alleviate poverty 3. Emergence of affluent, Black middle class 4. Private security firms filling gaps left by the police 5. Inter-regional trade agreements facilitate trade flows and reduce costs 6. Greater interregional freight connections envisaged 7. Government health funding to increase in real terms 8. Expansion of HIV treatment reducing pressure on public healthcare system 9. National health insurance (NHI) scheme prompting investment in the public healthcare system 10. Public-private partnership growth 11. Establishment of the new medical device regulator (SAHPRA) 12. New regulations will establish internationally aligned regulatory framework 13. Aesthetic medical device market growth 14. Alternative clinical therapies are presenting untapped sources of innovation 15. Serving low income, under-served populations who have difficulties accessing specialists	1. High levels of HIV/AIDS impact on economic growth 2. Political/policy uncertainty undermining investor confidence 3. Cost of compliance to Black Economic Empowerment requirements 4. Land reform uncertainty 5. Health policy affected by politics, alleged cronyism and corruption 6. NHI implementation dependent on private practitioners contracting with the public sector uptake of which has been slow 7. Increased imports, especially cheap imports of inferior quality 8. Inefficient public procurement and payment 9. Exchange rate volatility 10. Skills loss due to emigration 11. Cost of certification for local manufacturing and exporting 12. Increasingly burdensome regulatory landscape increasing costs for local players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April 10 - 12, 2023
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FORECAST OF TRENDS IN MEDICAL DEVICES MARKET DEVELOPMENT IN AFRICAN COUNTRIES

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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 South African medical device industry was a previously unregulated industry, unlike most other medical device industries around the world [1]. To understand why local medical device manufacturers are not starting up in the African industry, the trends in challenges and experiences faced by local medical device manufacturers, and the opinions of key South African manufacturers, required investigation. Although the medical device industry is global, many restricting factors were attributed specifically to African regulations and the market environment [2].

Purpose: to analyze the dynamics, structure and trends in the market of medical products in African countries, to analyze the strengths and weaknesses in order to develop strategic directions for its development and improve the efficiency of the healthcare sector.

African health systems are underfunded, overstretched, and understaffed, rendering the challenge of addressing this double disease burden a monumental challenge. Good health is a precondition for development, and it is becoming clear that achievement of this goal is not reliant on the health sector alone; rather is mediated by environmental, social, infrastructural, and regulatory systems [1].

Trends in areas of types of different medical goods were investigated with data reports [3-4], analysis showed they have linear patterns of change, which is confirmed by a high coefficient R^2 which indicates a fairly high reliability in predicting trends 2023-2025. Thus, medical products market in African countries has good potential, capacity and will increase in future.

The forecast for the growth of the medical goods market in the countries of Africa is shown in the figure. The analysis was based on data from the South Africa Medical Devices Market Report and The Business of Health in Africa by the International Bank Group. The data was obtained by building a trend in Excel. The product categories being explored are Cardiology Devices, Ophthalmic Devices, Diagnostic Imaging Devices, General & Plastic Surgery Devices, Orthopedic Devices, and Other Medical

Devices. According to the reports for the period 2019-2022, trends in the change in the market for these medical products were built (Fig. 1).

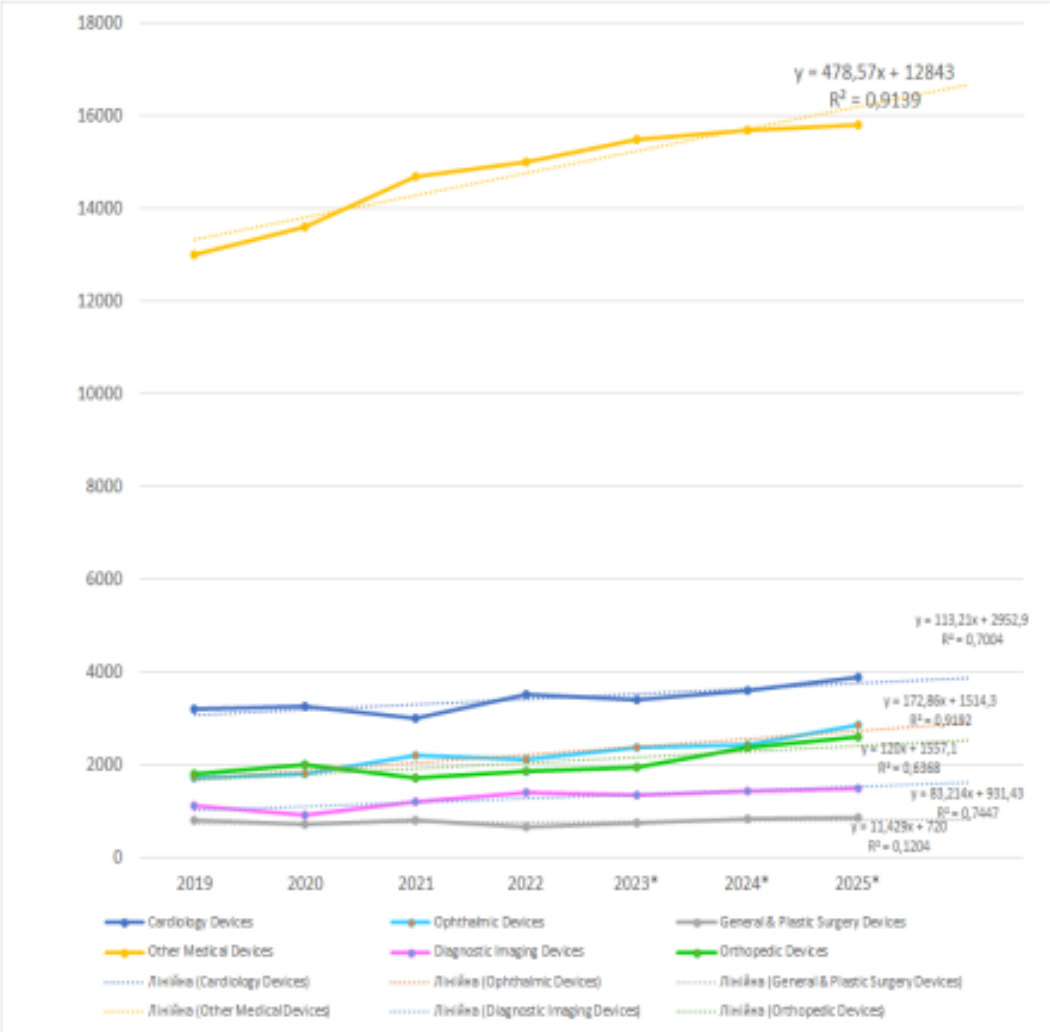

Figure 1. The forecast for the growth of the medical goods market in the countries of Africa to the period of 3 next years

All trends, with the exception of General & Plastic Surgery Devices, have linear patterns of change, which is confirmed by a coefficient R^2 that is in the range of 0,6-0,9 which indicates a fairly high reliability in predicting trends for the period 2023-2025. Thus, the market for medical products in African countries is promising and has good potential, capacity and will increase in the coming years. An important moment in the development of the medical goods market in African countries is the program of support, cooperation and management at the legislative level, social and economic (financial and investment).

Various countries across the world have established regulatory bodies that guide the medical device industry. Africa, Angola, Cameroon, Chad, Democratic Republic of the Congo, Niger, Nigeria, Senegal, Togo, United Republic of Tanzania, Zambia

and Zimbabwe lifted or reduced import tariffs on medical products. Other governments may have decided to follow suit to improve immediate access to essential life-saving goods. 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. Most of the countries with developed industries have used foreign investments and technology in the process of their development. In the long term, to prepare for future health crises and strengthen the African medical industries, government responses may include: Identifying goods for which key inputs are available locally or regionally, making the development of regional value chains feasible, facilitating investments into these sectors to ensure the availability of cost-efficient production technology, leveraging the AfCFTA to ensure a smooth functioning of trade along these regional value chains (i.e. ensuring that these goods trade duty-free within Africa and that other regulations are harmonized), promoting these products in non-African markets that aim to diversify their procurement [4].

Conclusions. The environment for pharmaceutical production and manufacturing is changing quite rapidly, both in Africa and abroad. Africa may choose a strategic mix of open markets, supply diversification and stronger regional value chains to combat the current health crisis, build the region's resilience against future pandemics and become a competitive supplier of certain healthcare products.

The current status of medical devices, drugs and vaccine manufacturing capabilities is not tenable [3]. Urgent action is needed to build commensurate industrial capabilities. The state is the only actor with the political legitimacy, control of resources and incentives, and ability to exercise immediate agency through public policy, to create the urgency to accelerate rolling out these highly political projects.

References:

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Ф А 2.2.1–32-366

National University of Pharmacy

Faculty for foreign citizens' education
Department of pharmaceutical management and marketing
Level of higher education master
Specialty 226 Pharmacy, industrial pharmacy
Educational program Pharmacy

APPROVED
The Head of Department
of Organization and
Economics of Pharmacy

_____

Alla NEMCHENKO
"26" of June 2022

ASSIGNMENT
FOR QUALIFICATION WORK
OF AN APPLICANT FOR HIGHER EDUCATION

Abdelsamie Samah SOLIMAN METWALLY

1. Topic of the qualification work: «Investigation of peculiarities of the medical products market development in African countries in the conditions of globalization» supervisor of qualification work: Rita SAGAYDAK-NIKYTYUK, Doctor of Pharm. Sc., Professor

approved by order of NUPh from "06st" of February 2023 № 35

2. Deadline for submission of qualification work by the applicant for higher education: April 2023.

3. Outgoing data for qualification work: is scientific literature, medical goods market report, data of conferences, seminars and workshops for MRs, WHO statistics and analysis.

4. Contents of the settlement and explanatory note (list of questions that need to be developed): to analyse the historical peculiarities of the medical goods market development, its structure in African countries, to characterize the features of the medical goods market, its development trends in the world and in African countries, identify strengths and weaknesses, as well as determine strategic prospects in the development of the medical goods market; to determine development prospects and predict changes in its structure and capacity, to develop the recommendations for medical goods market effectiveness and grows in connection with healthcare in African countries.

5. List of graphic material (with exact indication of the required drawings): figures – 17

6. Consultants of chapters of qualification work

Chapters	Name, SURNAME, position of consultant	Signature, date	
		assignment was issued	assignment was received
1	Nataliia DEMCHENKO, Associate Professor of the Department of Organization and Economics of Pharmacy	01.09.2022	01.09.2022
2	Nataliia DEMCHENKO, Associate Professor of the Department of Organization and Economics of Pharmacy	20.01.2023	20.01.2023
3	Nataliia DEMCHENKO, Associate Professor of the Department of Organization and Economics of Pharmacy	15.03.2023	15.03.2023

7. Date of issue of the assignment: «26» June 2022

CALENDAR PLAN

№ з/п	Name of stages of qualification work	Deadline for the stages of qualification work	Notes
1	Collection and generalization of data from the scientific literature in the areas of qualification work (part 1)	January 2022	**Done**
2	Analysis of Medical Goods market in Africa (part 2)	February 2022	**Done**
3	Recommendations for the development and improvement of the medical products market in African countries (part 3)	March 2022	**Done**
4	Writing and design of a qualification work	April 2022	**Done**
5	Approbation of a qualification work	May 2023	**Done**
6	Submission of a qualification work to the EC of NUPh	June 2023	**Done**

An applicant of higher education _____ Abdelsamie Samah SOLIMAN METWALLY

Supervisor of qualification work _____ Nataliia DEMCHENKO

ВИТЯГ З НАКАЗУ № 35
По Національному фармацевтичному університету
від 06 лютого 2023 року

нижченаведеним студентам 5-го курсу 2022-2023 навчального року, навчання за освітнім ступенем «магістр», галузь знань 22 охорона здоров'я, спеціальності 226 фармація, промислова фармація, освітня програма – фармація, денна форма здобуття освіти (термін навчання 4 роки 10 місяців та 3 роки 10 місяців), які навчаються за контрактом, затвердити теми кваліфікаційних робіт:

Прізвище студента	Тема кваліфікаційної роботи		Посада, прізвище та ініціали керівника	Рецензент кваліфікаційної роботи
• **по кафедрі організації та економіки фармації**				
Абделсамі Самах Соліман Метваллі	Дослідження особливостей розвитку ринку медичних товарів в країнах Африки в умовах глобалізації	Investigetion of peculiarities of the medical products market development in African countries in the conditions of globalization	доц. Демченко Н.В.	проф. Сагайдак-Ніакітюк Р.В.

Підстава: подання декана, згода ректора

Ректор

Вірно. Секретар

Ф А2.8-47-110

ВИСНОВОК

Комісії з академічної доброчесності про проведену експертизу щодо академічного плагіату у кваліфікаційній роботі здобувача вищої освіти

№ 112167 від « 3 » квітня 2023 р.

Проаналізувавши випускну кваліфікаційну роботу за магістерським рівнем здобувача вищої освіти денної форми навчання Абделсамі Самах Соліман Метваллі, 5 курсу, _____ групи, спеціальності 226 Фармація, промислова фармація, на тему: «Дослідження особливостей розвитку ринку медичних товарів в країнах Африки в умовах глобалізації / Investigetion of peculiarities of the medical products market development in African countries in the conditions of globalization», Комісія з академічної доброчесності дійшла висновку, що робота, представлена до Екзаменаційної комісії для захисту, виконана самостійно і не містить елементів академічного плагіату (компіляції).

Голова комісії,
професор **Інна ВЛАДИМИРОВА**

0%

29%

Ф А 2.2.1-32-353

REVIEW

of scientific supervisor for the qualification work of the master's level of higher education of the specialty 226 Pharmacy, industrial pharmacy

Abdelsamie Samah SOLIMAN METWALLY

on the topic: «Investigation of peculiarities of the medical products market development in African countries in the conditions of globalization»

Relevance of the topic. It is widely recognized that the medical device (MD) industry in South Africa can contribute more significantly to economic growth, job creation, enhanced health outcomes and improved quality of life.

South Africa has relatively limited production capacity for medical devices. The market is therefore largely dependent on imports. Local production is not homogeneous. In most African countries, over 90% of the medical devices in public hospitals are imported and local production is very limited. Even in South Africa, a country with a well-established medical device sector in terms of companies registered to sell medical devices, there are few local manufacturing firms. The sector faces technological, market and regulatory barriers that are holding back the emergence of SMEs and the growth of the sector in Africa. Innovative public health procurement can be used as an active industrial policy to support this sector. Currently, medical device companies are dependent on European Notified Bodies and this greatly increases their compliance costs. The development of recommendations for the management and modernization of the medical goods market in African countries is necessary both for the future development of the economies of the countries of the region and for improving the efficiency of the healthcare sector.

Practical value of conclusions, recommendations and their validity. The research results are of great importance for future medical goods market development in African countries and to increase effectiveness of healthcare and wellness.

Assessment of work. Abdelsamie Samah SOLIMAN METWALLY significant research work and successfully coped with it, showed the ability to analyze and summarize the data of literary sources, to work independently. The results of research are properly interpreted and illustrated. In performing the qualification works, the higher education seeker showed creativity, purposefulness, independence, perseverance.

General conclusion and recommendations on admission to defend. Qualification work of the 5th year student of higher education of the group

Phm18*(5.0)-eng-08 S Abdelsamie Samah SOLIMAN METWALLY on the topic "Investigation of peculiarities of the medical products market development in African countries in the conditions of globalization" is a completed research study, which in terms of significance meets the requirements for qualification works, and can be relevance, scientific novelty, theoretical and practical submitted to the EC of NUPh.

Scientific supervisor _____ Nataliia DEMCHENKO

«14» of April 2023

Ф А 2.2.1-32-356

REVIEW

for qualification work of the master's level of higher education, specialty 226 Pharmacy, industrial pharmacy

Abdelsamie Samah SOLIMAN METWALLY

on the topic: «Investigation of peculiarities of the medical products market development in African countries in the conditions of globalization»

Relevance of the topic. Of particular relevance is the question of how African countries can best use the lessons of the Covid-19 pandemic and relevant local manufacturing experience to develop and expand sustainable local manufacturing capabilities for medical products. The medical devices sector is among the most under-studied on the continent. Generally, there is a high reliance on imports across different countries. Local production is patchy. Its rapid emergence and prevalence will depend on careful structuring of a technological innovation system that supports the seven component areas of entrepreneurial activity: knowledge development, knowledge diffusion, guidance of search, resource mobilisation, market formation, and legitimation.

Theoretical level of work. To analyze the dynamics, structure and trends of the medical devices market in African countries, its strengths and weaknesses in order to develop strategic directions for its development and improve the efficiency of the healthcare sector.

Author's suggestions on the research topic. Recommendations for medical goods market development, including research and development management, financing and industry support from the public and private sectors was developed. They are: to invest more in ensuring increase in the presence of more pharmaceutical companies, developing structural models to address any local barriers, for example, corrupt practices, strengthening digitalization of supply chain activities, increase in budgetary allocation to health in African countries and invest directly in supporting manufacturing industries through capacity building, improved access to infrastructure, and building local talents.

Practical value of conclusions, recommendations and their validity. The results of research and forecasting of trends in the development of the medical goods market, taking into account the assessment of opportunities and threats in the

context of globalization, can serve as the basis for making strategic management decisions for the development of the health sector in the African region.

Disadvantages of work. As a remark, it should be noted that some of the results of the literature review, which are presented in the first section, need stylistic refinement. In general, these comments do not reduce the scientific and practical value of qualifying work.

General conclusion and assessment of the work. The qualification work of Abdelsamie Samah SOLIMAN METWALLY on the topic "Investigation of peculiarities of the medical products market development in African countries in the conditions of globalization" is a science-based analytical study that has theoretical and practical significance. Qualification work meets the requirements for qualification work and can be submitted to the EC of the National University of Pharmacy.

Reviewer _____ Doctor of Pharm. Sc., Professor

Rita SAGAYDAK-NIKITYUK

«22» of April 2023

Ф А2.2.1-91-287

МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ
НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

ВИТЯГ З ПРОТОКОЛУ № 23

«26» квітня 2023 року

м. Харків

засідання кафедри

Організації та економіки фармації

Голова: завідувачка кафедри, доктор фарм. наук, професор Алла НЕМЧЕНКО.

Секретар: канд. фарм. наук, доцент Алла ЛЕБЕДИН.

ПРИСУТНІ:

зав. каф., проф. Алла НЕМЧЕНКО, проф. Ганна ПАНФІЛОВА, проф. Вікторія НАЗАРКІНА, проф. Інна БАРАНОВА, доц. Віталій ЧЕРНУХА, доц. Геннадій ЮРЧЕНКО, доц. Наталія ТЕТЕРИЧ, доц. Ірина ПОПОВА, доц. Наталія ДЕМЧЕНКО, доц. Вікторія МІЩЕНКО, доц. Алла ЛЕБЕДИН, доц. Тетяна ДЯДЮН.

ПОРЯДОК ДЕННИЙ:

Про представлення до захисту в Екзаменаційну комісію кваліфікаційних робіт здобувачів вищої освіти випускного курсу НФаУ 2023 року випуску.

СЛУХАЛИ: про представлення до захисту в Екзаменаційну комісію кваліфікаційної роботи на тему: «Дослідження особливостей розвитку ринку медичної продукції в країнах Африки в умовах глобалізації», здобувача вищої освіти Фм18*(5,0д)англ-08 групи НФаУ 2023 року випуску Абделсамі Самах СОЛІМАН МЕТВАЛЛІ

Науковий керівник Наталія ДЕМЧЕНКО
Рецензент Ріта САГАЙДАК-НІКІТЮК

УХВАЛИЛИ: Рекомендувати до захисту кваліфікаційну роботу здобувача вищої освіти Абделсамі Самах СОЛІМАН МЕТВАЛЛІ групи Фм18*(5,0д)англ-08 на тему: «Дослідження особливостей розвитку ринку медичної продукції в країнах Африки в умовах глобалізації».

Зав. кафедри організації та
економіки фармації Алла НЕМЧЕНКО

Секретар кафедри Алла ЛЕБЕДИН

Ф А2.2.1-32-042

НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

ПОДАННЯ
ГОЛОВІ ЕКЗАМЕНАЦІЙНОЇ КОМІСІЇ
ЩОДО ЗАХИСТУ КВАЛІФІКАЦІЙНОЇ РОБОТИ

Направляється здобувач вищої освіти Абделсамі Самах СОЛІМАН МЕТВАЛЛІ до захисту кваліфікаційної роботи
за галуззю знань 22 Охорона здоров'я
спеціальністю 226 Фармація, промислова фармація
освітньою програмою Фармація
на тему: «Дослідження особливостей розвитку ринку медичної продукції в країнах Африки в умовах глобалізації».

Кваліфікаційна робота і рецензія додаються.

Декан факультету _____ / Світлана КАЛАЙЧЕВА /

Висновок керівника кваліфікаційної роботи

Здобувачка вищої освіти Абделсамі Самах СОЛІМАН МЕТВАЛЛІ виконала на кафедрі організації та економіки фармації НФаУ кваліфікаційну роботу, яка присвячена аналізу ринку медичних товарів в країнах Африки в умовах глобалізації.

У першому розділі проведено огляд економічних та історичних особливостей розвитку ринку медичних товарів та сфери охорони здоров'я в країнах Африки. В аналітичні частинні проведено SWOT-аналіз щодо ринку медичних виробів, проаналізована його структура та спрогнозовані тенденції його розвитку шляхом побудови ліній трендів. У третьому розділі запропоновано рекомендації щодо розвитку ринку медичних товарів на основі ефективного менеджменту та побудови відносин із стейкхолдерами, залученні інвестицій та капіталу.

У цілому подана до захисту кваліфікаційна робота Абделсамі Самах СОЛІМАН МЕТВАЛЛІ на тему «Дослідження особливостей розвитку ринку медичної продукції в країнах Африки в умовах глобалізації» відповідає вимогам, що висуваються до кваліфікаційних робіт, оцінюється позитивно і може бути рекомендована для захисту в Екзаменаційну комісію НФаУ.

Керівник кваліфікаційної роботи

_____ Наталія ДЕМЧЕНКО

«14» квітня 2023 р.

Висновок кафедри про кваліфікаційну роботу

Кваліфікаційну роботу розглянуто. Здобувач вищої освіти Абделсамі Самах СОЛІМАН МЕТВАЛЛІ допускається до захисту даної кваліфікаційної роботи в Екзаменаційній комісії.

Завідувач(ка) кафедри
організації та економіки фармації
_____ Алла НЕМЧЕНКО

«26» квітня 2023 року

Qualification work was defended

of Examination commission on

« __ » _____2023

With the grade _____

Head of the State Examination commission,

DPharmSc, Professor

_____ / Oleh SHPYCHAK /