UDC 658.5:339.56

MEDICAL DEVICES MARKET DEVELOPMENT IN AFRICAN COUNTRIES: PROBLEMS AND PROSPECTS

Demchenko Nataliia, Samah Soliman Metwally Abdelsamie
National University of Pharmacy, Kharkiv, Ukraine,
demchenata@ukr.net

SUMMARY. In the study the 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.

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

Introduction. The African medical device industry was a previously unregulated industry, unlike most other medical device industries around the world. African countries mostly do 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.

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 and to define barriers to medical device innovation.

Materials and methods. The following methods were used in the study: content analysis, historical, logical, correlation and regression analysis, statistical, graphic.

Results. 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 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% [1-2]. 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. Such indicators allow us to conclude that the market for general medical goods is developing steadily and is quite promising (Fig. 1.).

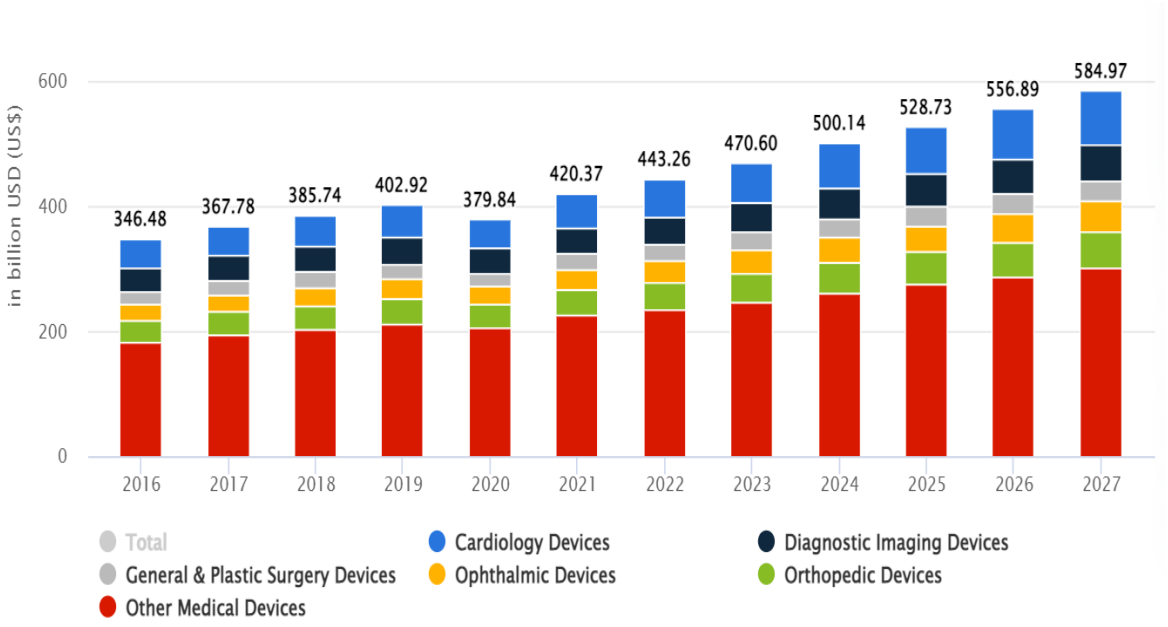

Fig.1. Forecast for the development of individual segments of the global market for medical products

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. This sector includes bandages and dressings,

suturing materials, syringes, needles, catheters, etc. Currently estimated at $240 million [3], this market will grow around 1,7% in 2022.

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.

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 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.

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 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 [4]. Fig. 2 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.

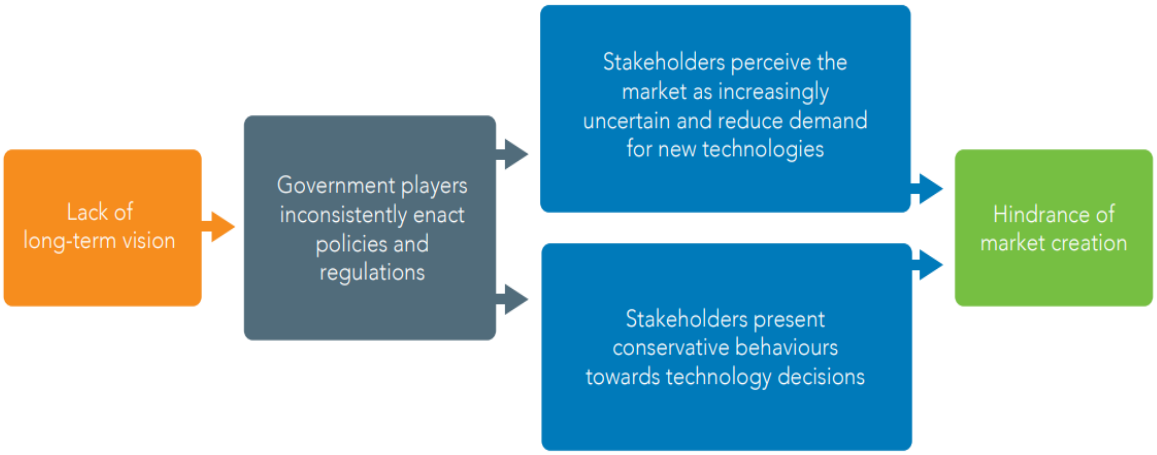

Fig. 2. Example of ambiguous behavior by Government as blocking mechanism

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 presents the results of a coding of different responses into different barrier categories.

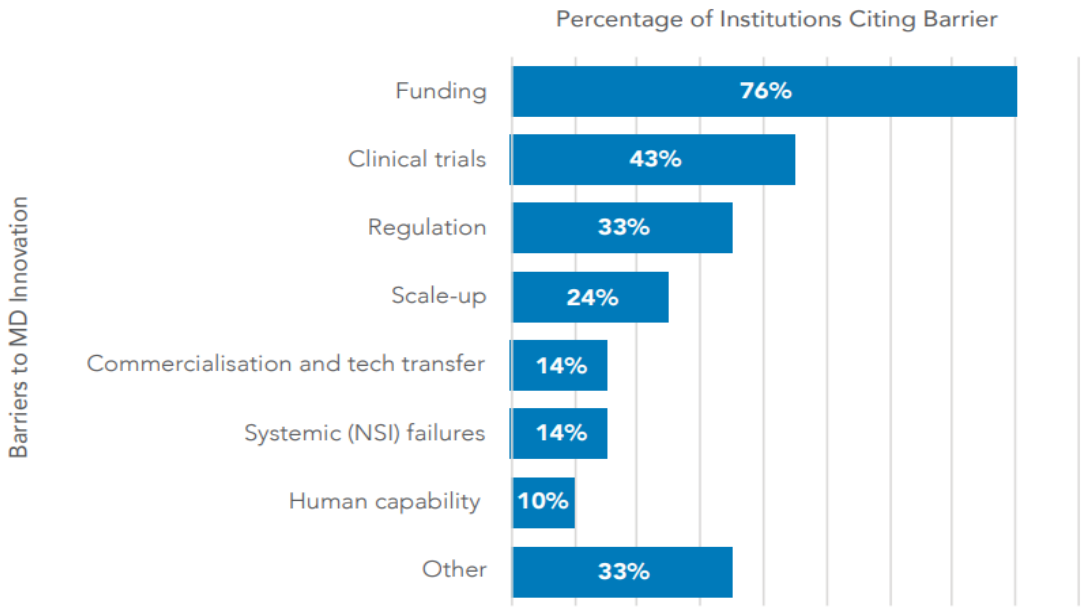

Fig. 3. Barriers to medical device innovation cited by STI institutions

Gaps in the development and commercialization of medical devices in African countries are also requires attention. The gaps in the development and commercialization of medical devices in 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.

Conclusions. 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. 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.

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.

References:

1. WHO. Tracking Universal Health Coverage in the WHO African Region, 2022. URL: https://www.afro.who.int/publications/tracking-universal-health-coverage-who-african-region-2022

2. Health in Africa ESTA & OSHD over the next 50 Years URL: https://www.afdb.org/fileadmin/uploads/afdb/Documents/Publications/Economic_Brief_-_Health_in_Africa_Over_the_Next_50_Years.pdf

3. Atlas of African Health Statistics 2022 – Health situation analysis of the African Region – Summary Report. URL: https://www.afro.who.int/publications/atlas-african-health-statistics-2022-health-situation-analysis-who-african-region-0

4. The Joint United Nations Programme on HIV/AIDS (UNAIDS). 2020. URL: https://www.unaids.org/sites/default/files/media_asset/2020_aids-data-book_en.pdf

РЕЗЮМЕ. У статті 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.

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