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UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TMDA
Tanzania Medicines & Medical Devices Authority

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

ACTION PLAN TO PROMOTE DOMESTIC MEDICAL PRODUCTS MANUFACTURING FACILITIES

2022/23 – 2026/27

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ACRONYMS AND ABBREVIATIONS

ADDOs	-	Accredited Drug Dispensing Outlets
AfCFTA	-	African Continental Free Trade Area
AMA	-	African Medicines Agency
AMRH	-	African Medicines Regulatory Harmonization
APIs	-	Active Pharmaceutical Ingredients
BOT	-	Bank of Tanzania
BRELA	-	Business Registration and Licensing Authority
CAPA	-	Corrective Action and Preventive Action
CSC	-	Clients' Service Charter
DMC	-	Director of Medical Products Control
EAC	-	East African Community
EAHRC	-	East African Health Research Commission
EIA	-	Environmental Impact Assessment
EPZA		Export Processing Zones Authority
ETP	-	Effluent Treatment Plant
FEAPM	-	Federation of East African Pharmaceutical Manufacturers
FIFO	-	First In First Out
GCLA	-	Government Chemist Laboratory Authority
GIZ	-	Deutsche Gesellschaft für Internationale Zusammenarbeit
GMP	-	Good Manufacturing Practices
HR	-	Human Resources
HSSPV	-	Health Sector Strategic Plan V
HVAC	-	Heating, Ventilation and Air Conditioning System
ISO	-	International Standardization Organization
ITM	-	Institute of Traditional Medicine
IUDs	-	Intrauterine Devices
LMIC	-	Lower Middle Income Country
M&E	-	Monitoring and Evaluation
MCIE	-	Manager of Medicines and Complementary Products Inspection and Enforcement
MCPE	-	Manager of Communication and Public Education
MICT	-	Manager of Information and Communication Technology
MMDC	-	Manager of Medical Devices and Diagnostics Control
MMRE	-	Manager of Medicines Registration and Evaluation

MoHCDGEC	-	Ministry of Health, Community Development Gender, Elderly and Children
MSD	-	Medical Stores Department
MUHAS	-	Muhimbili University of Health and Allied Sciences
NDC	-	National Development Corporation
NEMC	-	National Environmental Management Council
NEMLT	-	National Essential Medicines List of Tanzania
NIDA	-	National Identification Authority
NIMR	-	National Institute for Medical Research
NMRAs	-	National Medicines Regulatory Authorities
NOVABI	-	Novel Vaccines and Biological Company
OSD	-	Oral Solid Dosage Form
OSHA	-	Occupational Safety and Health Authority
PMS	-	Post-Marketing Surveillance
PSI	-	Population Service International
QA	-	Quality Assurance
QMS	-	Quality Management System
R&D	-	Research and Development
RECs	-	Regional Economic Communities
RPMPOA	-	Regional Pharmaceutical Manufacturing Plan of Action
SADC	-	Southern African Development Community
SIDO	-	Small Industries Development Organization
STG	-	Standard Treatment Guideline
SWOC	-	Strength, Weakness, Opportunity and Challenges
TAEC	-	Tanzania Atomic Energy Commission
TANESCO	-	Tanzania Electricity Supply Company Limited
TBS	-	Tanzania Bureau of Standards
TEIW	-	Tanzania Electronic Investment Window
TIC	-	Tanzania Investment Centre
TMDA	-	Tanzania Medicines and Medical Devices Authority
TPI	-	Tanzania Pharmaceutical Industry
TPMA	-	Tanzania Pharmaceutical Manufacturers Association
TRA	-	Tanzania Revenue Authority
TRIPS	-	Trade-Related Aspects of Intellectual Property Rights
UNECA	-	United Nations Economic Commission for Africa
UNIDO	-	United Nations Industrial Development Organization

VAT	-	Value Added Tax
WHO	-	World Health Organization
WTO	-	World Trade Organization

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- Mr. Emmanuel Alphonce
- Adv. Iskari Fute
- Mr. Sunday Kisoma
- Mr. Bryceson Kibassa
- Mr. Maganga Bundala
- Mr. Paul Sonda
- Mr. Alex Juma
- Mr. Paul Makaranga
- Ms. Doreen Nyaki

I'm indeed grateful for what they have done and would like to take the opportunity to thank them all. The daunting secretarial task offered by Ms. Joyce Komba is likewise notable and again would also like to acknowledge her service towards the completion of this document.

During drafting several reference materials were cited for recapping of what had been achieved earlier including gaining experience for better shaping-up of the document. I would like to also acknowledge all who made their documents available for reference.

Lastly, the TMDA Management is indebted for constructive criticism and final endorsement of this Plan.

Dr. Yonah H. Mwalwisi
ACTING DIRECTOR OF MEDICAL PRODUCTS CONTROL

FOREWORD

Pharmaceutical and medical device manufacturing facilities play a significant role in any state to ensure an uninterrupted supply of medicines and other health commodities that are essential to save lives. Creating an enabling environment for such industries to be established is pivotal. Deliberate measures need to be put in place including analyzing all policies governing their set-up to facilitate their establishment.

In recent times many health authorities in Africa and Regional Economic Communities (RECs) have been inclined to craft and publish action plans for promoting pharmaceutical manufacturing with clearly defined goals. Several strategies have been put forward all intending to provide impetus and stir-up domestic pharmaceutical production. The recent COVID-19 pandemic has also alerted countries on the importance of having industries within their territories for quick and immediate supply of pharmaceutical and other medical products.

In East Africa through the East African Community (EAC), the Regional Pharmaceutical Manufacturing Plan of Action was initially launched in 2012 and the same have been revised in 2017. The initial plan took 4 years of implementation up to 2016 and the current one will run up to 2027. The initial plan was somehow well implemented but with some notable challenges which were taken on board in the revised plan. The overall intention is still to catalyze and mobilize available resources including streamlining policies towards regional pharmaceutical production.

Moving forward and trickling down this agenda item to national authorities, the Tanzanian Ministry responsible for health drafted the National Pharmaceutical Manufacturing Plan of Action in 2014 but the same had not been officially approved. Nonetheless, the National Industrialization Agenda – 2025 was endorsed in 2015 to again energize the private sector to invest in the industrial sector including medical products manufacturing in the next decade. Since then many industries have been established mainly in the Coast, Dar es Salaam, Morogoro, Arusha and Mwanza regions. Consequently, there has been a 3-fold increase of companies built within a very short period. This has revolutionized the pharmaceutical and medical devices manufacturing industry in the country.

In tandem with all these efforts, the TMDA has likewise decided to craft this Plan focusing on the regulatory roles and responsibilities. In all previous and existing plans, there have always been strategies targeting strengthening regulatory systems as this has proven to be utterly critical in ensuring that products manufactured meet good manufacturing practice (GMP) standards. Since 2003, the TMDA has been working closely with owners of pharmaceutical industries to facilitate and guide them to meet GMP standards. Despite the efforts, many are still not complying with the minimum requirements set and this has also been the reason why this plan is being developed.

This Action Plan will run for 5 years in line with the timeline of implementation of the TMDA Strategic Plan. It is envisaged that the strategic objectives outlined will assist in providing a direction towards GMP compliance including improving the existing and upcoming industries to be established. It will as well help the industries to deploy competent personnel including designing, installing and operating in accordance with the laid down regulatory requirements.

Furthermore, TMDA advocates for the strengthening of the Tanzania Pharmaceutical Manufacturers Association (TPMA) which plays a significant role as a conduit in the exchange of information between the two. We urge TPMA to be more active and engage all

owners of industries including recently established facilities. Through TPMA, TMDA will be able to effectively communicate and reach out to all members to discuss and agree on matters of concern to the industry, including offering any technical assistance needed.

Lastly, TMDA pledges to continue working in partnership with all stakeholders including government departments responsible for ensuring that facilitative environments are created for industries to be established in the country. Comments from stakeholders are further welcomed for improvement of this Plan.

The Plan will be monitored for its effective implementation and evaluated at mid and end terms as specified. The TMDA Management will set aside resources needed as provided for in the annexed budget for successful implementation of this Plan.

Adam M. Fimbo
DIRECTOR GENERAL

DEFINITION OF TERMS

For this plan, the following words or phrases are defined as follows;

Activity
Means action is taken or work performed to produce a given target;

Baseline Indicator Value
Means historical value of an indicator and includes the baseline indicator date;

CAPA Clinics
An arrangement made by the Authority which means to support the process of inspection or audit follow up to streamline preparing corrective and preventive actions, including the designation of responsibility and due dates by the domestic medical products manufacturers;

Drug Utilization Studies
Means studies of the marketing, distribution, prescription and use of drugs in society with special emphasis on the resulting medical, social and economic consequences;

Environmental Impact Assessment
Means a systematic examination conducted to determine whether or not a programme, activity or project will have any adverse impacts on the environment;

Evaluation
Means a periodic assessment of the efficiency, effectiveness, impact, sustainability and relevance in the context of stated objectives;

Good Manufacturing Practices
Means that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization and product specifications;

Indicator
Means a quantitative or qualitative factor or variable that provides a simple and reliable means to measure achievement, to reflect the changes connected to an intervention, or to help assess the performance of a party or institution;

Medical products
Means medicines, medical devices, or diagnostics;

Milestone
Means an activity tagged or singled out for special monitoring in terms of progress or completion;

Monitoring
Means a continuing function that uses systematic collection of data on specified indicators to provide management and the main stakeholders of an ongoing intervention with indications of the extent of progress and achievement of objectives and progress in the use of allocated resources;

Objective

Means a broad statement of what is to be achieved and the improvements to be made describing an intended outcome or impact and summarizes why a series of actions have been undertaken;

Operating Capacity
Means the maximum amount that the manufacturing operation can produce;

Outcome
Means the likely or achieved short-term and medium-term effects of an intervention's outputs;

Output
Means services that result from intervention and may also include changes (usually of an immediate nature) resulting from the intervention which are relevant to the achievement of outcomes;

Production Capacity
Means the maximum output that can be achieved in one production cycle;

Quality assurance
Means a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made to ensure that pharmaceutical products are of the quality required for their intended use;

Quality audit
Means a systematic, independent, and documented process that serves to obtain evidence and evaluate it objectively to determine if defined criteria are met in the manufacture of medical devices and diagnostics

Quality Management System
The aspect of management function that determines and implements the "quality policy" that is, the overall intention and direction of an organization as formally expressed and authorized by top management.

Query Clinics
An arrangement made by the Authority which means to support the process of query responses by streamlining the preparation of query responses including interpretation of various requirements communicated to the domestic medical products manufacturers;

Target
Means the services provided over a given period to achieve its objectives;

Technology Transfer
Means a logical procedure that controls the transfer of any process together with its documentation and professional expertise between development and manufacture or between manufacture site OR a systematic procedure that is followed to pass the documented knowledge and experience gained during the development and or commercialization to an appropriate, responsible and authorized party; and

Utilized Capacity

Means manufacturing and production capabilities that are being utilized by the manufacturer.

1. INTRODUCTION

The health sector in Tanzania largely depends on the importation of medicines, medical devices and in-vitro diagnostics. It has been estimated that 80% of pharmaceuticals and almost 100% of medical devices are imported from various countries. The large shares of imported pharmaceuticals and medical devices are imported from India and China respectively.

As part of efforts to reverse this situation and to promote domestic medical products manufacturing, the Government through the Health Sector Strategic Plan 5 of July 2021 - June 2026 (HSSPV) has prioritized the strengthening of domestic manufacturing facilities including research and development. TMDA as the national medicines regulatory body has developed this action plan in cognizant of the challenges facing domestic manufacturers and in line with the HSSPV, National Industrialization Agenda - 2025, and TMDA Strategic Plan 2021/22 - 2025/26.

The Action Plan describes the challenges and is intended to solve problems that have been highlighted. This Plan will be implemented for five (5) years and it is divided into the following parts; objectives, situational analysis at continental, regional, and national levels including the SWOC analysis, activity plan, budget, and monitoring and evaluation framework.

The activity plan details activities that will be performed and identify indicators, timelines, and responsible personnel. The monitoring and evaluation framework includes mid and end-term evaluation. A total of 58 output and 6 outcome indicators to measure performance are included in the M&E framework. It is estimated that a total budget of **T 1, 632,230,000** will be required for the implementation of this Plan.

2. OBJECTIVES

2.1 General Objective

To promote domestic medical products manufacturing facilities.

2.2 Specific objectives

(a) To facilitate pharmaceutical manufacturing facilities to meet Good Manufacturing Practice requirements

(b) To facilitate medical devices and diagnostics manufacturing facilities to meet Quality Audit requirements

(c) To ensure timely decision making on marketing authorization submissions for domestically manufactured products

(d) To foster collaboration with government departments and other stakeholders to support pharmaceutical and medical devices manufacturing

(e) To monitor and evaluate the implementation of this Plan

3. SITUATIONAL ANALYSIS

3.1 Status of Medical Product Industries

There is a total of 42 medical products manufacturing facilities of which 18 are engaged in manufacturing pharmaceutical products and 24 medical devices as indicated in **Annex I**. The first pharmaceutical industry which is Mansoor Daya Chemicals Limited was established in 1962. From 1962 up to 2015, there were only 9 facilities that were established and in operation. Beginning 2015 there has been an upsurge of pharmaceutical and medical devices manufacturing facilities in the country of which 32 have been constructed.

Almost all of the existing and newly constructed industries are privately owned except five (5) which are partly owned by the Government of Tanzania through the Treasury Registrar. These are Keko Pharmaceutical Industries (1997) Ltd, Tanzania Pharmaceutical Industries Ltd (TPI), Medical Stores Department (MSD) (Keko), MSD (Idofi), and Tanzania Vaccines Institute (TVI).

Annex II of this document highlights the list of both pharmaceutical and medical device industries under construction as of January 2022. Out of these seven (7) will be engaged in pharmaceuticals and one (1) medical devices manufacturing.

3.2 Implementation of Pharmaceutical Manufacturing Plans of Action

3.2.1 Implementation at continental level

The Pharmaceutical Manufacturing Plan for Africa was officially endorsed in 2012 in Addis Ababa, Ethiopia with the overall goal of catalyzing the local pharmaceutical production to improve public health outcomes. The design was to ensure access, quality, availability, and affordability of much-needed essential products on one hand and economic benefits through sustainability, competitiveness, and self-reliance of the pharmaceutical industry on the other hand.

The Plan focused on six main strategic areas namely:-

- Human Resources (HR) Development
- Access to product and technology
- Access to affordable finances and time-limited incentives
- Regulatory systems strengthening and enforcement
- Partnership collaborations and fostering business linkages
- Enhancing market data collection and facilitating market access

Under HR development, the Kilimanjaro School of Pharmacy has been designated as the center of excellence for industrial pharmacy by the United Nations Economic Commission for Africa (UNECA) after recording excellence in enrolling and training experts in pharmaceutical manufacturing.

Access to technology has also improved in the newly constructed facilities after commissioning experts from China and India who have advanced in pharmaceutical manufacturing.

On access to affordable finances and time-limited incentives, this has not been well-coordinated and letters of credit are not issued due to various reasons. However, there have been VAT exemptions for importers of pharmaceutical raw materials including equipment.

Regulatory systems have been strengthened as many independent and semi-autonomous Authorities have been established to conduct oversight and enforcement of regulatory requirements. The African Medicines Regulatory Harmonization (AMRH) Initiative was also launched to converge regulatory requirements amongst RECs and National Medicines Regulatory Authorities (NMRAs). Under the same strategy, the specialized continental regulatory body namely the African Medicines Agency (AMA) has been established to support regulatory systems strengthening.

Collaboration and linkages have also improved as regional associations for pharmaceutical manufacturers and importers have been established to foster partnerships on generic products manufacturing, issues related to intellectual property rights, and trade agreements. During the same period, the African Continental Free Trade Area (AfCFTA) was established to address the major challenge of small fragmented markets.

The strategy on enhancing market data collection and facilitating market access is still experiencing some mounting challenges as sharing of information is not practiced and domestic companies do not suffice market demands.

3.2.2 Implementation at the regional level

The EAC through its Secretariat published the first Regional Pharmaceutical Manufacturing Plan of Action 2012–2016 which highlighted some strategies designed towards stimulating regional pharmaceutical production. The main achievements and challenges are summarized in **Table 5** below. It can be depicted from the table that, despite the achievements, there were more challenges in the implementation of the plan that necessitated the development of the Second Regional Pharmaceutical Manufacturing Plan of Action 2017–2027. The revised edition will run for 10 years instead of 4 which was approved before. It is almost 5 years since the commencement of implementation of the revised plan which has essentially maintained the below-listed pillars as provided for in the previous edition:

- Promotion of competitive and efficient pharmaceutical production;
- Facilitation of increased investment in pharmaceutical production;
- Strengthening of pharmaceutical regulatory capacity;
- Development of appropriate skills and knowledge on pharmaceutical production;
- Utilization of WTO TRIPS flexibilities and technology transfer in improving local production of pharmaceuticals; and
- Mainstreaming innovation, research, and development within the pharmaceutical industry.

Comparing and contrasting with the previous plan, it is only priority areas that have been revised to see through the implementation of the current plan. It can be observed that most plans of action focus on pharmaceuticals and not medical devices and diagnostics manufacturing industries.

Table 5: Summary of main achievements and challenges of the first phase, EAC-RPMPOA: 2012–2016

Strategic objectives	Main achievements	Challenges
Promotion of competitive and	• Local pharmaceutical production is a priority area at	Collection of reliable market data for demand

efficient regional pharmaceutical production	both national and regional levels (e.g. policies and strategic plans). • The regional manufacturers' association, FEAPM, has been established and is engaged in lobbying and advocacy activities. • Expanded pharmaceutical operations and improved quality standards of local firms. • Joint ventures/buyouts reported.	Quantification and production capacity proved difficult. Key stakeholders were reluctant to provide data.
Facilitation of increased investment in pharmaceutical production regionally	• Round-table advocacy discussions held in all Partner States and a first international high-level conference on investment in pharmaceutical manufacturing (2016). The local pharmaceutical production received attention at the highest level of policy making. • Improved operating business environment in the region has had a positive impact on the pharmaceutical sector.	• Costly and unreliable access to electricity. • Unfavorable market access conditions for local manufacturers.
Strengthening pharmaceutical Regulatory capacity in the region	• Strengthened regulatory capacity and infrastructure in the EAC Partner States. • Increased technical cooperation (e.g. common guidelines, joint assessments and inspections, PMS) in the region.	• Varying levels of regulatory capacity among EAC States' NMRAs. • Mutual recognition is not in place and therefore decisions from joint evaluation and inspections are non-binding.
Development of appropriate skills and knowledge for pharmaceutical production in the region	• More than 300 technical personnel trained in e.g. PV, PMS, clinical trials, dossier evaluation, GMP inspection, proficiency testing, calibration and validation, preventative maintenance of critical quality control equipment. • The academia-industry internship programme is supported by GIZ and UNIDO.	• High costs for equipping and accrediting regional training institutions. • Skills mix should go beyond pharmaceutical personnel and also include e.g. engineers, chemists, and biologists/microbiologists

Utilization of WTO TRIPS flexibilities to improve local production of pharmaceuticals in East Africa	• EAC WTO TRIPS policy and a model law in place to guide the Partner States. • Training, workshops and blended learning courses sensitized EAC stakeholders on the use of public health-related WTO TRIPS flexibilities	• Despite the training, there is still a lack of awareness and understanding of IP issues and the public health-related WTO TRIPS flexibilities. • Partner States have not approximated their national laws to take full advantage of WTO TRIPS flexibilities.
Innovation, research and development within regional Pharmaceutical industry	• The East African Health Research Commission (EAHRC) has been established. • Pilot projects to promote pharmaceutical R&D capacity in the region, e.g. with MUHAS and Kilimanjaro School of Pharmacy, with the support of GIZ.	• Weak links between industry and academia. • A regional innovation fund for the pharmaceutical sector does not exist. • National innovation funds thinly spread their resources to priority sectors. • No significant R&D activities but a focus on generics. • Donor-funded programmes do not prioritize downstream pharmaceutical R&D.

3.2.2 Implementation at the national level

The then Ministry of Health & Social Welfare drafted the Strategy for Promotion of Domestic Pharmaceutical Production in Tanzania in 2013 which was however not officially approved for implementation. The draft document amongst others articulated envisaged strategies that also aimed at promoting domestic pharmaceutical production. Despite that the Strategy was not approved, several other initiatives were undertaken by the government to promote investment and establishment of pharmaceutical and medical devices manufacturing facilities in the country.

Currently, the Tanzania Investment Centre (TIC) which was established in 1997 oversees policy coherence on investment of all industries including the pharmaceutical and medical devices industry. Through TIC investors submit their applications for the establishment of facilities. TIC coordinates all other Ministries and Government Departments responsible for investment including the Ministry of Lands, Housing and Settlement, Immigration, TRA, BRELA, OSHA, NEMC, NIDA, TBS, TANESCO and TMDA. These responsible ministries and government departments operate at the TIC office under a one-stop shop.

Through all these efforts and the National Industrialization Agenda 2025, Tanzania has observed a three-fold increase in investment in pharmaceuticals and medical devices manufacturing facilities. The Research and Development Laboratory has also been

established at the School of Pharmacy, Muhimbili University of Health and Allied Sciences. The Regional Centre of Excellence on Medicine Evaluation and Registration has as well been established and designated as such to offer training on medicines evaluation, GMP and dossier compilation.

In line with the creation of the Federation of East African Pharmaceutical Manufacturers (FEAPM), the Tanzania Pharmaceutical Manufacturers Association (TPMA) was established to bring together manufacturers of pharmaceutical products to forge ahead agenda items of national interest. Nevertheless, only a few members are active and efforts need to be put in place to encourage others to join. On the flip side, no association has been established for medical devices and diagnostics manufacturing industries.

3.2 SWOC analysis

Factors that may impact efforts in the promotion of domestic medical products manufacturing facilities in short and long-term periods have been identified through SWOC analysis as highlighted in **Table 6**.

Table 6: SWOC analysis

S/N	Strengths	Weaknesses	Opportunities	Challenges
1.	Political will and support	Inadequate domestic expertise	Availability of market	Unreliable power and water supply
2.	Sufficient land	Multiple institutions regulating the same industry	Existence of medical stores department for bulk procurement and supply	Overreliance on imported products
3.	Large population	Under utilization of the existing operating capacity	Harmonized regulatory requirements	Inadequate industrial pharmacists
4.	Availability of sea ports connecting with other countries	Inadequate capacity of manufacturers to compile dossier submissions	Fair competition in the market	Lack of APIs and excipients manufacturing facilities
5.	Availability of higher learning institutions	Delays in obtaining licenses and permits from various government departments	Strong and facilitative regulatory mechanism	Inadequate financial resources and credit facilities to sustain manufacturing
6.	Existence of functional Regulatory Authority	Inadequate marketing strategies amongst domestic industries	Established One Stop Shop at TIC	Medicines purchasing is mainly out of pocket
7.	Availability of higher learning institution	Failure to comply with GMP and Quality Audit requirements	Abolished fees and charges for domestic manufacturers	Limited availability of reference standards and consumables

8.	Existence of Industrial Policy, Investment Policy, Medicines Policy, and other related policies	The negative perception of domestically manufactured products	Existence of ADDOs	Absence of experts to conduct manufacturing and laboratory equipment maintenance and service
9.	Existence of EAC GMP Compendium	Absence of R&D centers	Availability of financial institutions for borrowing or lending money for domestic investment	Inadequate infrastructure in terms of roads, passages, and railway networks.
10.	Existence of EAC Medicines Registration Compendium of Guidelines	The narrow range of dosage forms manufactured by domestic companies	Existence of associations of manufacturers	Inadequate number of laboratory proficiency testing scheme providers
11.	Existence of medical devices regulatory framework	Only a few Class A medical devices are manufactured in the country	Presence of bilateral and multilateral agreements on collaborations	Absence of Bioequivalence Studies Centers
12.	Good communication between the public and private sectors	Few packaging materials manufacturers	Existence of EPZA	Lack of diagnostics manufacturing facilities
13.	Existence of the National Industrialization Agenda 2025	Lack of legal framework on TRIPS flexibilities	Transfer of technology through foreign investors	Lack of waste disposal mechanisms
		Inadequate drug utilization studies	Existence of universal health insurance scheme	

4. THE PLAN

The Plan has identified five main strategic objectives as highlighted before to be implemented over 5 years (2022/2023 - 2026/2027). The overall goal is to assist domestic manufacturers to attain and maintain GMP requirements and therefore ensure the availability of good quality, safe and efficacious medical products.

4.1 To facilitate domestic pharmaceutical manufacturing facilities to meet Good Manufacturing Practice requirements

Good manufacturing practice ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by TMDA. The Tanzania Medicines and Medical Devices (Good Manufacturing Practices) Regulations came into force in 2018 and the guidelines for GMP for both domestic and foreign manufacturers are currently enforced since 2014. These statutory documents provide in detail the technical requirements for manufacturers to comply with before authorizing their products for marketing in Mainland Tanzania.

Through annual inspections conducted by TMDA since 2003, most of the facilities have been found not to comply with GMP requirements. The reasons for non-compliance cited by manufacturers vary from inadequate resources, less capital, inadequate skill mix, and low technological advancement. To address these and many other challenges this Plan has been developed by TMDA to reverse the status quo and facilitate manufacturers to meet requirements

4.2 Facilitation of medical devices and diagnostics manufacturing facilities to meet Quality Audit requirements

Manufacturers of medical devices and diagnostics are required to meet Quality Audit standards and not GMP requirements. Quality audit standards are provided for in the ISO13485 promulgated by the International Organization on Standardization. The WHO Global Model Framework for Medical Devices and In-vitro diagnostics also recommends the adoption of ISO13485 by National Regulatory Authorities to ensure the quality, safety, and performance of medical devices and diagnostics. TMDA has also adopted these standards through the Tanzania Medicines and Medical Devices (Control of Medical Devices) Regulations, 2015. All Quality Audits conducted by TMDA inspectors verify compliance with these standards.

By 2019 six domestic medical devices manufacturing facilities had been inspected by TMDA on annual basis. All of them have been found not to comply with the requirements of ISO13485. A common finding observed through repeated audits over the years has been the overall lack of quality systems and their implementation. This has been the basis of developing this Plan to address this challenge.

4.3 To ensure timely decision making on marketing authorization submissions for domestically manufactured products

The TMDA has issued the 4th edition of the Clients' Service Charter in 2020 which amongst others outlines the timeline for offering various services to its customers. One of its services is to evaluate applications submitted by domestic manufacturers for marketing authorization within 60 working days for medicines and 20 days for medical devices. The timeline set for evaluation of query responses for medicines is 30 days making a total of 90 days up to decision on marketing authorization. The assumption is that there will be one round of queries and responses.

The Tanzania Medicines and Medical Devices (Registration of Medicinal Products) Regulations, 2015 requires applicants to submit query responses within 6 months failure of which applications are considered withdrawn. However, applicants can request for extension of time in case there are justifications to do so.
Despite all these requirements, the understanding of most customers is that the timeline set begins from submission up to the issuance of a decision on marketing authorization. As the current practice has been to stop the clock after sending queries to customers and waiting for their responses, this Plan intends to ensure that domestically manufactured products are decided on their marketing authorization within the timelines as set out in the CSC.

4.4 To foster collaboration and communication with government departments and other stakeholders

There are many other Ministries and government departments which are responsible for creating enabling environment for setting up pharmaceuticals and medical devices facilities. Their roles and responsibilities are outlined in **Table 8** below.

Table 8: Roles and responsibilities of Ministries and Government Departments

S/N	Name of Ministry or Department	Responsibilities
1.	Ministry of Lands, Housing and Human Settlements	• Acquisition of land • Preparing documents related to the right of occupancy • Overseeing all issues related to land administration
2.	Ministry of Health, Community Development, Gender, Elderly, and Children	• Overseeing implementation of National Drug Policy • Developing and updating the NEMLT and STG • Providing policy directives on investment in pharmaceutical and medical devices manufacturing • Acting as a link between the Government and private investors • Authorizing types of human vaccines to be manufactured
3.	Ministry of Industry and Trade	• Overseeing implementation of Industrial Policy • Promoting implementation of industrialization agenda 2025 • Setting up Special Economic Zones and Export Processing Zones
4.	Ministry of Finance and Planning	• Overseeing implementation of fiscal policies • Developing tax regimes
5.	Ministry Livestock and Fisheries	• Overseeing implementation of fiscal policies • Authorizing types of veterinary vaccines to be manufactured
6.	Commissioner of Labour	• Issuing work permits
7.	Commissioner of Lands	• Issuing building permits • Issuing title deeds
8.	Bank of Tanzania	• Regulating interest rates
9.	Tanzania Investment Centre	• Promoting investment in Tanzania • Overseeing implementation of investment policy • Coordinating investment in the country through One-Stop-Shop • Advising the Government on investment issues • Acquiring derivative rights on land acquisition • Issuing certificates of incentive
10.	Tanzania Revenue Authority	• Tax administration including tax exemptions, waivers, holidays, and others • Clearance of goods at customs • Tax clearance
11.	Tanzania Bureau of Standards	• Setting standards • Conformity assessments • Clearance of goods at ports of entry • Calibration and testing
12.	National Environmental Management Council	• Conducting Environmental Impact assessment • Issuing site suitability approvals

		• Supervising disposal of unfit products • Certification of ETPs
13.	Immigration	• Issuing work permits • Issuing residence permit • Clearance of goods at ports of entry • Calibration and testing
14.	National Identification Authority	• Issuing ID cards
15.	Occupational Safety and Health Authority	• Promoting occupational health • Issuing health and safety certificates
16.	Business Registration and Licensing Authority	• Issuing business and industrial licenses • Registration of business names • Registration of trade and service marks • Patenting of innovations • Registration of companies
17.	Higher Learning Institutions	• Offering research and development services • Training of personnel including Industrial pharmacy training • Identifying skill gaps • Conducting drug utilization studies
18.	National Council for Technical Education	• Coordinating provision of technical education • Certifying standards of technical education
19.	Water supply Authorities	• Supplying clean and safe water • Waste disposal and management
20.	Tanzania Industrial Research Development Organization	• Assisting the industrial sector by providing technical expertise
21.	Medical Stores Department	• Bulk procurement of domestic products and supply to public health facilities • Pooled procurement under SADC initiative
22.	National Development Corporation	• Leasing land • Stimulating industrialization in partnership with the private sector
23.	Banks and other financial institutions	• Lending of money • Issuing letters of credit

Consented efforts will be needed for all these Ministries and Departments to work in partnership to ensure that more investors are enticed to invest in the pharmaceutical and medical devices industry in Tanzania. The Tanzania Electronic Investment Window (TEIW) recently developed will be a good platform for bringing together all government departments and integrating their operations for investors to access.

Annex III illustrates in detail the activities to be implemented under each specific objective.

5. MONITORING AND EVALUATION

Monitoring and evaluation (M&E) are critical when it comes to ensuring that objectives are realized and milestones attained. The monitoring of this Action Plan will comprise of measuring indicators and their respective descriptions, indicator target values, indicator reporting frequency, and the responsible person. A total of 64 key performance disaggregated indicators (both output 58 and outcome 6) will be monitored and reported on

a quarterly, biannually, and annually basis, to track the performance of the planned activities as detailed in this Plan.

Two (2) formal performance reviews will be conducted at mid-term and end of term during the execution of this Plan. The mid-term review intends to track progress on achievement of targets and use the findings to adjust the action plan whenever necessary.

The final review will be conducted in the fifth year (2026/27) to determine whether or not the planned outputs and outcomes over the five years have been achieved against the indicators and the reasons in case of underachievement. The review will further assess the extent to which targets have contributed towards the achievement of five-year expected outcomes as well as challenges and lessons learned over the period.

The Director of Medical Products Control shall be responsible for the execution and completion of this Action Plan. The indicators to be monitored and evaluated as well as milestones to be achieved are highlighted in **Table 9** below:

Table 9: Indicators and Milestones

S/N	Indicator and Indicator description	Baseline		Indicator Target Values				
				Values				
		Date	Value	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5
Output-Based Indicators								
1.	Number of gaps identified (medicines)	July, 2022	0	-	-	-	-	-
2.	Implementation Plan developed	July, 2022	0	1	-	-	-	-
3.	Number and percentage of gaps addressed	July, 2022	0	50	70	80	90	100
4.	GMP Training Manual developed	July, 2022	0	1	-	-	-	-
5.	Number of facilities trained	July, 2022	9	5	10	15	20	25
6.	Number of key personnel trained	July, 2022	25	20	40	60	80	100
7.	Percentage of GMP areas covered	July, 2022	0	100	100	100	100	100
8.	Number of facilities facilitated	July, 2022	9	5	10	15	20	25
9.	Number of facilities inspected	July, 2022	15	25	25	25	25	25
10.	Number of CAPA clinics conducted	July, 2022	4	25	25	25	25	25
11.	Number and percentage of non-conformances addressed	July, 2022	0	50%	70%	80%	90%	100 %

12.	GMP and Quality Audit Technical Committee established	July, 2022	0	1	-	-	-	-
13.	Number of utilization studies conducted	July, 2022	0	-	1	-	1	-
14.	Number and types of products highly consumed	July, 2022	0	-	-	-	-	-
15.	Number of manufacturers assessed	July, 2022	0	25	-	25	-	-
16.	Percentage utilized	July, 2022	0	-	-	-	-	-
17.	Percentage consumption rate of pharmaceuticals in all health facilities	July, 2022	0	-	-	-	-	-
18.	Number of gaps identified (medical devices)	July, 2022	0	-	-	-	-	-
19.	Implementation Plan developed	July, 2022	0	1	-	-	-	-
20.	Number and percentage of gaps addressed (medical devices)	July, 2022	0	50	70	80	90	100
21.	Quality Audit Training Manual developed	July, 2022	0	1	-	-	-	-
22.	Number of facilities trained	July, 2022	0	10	15	20	25	30
23.	Number of personnel trained	July, 2022	40	50	70	90	110	150
24.	Number of facilities facilitated	July, 2022	0	2	4	6	8	10
25.	Number of facilities inspected	July, 2022	0	24	25	26	28	30
26.	Number of CAPA clinics conducted	July, 2022	0	30	30	30	30	30
27.	Number and percentage of non-conformances addressed	July, 2022	0	50%	70%	80%	90%	100 %
28.	Number of meetings conducted	July, 2022	0	1	1	1	1	1
29.	Number of common deficiencies identified	July, 2022	0	-	-	-	-	-
30.	Dossier compilation Training Manual developed	July, 2022	0	1	-	-	--	-
31.	Number of facilities trained	July, 2022	0	5	10	15	20	25

32.	Number of key personnel trained	July, 2022	0	20	40	60	80	100
33.	Number of publications	July, 2022	0	-	1	-	-	-
34.	Number of Query clinics conducted	July, 2022	0	50	50	50	50	50
35.	Number of queries addressed	July, 2022	0	-	-	-	-	-
36.	Tracking system in operation	July, 2022	0	1	-	-	-	-
37.	Number of meetings conducted	July, 2022	0	0	1	1	1	1
38.	Number of common deficiencies identified	July, 2022	0	0	-	-	-	-
39.	Dossier compilation Training Manual developed	July, 2022	0	1	-	-	-	-
40.	Number of facilities trained	July, 2022	0	24	25	26	28	30
41.	Number of personnel trained	July, 2022	0	50	70	90	110	150
42.	Number of publications	July, 2022	0	-	-	1	-	-
43.	National Committee for Promoting Domestic Manufacturing revived	July, 2022	1	1	-	-	-	-
44.	Number of meetings conducted	July, 2022	0	1	1	1	1	1
45.	Number and types of attendees	July, 2022	0	-	-	-	-	-
46.	Number and percentage of resolutions implemented	July, 2022	0	60	70	80	90	100
47.	Number of meetings conducted	July, 2022	0	1	1	1	1	1
48.	Number and types of attendees	July, 2022	0	-	-	-	-	-
49.	Number and percentage of resolutions implemented	July, 2022	0	60	70	80	90	100
50.	Number of new members	July, 2022	4	25	-	-	-	-
51.	Number of TPMA meetings conducted	July, 2022	0	1	1	1	1	1

52.	Association of medical device manufacturers established	July, 2022	0	1	-	-	-	-
53.	Comprehensive guide developed	July, 2022	0	1	-	-	-	-
54.	Web link created	July, 2022	0	1	-	-	-	-
55.	Joint CSC developed	July, 2022	0	-	1	-	-	-
56.	Monitoring and evaluation framework developed	July, 2022	0	1	-	-	-	-
57.	Indicators monitored	July, 2022	0	1	1	1	1	1
58.	Number of publication	July, 2022	0	-	-	-	-	1
Outcome-Based Indicators								
1.	Percentage GMP compliance	July, 2022	36	40	45	50	60	80
2.	Percentage demand of pharmaceutical production	July, 2022	0	-	-	-	-	-
3.	Percentage compliance (medical devices)	July, 2022	0	10	20	30	40	50
4.	Percentage compliance to submission requirements	July, 2022	0	-	-	-	-	-
5.	Mid-term evaluation conducted	July, 2022	0	-	-	1	-	0
6.	End term evaluation conducted	July, 2022	0	-	-	0	-	1

6. BUDGET AND JUSTIFICATION

A total budget of **1,632,230,000** (equivalent to USD 709,665) is proposed in this Plan taking into consideration that activities will be implemented for five years beginning 2022/2023 financial year. The budget has been deduced taking into account resources needed to promote domestic manufacturing. The focus of the budget is mainly to facilitate domestic manufacturers to attain GMP and Quality Audit requirements. It is envisaged that by the end of the implementation period of this Plan, all domestic pharmaceutical and medical devices facilities will meet requirements by 80% and 50% respectively.

The budget has been divided into five years whereby Tshs 462,890,000 (equivalent to USD 201,256), 293,065,000 (equivalent to USD 127,419), 284,955,000 (equivalent to USD 123,893), 270,835,000 (equivalent to USD 117,754) and 320,485,000 (equivalent to USD 139,341) will be utilized in 2022/2023, 2023/2024, 2024/2025, 2025/2026 and 2026/2027 financial years respectively. The USD rates are based on exchange rates of Bank of Tanzania cited on 24th December, 2021 (1 USD = 2300 Tshs). The detailed budget is appended as **Annex IV** of this Plan.

7. APPENDICES

Annex I: List of existing medical products manufacturing facilities

Annex II: List of pharmaceutical and medical device facilities under construction

Annex III: Activity Plan

Activity IV: Budget

Annex I: List of existing medical products manufacturing facilities

(a): List of existing pharmaceutical manufacturing facilities

SN	Name of facility	Physical address	Year of establishment	Types of products manufactured	Production capacity (per annum) *	Operating capacity (per annum)
1.	Mansoor Daya Chemicals Ltd	Plot No.: 23, Industrial Area, Julius Nyerere Road, Temeke, **Dar es Salaam**	1962	Oral solids	81,200,000 tabs	184,832,825 tabs
				Oral Liquids and	1,558,000 Bottles	2,143,000 Bottles
				Topical preparations	48,000 Litres	58,780 Litres
2.	Shelys Pharmaceuticals Ltd	New Bagamoyo Road, Mwenge, Plot No. 696, Block No. 32 P.O. Box: 32781, **Dar-es-Salaam**	1984	Tablets and capsules	65 million tabs/caps	65 million tabs/caps
				Dry powders and solutions	1.2 million bottles, 0.06 million dry syrups, and 0.6 million sachets	1.2 million bottles, 0.06 million dry syrups, and 0.6 million sachets
				Creams and ointments	0.1 million creams and ointments	0.1 million creams and ointments
3.	Keko Pharmaceuticals Industries (1997) Ltd	Off Nyerere Road, Keko Mwanga Area, P. O. Box 40164, **Dar es Salaam.**	1997	Tablets	178,503,800 tablets	1,440,000,000 tablets
				Capsule	8,985,900 capsules	288,000,000 capsules
4.	Zenufa Laboratories Ltd	Nyerere Road, Kipawa Industrial Area, Ilala Municipal, Plot No. 131/132, **Dar es Salaam.**	2004	Tablets (General Block)	373,475,500	396,000,000
				Capsules (General Block)	10,122,100	52,800,000
				Capsules (Beta Block)	52,658,800	132,000,000
				Liquids orals (Beta Block)	3,838,20	7,920,000
				Dry syrup (Beta Block)	265,000	3,801,600
5.	Tanzania Pharmaceutical Industries Ltd (TPI)*.	Plot No. 34, Themi Industrial Area, P.O. Box 7063, Arusha.	1978	Tablets	31,230,240 tablets	-

6.	Tanzania Pharmaceutical Industries (TPI) ARV Limited, Arusha.*	Plot No. 34, Themi Industrial Area, P.O. Box 7063, Arusha.		-	-	-
7.	A.A. Pharmaceuticals Ltd	Mbezi Industrial Area Plot No. 31, **Dar es Salaam.**	2003	Topical Liquids	138875 Liters	200000 Liters
				Topical suspension	15600 Liters	30000 Liters
				Ointment	480kg	1000kg
				Disinfectant	300 Liters	10000 Liters
8.	Sri Balaj Pharmaceuticals Ltd, Dar-es-Salaam.	Plot No. 12, Nyerere Road, Vingunguti, P.O Box 40201, **Dar es Salaam**	2013	Antiseptics	321,375 pcs	175,000 Bottles
				Disinfectants	122,790 pcs	30000 Liters
				Topical prep.	200,000pcs	78,000 gallons and 10000 Liters
9.	Prince Pharmaceuticals Ltd,	Plot No. 4/1, Buhongwa Industrial Area, P.O. Box 11415, **Mwanza.**	2017	Syrups/Suspension	960,000 Litres	960,000 Litres
				Glucose powder	144,000 Kg	
				Cream/Ointment	72,000 Kg	43,200 kg
				Liquid external preparation	960,000 Litres	576,000 Litres
10.	Tanzania Veterinary Laboratory Agency, Tanzania Vaccine Institute (TVI) Inspection Report	P. O. Box 30137, Plot No. 34, Pangani Area, Kibaha, **Pwani.**	1980 (Temeke) 2012 (shifted to Kibaha)	Veterinary vaccines	50 circles and each circle producing 1,600,000 doses of vaccine.	Installed capacity is 1,000,000 vials
11.	Farmers Centre Ltd-Veterinary Pharmaceutical Factory	Plot No. 32 Block A Industrial Area, Buguruni Malapa, P. O. Box 22779, **Dar es Salaam.**	1994 and began operations in 2009	Water soluble powders	360,000 liters	360,000 liters
				Feed Premixes	60,000 kg	60,000 kg
				Oral solution and suspensions	240,000 Kg	240,000 Kg
12.	Farm Access Limited, Arusha Tanzania	Ngaramtoni, Ilkiushin, Arusha, Tanzania P.O. Box 15780, Ngaramtoni, Ilkiushin, **Arusha.**	2013	Veterinary Oral Powder	1,222,042Kg	194,305Kg
				Veterinary oral liquid	8,792,064 Litres	1,397,938 Litres
				Topical Powder	94,003Kg	14,947 Kg
13.	Kairuki Pharmaceuticals Industry Ltd (KPIL)	Plot No. 192, Zegereni Industrial Area, Kibaha TC, **Pwani.**		Large volume parenterals /IV fluids	64,000,000	To be established during commercial production bottles

14.	Biotec Laboratories Ltd	Plot No. 60 & 62, Lulanzi, Kibaha TC, **Pwani.**		Oral liquids	720,000 bottles (100mls)	936,000 bottles	
				Powder	291,000 containers (100g & 500g)	336,938 containers	
15.	Hester Biosciences Africa Ltd	Plot No. 11&12, Tamco Industrial Estate – Kibaha TC, **Pwani.**		Veterinary Vaccines	1.5 billion doses	To be established during commercial production	
16.	Bhanji Pharmaceuticals Ltd'	Keko Mwanga, **Dar es Salaam.**		Topical formulations	-	-	
17.	Afravet/Novel Vaccines and Biological Company Ltd (NOVABI)	Plot Na. 91-96, Ploti A, Kihonda, Morogoro MC, **Dar es Salaam.**		Veterinary Vaccines	NA	NA	NA

*****_Has stopped production_

(b): List of existing medical device facilities

S/N	Name of facility	Physical address	Year of establishment	Types of products manufactured	Production capacity (per annum)*	Operating capacity (per annum)	Uti cap
1.	Technotrade Investment Ltd	SIDO Region Office, Vingunguti Industrial area, **Dar es Salaam**	2002	Medical Safety Boxes	504,000	300,000	59
2.	Ngochilo Pharmaceutical Limited	Plot No 34 Mikocheni B,Sewa-Kinondoni, P.O.Box 1074, **Dar es Salaam**	2020	Disposable surgical masks	26,000,000 pieces per	16,128,000 pieces per	62
3.	Dream Medical Company Ltd	Mikocheni B,Sewa-Kinondoni, Dar es salaam **Dar es Salaam**	2019	Disposable face masks	15,000,000 pieces	5,000,000 pieces	33

4.	Keds Tanzania Company Limited	Kibaha urban Lulanzi Industrial area, behind Puma filling station, **Dar es Salaam**	2018	Baby Diapers	201,600,000 pcs	201,600,000 pcs	100
				Sanitary Pads	127,680,000 pads	127,680,000 pads	100
5.	Drafco Group Ltd	Plot No. 2184, Kisemvule Industrial Area, Mkuranga District, **Pwani.**	2019	Disposable face mask, baby diaper, maternity pad	200,000,000 pieces of diapers 116,000,000 pieces of sanitary pads 25,000,000 pieces of disposable face mask	180,000,000 pieces of diapers 93,000,000 pieces of sanitary pads 18,000,000 pieces of disposable face mask	90 80 72
6.	Population Services International (PSI)	Plot No.50 Industrial way road, Mikocheni, Kinondoni, **Dar es Salaam.**	2019	Repackaging of male latex condoms and Intrauterine devices (IUD)	5,168,448	400,000	8
7.	Msagara Investment Company Limited	Bagamoyo, Kiromo, Kitopeni, **Pwani.**	2019	Medical Gauzes	1,411,200 200,800	201,600 100,800	14 50
8.	Pristine Manufacturing Company Limited	Plot No.78, Vingunguti Industrial Area,Ilala, **Dar es Salaam.**	2020	Disposable face masks and Bouffant Caps	29,030,000	15,000,000	51

9.	Medical Stores Department (MSD)	Off Nyerere Road, Keko Mwanga, **Dar es salaam.**	2020	Disposable face mask	20,736,000 pieces	10,368,000 pieces	50
10.	Mony Industrial Limited	Uvumba Street Kibada Kigamboni, **Dar es Salaam.**	2021	Disposable and surgical face mask	144,000,000	28,800,000	20
11	Excel Biotech	Plot No 5 Changombe Road Kekobora Ward, Temeke, **Dar es Salaam.**	2019	Pregnancy test strip, H. pylori test strip	4,500,000 strips	2,808,000 strips	62
12	Inhemeter (T) Limited	Kinondoni East Street, **Dar es Salaam.**	2021	Disposable Face Mask	15,059,000	4,000,000	27
13	Shahi Engineering and Construction Company Limited	Plot No 435/B-Kipawa-Pugu Road, **Dar es Salaam.**	2020	Ravs Disposable Face mask	9,500,000 pieces	3,380,000 pieces	36
14.	Prance International Trade Co. Limited	Misugususgu, Zogowale Ward Kibaha District, **Pwani.**	2020	Baby Diapers and sanitary pads	156,600,000 105,700,000	156,600,000 105,700,000	100 100
15	Medtrust Company Limited	Mbezi Industrial area, Makonde, **Dar es salaam**	2020	Disposable face mask	15,059,000 pieces	8,400,000 pieces	56
16.	Aleka Holding Limited	Mikocheni/Solding Road, **Dar es Salaam.**	2021	Medical face mask	15,059,000	8,640,000	57
17.	Muhimbili National Hospital	Barabara ya Maliki/Kalenga-Upanga, **Dar es Salaam.**	2020	Disposable Face mask	9,000,000	4,000,000	44
18.	A to Z Textile Mills Ltd	Plot no 689, Netword area- Kisongo, **Arusha.**	2020	Coverall	500,000	300,000	60
19	Meru District Hospital	Patandi- Akheri, **Arusha.**	2020	Disposable Face Mask	9,000,000	2,000,000	22

20	Sunflag (T) Ltd	Plot no. 33-36, Block E, Themi Industrial Area, **Arusha.**	2020	Disposable Face Mask	15,059,000	5,000,000	33
21	Hanspaul Industries Limited	Plot no. 29/1 Themi Industrial Area, **Arusha.**	2020	Hospital bed Safety box	6,000 600,000	1,000 300,000	16 50
22	TEMDO	Plot 268/B Njiro Hills, **Arusha.**	2021	Hospital bed Drip Stand Examination table Standard Mortuary Cabinet Biomedical Waste Incinerator	7,200 14,400 9,600 60 60	1,000 5,400 3,000 5 2	13 38 31 8 3
23	Afyacare	Iringa Town	2020	Re-usable sanitary pad	150,000	10,000	7
24	KM Paper Products Company Limited	Nala, **Dodoma**	2020	Disposable Face mask	15,059,000	3,000,000	20

Annex II: List of pharmaceutical and medical device facilities under construction

S/N	Name of facility	Location		Type of products	Percentage completion (as of January, 2022)
		Region	District/Location		
1.	Emedics Pharmaceuticals Limited	Coast	Kerege, Bagamoyo	Human External preparations, Tablets, Creams and Ointments	• 80%
2.	Vine Vision Infusion Limited	Arusha	Plot No. 1053 Moshomo, Arusha MC	Sterile Eye drops for human use	• 60% • Drawings still under review
3.	Medical Stores Department (MSD)	Dar es Salaam	Temeke/Keko Mwanga	Human External preparations	• 50% • Drawings approved
4.	Medical Stores Department (MSD)	Njombe	Mhidze Road, Idofi, Makambako	Capsules, Tablets and Liquid Orals for human use	• 50% • Drawings approved • Construction ongoing
5.	Medical Stores Department (MSD)	Njombe	Mhidze Road, Idofi, Makambako.	Examination and surgical gloves	• 80% • Drawings approved • Construction ongoing
6.	Boka Pharmaceuticals Industries	Dar es Salaam	Kigamboni/Kimbiji- Golan Industrial Area	External preparations (creams and Ointments), OSD and Oral Liquids for human use.	• 0% • Drawings approved Conducting EIA – NEMC
7.	Resha Pharmaceuticals Ltd	Mwanza	Misungwi , Bulokelo Village	Topical formulations and Oral Liquids	• 85% completion • Still completing modification of the drawings
8.	Cure Afya Pharmaceuticals Limited	Dar es Salaam	Plot No. 69, Plot A, Kimbiji, Kigamboni MC	• Oral Solid Dosage forms • Oral liquids	• 85% completion
9.	Vista Pharma Limited	Pwani	Plot No. 4, Zegereni Industrial Area, Kibaha TC	• Oral Solid Dosage forms • Oral liquids	• 100% construction**
10.	Alfa Pharmaceuticals Limited	Dar es Salaam	Plot No. 14, Mbagala Industrial Area, Temeke,	• Large Volume Parenterals	• 100% construction**

S/N	Name of facility	Location		Type of products	Percentage completion (as of January, 2022)
		Region	District/Location		
11.	National Institute for Medical Research (NIMR)	Dar es Salaam	Mabibo External, Ubungo	• Human herbal preparations	• 100% construction**

** *Production has not commenced*

Annex III: Activity Plan

SPECIFIC OBJECTIVE 1: To facilitate pharmaceutical manufacturing facilities to meet Good Manufacturing Practice requirements					
S/N	**TARGETS**	**ACTIVITIES**	**INDICATORS**	**RESPONSIBLE PERSON**	**TIMELIN**
1.1	80% of all pharmaceutical manufacturing facilities meeting GMP requirements by June 2027	1.1.1To conduct assessment to identify gaps hindering GMP compliance	Number of gaps identified Percentage GMP compliance	MCIE	September
		1.1.2 To develop implementation plan to address gaps identified	Implementation Plan developed Number and percentage of gaps addressed Percentage GMP compliance	MCIE	September
		1.1.3 To develop a tailor made GMP training manual for manufacturers	GMP Training Manual developed	DMC	December
		1.1.4 To conduct training on GMP to all personnel working in manufacturing industries	Number of facilities trained Number of key personnel trained Percentage of GMP areas covered	MCIE and Zone Managers	On-goi
		1.1.5 To conduct regular facilitative GMP inspection of all licensed facilities to assist in meeting GMP requirements from the design stage	Number of facilities facilitated Number of visits per facility Percentage of GMP compliance	MCIE and Zone Managers	On-goi
		1.1.6 To conduct annual GMP inspection of all licensed facilities	Number of facilities inspected	MCIE and Zone Mangers	On-goi

			Percentage of GMP compliance		
		1.1.7 To conduct regular meetings with manufacturers to address non-conformances observed after GMP inspections (CAPA Clinics)	Number of CAPA clinics conducted Number of non-conformances addressed Percentage compliance	MCIE and Zone Managers	On-goi
		1.1.8 To establish GMP and Quality Audit Technical Committee to advise TMDA on related matters	GMP and Quality Audit Technical Committee established	DMC	Jan, 20
		1.1.9 To conduct at least two drug utilization studies	Number of studies conducted Number and types of products highly consumed	DMC	June, 2023 and 2026
		1.1.10 To assess capacity of domestic pharmaceutical manufacturer	Number of manufacturers assessed Operating and production capacities established Percentage Demand of pharmaceutical production	DMC	June, 20
SPECIFIC OBJECTIVE 2: To facilitate medical devices and diagnostics manufacturing facilities to meet Quality Audit requirements					
2.1	50% of all medical devices and diagnostics manufacturing facilities meeting Quality Audit requirements by June 2027	2.1.1To conduct assessment to identify gaps hindering compliance to ISO 13485	Number of gaps identified Percentage compliance	MMDC	September
		2.1.2 To develop implementation plan to address gaps identified	Implementation Plan developed	MMDC	September

			Number of gaps addressed Percentage compliance		
		2.1.3 To develop a tailor made Quality Audit training manual for manufacturers	Quality Audit Training Manual developed	DMC	December
		2.1.4 To conduct training on Quality Audit to all personnel working in manufacturing industries	Number of facilities trained Number of personnel trained Percentage of areas covered	MMDC and Zone Managers	On-goi
		2.1.5 To conduct regular facilitative Quality Audit inspection of all licensed facilities to assist in meeting ISO 13485 requirements from the design stage	Number of facilities facilitated Number of visits per facility Percentage compliance	MMDC and Zone Managers	On-goi
		2.1.6 To conduct annual Quality Audit of all licensed facilities	Number of facilities inspected Percentage compliance	MMDC and Zone Mangers	On-goi
		2.1.7 To conduct regular meetings with manufacturers to address non-conformances observed after Quality Audits (CAPA Clinics)	Number of CAPA clinics conducted Number of non-conformances addressed Percentage compliance	MMDC and Zone Managers	On-goi
SPECIFIC OBJECTIVE 3: To ensure timely decision making on marketing authorization submissions for domestically manufactured products					
3.1	100% of submitted applications for marketing authorization of domestically manufactured medicines timely concluded by June 2027	3.1.1 To conduct annual meetings with all medicines domestic manufacturers to discuss on general requirements of marketing authorization.	Number of meetings conducted Percentage compliance	MMRE	Annua

		3.1.1To conduct a special exercise/programme to identify common deficiencies observed in submission of dossiers by existing domestic manufacturer	Number of common deficiencies identified Percentage compliance	MMRE	September
		3.1.2 To develop a tailor made dossier compilation training manual for domestic manufacturers	Dossier compilation Training Manual developed	DMC	December
		3.1.3 To conduct training on dossier compilation to key personnel working in domestic manufacturing industries	Number of facilities trained Number of key personnel trained Percentage of areas covered	MMRE	On-goi
		3.1.4 To publish the outcome of the exercise on common deficiencies observed in submission of dossiers by domestic manufacturers	Number of publications made Percentage compliance to submission requirements	MMRE	On-goi
		3.1.5 To conduct regular meetings with manufacturers to assist in how to properly address queries communicated following evaluation of the submitted dossiers (Query Clinics)	Number of Query clinics conducted Number of queries addressed Percentage compliance	MMRE	On-goi
		3.1.6 To create a spreadsheet and operationalize a tracking system installed in RIMS to monitor FIFO and timelines for submission of applications of domestically manufactured products	Tracking system in operation	MMRE/MMDC/MICT	On-goi
3.2	100% of submitted applications for marketing authorization of domestically manufactured medical devices and diagnostics timely concluded by June 2027	3.2.1 To conduct annual meetings with all medical devices and diagnostics domestic manufacturers to discuss on general requirements of marketing authorization.	Number of meetings conducted Percentage compliance	MMDC	Annua

		3.2.2To conduct a special exercise/programme to identify common deficiencies observed in submission of medical devices and diagnostics dossiers by domestic manufacturer	Number of common deficiencies identified Percentage compliance	MMDC	September
		3.2.3 To develop a tailor made medical devices and diagnostic dossier compilation training manual for domestic manufacturers	Dossier compilation Training Manual developed	DMC	December
		3.2.4 To conduct training on medical devices dossier compilation to key personnel working in domestic manufacturing industries	Number of facilities trained Number of key personnel trained Percentage of areas covered	MMDC	On-goi
		3.2.5 To publish the outcome of the exercise on common deficiencies observed in submission of medical devices and diagnostics dossiers by domestic manufacturers	Number of publications made Percentage compliance to submission requirement	MMDC	December
		3.2.7 To conduct regular meetings with manufacturers to assist in how to properly address queries communicated following evaluation of the submitted dossiers (Query Clinics)	Number of Query clinics conducted Number of queries addressed Percentage compliance	MMDC	On-goi
SPECIFIC OBJECTIVE 4 :To foster collaboration and communication with government departments and other stakeholders to support pharmace medical devices manufacturing					
4.1	Collaboration with government departments and other stakeholders to support domestic manufacturing established by 2027	4.1.1To revive the National Committee for Promoting Domestic Manufacturing	National Committee for Promoting Domestic Manufacturing revived	MCIE	January,
		4.1.2To conduct annual meetings of National Committee for Promoting Domestic Manufacturing	Number of meetings conducted	MCIE	Annua

			Number and types of attendees Number of resolutions implemented		
		4.1.3To conduct annual stakeholders meeting to discuss matters related to domestic manufacturing	Number of meetings conducted Number and types of attendees Number of resolutions implemented	MCIE	Annua
		4.1.4To advocate for active membership and regular TPMA meetings	Number of existing members Number of new members Number of TPMA meetings conducted	MCIE	On-goi
		4.1.5 To sensitize for establishment of association of medical device manufacturers	Association of medical device manufacturers established	MMDC	December
		4.1.6 To develop a comprehensive guide on investment in medical products domestic manufacturing	Comprehensive guide developed	MCIE/MMDC	January,
		4.1.7 To create a web link with information relevant to domestic manufacturers	Web link created	MICT/MCPE	June, 20
		4.1.8 To develop a joint Clients' Service Charter with all government departments	Joint CSC developed	MCPE	June, 20
SPECIFIC OBJECTIVE 5: To monitor and evaluate implementation of this Plan					
5.1	Action Plan monitored and evaluated by June, 2027	5.1.1 To develop monitoring and evaluation framework	monitoring and evaluation framework developed	MPME	June, 20
		5.1.2 To monitor progress in implementation of the Plan	Indicators monitored	Managers	On-goi

		5.1.3 To conduct mid-term evaluation of the implementation of the Plan	Mid-term evaluation conducted	MPME	June, 20
		5.1.4 To conduct end term evaluation of the plan	End term evaluation conducted	MPME	June, 20
		5.1.5 To publish results of implementation of the plan in peer reviewed journals	Number of publications	DMC	June, 20

Annex IV: Budget

ANNEX 1: ACTIVITIES COSTING SHEET FOR PROMOTION OF DOMESTIC MEDICAL PRODUCTS MANUFACTURING FACILITIES															
SPECIFIC OBJECTIVE : 01		To facilitate pharmaceutical manufacturing facilities to meet Good Manufacturing Practices (GMP) requirements													
Segment 2 Code and Description	Segment 4 (GFS Code)	Required inputs			**Budget Estimates 2022/23**		**Annual Forward Budget Estimates 2023/24**		**Annual Forward Budget Estimates 2024/25**		**Annual Forward Budget Estimates 2025/26**		**Annual Forward Budget Estimates 2026/27**	
		Segment 4 Description (GFS Code Description)	**Unit of Measure**	Unit Cost of Input	**No. of Units**	Estimates	**No. of Units**	Estimates	**No. of Units**	Estimates	**No. of Units**	Estimates	**No. of Units**	Estimates
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
1.1 TARGET	80% of all pharmaceutical manufacturing facilities meet GMP requirements by June, 2027													
To conduct assessment to identify gaps hindering GMP compliance of pharmaceutical manufacturing facilities by September, 2022	22010105	Per Diem - Domestic	Person - Days	150,000	50	7,500,000	-	-	-	-	-	-	-	-
	21121103	Food and refreshments	Person	25,000	50	1,250,000	-	-	-	-	-	-	-	-
	22007109	Conference facilities	Days	250,000	5	1,250,000	-	-	-	-	-	-	-	-
	22003102	Diesel	Litres	2,500	300	750,000	-	-	-	-	-	-	-	

		22010102	Ground travel (bus, railways)	Trip	80,000	6	480,000	-	-	-	-	-	-	-	-
		22011102	Air Travel Tickets	Person - Days	500,000	4	2,000,000	-	-	-	-	-	-	-	-
	Total Activity						**13,230,000**	-	-	-	-	-	-	-	-
2.	To disseminate assessment report on gaps hindering GMP compliance by September, 2022	21121103	Food and refreshments	Person	25,000	40	1,000,000	-	-	-	-	-	-	-	-
		22001101	Stationeries and Office Consumables	Pcs	200,000	1	200,000	-	-	-	-	-	-	-	
		22010102	Ground travel (bus, railways)	Trip	80,000	10	800,000	-	-	-	-	-	-	-	-
	Total Activity						**2,000,000**	0	-	0	-	0	-	0	-
3.	To develop a tailor made GMP training manual for manufacturers by December, 2022	22010105	Per Diem - Domestic	Person - Days	150,000	70	10,500,000	-	-	-	-	-	-	-	-
		21121103	Food and refreshments	Person	25,000	70	1,750,000	-	-	-	-	-	-	-	-
		22001101	Stationeries and Office Consumables	Pcs	400,000	1	400,000	-	-	-	-	-	-	-	-
		22007109	Conference facilities	Days	250,000	5	1,250,000	-	-	-	-	-	-	-	-
		22003102	Diesel	Litres	2,500	350	875,000	-	-	-	-	-	-	-	-

4.	**Total Activity**						**14,775,000**	0	-	0	-	0	-	0	-
	To conduct training on GMP to key technical personnel working in medicines manufacturing facilities by June, 2027	22010105	Per Diem - Domestic	Person - Days	150,000	50	7,500,000	50	7,500,000	50	7,500,000	50	7,500,000	60	9,000,000
		21121103	Food and refreshments	Person	25,000	50	1,250,000	50	1,250,000	50	1,250,000	50	1,250,000	60	1,500,000
		22011102	Air Travel Tickets	Person - Days	500,000	5	2,500,000	5	2,500,000	5	2,500,000	5	2,500,000	10	5,000,000
		22003102	Diesel	Litres	2,500	350	875,000	350	875,000	350	875,000	350	875,000	350	875,000
	Total Activity						**12,125,000**		**12,125,000**		**12,125,000**		**12,125,000**		**16,375,000**
5.	To conduct facilitative GMP inspections for all pharmaceutical manufacturing facilities to assist in meeting GMP requirements from the designing stage by June, 2027	22010105	Per Diem - Domestic	Person - Days	150,000	50	7,500,000	50	7,500,000	50	7,500,000	50	7,500,000	60	9,000,000
		22011102	Air Travel Tickets	Person - Days	500,000	5	2,500,000	5	2,500,000	5	2,500,000	5	2,500,000	10	5,000,000
		21121103	Food and refreshments	Person	25,000	50	1,250,000	50	1,250,000	50	1,250,000	50	1,250,000	60	1,500,000
		22003102	Diesel	Litres	2,500	350	875,000	350	875,000	350	875,000	350	875,000	350	875,000
	Total Activity						**12,125,000**		**12,125,000**		**12,125,000**		**12,125,000**		**16,375,000**
	To conduct at least two (2) drug utilization	22031104	Consultancy fee	lumpsum	15000000	1	15,000,000	-	-	1	15,000,000	-	-	-	-

studies by June, 2026														
	21121103	Food and refreshments	Person	25,000	50	1,250,000			50	1,250,000				
	22011102	Air Travel Tickets	Person - Days	500,000	6	3,000,000			6	3,000,000				
	22003102	Diesel	Litres	2,500	350	875,000			350	875,000				
	22007109	Conference facilities	Days	250,000	5	1,250,000			5	1,250,000				
	22010105	Per Diem - Domestic	Person - Days	150,000	80	12,000,000	-	-	80	12,000,000	-	-	-	-
Total Activity						**33,375,000**		**-**		**33,375,000**	**0**	**-**	**0**	**-**
To conduct GMP inspections for pharmaceutical manufacturing facilities annually by June, 2027	22010105	Per Diem - Domestic	Person - Days	150,000	300	45,000,000	300	45,000,000	300	45,000,000	300	45,000,000	300	45,000,000
	22011102	Air Travel Tickets	Person - Days	500,000	5	2,500,000	5	2,500,000	5	2,500,000	5	2,500,000	5	2,500,000
	22003102	Diesel	Litres	2,500	2,500	6,250,000	2,500	6,250,000	2,500	6,250,000	2,500	6,250,000	2,500	6,250,000
Total Activity						**53,750,000**		**53,750,000**		**53,750,000**		**53,750,000**		**53,750,000**

	To conduct meetings with manufacturers to address non - conformances observed after GMP inspections (CAPA Clinics) by June, 2027	21121103	Food and refreshments	Person	25,000	50	1,250,000	50	1,250,000	50	1,250,000	50	1,250,000	50	1,250,000
		22011102	Air Travel Tickets	Person - Days	500,000	5	2,500,000	5	2,500,000	5	2,500,000	5	2,500,000	5	2,500,000
		22010105	Per Diem - Domestic	Person - Days	150,000	50	7,500,000	50	7,500,000	50	7,500,000	50	7,500,000	50	7,500,000
		22003102	Diesel	Litres	2,500	350	875,000	350	875,000	350	875,000	350	875,000	350	875,000
	Total Activity						**12,125,000**		**12,125,000**		**12,125,000**		**12,125,000**		**12,125,000**
	To facilitate GMP and Quality Audit Technical Committee meetings by June, 2027	21121103	Food and refreshments	Pcs	25000	60	1,500,000	120	3,000,000	60	1,500,000	60	1,500,000	60	1,500,000
		22010105	Per Diem - Domestic	Man-day	150000	18	2,700,000	18	2,700,000	18	2,700,000	18	2,700,000	18	2,700,000
		21113114	Sitting allowance	Day	150000	70	10,500,000	150	22,500,000	70	10,500,000	70	10,500,000	70	10,500,000
		22003102	Diesel	litre	2500	200	500,000	400	1,000,000	200	500,000	200	500,000	200	500,000
		22010102	Ground travel domestic	Trips	80000	10	800,000	32	2,560,000	10	800,000	10	800,000	10	800,000
	Total Activity						**16,000,000**		**31,760,000**		**16,000,000**		**16,000,000**		**16,000,000**

	Total Specific Objective 01						169,505,000		121,885,000		139,500,000		106,125,000		114,625,000
SPECIFIC OBJECTIVE : 02		To facilitate medical devices and diagnostics manufacturing to meet Quality Audit requirements													
TARGET		50% of all medical devices and diagnostics manufacturing facilities meet Quality Audit requirements by June, 2027													
	To conduct assessment to identify gaps hindering compliance to ISO 13485 by September, 2022	22010105	Per Diem - Domestic	Person - Days	150,000	50	7,500,000	-	-	-	-	-	-	-	-
		21121103	Food and refreshments	Person	25,000	50	1,250,000	-	-	-	-	-	-	-	-
		22007109	Conference facilities	Days	250,000	5	1,250,000	-	-	-	-	-	-	-	-
		22010102	Ground travel (bus, railways)	Trip	80,000	6	480,000	-	-	-	-	-	-	-	-
		22011102	Air Travel Tickets	Person - Days	500,000	5	2,500,000	-	-	-	-	-	-	-	-
	Total activity						**12,980,000**								
	To disseminate assessment report on gaps hindering compliance to ISO 13485 by September, 2022	21121103	Food and refreshments	Person	25,000	50	1,250,000	-	-	-	-	-	-	-	-
		22001101	Stationeries and Office Consumables	Pcs	200,000	1	200,000	-	-	-	-	-	-	-	-
		22010102	Ground travel (bus, railways)	Trip	80,000	8	640,000	-	-	-	-	-	-	-	-

	Total Activity						2,090,000	0	-	0	-	0	-	0	-
	To develop a tailor made Quality Audit training manual for manufacturers by December, 2022	22010105	Per Diem - Domestic	Person - Days	150,000	70	10,500,000	-	-	-	-	-	-	-	-
		21121103	Food and refreshments	Person	25,000	70	1,750,000	-	-	-	-	-	-	-	-
		22001101	Stationeries and Office Consumables	Pcs	400,000	1	400,000	-	-	-	-	-	-	-	-
		22007109	Conference facilities	Days	250,000	5	1,250,000	-	-	-	-	-	-	-	-
		22003102	Diesel	Litres	2,500	400	1,000,000	-	-	-	-	-	-	-	-
	Total Activity						**14,900,000**	**0**	**-**	**0**	**-**	**0**	**-**	**0**	**-**
	To conduct training on Quality Audit to personnel working in medical devices and diagnostics manufacturing facilities by June, 2027	22010105	Per Diem - Domestic	Person - Days	150,000	50	7,500,000	50	7,500,000	50	7,500,000	50	7,500,000	50	7,500,000
		21121103	Food and refreshments	Person	25,000	50	1,250,000	50	1,250,000	50	1,250,000	50	1,250,000	50	1,250,000
		22011102	Air Travel Tickets	Person - Days	500,000	5	2,500,000	5	2,500,000	5	2,500,000	5	2,500,000	5	2,500,000
		22003102	Diesel	Litres	2,500	350	875,000	350	875,000	350	875,000	350	875,000	350	875,000
	Total Activity						**12,125,000**		**12,125,000**		**12,125,000**		**12,125,000**		**12,125,000**

	To conduct facilitative Quality Audit inspections for all medical devices and diagnostics manufacturing facilities to assist in meeting ISO 13485 requirements from the designing stage by June, 2027	22010105	Per Diem - Domestic	Person - Days	150,000	50	7,500,000	50	7,500,000	50	7,500,000	50	7,500,000	50	7,500,000
		22011102	Air Travel Tickets	Person - Days	500,000	5	2,500,000	5	2,500,000	5	2,500,000	5	2,500,000	5	2,500,000
		21121103	Food and refreshments	Person	25,000	50	1,250,000	50	1,250,000	50	1,250,000	50	1,250,000	50	1,250,000
		22003102	Diesel	Litres	2,500	350	875,000	350	875,000	350	875,000	350	875,000	350	875,000
	Total Activity						**12,125,000**		**12,125,000**		**12,125,000**		**12,125,000**		**12,125,000**
	To conduct annual Quality Audit for all licensed medical devices facilities by June, 2027	22010105	Per Diem - Domestic	Person - Days	150,000	250	37,500,000	250	37,500,000	250	37,500,000	250	37,500,000	250	37,500,000
		22011102	Air Travel Tickets	Person - Days	500,000	6	3,000,000	6	3,000,000	6	3,000,000	6	3,000,000	6	3,000,000
		22003102	Diesel	Litres	2,500	2,000	5,000,000	2,000	5,000,000	2,000	5,000,000	2,000	5,000,000	2,000	5,000,000
	Total Activity						**45,500,000**		**45,500,000**		**45,500,000**		**45,500,000**		**45,500,000**
	To conduct meetings with manufacturers to address non - conformances observed after Quality Audits	21121103	Food and refreshments	Person	25,000	50	1,250,000	50	1,250,000	50	1,250,000	50	1,250,000	50	1,250,000

	(CAPA Clinics) by June, 2027														
		22011102	Air Travel Tickets	Person - Days	500,000	4	2,000,000	4	2,000,000	4	2,000,000	4	2,000,000	4	2,000,000
		22010105	Per Diem - Domestic	Person - Days	150,000	50	7,500,000	50	7,500,000	50	7,500,000	50	7,500,000	50	7,500,000
		22003102	Diesel	Litres	2,500	350	875,000	350	875,000	350	875,000	350	875,000	350	875,000
	Total Activity						11,625,000		11,625,000		11,625,000		11,625,000		11,625,000
	Total Specific Objective 02						**111,345,000**		**81,375,000**		**81,375,000**		**81,375,000**		**81,375,000**
SPECIFIC OBJECTIVE: 03		To ensure timely decision making on marketing authorization submissions for domestically manufactured products													
TARGET		100% of submitted applications for marketing authorization of domestically manufactured medicines timely concluded by June, 2027													
	To conduct annual meetings with all domestic manufacturers to discuss on general requirements of marketing authorization by June, 2027	21121103	Food and refreshments	Person	25,000	100	2,500,000	100	2,500,000	100	2,500,000	100	2,500,000	100	2,500,000
		22010102	Ground travel (bus, railways)	Trip	80,000	10	800,000	10	800,000	10	800,000	10	800,000	10	800,000
	Total Activity						**3,300,000**		**3,300,000**		**3,300,000**		**3,300,000**		**3,300,000**

	To conduct assessment to identify common defficiencies observed in submission of dossiers from existing domestic manufacturers by September, 2022	22010105	Per Diem - Domestic	Person - Days	150,000	50	7,500,000	-	-	-	-	-	-	-	-
		21121103	Food and refreshments	Person	25,000	60	1,500,000	-	-	-	-	-	-	-	-
		22007109	Conference facilities	Days	250,000	5	1,250,000	-	-	-	-	-	-	-	-
		22011102	Air Travel Tickets	Person - Days	500,000	4	2,000,000	-	-	-	-	-	-	-	-
		22010102	Ground travel (bus, railways)	Trip	80,000	6	480,000	-	-	-	-	-	-	-	-
	Total Activity						**12,730,000**	**0**	**-**	**0**	**-**	**0**	**-**	**0**	**-**
	To develop a tailor made dossier compilation training manual for domestic manufacturers by December, 2022	22010105	Per Diem - Domestic	Person - Days	150,000	70	10,500,000	-	-	-	-	-	-	-	-
		21121103	Food and refreshments	Person	25,000	75	1,875,000	-	-	-	-	-	-	-	-
		22001101	Stationeries and Office Consumables	Pcs	400,000	1	400,000	-	-	-	-	-	-	-	-

	22007109	Conference facilities	Days	250,000	5	1,250,000	-	-	-	-	-	-	-	-
	22010102	Ground travel (bus, railways)	Trip	80,000	6	480,000	-	-	-	-	-	-	-	-
	22003102	Diesel	Litres	2,500	350	875,000	-	-	-	-	-	-	-	-
Total Activity						**15,380,000**								
To conduct training on dossier compilation for key technical personnel working in domestic manufacturing facilities by June, 2027	22010105	Per Diem - Domestic	Person - Days	150,000	60	9,000,000	60	9,000,000	60	9,000,000	60	9,000,000	60	9,000,000
	21121103	Food and refreshments	Person	25,000	50	1,250,000	50	1,250,000	50	1,250,000	50	1,250,000	50	1,250,000
	22011102	Air Travel Tickets	Person - Days	500,000	5	2,500,000	5	2,500,000	5	2,500,000	5	2,500,000	5	2,500,000
	22003102	Diesel	Litres	2,500	350	875,000	350	875,000	350	875,000	350	875,000	350	875,000
Total Activity						**13,625,000**		**13,625,000**		**13,625,000**		**13,625,000**		**13,625,000**
To publish outcome of common defficiences observed in submission of dossiers by domestic	22031104	Consultancy fee	lumpsum	0	2	-	-	-	-	-	2	-	-	-

	manufacturers by June, 2027													
		22010105	Per Diem - Domestic	Person - Days	150,000	100	15,000,000	-	-	-	-	100	15,000,000	-	-
		21121103	Food and refreshments	Person	25,000	70	1,750,000	-	-	-	-	70	1,750,000	-	-
		22001101	Stationeries and Office Consumables	Pcs	400,000	1	400,000	-	-	-	-	1	400,000	-	-
		22007109	Conference facilities	Days	250,000	5	1,250,000	-	-	-	-	5	1,250,000	-	-
		22003102	Diesel	Litres	2,500	150	375,000	-	-	-	-	150	375,000	-	-
		22010102	Ground travel (bus, railways)	Trip	80,000	6	480,000	-	-	-	-	6	480,000	-	-
	Total Activity						**19,255,000**						**19,255,000**		
	To conduct meetings with manufacturers to assist in addressing queries following evaluation of the submitted dossiers (Query Clinics) by June, 2027	22010105	Per Diem - Domestic	Person - Days	150,000	70	10,500,000	70	10,500,000	70	10,500,000	70	10,500,000	70	10,500,000
		21121103	Food and refreshments	Person	25,000	50	1,250,000	50	1,250,000	50	1,250,000	50	1,250,000	50	1,250,000

	22011102	Air Travel Tickets	Person - Days	500,000	5	2,500,000	5	2,500,000	5	2,500,000	5	2,500,000	5	2,500,000
	22003102	Diesel	Litres	2,500	350	875,000	350	875,000	350	875,000	350	875,000	350	875,000
Total Activity						**15,125,000**		**15,125,000**		**15,125,000**		**15,125,000**		**15,125,000**
TARGET	100% of submitted applications for marketing authorization of domestically manufactured medical devices and diagnostics timely concluded by June, 2027													
To conduct annual meetings with all medical devices and diagnostics domestic manufacturers to discuss on general requirements of marketing authorization by June, 2027	21121103	Food and refreshments	Person	25,000	100	2,500,000	100	2,500,000	100	2,500,000	100	2,500,000	100	2,500,000
	22010102	Ground travel (bus, railways)	Trip	80,000	10	800,000	10	800,000	10	800,000	10	800,000	10	800,000
Total Activity						**3,300,000**		**3,300,000**		**3,300,000**		**3,300,000**		**3,300,000**
To conduct assessment to identify common defficiencies observed in submission of medical devices and diagnostics dossiers from existing domestic manufacturers	22010105	Per Diem - Domestic	Person - Days	150,000	50	7,500,000	-	-	-	-	-	-	-	-
	21121103	Food and refreshments	Person	25,000	60	1,500,000	-	-	-	-	-	-	-	-

by September, 2022														
	22011102	Air Travel Tickets	Person - Days	500,000	4	2,000,000	-	-	-	-	-	-	-	-
	22007109	Conference facilities	Days	250,000	5	1,250,000	-	-	-	-	-	-	-	-
	22010102	Ground travel (bus, railways)	Trip	80,000	6	480,000	-	-	-	-	-	-	-	-
Total Activity						**12,730,000**	**0**	**-**	**0**	**-**	**0**	**-**	**0**	**-**
To develop a tailor made medical devices and diagnostics dossier compilation training manual for domestic manufacturers by December, 2022	22010105	Per Diem - Domestic	Person - Days	150,000	70	10,500,000	-	-	-	-	-	-	-	-
	21121103	Food and refreshments	Person	25,000	70	1,750,000	-	-	-	-	-	-	-	-
	22001101	Stationeries and Office Consumables	Pcs	400,000	1	400,000	-	-	-	-	-	-	-	-
	22007109	Conference facilities	Days	250,000	5	1,250,000	-	-	-	-	-	-	-	-
	22003102	Diesel	Litres	2,500	350	875,000	-	-	-	-	-	-	-	-

	Total Activity						**14,775,000**	-	-	-	-	-	-	-	-
	To conduct training on medical devices and diagnostics dossier compilation for personnel working in domestic manufacturing facilities by June, 2027	22010105	Per Diem - Domestic	Person - Days	150,000	60	9,000,000	60	9,000,000	60	9,000,000	60	9,000,000	60	9,000,000
		22011102	Air Travel Tickets	Person - Days	500,000	4	2,000,000	4	2,000,000	4	2,000,000	4	2,000,000	4	2,000,000
		22003102	Diesel	Litres	2,500	400	1,000,000	400	1,000,000	400	1,000,000	400	1,000,000	400	1,000,000
		21121103	Food and refreshments	Person	25,000	50	1,250,000	50	1,250,000	50	1,250,000	50	1,250,000	50	1,250,000
	Total Activity						**13,250,000**		**13,250,000**		**13,250,000**		**13,250,000**		**13,250,000**
	To publish outcome of common defficiences observed in submission of dossiers by medical devices and diagnostics domestic manufacturers by June, 2027	22031104	Consultancy fee	lumpsum	3150000	0	-	-	-	-	-	-	-	-	-
		22010105	Per Diem - Domestic	Person - Days	150,000	100	15,000,000	-	-	-	-	-	-	-	-

		21121103	Food and refreshments	Person	25,000	70	1,750,000	-	-	-	-	-	-	-	-
		22001101	Stationeries and Office Consumables	Pcs	400,000	1	400,000	-	-	-	-	-	-	-	-
		22007109	Conference facilities	Days	250,000	5	1,250,000	-	-	-	-	-	-	-	-
		22003102	Diesel	Litres	2,500	150	375,000	-	-	-	-	-	-	-	-
		22010102	Ground travel (bus, railways)	Trip	80,000	6	480,000	-	-	-	-	-	-	-	-
	Total Activity						**19,255,000**		-	-	-	-	**-**		
		22011102	Air Travel Tickets	Person - Days	500,000	5	2,500,000	5	2,500,000	5	2,500,000	5	2,500,000	5	2,500,000
	Total Activity						2,500,000		2,500,000		2,500,000		2,500,000		2,500,000
	Total Specific Objective: 03						145,225,000		47,800,000		47,800,000		67,055,000		47,800,000
Specific Objective: 04		To foster collaboration and communication with government departments and other stakeholders to support pharmaceuticals and medical devices manufacturing													
TARGET		Collaboration with government departments and other stakeholders to support domestics manufacturing established by June, 2027													
	To facilitate annual meetings for National Committee for promoting domestic manufacturing by June, 2027	22010105	Per Diem - Domestic	Person - Days	150,000	50	7,500,000	50	7,500,000	50	7,500,000	50	7,500,000	50	7,500,000
		21121103	Food and refreshments	Person	25,000	50	1,250,000	50	1,250,000	50	1,250,000	50	1,250,000	50	1,250,000
		22007109	Conference facilities	Days	250,000	5	1,250,000	5	1,250,000	5	1,250,000	5	1,250,000	5	1,250,000

		22010102	Ground travel (bus, railways)	Trip	80,000	6	480,000	6	480,000	6	480,000	6	480,000	6	480,000
		22011102	Air Travel Tickets	Person - Days	500,000	5	2,500,000	5	2,500,000	5	2,500,000	5	2,500,000	5	2,500,000
	Total Activity						**12,980,000**		**12,980,000**		**12,980,000**		**12,980,000**		**12,980,000**
	To conduct annual stakeholders meetings to discuss matters related to domestic manufacturing by June, 2027	21121103	Food and refreshments	Person	25,000	100	2,500,000	100	2,500,000	100	2,500,000	100	2,500,000	100	2,500,000
		22010102	Ground travel (bus, railways)	Trip	80,000	10	800,000	10	800,000	10	800,000	10	800,000	10	800,000
	Total Activity						**3,300,000**		**3,300,000**		**3,300,000**		**3,300,000**		**3,300,000**
	To conduct sensitization meeting for establishment of medical device manufacturers by December, 2022	21121103	Food and refreshments	Person	25,000	100	2,500,000	-	-	-	-	-	-	-	-
		22010102	Ground travel (bus, railways)	Trip	80,000	10	800,000	-	-	-	-	-	-	-	-
	Total Activity						**3,300,000**								

	To develop guide on investment in medical products manufacturing by January, 2023	22010105	Per Diem - Domestic	Person - Days	150,000	50	7,500,000	-	-	-	-	-	-	-	-
		21121103	Food and refreshments	Person	25,000	60	1,500,000	-	-	-	-	-	-	-	-
		22001101	Stationeries and Office Consumables	Pcs	400,000	1	400,000	-	-	-	-	-	-	-	-
		22007109	Conference facilities	Days	250,000	5	1,250,000	-	-	-	-	-	-	-	-
		22010102	Ground travel (bus, railways)	Trip	80,000	6	480,000	-	-	-	-	-	-	-	-
	Total Activity						**11,130,000**	-	-	-	-	-	-	-	-
	To develop a web link with information relevant to domestic manufacturers by December, 2022	22010105	Per Diem - Domestic	Person - Days	150,000	25	3,750,000	-	-	-	-	-	-	-	-
		21121103	Food and refreshments	Person	25,000	25	625,000	-	-	-	-	-	-	-	-
		22007109	Conference facilities	Days	250,000	5	1,250,000	-	-	-	-	-	-	-	-
		22010102	Ground travel (bus, railways)	Trip	80,000	6	480,000	-	-	-	-	-	-	-	-
	Total Activity						**6,105,000**								

	Total Specific Objective 04						36,815,000		**16,280,000**		**16,280,000**		**16,280,000**		**16,280,000**
Specific Objective: 05		To monitor and evaluate implementation of the plan													
TARGET		Action plan for promoting domestic medical products manufacturing facilities monitored and evaluated by June, 2027													
	To develop monitoring and evaluation framework by June, 2024	22010105	Per Diem - Domestic	Person - Days	150,000			35	5,250,000	-	-	-	-	-	-
		21121103	Food and refreshments	Person	25,000	-	-	30	750,000	-	-	-	-	-	-
		22001101	Stationeries and Office Consumables	Pcs	400,000	-	-	1	400,000	-	-	-	-	-	-
		22007109	Conference facilities	Days	250,000	-	-	5	1,250,000	-	-	-	-	-	-
		22003102	Diesel	Litres	2,500	-	-	200	500,000	-	-	-	-	-	-
		22010102	Ground travel domestic	Trips	80000	-	-	5	400,000	-	-	-	-	-	-
	Total Activity								**8,550,000**	-	-	-	-	-	-
	To conduct mid-term evaluation of the implementation of the plan by June, 2024	22010105	Per Diem - Domestic	Man-day	150000	-	-	80	12,000,000	-	-	-	-	-	-
		22010102	Ground travel domestic	Trips	80000	-	-	10	800,000	-	-	-	-	-	-
		21121103	Food and refreshmentss	Person	25000	-	-	70	1,750,000	-	-	-	-	-	-
		22007109	Conference facilities	Day	250000	-	-	5	1,250,000	-	-	-	-	-	-

	22003102	Diesel	Litre	2500	-	-	150	375,000	-	-	-	-	-	-	
	22010101	Air Travel Tickets domestic	Trips	500000	-	-	2	1,000,000	-	-	-	-	-	-	
Total Activity								**17,175,000**							
To conduct end-term evaluation of the plan by June, 2027	22010105	Per Diem - Domestic	Man-day	150000	-	-	-	-	-	-	-	-	200	30,000,000	
	22010102	Ground travel domestic	Trips	80000	-	-	-	-	-	-	-	-	20	1,600,000	
	21121103	Food and refreshmentss	Person	25000	-	-	-	-	-	-	-	-	100	2,500,000	
	22007109	Conference facilities	Day	250000	-	-	-	-	-	-	-	-	10	2,500,000	
	22003102	Diesel	Litre	2500	-	-	-	-	-	-	-	-	250	625,000	
	22010101	Air Travel Tickets domestic	Trips	500000	-	-	-	-	-	-	-	-	4	2,000,000	
Total Activity														**39,225,000**	
To publish results of implementation of the plan in peer reviewed journals by June, 2027	22031104	Consultancy fee	lumpsum	3150000	0	-	-	-	-	-	-	-	2	6,300,000	
	22010105	Per Diem - Domestic	Man-day	150000	70	-	-	-	-	-	-	-	70	10,500,000	
	21121103	Food and refreshments	Person	25,000	70	-	-	-	-	-	-	-	70	1,750,000	

		22001101	Stationeries and Office Consumables	Pcs	400,000	1	-	-	-	-	-	-	-	1	400,000
		22007109	Conference facilities	Days	250,000	5	-	-	-	-	-	-	-	5	1,250,000
		22003102	Diesel	Litres	2,500	200	-	-	-	-	-	-	-	200	500,000
		22010102	Ground travel (bus, railways)	Trip	80,000	6	-	-	-	-	-	-	-	6	480,000
	Total Activity						-	-	-	-	-	-	-		21,180,000
	Total Specific Objective 05						**-**		**25,725,000**						60,405,000
	Total Each Financial Year						**462,890,000**		**293,065,000**		**284,955,000**		**270,835,000**		**320,485,000**
	Grand Total for Five (5) Years						**1,632,230,000**								

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