



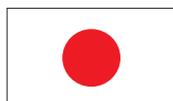
THE ACCESS AND
DELIVERY PARTNERSHIP

New Health Technologies for TB, Malaria and NTDs

Legal and Policy Coherence to Promote Access to Health Technologies in the United Republic of Tanzania



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Resilient nations.



From the People of Japan

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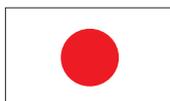
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About the Access and Delivery Partnership

The adverse impact of tuberculosis (TB), malaria and neglected tropic diseases (NTDs) on development outcomes has resulted in new approaches and partnerships to tackle the global deficiencies in research and development, and treatment access. One such initiative is the strategic partnership between the Government of Japan and United Nations Development Programme (UNDP), which promotes research and development, and expedites access to and delivery of health technologies used to address TB, malaria and NTDs. This partnership comprises two complementary components, which reflect the Government of Japan's and UNDP's strategic goals on global health:

The **Global Health Innovative Technology (GHIT) Fund**, which focuses on the promotion of innovation and research through the development of drugs, diagnostics and vaccines for TB, malaria and NTDs. The GHIT Fund stimulates research and development of new health technologies through funding research and product development partnerships between Japanese and non-Japanese organizations.

The **Access and Delivery Partnership (ADP)**, which aims at assisting low- and middle-income countries (LMICs) enhance their capacity to access, deliver and introduce new health technologies for TB, malaria and NTDs.

Led and coordinated by UNDP, the ADP is a unique collaboration between UNDP, TDR (the Special Programme for Research and Training in Tropical Diseases, which is co-sponsored by UNICEF, UNDP, the World Bank and WHO) and PATH. Working together, the project partners leverage the expertise within each organization to provide the full range of technical skills necessary to strengthen capacity in LMICs. The ADP emphasizes consultation, collaboration and implementation with partner-country governments and stakeholders, working to develop LMICs' capacities to access and introduce new technologies.

New health technologies are broadly defined as drugs, diagnostic tools and vaccines that are relevant for the prevention, treatment or cure of TB, malaria and NTDs, but are not yet available for market introduction or have not been introduced in LMICs. The introduction of new health technologies can place burdens on existing health systems, including new requirements for drug regulation, supply and distribution and health personnel training. Accordingly, the ADP will focus on providing LMIC stakeholders with the necessary skills to develop the systems and processes required to effectively access new health technologies, and introduce them to populations in need.

The ADP is a five-year project, running from April 2013 until March 2018.



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The views expressed are those of the author and do not necessarily represent those of the United Nations, including UNDP, or the UN Member States.



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Contents

Executive Summary	1
1. Introduction and Context of Study	4
2. Policy Coherence	4
3. Subregional Frameworks and Initiatives	5
4. Situational Analysis of Tanzania	11
5. Key Focus Areas	16
6. Linkages, Alignment and Priority Areas	20
7. Recommendations.	22
8. Way Forward	26
9. BIBLIOGRAPHY	26
10. Annex	29

Acronyms and Abbreviations

ADP	Access and Delivery Partnership
AMRH	African Medicines Regulatory Harmonization
ANDI	African Network for Drugs and Diagnostics Innovation
API	Active pharmaceutical ingredient
ARIPO	African Regional Intellectual Property Organization
AU	African Union
COHRED	Council on Health Research for Development
DNDi	Drugs for Neglected Diseases Initiatives
EAC	East African Community
GMP	Good Manufacturing Practice
ICESCR	International Covenant on Economic, Social and Cultural Rights
IPR	Intellectual property right
ISC	Inter-sectoral Committee
LDC	Least developed country
MSD	Medical Stores Department
NEPAD	New Partnership for Africa's Development
OECD	Organisation for Economic Co-operation and Development
PMPA	Pharmaceutical Manufacturing Plan of Action
RECS	Regional Economic Communities
RIDSP	Regional Indicative Strategic Development Plan
SADC	Southern African Development Community
TB	Tuberculosis
TFDA	Tanzania Food and Drugs Authority
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNDP	United Nations Development Programme
WHO	World Health Organization
WTO	World Trade Organization

Executive Summary



The issue of policy incoherence in government is a widespread problem in both developed and developing countries. This report is an attempt to address the phenomenon in the context of the United Republic of Tanzania, with a view to addressing the challenge of access to health technologies.

Tanzania was selected as one of the four initial focus countries of the Access and Delivery Partnership (ADP), based on an assessment of where the prevalence of tuberculosis, malaria and neglected tropical diseases is highest, and where the political will and commitment to combatting those diseases is demonstrated by the country. Other considerations included: its leading role in regional efforts to establish regulatory harmonization for medicines; investment in initiatives to strengthen sustainable local production of medicines; support of local pharmaceutical research and development; and its work to scale up national health insurance to achieve universal coverage.

This study includes the following: the Tanzanian context (chapter 1); the notion of policy coherence (chapter 2); subregional efforts to address some of the challenges confronting the East and Southern African regions (chapter 3); a situational analysis of the relevant issues for the Tanzanian context (chapter 4); identifying the key focus areas to address potential policy incoherencies in Tanzania, their linkages, alignment and priority areas for attention (chapters 5 and 6); and concrete recommendations and a suggested way forward (chapters 7 and 8).

Chapter 1 observes that Tanzania has been classified as a “low human development country” which, despite progress on some indicators, continues to be burdened with chronic malnutrition, which still claims a significant proportion of under-five deaths.

Chapter 2 points to the critical need for policy coherence – a coordinated approach to the implementation of laws, policies and programmes – if Tanzania is to succeed in its development objectives.

Chapter 3 reviews a number of subregional frameworks and initiatives, including the African Union Pharmaceutical Manufacturing Plan of Action, 2007, the EAC Regional Intellectual Property Policy on Utilization of Public Health-Related World Trade Organization- Trade-Related Aspects of Intellectual Property Rights (TRIPS) Flexibilities and the Approximation of National Intellectual Property Legislation, 2013, and various regional and continental development strategies and harmonization efforts. These examples illustrate the existence of well-researched frameworks and plans on which to base the enhancement of Tanzania’s legal and policy reforms in order to improve access to health technologies and capacitate local manufacturing industry in pharmaceuticals.

Chapter 4 undertakes a situational analysis of Tanzania, including its legal and institutional frameworks, and makes two noteworthy observations. Firstly, that while Tanzania has a highly developed medicines regulatory system, its early adoption of the provisions of TRIPS Agreement has placed it at the disadvantage of prematurely recognizing pharmaceutical patents when, as a least developed country, it could have delayed doing so until at least 2033. Secondly, it has a nascent pharmaceutical manufacturing industry, which could develop with the introduction of a number of supportive measures from government.

Chapter 5 identifies the key focus areas germane to attaining policy coherence, which are: access to health; intellectual property issues; medicines regulation; local production of medicines; and research and development and innovation. On access to health, given that this remains a major challenge, the lack of an express constitutional provision restricts the ability of citizens to advocate for improved access. On the intellectual property issue, the key feature identified is the sub-optimal utilization of the flexibilities permitted by the TRIPS Agreement, in particular, the transitional leeway available to least developed countries. On the medicines regulation aspect, the study recognizes that the Tanzania Food and Drug Authority is an established, efficient regulator. On local production, the challenge identified is to improve manufacturing capacity to achieve the goals of sustainability and affordability. Finally, as regards research and development and innovation, the study observes that Tanzania has a limited but growing capacity in this area, and its research agenda is driven by the National Institute for Medical Research established in 1979.

Chapter 6 consolidates the discussion on the key focus areas, exploring the feasibility and prospects of aligning policies across these focus areas with a view to achieving greater policy coherence. It advances the notion of the “whole of government” approach as opposed to different portfolios working in “silos”, and proposes the establishment of an interministerial committee to drive this project.

Chapter 7 outlines a list of 24 recommendations across the different focus areas to attain policy coherence. Among the key recommendations are:

- The right of access to health care to be written into the Draft Constitution, 2013
- Substantial reform to the supply chain management system
- The adoption the TRIPS LDC pharmaceutical waiver
- The adoption of all available flexibilities permitted by the TRIPS Agreement, including: stricter patentability criteria and disclosure requirements; early working exceptions; additional grounds for granting compulsory licences, and streamlined administrative procedures; data protection but not exclusivity; decriminalization of patent infringement; expansive parallel importation rules; and the definition of “counterfeit drugs” to be amended to specifically exclude legitimately-produced and quality-assured generics
- The medicines regulator to function independently of the executive branch of the government, and its activities to be conducted in a transparent manner, in the public interest
- Several reforms to enhance local production, including: the development of an industrial policy and establishment of a national task force to this end; and for government to facilitate the provision of financial incentives and market access for local producers
- Increased government investment in research and development and innovation, and collaboration with research centres such as ANDI and DNDi

Chapter 8 concludes that the implementation of these recommendations be delegated to a high-level Intersectoral Committee with a defined agenda and time-frames.



1. Introduction and Context of Study

This study on legal and policy coherence to promote access to health technologies in the United Republic of Tanzania (Tanzania) has its genesis in two key initiatives of the United Nations Development Programme (UNDP). First, it is based on one of the three types of support that UNDP provides to countries in the areas of HIV and AIDS and health and development, that of “effective implementation of complex, multilateral and multisectoral health projects, while simultaneously investing in capacity development so that national and local partners can assume these responsibilities over time”.¹ Second, it constitutes a key pillar of the Access and Delivery Partnership (ADP), whose basic premise is that “access to, and delivery of new health technologies is a multi-faceted and complex issue, which requires an integrated and coherent approach ... that can effectively address the various intersections between public health, socio-economic development, and industrial and fiscal policies”.² In this context, the ADP supported a study on the situational analysis of the local pharmaceutical sector that identified challenges and opportunities in order to enhance local manufacturing capacity.³

Tanzania was selected as one of the four initial focus countries of the ADP, based on an assessment of where the prevalence of tuberculosis, malaria and neglected tropical diseases is highest, and where the political will and commitment to combatting those diseases is demonstrated by the country.⁴ In addition, several other factors have contributed to the selection of Tanzania as a focus country: its leading role in regional efforts to establish regulatory harmonization for medicines; investment in initiatives to strengthen sustainable local production of medicines; support of local pharmaceutical research and development; and its work to scale up national health insurance to achieve universal coverage.⁵

According to the *Human Development Report 2014*, Tanzania is ranked 159 out of 187 countries in the Human Development Index Countries and Ranks, 2013, thereby classifying it as a “low human development” country.⁶ It is one of 48 countries categorized as a Least Developed Country (LDC) by the United Nations as at May 2016.⁷ The United Nations defines LDCs as: “low-income countries confronting severe structural impediments to sustainable development”.⁸ While significant progress has been made in Tanzania’s health sector, with life expectancy rising from 51 years in 2002 to 61 years in 2012, and infant mortality declining from 68 per 1,000 live births in 2005 to 45 per 1,000 live births in 2010, chronic malnutrition still accounts for over one-third of the under-five mortality rate.⁹

Tanzania attained a growth rate of above 6 percent per annum in the years 2001 to 2012, below its target of 9 percent per annum, but above the sub-Saharan regional average of 4.2 percent. The poverty rate has only marginally declined from 33.3 percent in 2007 to 28.2 percent in 2012.¹⁰

2. Policy Coherence

Policy coherence is an accepted precondition for a coordinated approach to implementation of rules, laws, policies and programmes to advance particular development objectives. It involves “the systematic promotion of mutually reinforcing policy actions across government departments and agencies creating synergies towards achieving the agreed objectives” and requires that a country “pursues policies that support, and do not undermine, specific efforts it is making to help and develop the development process”. In this regard “building political agreement among stakeholders with diverse interests is the key to progress”.¹¹

1 UNDP

2 2014 Access and Delivery Partnership: New Health Technologies for TB, Malaria and NTDs booklet, 2014

3 S. Chaudhuri, How Local Production of Pharmaceuticals can be Promoted in Africa: The Case of Tanzania Report submitted to UNDP, July 2014

4 ADP Status Report 2014

5 *ibid*

6 Human Development Report 2014, United Nations Development Programme, New York, 2014, p. xi

7 http://www.un.org/en/development/desa/policy/cdp/ldc/ldc_list.pdf (last accessed on 26 September 2016)

8 http://www.un.org/en/development/desa/policy/cdp/ldc_info.shtml (last accessed on 26 September 2016)

9 Human Development Report 2014, United Nations Development Programme, New York, 2014, p. 12

10 UNDP Tanzania National Development Report 2014

11 OECD Policy coherence: Vital for global development, Policy Brief July 2003

At the national level, policy coherence is required among various categories of public policies, levels of government (national, provincial and local), and stakeholders. It also extends to the interplay of policies at regional and international levels. The understanding of policy coherence needs to evolve to keep pace with increasing institutional and economic complexities. Given that governments and institutions are often engaged in balancing competing interests, the resultant effect can lead to policy incoherence.

According to Robert Picciotto in *Policy Coherence and Development Evaluation Concepts, Issues and Possible Approaches*, “Absolute policy coherence implies that the preference functions of diverse groups can be aggregated without ambiguity. But economic theory demonstrates the exact opposite: majority rule leads to outcomes that depend less on preferences than on agenda setting and the sequencing of votes ... In order to reach consensus, dilemmas of collective action must be resolved. They are most intractable within large groups ... Hence, the rationale of committees or departments with jurisdictions over specialized domains. But breaking out complex issues into manageable segments encourages a ‘silo’ approach to policymaking.’

‘As a result, coherence within a specialized group may be secured at the expense of incoherence across groups... This is such a frequent occurrence that policy coherence is often equated with a ‘whole of government’ approach. Such an approach requires transparent information links among individual departments as well as strong leadership and transparent linkages between the specialized units and the sovereign body”.¹²

An apposite illustration of this conceptual notion may be the application of intellectual property rights (IPRs) and policies. The protection of IPRs under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is intended to promote research and innovation, but its application often results in strong pricing monopolies that restrict access to essential drugs and other knowledge-intensive products and services in, especially, low- and middle-income countries. This can result in a conflict with another policy priority, namely, securing positive health outcomes for the inhabitants of the country. This is the type of policy incoherence that needs to be prevented.

3. Subregional Frameworks and Initiatives

The legislation and policies of Tanzania operate in the broader context of continental and subregional frameworks in the areas relevant to this study. This section focuses on some of the key instruments or policies that impact on this discussion.

3.1 The African Union Pharmaceutical Manufacturing Plan of Action, 2007, and Business Plan, 2013

This document outlines the recommended approach in order to achieve the aims of the African Union Pharmaceutical Manufacturing Plan of Action (AU PMPA) to strengthen production ability and improve health outcomes.

Africa’s disproportionate burden of disease, and the expansion of non-communicable diseases in poor countries are the main motivators for the vision to develop industry in Africa to produce affordable medicines of assured quality, to improve health outcomes and to contribute to industrial and economic growth. The AU PMPA recognizes the multifarious stakeholders in the “pharmaceutical manufacturing system” comprised of the manufacturing companies, medicines regulatory authorities, government departments, trade associations, and distribution networks. The AU PMPA also takes account of the limited manufacturing capacity in Africa and the near non-existence of the production of active pharmaceutical ingredients (APIs) as well as a host of other challenges faced by developing countries and LDCs.

¹² R. Picciotto, *Policy Coherence and Development Evaluation Concepts, Issues and Possible Approaches*, Organisation for Economic Co-operation and Development (OECD) Room Document 2, May 2004.

Given the diversity of development levels in the pharmaceutical sector, the AU PMPA does not present a blueprint, but rather a generic package of solutions that countries may adapt to their particular circumstances. The package includes:

- Guidance on incentives in support of the sector
- A Good Manufacturing Practice road map and associated risk assessment of the World Health Organization (WHO) Essential Medicines List
- A syllabus for developing the human resources required for the long term sustainability of the industry
- Various mechanisms for accessing expertise in the short term
- Technical assistance to enable regulators to devise and implement organizational development plans
- A process by which the different stakeholders in a country can develop a shared strategy for the sector and means of implementation

Further good examples of attempts to attain policy coherence include designs for an environment to enable local producers to compete with imports, and a resolve to advocate for an extension of the TRIPS transition period for LDCs.

3.2 Council on Health Research for Development - New Partnership for Africa's Development Strengthening Pharmaceutical Innovation in Africa, 2010

Based on research conducted by the Council on Health Research for Development (COHRED) and the New Partnership for Africa's Development (NEPAD) in 2008 and 2009, the document *Strengthening Pharmaceutical Innovation in Africa, 2010* provides the evidence base for the initiative to strengthen pharmaceutical innovation in Africa.¹³ The study commences with an analysis of countries' needs and challenges, and provides a map of innovation and access activities in Africa. It proceeds to develop a planning tool, the Pharmaceutical Innovation Framework and Grid, which helps countries to undertake self-assessments, develop strategies, build capacity and develop partnerships to engage in innovation and improve access to essential medicines.

The main recommendations include:

- Support for harmonization and evaluation of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and the AU PMPA. This will include: establishing objectives and milestones for pharmaceutical innovation; creating mechanisms to stimulate research and development, technology transfer and other conditions to strengthen manufacturing in Africa; and creation of a coordination mechanism to ensure better synergy and improved intra and inter-regional support.
- Implementation of innovation in countries, including information management and workshops for governments and regulators to share information, expertise and lessons learned.
- Ensure access to: policies and regulations on substandard drugs; dumping and donations; building capacity to ensure safe, high quality medicines; strengthening capacity for inspection, quality control and laboratory work; addressing intellectual property obstacles; health insurance; regional partnerships to share expertise between countries; and sustainable financing.
- Promote manufacturing through: aligning university curricula to produce the required skills; government provision of dedicated funds for low interest loans and assistance to manufacturers to overcome challenges of prequalification; partnerships with technical agencies for WHO prequalification; building capacity in traditional and allied medicines; and increasing the competitiveness of local manufacturers.
- Capacity building for research and development, including: enabling a research environment, human and institutional resources for developing a critical mass of scientific leaders; development

¹³ COHRED-NEPAD Strengthening Pharmaceutical Innovation in Africa Final report, 2010.

of regional centres of excellence; capacity-building partnerships between research institutions and the private sector; and capacities for dealing with traditional medicines.

3.3 The African Union Roadmap on Shared Responsibility and Global Solidarity for AIDS, Tuberculosis and Malaria Response in Africa, 2012-2015

The African Union Roadmap on Shared Responsibility and Global Solidarity for AIDS, Tuberculosis and Malaria Response in Africa, 2012–2015 (AU Roadmap) promotes African-sourced solutions to these health crises, and entails three strategic pillars: diversified financing; access to affordable and quality-assured medicines; and enhanced leadership and governance.

The AU Roadmap is a response to the changing global context characterized by economic crises, new alignments in cooperation with emerging economies, and shrinking development aid budgets. Building on the emergency responses to the AIDS pandemic, the AU Roadmap seeks to leverage this support to address tuberculosis (TB), malaria and other infectious diseases by developing a new health financing partnership (shared responsibility and global response), enhance pharmaceutical security for these diseases, and promote innovative approaches to health governance.

The three strategic pillars cover:

- Country leadership for an orderly and strategic transition to more diversified, balanced and sustainable financing models for AIDS, TB and malaria (investment targets, diversified financing sources, financial sustainability through longer-term predictable external resources, and a greater proportion of domestic investments on budget in the context of shared but differentiated responsibility).
- Accelerated access to affordable and quality-assured medicines and health-related commodities per the PMPA (medicines' security enhanced by investing in local centres of excellence; medicines regulatory harmonization within Regional Economic Communities, to lay the foundations of an African Medicines Regulatory Agency; and medicines trade facilitated through concerted actions at global, continental, regional and country levels).
- Leadership, governance and oversight to implement African solutions for AIDS, TB and malaria based on sustainability, transparency and equity (address urgent needs; strategic; evidence- and rights-based; strengthen health systems; designed, implemented and evaluated through inclusive processes with the participation of affected communities; and with the AU Member States demonstrating strong leadership and ownership).

Finally, the AU Roadmap emphasizes the critical role of enhancing local pharmaceutical production and regulatory harmonization, two essential processes for policy coherence.

3.4 The East African Community Regional PMPA 2012-2016

The East African Community Regional PMPA 2012–2016 (EAC PMPA) serves as a guide for the East African Community (EAC) to develop an efficient and effective regional pharmaceutical manufacturing industry to supply national, regional and international markets. Local manufacturers accounted for between 25 and 30 percent of the pharmaceutical market in sub-Saharan Africa, amounting to some US\$3.8 billion in 2006, and for only a small share of the donor market worth between \$750 million and \$1 billion. This is because local manufacturers produce at a cost disadvantage to larger generic medicines manufacturers internationally owing to: lack of economies of scale, expensive asset bases with aging technology, higher financing costs, lack of API production, shortages of skilled personnel, and unreliable supporting infrastructure. The EAC PMPA was developed with a view to addressing industrial policy, economic and health objectives. It entails the following primary strategic objectives:

- Promotion of competitive and efficient pharmaceutical production regionally including: the strengthening of local capacity to meet WHO-Good Manufacturing Practice (GMP) and prequalification standards; regional and international collaboration including technology transfer; use of collective

purchasing preference schemes by public procurement agencies; pooled procurement of raw materials; and studies to establish regional demand quantification and production capacity

- Facilitation of increased investment in pharmaceutical production regionally, including: promotion of conducive investment environment; a feasibility study on financing options; sensitizing stakeholders on unique industry dynamics; development of a policy framework; and identification of locations for pharmaceutical industry clusters and special economic zones
- Strengthening of pharmaceutical regulatory capacity in the region, including: addressing needs in terms of human resource capacity; infrastructure of regulatory bodies; and harmonization of regulations for various regulatory functions across the region
- Development of appropriate skills and knowledge on pharmaceutical production in the region, including identification, equipping and accreditation of training institutions and development and implementation of a gender-based human resources development strategy
- Utilization of TRIPS flexibilities towards improved local production of pharmaceuticals, including national and regional sensitization on IPRs and flexibilities related to public health; adoption of regional policy frameworks and guidelines to implement flexibilities; and domestication of flexibilities
- Mainstreaming innovation, research and development within regional pharmaceutical industries, including: enhancing pharmaceutical research and development capacity in the region; promotion of locally-sourced inputs for production of APIs; and mobilizing resources for a regional pharmaceutical innovation fund

The plan is accompanied by a budget of \$45 million, to be raised from EAC Partner States, regional industry, and development partners, as well as a framework for regular monitoring, evaluation and review of progress.

3.5 The EAC Regional Intellectual Property Policy on Utilization of Public Health-Related World Trade Organization (WTO)-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation, 2013

The objective of the EAC Regional Intellectual Property Policy on Utilization of Public Health-Related World Trade Organization (WTO)-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation, 2013 (EAC TRIPS Flexibilities) is to provide a comprehensive road map on the use of public health-related flexibilities in order to enable EAC Partner States (Burundi, Kenya, Rwanda, Tanzania and Uganda) to optimize access to health and related products.¹⁴ In particular, it is anticipated that the policy will enable EAC Partner States to:

- Optimize access by the population to health products and medical devices
- Broaden the public domain in order to ensure that intellectual property embedded products and services with respect to health are available and accessible at an affordable cost to all of the EAC Partner States' populations
- Achieve public health objectives
- Promote pharmaceutical manufacturing and innovation industries
- Improve mutual cooperation in regional markets

The document proceeds to elaborate policy statements on the required amendments to EAC Partner States' legislation. In particular, the following flexibilities are identified (with recommended formulations to be considered for adoption):

¹⁴ EAC Regional Intellectual Property Policy on the Utilization of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation, February 2013.

- Transition periods to allow for LDC Partner States to take advantage of the 2016 transition period and provide for an extension as may be agreed by the TRIPS Council and to abolish any “mailbox” provision in existing legislation.
- Patentability criteria: to be strictly defined in the law and examination guidelines in the public interest, applying the absolute novelty standard; inventive step to be defined by reference to a “highly” skilled person in the art; and as regards industrial applicability, to limit the patentability of research tools to those for which a specific use has been identified.
- Exclusions from patentability to include: diagnostic, therapeutic and surgical methods; plants and animals, and essentially biological processes for their production; defining an “invention” to exclude natural substances, new medical uses and derivatives of medical products that do not show significantly enhanced therapeutic efficacy or superior properties; and provisions for compensatory liability to protect small-scale innovations where the invention is used for follow-up improvements.
- Research exceptions: to explicitly authorize research for scientific, non-commercial and commercial purposes with the aim of generating new knowledge of the patented substance; and to provide the right to claim a non-exclusive licence for the use of patented research tools against payment of compensation.
- Marketing approval: to authorize the use of the patented substance by parties seeking marketing approval from national and foreign regulatory authorities; and clarify the scope of such use to acts “reasonably related” to that objective.
- Test data protection: upon expiry of the transition period, LDCs to protect test data against unfair commercial use and disclosure, leaving regulatory authorities free to rely on the data from domestic and foreign approvals when assessing safety and efficacy of generic competing products; and no linkage to be established between patent protection and marketing authorization when granting marketing approval for generics while the patent is in force.
- Disclosure requirements: patent applicants to disclose all, including the best, mode for carrying out an invention; and to disclose the International Non-proprietary Name of a pharmaceutical ingredient as soon as it is available.
- Administrative opposition procedures: to provide, in addition to post-grant tribunal/court procedures, for effective pre- and post-grant administrative opposition procedures; and Partner States that are also members of the African Regional Intellectual Property Organization (ARIPO), to discuss an amendment to the Harare Protocol on Patents and Industrial Designs to take account of third party oppositions; and to subject patents in their territories that were granted by ARIPO to the written approval of the respective national patent offices, which shall be submitted to ARIPO within a reasonable period beyond the current six-month period.
- Parallel importation: Partner States to admit international IPR exhaustion under their patent, copyright and trademark legislation.
- Compulsory licensing provisions to enable Partner States to:
 - Be free to determine and stipulate the grounds for granting such licences
 - Amend their provisions to include authorization of exports of up to 100 percent of medicines produced, to countries lacking manufacturing capacity
 - Draft guidelines and regulations as both exporting and importing countries under draft Article 31 bis of TRIPS
 - When importing under Article 31 bis of TRIPS, waive remuneration for the patent holder in the exporting country
 - Include a provision limiting remuneration to 4 percent, and take anti-competitive behaviour into account when determining the rate of remuneration
 - Include a maximum period of 90 days for prior negotiations
 - Specify the four situations in which prior negotiations can be waived: national emergency, situation of extreme urgency, public non-commercial/government use, and anti-competitive behaviour of the patent holder

- Exclude injunctive relief as a remedy available under independent review of government use licences
 - Authorize administrative entities to grant all types of compulsory licences
 - Institute monitoring mechanisms for determining and implementing the four situations in which prior negotiations can be waived
- Anti-competitive behaviour and patent abuse: to list the licensing terms that may be considered to be unjustified restrictions on competition, and authorize the patent office to refuse the registration of such terms; and provide for remedies for abuse in this regard, such as compulsory licences.
 - Implementation arrangements: to include rejection of attempts during trade negotiations to hinder the full utilization of flexibilities; apply enforcement measures such that they avoid the creation of barriers to legitimate trade; strengthen drug regulatory authorities to ensure safety, efficacy and quality; enabling an environment and providing funding and incentives for establishing regional and national medicines manufacturing capacities; and to implement the World Intellectual Property Organization Development Agenda and the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

3.6 East African Community Development Strategy (2011/2012–2015/2016) Deepening and Accelerating Integration, 2011

The East African Community Development Strategy on Deepening and Accelerating Integration (2011) outlines the broad strategic goals of the EAC as well as the specific targets to be achieved during the period 2011/2012 to 2015/2016. It includes priority projects and programmes, such as consolidation of the Customs Union and Common Market, as well as the promotion of an economic infrastructure to support and spur growth in the region. It recognizes that improvement in the quality of life depends on provision, affordability and access to good health services. It records the key achievements as including the strengthening of regional cooperation and integration in the health sector through the harmonization of national policies, legislation, strategies, standards and regulatory systems. Weak institutional coordinating frameworks, inadequate financial and human resources and limited access to essential medicines and quality services are identified as some of the critical challenges confronting the region.

3.7 Southern African Development Community (SADC) Regional Indicative Strategic Development Plan, 2001

The Southern African Development Community (SADC) Regional Indicative Strategic Development Plan (2001) (SADC-RISDP) is a comprehensive 15-year strategic road map that provides direction for achieving the long-term social and economic goals of SADC. It also provides clear guidelines on the approved social and economic priorities and policies of SADC in order to enhance its effectiveness and coordinating role. The Development Plan was approved at the Summit of the Heads of State and Government of SADC (Dar es Salaam, 25–26 August 2003) and its effective implementation began in 2005.

The Development Plan lists the 12 priority areas identified by the SADC Council in which action must be taken in order to achieve the overarching goal of regional integration and provides milestones and targets for each priority area. The goal of the HIV and AIDS priority intervention area is to decrease the number of HIV and AIDS infected and affected individuals and families in the SADC region so that HIV and AIDS are no longer a threat to public health and to the socio-economic development of SADC Member States. The main strategy is to promote the reallocation of responsibilities for planning, coordination, implementation, monitoring and evaluation of the response of SADC across all its sectors.

The Development Plan also recognizes the importance of science and technology to economic development and increasing competitiveness. The goal of this priority intervention area is to develop and strengthen national systems of innovation in order to provide scientific and technological solutions to or for sustainable socio-economic development, regional integration and poverty eradication. The Development Plan emphasizes cooperation in infrastructure development in order to create a platform that will support and sustain regional economic development, trade, investment and agriculture.

3.8 African Medicines Regulatory Harmonization Programme

The main aim of the African Medicines Regulatory Harmonization (AMRH) programme is to improve public health by increasing access to high quality, safe and effective medicines through the harmonization of medicines regulation, including faster registration of essential medicines for the treatment of diseases. The AMRH programme aims to improve access to, availability and affordability of medicines.

The AMRH programme works to strengthen the legislative environment for harmonization of medicines regulation in Africa, given the weak legal and regulatory frameworks in many countries. Although policies, treaties and protocols aimed at medicines regulatory harmonization already exist in the majority of Regional Economic Communities (RECs) recognized by the African Union, implementation by member states remains unfulfilled because such treaties are non-self-executing, and require the domestication of such decisions through national laws.

The lack of comprehensive medicines legislation in many countries in Africa remains a challenge. An analysis of medicines legislation in African regions through a NEPAD-commissioned situation analysis in 2010 shows numerous gaps in legislation and in legal frameworks. While some countries have legislation in line with the core elements as recommended by WHO, others do not have medicines regulatory laws in place.

The NEPAD and the Pan-African Parliament have joined forces to support the process of medicines regulatory harmonization in Africa through the development of a Medicines Regulation Model Law. The Law will assist the RECs and/or countries in their endeavour to enact or review their national laws and subsequent harmonization of national laws with regional policies, protocols and treaties. A Draft Model Law was discussed in extensive consultations in the RECs and was approved as the AU Model Law on Medical Products Regulation by AU Heads of States in January 2016.

The construct of the Draft Model Law is that of an enabling framework (as opposed to a detailed law) with many of the details delegated to subordinate legislation in the form of national regulations. Within this construct, countries still have a degree of autonomy, for example, on whether to limit the remit of their legislation to medicines, biologics and medical devices, or to cover the full panoply of substances and technologies to be regulated. Among its key features are:

- Vesting decision-making of the regulatory authority in an independent structure
- An in-principle approach to maximizing transparency in the regulatory process
- A pro-public health approach to intellectual property that meets the minima required by international agreements such as TRIPS
- The means to achieve harmonization between national regulatory bodies with different capacities in the context of the AMRH project

4. Situational Analysis of Tanzania

4.1 Legal and Institutional Frameworks

This section presents an overview of the legislative and policy frameworks relevant to this project.

The Constitution of Tanzania

Tanzania is in the process of revising its Constitution, following both civil society requests and an EAC commitment to review the constitutions of its Partner States. A Constitutional Review Commission was established in terms of the Constitutional Review Act 8 of 2011, with a mandate to adopt a participatory process, which culminated in the presentation of the Draft Constitution of 2013.

The Draft Constitution incorporates a human rights and rule of law-based approach. In this regard, it contains extensive provisions for the protection of civil and political rights, although it has been criticized

for including limitations to specific rights as they are declared, as opposed to having a general limitations clause.¹⁵ Moreover, it does not provide for non-derogation from certain fundamental rights (i.e. fair hearing, freedom from torture, slavery, or other degrading treatments), which is commonplace in international and national instruments. With regard to gender, the Draft Constitution includes achieving parity for women, but neither the equality provision nor any other article extends this protection to sexual minorities.

There is limited provision for the protection of socio-economic rights, with the notable absence of any express provision protecting the right of access to health care or basic services. In this respect, it is not in alignment with the African Charter on Human and People's Rights (ratified by Tanzania in 1984), which protects the "right to enjoy the best attainable state of physical and mental health accompanied by a state duty to take the necessary measures".¹⁶ The Draft Constitution is also not consistent with the International Covenant on Economic, Social and Cultural Rights (ICESCR), which Tanzania acceded to in 1976, and which provides the broadest codified protection of the right to health, namely "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health".¹⁷

United Republic of Tanzania Public Health Act, 2009

This Act provides for the promotion, preservation and maintenance of public health with a view to ensuring the provision of comprehensive, functional and sustainable public health services to the general public, and for other related matters.

Tanzania Food, Drugs and Cosmetics Act, 2003

The Tanzania Food, Drugs and Cosmetics Act of 2003 provides for the efficient and comprehensive regulation and control of food, drugs, medical devices, cosmetics, herbal drugs and poisons and repeals the Food (Control of Quality) Act of 1978 and the Pharmaceuticals and Poisons Act of 1978.

The Tanzania Food and Drugs Authority (TFDA), an Executive Agency, is the regulatory body for approval of all products under the Act, including clinical trials and issuing of certificates, licences and permits. The Director-General of the TDFA is appointed by the Minister of Health on the advice of the Civil Service Commission following the submission of the Ministerial Advisory Board's short list under an open and competitive system.

The governance structure is the Ministerial Advisory Board, which is an "executive agency" described as a "semi-autonomous (agency) within the ambit of Government ministries for the purpose of providing public services in selected areas in a more efficient and effective manner".¹⁸ As its name suggests, its function is advisory, with real authority for decision-making vesting in the Minister and the Director-General.¹⁹ In contrast, the AU Model Law proposes the establishment of an independent board which, while working in consultation with the Minister, will have significant autonomy and decision-making powers.

The Ministerial Advisory Board consists of the Permanent Secretary who serves as Chairperson; not more than twelve other members appointed by the Minister; and the Director-General, who serves as the Secretary to the Board.

As in other jurisdictions, the registration of a drug is approved if its availability is in the public interest and if it is safe, efficacious and of acceptable quality. Under Section 51, the TDFA is also authorized to ensure that manufacturing premises comply with GMP.

Under Section 13, it has the authority to establish Technical Committees to advise the Director-General on matters regulated under the Act. There is a significant amount of detail regarding the inner workings of the TFDA, matters that can easily (and more efficiently) be dealt with in regulations.

While there is a provision for "parallel importation" of the international exhaustion variety, it does not indicate whether this includes both innovator and generic products.

¹⁵ Kituo Cha Katiba, Report on the Tanzania Draft Constitution, January 2014.

¹⁶ African Charter on Human and Peoples' Rights, Article 16.

¹⁷ International Covenant on Economic and Social Rights, Article 12.

¹⁸ The Executive Agencies Act 30 of 1997.

¹⁹ Ibid, Section 7.

The prohibition and definition of “counterfeit drugs” may be too wide so as to potentially affect legitimate generic medicines of assured quality – included is “an imitation of, or substitute for, another drug, medical device or herbal drug” (section 76 93(b)).

It is positive that, unlike various other regulatory legislation (for example, in South Africa), there is no provision for secrecy, which enables transparency of the work of the regulator. Presumably, access to information in the interest of the public, though not expressly included, will be possible under other legislation, for example, section 30(3) of the Draft Constitution.

Patents Registration Act, 1995

As an LDC, Tanzania is not required to provide protection for pharmaceutical patents until after the end of the relevant TRIPS transition period (presently extended to 2033), but it nonetheless amended its patent legislation to become compliant with some aspects of the TRIPS Agreement. Thus, while the Patents Registration Act of 1995 does provide patent protection on pharmaceutical products, the term of a patent in Tanzania is 10 years, which may be extended for two further periods of five years each. It has also incorporated some of the flexibilities into its domestic legislation.

In defining an invention, the Act specifically excludes the following: discoveries and scientific and mathematical theories; plants or animals; schemes, rules or methods for doing business, performing purely mental acts or playing games; surgical, therapeutic or diagnostic methods for the treatment of the human or animal body (excluding products for use in such methods); and the mere presentation of information.

In order to be patentable, an invention must satisfy the requirements of novelty, inventive step and industrial applicability. The Act embraces the absolute novelty standard. For the inventive step requirement, the invention should not be obvious merely to a “person skilled in the art” and the disclosure has to be of the “best mode known” to the applicant. The Act provides for an examination as to substance, as well as for judicial review in the case of a refusal of a patent. It contains a strong scientific research exception although no early working or “Bolar” provision.²⁰

While the Act includes a long list of prohibited terms in licence contracts, there is no express prohibition based on anti-competitive grounds. Several categories of compulsory licences are permitted (failure to work locally; demand not being met on reasonable terms; refusal to license; dependent patents; and on defence, economic or public health grounds). Government use is also permitted in instances of vital public interest. The Act does not cater for parallel importation under the international exhaustion regime nor for data protection and, furthermore, it criminalizes wilful infringement of a patent.

4.2 Local Production of Medicines

In the PMPA, the African Union recognizes the need to promote local manufacturing on the continent. It identifies the following barriers to local production:

- Weak policy implementation and limited government support for domestic investment
- Small national markets, making it difficult to achieve economies of scale
- Importation of most APIs and medicines, which tends to weaken local production and perpetuates the lack of technology transfer
- High tariffs on imports, high credit rates, and unreliable support infrastructure for industry
- Shortfalls in capital and technology, and a dependence on external funding
- Shortfalls in relevant skills, scientists, industrial pharmacists, and laboratories
- Limited international mechanisms and intellectual property constraints on technology transfer and the sourcing of APIs
- Prohibitive intellectual property regimes, which bar or delay competition from generic manufacturers

20 The “Bolar” provision is based on the outcome of the case *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858 (1984).

- Gaps in the regulatory framework and enforcement to ensure the quality, safety and efficacy of medicines

Weak or non-existent capacities for research and development²¹

Similar observations were made in other studies.²²

- According to Sudip Chaudhuri,²³ the pharmaceutical industry in Tanzania reflects the following features:
- Sixty-eight percent of its medicines requirement is imported, and 32 percent is sourced locally.
- The cost of imports is worth \$168 million, with India at 36 percent, Kenya at 25 percent, the United States at 10 percent, Denmark at 8 percent, Switzerland at 7 percent, and China at 6 percent among the leading exporters.
- In terms of local production, the largest manufacturer is Shelys Pharmaceutical (Dar es Salaam, Tanzania), which contributes more than half of local production, and which is now wholly owned by Aspen Pharmacare (Durban, South Africa).
- Local companies manufacture a simple list of formulations, with Shelys having been the first to comply with the WHO GMP, and Zenufa Laboratories S.P.R.L. (Kinshasa, Democratic Republic of Congo) in the process of obtaining certification from the TFDA.
- Local manufacturers endure inherent cost disadvantages on account of various factors: limited access to finance; high cost of utilities; generally poor infrastructure; a dire lack of technical expertise; and the high cost of imported materials and machinery.

Furthermore, the pharmaceutical market structure in Tanzania is divided between the institutional and retail markets (roughly 51 percent and 49 percent, respectively). With regard to the former, the government's Medical Stores Department (MSD) is the largest distributor of drugs (mainly funded by international donors such as the Global Fund to Fight AIDS, Tuberculosis and Malaria or purchased by the government from its own revenues). An added complication is that none of the locally-manufactured products has WHO pre-qualification. The MSD sources 71 percent of its medicines from foreign suppliers and 29 percent from local manufacturers who face stiff competition from international suppliers despite enjoying a government-supported 15 percent price preference. The retail market is essentially a branded generic market (both imported and local). Only 8 percent of drugs registered with the TFDA for sale are supplied by the eight Tanzania-based manufacturers.

Multinational corporations cover a small market in the urban areas, supplying new patented drugs sold under brand names even after patent expiry. The market is dominated by Indian generic companies, with Cipla Limited (Mumbai, India) being the second largest supplier (at 16 percent) after local producer Shelys (at 21 percent), ahead of multinational corporations.²⁴

In terms of pricing practices, the MSD purchases in the institutional market through international competitive bidding among eligible suppliers, where price counts, and products are not differentiated by branding or other means. Imported medicines are expensive and unaffordable to the majority of Tanzanians. A joint survey conducted by the Tanzania Ministry of Health and Social Welfare and WHO in 2004 revealed that for three innovator brands, prices were 12, 94 and 18 times higher than generics which, in turn, were 3, 19 and 4 times higher than the international reference price.²⁵

Finally, although Shelys/Aspen is the leading supplier of locally-produced essential medicines in Tanzania, the country does not have an explicit policy or strategy focused on meeting the needs of the poor by providing access to essential medicines through local production and/or affordable pricing.²⁶

21 AU PMPA Business Plan, 2013

22 R.M. Mhamba and S. Mbirigenda, 2010; Equinet Policy Series No. 39, 2014

23 Sudip Chaudhuri, *How Local Production of Pharmaceuticals can be Promoted in Africa: The Case of Tanzania*, UNDP, July 2014.

24 Chaudhuri, 2014

25 Tanzania WHO survey, 2004

26 R.M. Mhamba and S. Mbirigenda *The pharmaceutical industry and access to essential medicines in Tanzania* Equinet Discussion Paper 83, July 2010.

4.3 Research and Development and Innovation

Tanzania has made some progress in building capacity in research and development and innovation, which is a key area of development in the AU PMPA, as well as in other strategic frameworks. The Government of Tanzania recognizes that health research is fundamental in order to provide information for health planning and decision-making. As resources are scarce, it has been necessary to identify high priority areas for research. Health research priorities therefore direct attention to “diseases, condition and risk factors that produce a significant burden of disease but lack an effective intervention for their control”.²⁷

Globally, priority setting for health research has been led by COHRED. In response to the 90/10 problem, where only 10 percent of research spending is directed to problems causing 90 percent of the disease burden in poor countries, the following approaches have been devised:

- Research should be demand-driven.
- Priorities must be based on magnitude, urgency of problems, but also embody values of social justice and equity.
- Research must be ethically, socially and politically acceptable.
- It must be feasible to undertake the proposed research.
- It must complement existing knowledge and avoid duplication.²⁸

Health research in Tanzania is driven by the National Institute for Medical Research established in 1979. The Tanzania National Health Research Forum was established in 1999 to bring together partner institutions in health research, as a consultative and advisory body to policy and decision-making. It includes research institutes (government and university) and representatives of social, religious, educational, health, human rights and media organizations.

An early health research-setting exercise was conducted in Tanzania in 1999. It identified 10 priority areas, with malaria, poorly trained personnel, and food taboos in pregnancy, ranked at the top of the three lists of priority categories of disease control, health systems, and social and cultural issues, respectively.

The next major health research priority exercise in Tanzania was initiated in early 2005. An extensive consultative process that included stakeholder workshops culminated in the document “Tanzania Health Research Priorities, 2006–2010”.

According to the document, “Priority setting process in Tanzania used the Essential National Research Approach. This involved systematic analysis of health needs, community and professional expectations. It involved researchers, policy makers, national disease control programme managers, health care providers, community and donors. This was done in a participatory and transparent process”.²⁹ The final summary table attempts to incorporate the various components of the research priority-setting exercise – biomedical, health systems, and sociocultural determinants of health. These components, elaborated below, are the parameters that it is hoped will serve as guidelines to the national priority areas for health research in Tanzania.

With regard to biomedical research, the following priority areas were identified in terms of a system of ranking that emerged from the consultations:

- Communicable diseases of major public health importance
- Communicable diseases neglected and/or of local priority
- Non-communicable diseases
- Nutrition
- Maternal and child health

27 J.L. Bobadilla “Priority Setting and Cost Effectiveness” Janovsky, K., Ed. Health Policy and Systems Development: An Agenda for Research (WHO/SHS/NHP/96.1). World Health Organization, 1996.

28 Global Forum for Health Research, 2002

29 Tanzania National Health Research Priorities, 2006-2010

- Basic research
- Disease control
- Gender
- Environmental health
- Product development and evaluation
- Occupational health
- Traditional and alternative medicine

With regard to health systems research, the following priority areas were identified:

- Human resources
- Health financing
- Reproductive and child health
- Service delivery
- Health information systems
- Decentralization
- Health policy
- Inter-sectoral collaboration
- Drugs, medical equipment and supplies
- Sociocultural determinants
- HIV and AIDS
- Essential health intervention packages
- International funding initiatives
- Public-private partnerships

5. Key Focus Areas

5.1 Access to Health

Key question: How can access to health be entrenched and enhanced in Tanzania?

As indicated earlier in this report, neither the existing Constitution nor the Draft Constitution, 2013 explicitly provide for a right to access to health care, despite Tanzania having ratified instruments (i.e. International Covenant on Economic, Social and Cultural Rights in 1976) and regional instruments (i.e. African Charter on Human and Peoples' Rights in 1984) that entrench these rights. The reason may partly be attributed to traditions and sociocultural beliefs and practices that "...still have a dominant role in people's lives and a negative impact on their human rights, including the right to enjoy the highest attainable standard of health. For example, early marriages affect the reproductive and maternal health of many Tanzanian girls and women".³⁰ The Tanzanian Ministry of Health and Social Welfare, the main driver of health policy and its implementation, states that the health sector's mission is to "facilitate the provision of quality health and social welfare to all people to enable them to improve their well-being".³¹ Various policies and strategies have been adopted to give effect to the government's commitment to improving the health of Tanzanians. They include: the Tanzania Development Vision 2025 and Poverty Reduction Strategy Programme; the Second National Strategy for Growth and Reduction of Poverty (2010/11–2014/15); the Primary Health Service Development Programme; the National Policy

³⁰ GTZ Annual Report 2008

³¹ MOHSW Health Sector Strategic Plan III, 2008

on HIV and AIDS (2001); the National Multi-Sectoral Strategic Framework on HIV and AIDS (2008–2012), 2007; the National Plan of Action for Elimination of Female Genital Mutilation (2001–2015); the National Insurance Scheme – Community Health Funds (2001); the National Policy on Disability (2004);³² and the Third National Multi-Sectoral Strategic Framework for HIV and AIDS (2013/14–2017/18), which recognizes that “HIV transmission rates among key populations, women, and in certain regions are not being controlled” and addresses itself to “the long term goals of elimination of new HIV infections, deaths from HIV and HIV-coincident stigma and discrimination”.³³

The *Dartmouth Business Journal* reported in 2015 that, on average, citizens’ overall health is still low in Tanzania owing to poverty and gaps in health care delivery, despite the fact that significant improvements have been achieved, such as a decrease in the under-five mortality rate and increasing rates of child immunization. The ongoing challenges are: inefficiencies in the use of resources to adequately provide proper universal health care; discrepancies in health well-being across socio-economic classes; staff shortages to effectively implement decentralization of services to the district level; inadequate coverage (only 8.6 percent of the population) of the National Health Insurance Fund and the Community Health Fund; and the implementation of user fees in the public health system. Therefore, there is a need for additional safeguards to protect the poorest of society who cannot afford prepaid health insurance.³⁴

Thus, it is evident that universal access to health care services continues to remain a major challenge, and the lack of an express provision entrenching this fundamental right restricts citizens’ and health authorities’ ability to advocate for it.

Additionally, a number of regional efforts have been suggested over time to improve accessibility and affordability of medicines. For example, a plan of action for implementing the EAC regional pooled procurement mechanism, as recommended by the EAC Council of Ministers in 2008, has not been implemented. Thus, the EAC Sectoral Council on Health, in its last session in 2014, has urged that this initiative be expedited.³⁵

5.2 Intellectual Property issues

Key question: How can Tanzania’s intellectual property system be optimized to enhance access to medicines and other health technologies?

The implementation of the TRIPS Agreement in Tanzania, coupled with the sub-optimal utilization of the transition provisions and flexibilities available to LDCs, has resulted in an intellectual property regime that significantly restricts access to new health technologies. Nonetheless, the Patent Registration Act, 1995 does include some of the public health-related flexibilities available within the TRIPS Agreement. Even though Tanzania allows patents to last for 10 years (with the renewal of two further five-year terms largely a formality) as opposed to the requirement of 20 years under the TRIPS Agreement, it is unclear how this is impacted in the case of an ARIPO-approved patent for the full 20-year term. Other flexibilities incorporated in Tanzania include: a useful definition of “invention” with important exclusions; provision for substantive examination of patent applications; loosely-defined patentability criteria; a scientific research exception; and some provisions for compulsory licences.

The legislation could benefit from stricter criteria for approving patents and guidelines for examination: with explicit exclusion of new use and new formulation patents; a higher standard of disclosure requirements; an express early working exception; the expansion of the grounds for compulsory licences on public health and public interest bases; streamlined administrative procedures for their grant; and parallel importation and data protection measures that do not bar a medicines regulatory authority from reliance on innovator clinical trial data when considering approval of a generic equivalent.

These issues are revisited in the recommendations contained in Chapter 7.

32 GTZ Annual Report , 2008

33 Tanzania Third National Multi-Sectoral Strategic Framework for HIV and AIDS (2013 – 2017)

34 K Wong *Tanzania’s Faltering Health System: Poor Quality of Care and Socioeconomic Inequity* Dartmouth Business Journal, 2015

35 N. Syam *Regional Pooled Procurement of Medicines in the East African Community* South Centre Research Paper 53, September 2014.

5.3 Medicines Regulation

Key question: How can Tanzania's regulatory framework be further improved to ensure the best outcomes for the country and region?

One of Tanzania's major successes has been its Food and Drug Authority (TFDA), a highly functional agency that is regarded as a leader in the EAC.³⁶ The TFDA enjoys semi-autonomy under the Ministry of Health and Social Welfare, its remit covers both medicines and food, and its operation is extensive in scope. It is responsible for executing the following regulatory functions:

- Licensing of pharmaceutical manufacturers, imports, wholesale trade, retail and dispensing outlets
- Product assessment and registration/market authorization of medicines
- Good manufacturing practice inspection
- Inspection of distribution channels
- Performing medicine quality tests/quality control laboratory
- Control of prescribing
- Coordination of medicines regulation centrally at national level

In addition, the TFDA uses external experts to provide opinions on medicines regulatory inspection, medical devices, drug reactions, safety monitoring of drugs, access to medicines and evaluation of clinical trials, among others.³⁷

Tanzania is thus well-placed to participate in and lead the harmonization process in the EAC and beyond.

5.4 Local Production of Medicines

Key question: How can Tanzania's local pharmaceutical manufacturing capacity be improved to achieve the goals of sustainability and affordability?

In the first instance, any strategy to respond to this question will have to address the barriers and obstacles identified in the literature, here and elsewhere. In this context, a central concern is the country's dependence on imported sources of supplies of its pharmaceutical requirements, presumably because the costs of producing locally are higher. This view is to some extent supported by the findings alluded to earlier that generics sourced in terms of international reference pricing were the cheapest.³⁸ Professor Chaudhuri, however, argues that "It is possible to promote a viable local industry without sacrificing the objectives of affordability and accessibility of medicines" and makes some policy proposals to this end. He suggests that any response will have to, of necessity, address "inherent cost disadvantages" that local manufacturers face such as: the lack of financial support in the form of both working capital as well as long-term credit; the high cost and unreliability of supply of key utilities such as electricity and water; poor infrastructure in the form of roads and communication services; the lack of local technical expertise in the pharmaceutical industry; and the higher costs of imported materials and machinery. He therefore argues for an increasingly central role for government in facilitating cheaper credit, entering into cooperation with countries such as India to provide support for GMP compliance, and providing financial and technological support to manufacturers to compete on smaller profit margins, but with the assurance of a larger market so that volume will compensate for narrow profit margins.³⁹

One suggestion for increasing market share is for the government to secure the institutional market for local manufacturers, as MSD is the biggest purchaser of medicines in Tanzania. Other mechanisms proposed include the introduction of the method of tendering, which is restricted to local manufacturers.⁴⁰

36 UNDP Status Report, 2014

37 NEPAD EAC Situation Analysis, 2010

38 Tanzania Ministry of Health and Social Welfare and WHO, 2004

39 S. Chaudhuri, 2014.

40 Ibid

Professor Chaudhuri proposes that the government develop a coherent and holistic industrial policy that integrates many of the above features including: support for financing and infrastructure; use of public procurement as a tool for promoting local production; and, in some instances, limiting the access of foreign firms to domestic markets.

Attempts have been made to coordinate this function at the national level, including through the establishment of a multisector National Task Force for Promotion of Domestic Production of Pharmaceuticals, chaired by the Chief Pharmacist at the Ministry of Health and Social Welfare, with members from different ministries. But, as observed in the Mid-Term Review of the Health Sector Strategic Plan III 2009–2015 Pharmaceutical Services, it “is not very active”.⁴¹

5.5 Research and Development and Innovation

Key question: How can Tanzania's health research and innovation capacity be improved to facilitate greater access to medicines?

The multi-agency report *The Role of Research and Innovation in the Post-2015 Development Agenda* states that poverty and social vulnerability put people at greater risk for poor health, which in turn makes it more difficult for people to escape poverty. The post-2015 Development Agenda must recognize the value of improvements in the health sector for ending poverty and the role that research and innovation for health plays in achieving and sustaining that goal. Research and innovation of new health technologies not only improves health outcomes but also drives economic growth and activity in low and middle-income countries. As demonstrated in the report, *Global Health 2035*, published by the Lancet Commission on Investing in Health⁴² all countries must increase investment in research and innovation if we are to close the gap between the richest and poorest by 2030.⁴³

Given Tanzania's limited capacity to undertake research and development, the answer obviously lies in seeking collaboration with EAC partners and, critically, working with established research institutes who are currently conducting vital research into drug and vaccine development.

Among the research institutions working in developing countries are the African Network for Drugs and Diagnostics Innovation (ANDI) and the Drugs for Neglected Diseases Initiative (DNDi).

The mission of ANDI is: “to promote and sustain African-led health innovation to address the continent's public health needs through the assembly of collaborative networks and building of capacity to support development...(and it) works mainly on the development of essential and high impact technologies for diseases that disproportionately affect developing countries”.⁴⁴ It places an emphasis on technology development and manufacture, and brings together institutions and researchers with a track record in these areas, as well as companies with potential for GMP manufacture, with South-South cooperation featuring as a major interest.

Among its achievements are: mapping of the health innovation landscape and needs assessment in Africa; recognition of Pan-African Centres of Excellence and regional hubs; project funding; advocacy for innovation in Africa; and partnerships with the African Union, European Commission, WHO, United Nations Office for Project Services, African Development Bank, UNICEF and the World Bank.

The ANDI identifies its key challenges as: existing capacity not being coordinated and leveraged to solve local problems; limited intra-African collaboration and capacity utilization; limited South-South collaboration; and financing and regulatory issues.⁴⁵

Tanzania hosts one of the ANDI Centres of Excellence at the Kilimanjaro School of Pharmacy's ANDI Centre of Excellence in Manufacturing and Regulatory Training. The Centre focuses on pharmaceutical

41 Tanzania Ministry of Health and Social Welfare, 2013

42 <http://globalhealth2035.org/> (last accessed on 28 September 2016)

43 PATH. *The Role of Research and Innovation in the Post-2015 Development Agenda: Bridging the Divide Between the Richest and the Poorest Within a Generation*. Washington, DC: COHRED, Global Health Technologies Coalition, International AIDS Vaccine Initiative, PATH, 2014.

44 ANDI Pan African Centres of Excellence in Health innovation, 2015

45 S. Nwaka Health technology innovation in Africa: ANDI perspective Presentation to African Regional Meeting, Addis Ababa, April 2015.

manufacturing and regulatory training, APIs formulation and drug product development and manufacturing. It has successfully initiated a number of innovations for Africa and draws on the expertise of excellent drug development scientists to specifically promote access to medicines.⁴⁶

The DNDi is a non-profit organization founded in 2003 that employs an innovative patients' needs-driven research and development model to address the needs of the most neglected patients by harnessing resources from public research institutions, private industry and philanthropic entities. Its objectives are to: deliver 11 to 13 new treatments by 2018 for sleeping sickness, Chagas disease, leishmaniasis, malaria, paediatric HIV and specific helminth infections; establish a robust pipeline for future needs; and use and strengthen existing capacity in disease-endemic countries.

It ensures its independence through diversified sources of funding (public, private sector and foundations) with no single donor contributing more than 25 percent of its funding.

The organization has developed six new treatments since 2007: for malaria, sleeping sickness, visceral leishmaniasis and Chagas disease.

It attributes its successes to partnerships, through a global network to leverage resources, on the basis of a shared vision, mutual understanding and involvement throughout the entire process, and is utilizing and strengthening research capacities in disease-endemic countries.

It identifies its major challenges as those relating to intellectual property ownership, licensing rights, pricing of medicines, royalties, market segmentation, and confidentiality.

The DNDi aims to deliver affordable treatment and equitable access to patients in need, and to develop drugs as public goods, when possible.⁴⁷

While alignment with these initiatives will be a substantial start, countries must also give serious attention to increase their investment in health-related research and innovation.

6. Linkages, Alignment and Priority Areas

Having considered the various focus areas relevant to this project, it remains to consider the necessity, feasibility and prospects of aligning policies to enhance access to health technologies. To some extent, policy development tends to adopt the “silo” approach, with each portfolio working in relative isolation from the others, and possibly even from the national effort. Thus, government departments may promote different priorities, for example, health may favour access to health services and technologies, while trade and industry may have a stronger bias towards industrial policy, investment and protection of intellectual property rights. If such a lack of synergy and the resultant policy incoherence is to be avoided, then a holistic and synergistic approach will be required. Mr. Piccioto refers to this phenomenon as the “whole of government” approach. It presupposes that planning and policy development are a centralized government function, with individual departments developing their policies in a synergistic manner, based on transparency and information-sharing. It requires strong leadership, both from above and below, to drive the process on the basis of a democratically-formulated mandate.

One such effort was made at the Africa Regional Meeting on Promoting Policy Coherence for innovation in and access to health technologies, held in Addis Ababa in April 2015. Representatives of the Tanzania country group, drawn from the key departments and agencies, proposed the following national priorities or goals in the formulation of a National Action Plan for Intersectoral Policymaking (see Annex):

- Increasing access to medicines and diagnostics within the public supply chain system
- Promoting domestic pharmaceutical industries to manufacture medicines and aspire to meet WHO pre-qualification standards
- Link research and development with pharmaceutical industries to promote production, innovation and technology transfer

46 ANDI, 2015

47 P. Boulet An innovative Patients' Needs-Driven Research and Development model Presentation to African Regional Meeting, Addis Ababa, April 2015.

In order to advance these goals, several key policies and/or strategies were identified for alignment and implementation, including: medicines and health policy; procurement policy; intellectual property policy; health financing policy; industrial policy; science, technology and innovation policy; and various pharmaceutical manufacturing action plans at the national, regional and continental levels. The plan proceeds to identify the institutional mechanisms and frameworks and the key stakeholders implicated in the process.

A useful starting point would be the appointment of inter-ministerial committees to ensure policy alignment across their various portfolios. This is a commonly utilized mechanism, and indeed one that has been employed in Tanzania previously, as with the Interministerial Steering Committee that produced a Draft Health Financing Strategy in 2014.⁴⁸ While some assessments of the efficacy of interministerial or cabinet committees are available for European and other developed countries,⁴⁹ there appears to be little available with regard to the African experience.

Such a committee, or an equivalent cabinet-level structure, would be an essential core requirement to initiate the process of policy coordination and alignment. Only high-level engagement, subject to cabinet oversight, will be able to provide the leadership necessary for this important task. Thus all the realignments (in respect of disparate government functions and portfolios) required to attain the desired level of policy coherence, will have to attain support at the highest level.

The priority areas for revisiting the policy and instituting the necessary legislative reforms are as outlined in the preceding section:

- Access to health services: in addition to the various laws, policies, programmes and strategies undertaken by the Ministry of Health and Social Welfare, an overarching provision on the right to health must be inserted into the Draft Constitution, in order that such a right has judicial protection and is enforceable.
- Intellectual property issues: Tanzania should take full advantage of its status as an LDC to delay patent protection on pharmaceuticals for as long as it is an LDC, and at the same time utilize all available public health flexibilities to ensure affordable access to medicines for its citizens.
- Medicines regulation: Tanzania is fortunate to have a functional and effective medicines regulatory system in place. By adopting additional reforms to bring it in harmony with the AMHR process, it could play a leading role in not only securing medicines for the country, but also in terms of the regional and continental effort.
- Local production of medicines: The Government of Tanzania can and must play a critical role in providing the enabling environment for local industry to flourish through various measures, including: legislation; provision of favourable financing; financial incentives; and implementation of other measures to reduce the country's dependence on imported medicines.
- Research and development and innovation: Government institutes and universities must seek increased collaboration with organizations such as ANDI and DNDi to enhance their innovative capacities, and must also increase investment in research and development to support these capabilities.

Policy coherence and coordination by an appropriate cabinet-level committee will be a key factor in ensuring that all these policy imperatives coalesce, and contribute to the national effort to improve access to and delivery of health technologies. Alignment must also be sought with the key relevant subregional instruments, policies, initiative and frameworks. The specific recommendations for reform measures in respect of each focus area follow in Chapter 7.

48 P4H-Social Health Protection Network, 2014.

49 Sustainable Governance Indicators, Bertelsmann Stiftung, 2014.

7. Recommendations

It is proposed that the following recommendations be considered in order to achieve the required legislative and policy coherence to promote access to health technologies in Tanzania.

7.1 Access to Health

Recommendation No. 1: The right to access health care

To include in the Draft Constitution, 2013 a provision guaranteeing the right to access health care, consistent with Tanzania's obligations under international and regional human rights instruments, in the following terms:

"Everyone has the right to the enjoyment of the highest attainable standard of physical and mental health, and the state must take all reasonable measures, to the maximum of its available resources, to progressively achieve the full realization of this right".

Recommendation No. 2: Increasing access in public supply chain system

It is recommended that a combination of measures be adopted:

- Finalization of the Medicines Policy Review
- Updating of the Drug Policy and Essential Medicines List
- Strengthening of the Medical Stores Department's operations, particularly with regard to procurement and supply chain management
- Promotion and strengthening of universal health insurance schemes
- Price controls on medicines, and other mechanisms to promote access

Recommendation No. 3: Regional efforts to improve access

Multiple efforts to improve access should be explored and, in particular, the 2008 decision of EAC Ministers to institute a regional pooled procurement mechanism should be expedited.

7.2 Intellectual Property

As an LDC, Tanzania was exempted from granting patents on pharmaceutical products until 2016 (now extended to 2033) in terms of the WTO waiver. The following recommendations are directed to the use of flexibilities when the waiver comes to an end. In addition, Tanzania should adopt the flexibilities outlined in the EAC TRIPS Flexibilities.

Recommendation No. 4: The LDC pharmaceutical waiver

As TRIPS allows non-enforcement of pharmaceutical patents as a result of the WTO LDC waiver, the legislation should be amended to make an exception for pharmaceutical products, including microbiological materials and processes, until 2033 or such further period as may be agreed, or until Tanzania ceases to be an LDC.

Recommendation No. 5: Stricter patentability criteria

With regard to the patentability criterion of "inventive step", the following amendments need to be effected:

- The exclusion of patents on new uses, or new formulations, of a known substance unless it can be proven that they result in an enhancement of therapeutic efficacy

- Specification in guidelines to the patent office of the full range of derivatives considered to be the same substance
- The standard of inventive step is to be determined by reference to a person “highly skilled in the art”.

Recommendation No. 6: Disclosure requirements

It is recommended that patent applicants disclose all, including the best, mode for carrying out an invention, and that they disclose the International Non-proprietary Name (INN) of a pharmaceutical ingredient as soon as it is available.

Recommendation No. 7: Early working exception

The inclusion of an early working (or “Bolar”) exception to enable the manufacturer of a generic equivalent to use the patented product for the purpose of obtaining regulatory approval before the expiry of the patent, in order to be able to bring the generic to market promptly upon expiry of the patent.

Recommendation No. 8: Prohibited terms in licensing contracts

The scope of prohibited terms in licensing contracts should be expanded to include those that have the effect of proscribing competition, and in particular, disallow conditions that:

- Make the licence contract subject to acceptance of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of the contracts
- Require exclusive grant-back licences with respect to inventions and other innovations to the licensor
- Fail to pay reasonable compensation or royalties for any non-exclusive grant-back license or rights
- Require the licensee to not oppose or seek revocation or invalidation of the grant of a patent
- Require the licensee not to become a compulsory licensee with respect to a compulsory license issued in Tanzania or elsewhere

Recommendation No. 9: Additional grounds for compulsory licences

The grounds for the grant of compulsory licences should be expanded to include the following instances:

- Where a judicial or administrative body has determined that the manner of exploitation, by the patent owner or his licensee, is anticompetitive and the minister in consultation with relevant ministries, departments and agencies is satisfied that a compulsory licence would remedy such practice in which case there is no limit on the quantity of product that may be exported
- Where the prices charged are not affordable or are excessive for the ordinary Tanzanian or the invention is not available in sufficient quantities or qualities either through manufacture in Tanzania or through importation
- Where it is desirable to have multiple and uninterrupted sources of supplies of essential commodities, including medicines, or to combine patented technologies such as fixed-dose combinations of medicines
- Pursuant to the Decision of the WTO of 30 August 2003, either as an exporter or as an importer, but as an importer only so long as it is an LDC or otherwise certifies that it has insufficient manufacturing capacity with regard to the relevant pharmaceutical product. In the event that a Tanzanian compulsory licensee exports under such a provision, it is not bound by the requirement that it must be predominantly for domestic or regional use.

Recommendation No. 10: Administrative procedure for compulsory licences

Generally, court proceedings are protracted and expensive both to litigants and to the judiciary, so it is highly preferable to institute streamlined administrative procedures for the grant of a compulsory licence. Although the application is to the minister, he or she should consult with relevant ministries, departments

and agencies before making any decision. Additionally, such decisions should be subject to judicial review.

Recommendation No. 11: Parallel Importation under international exhaustion

The parallel importation provision in the Act must be amended to provide for importation under an international exhaustion regime, namely, from anywhere in the world.

Recommendation No. 12: Data protection

In order to avoid the problem of TRIPS-plus data exclusivity protections, an express provision should be inserted that protects clinical trial and other data filed by an innovator company from unfair commercial use, which provision should not disable a medicines regulator from reliance on such data for the approval of a follow-on generic product.

Recommendation No. 13: De-criminalizing patent infringement

The criminal penalties applied to wilful patent infringement are unnecessary. Criminal sanctions should not be applied to civil disputes between private parties.

7.3 Medicines Regulation

Recommendation No. 14: Governance of the medicines regulator

Presently the governance of the TDFA is in the hands of a semi-autonomous advisory board. It is recommended that, in line with the proposal in the AU Model Law on Medicines Regulation, the governance function be entrusted to a board that functions independently of the executive branch of the government.

Recommendation No. 15: Parallel importation provisions

While there is a provision in the law for "parallel importation" of the international exhaustion variety, it does not indicate whether this includes both innovator and generic products. It is recommended that the legislation specifically authorize the importation of both innovator and generic medicines, when appropriate.

Recommendation No. 16: Counterfeit drugs

The prohibition and definition of "counterfeit drugs" may be too wide so as to potentially affect legitimate generic medicines of assured quality – "an imitation of, or substitute for, another drug, medical device or herbal drug" – as generics are legitimate imitations of and bioequivalent substitutes of the innovator versions. It is recommended that:

- The relevant definition of counterfeit be amended to specifically exclude legitimately-produced and quality-assured generics.
- The TFDA adopt the WHO definition of substandard, spurious, falsified and falsely labeled medicines, and provide law enforcers with wide powers to clamp down on such trade.

Recommendation No. 17: Transparency Provisions

There is growing support globally for the affairs of the regulatory agencies to be conducted in a transparent manner, in the public interest. It is recommended that a provision be inserted ensuring transparency in the regulatory process, subject to the maintenance of the confidentiality of certain sensitive information, unless it is in the public interest to disclose it.

7.4 Local Production

Recommendation No. 18: Industrial policy to promote local production

As several commentators have noted, Tanzania does not have an explicit policy to promote local production, although some incentives have been introduced. It is therefore recommended that the country adopt a dedicated industrial policy on local production of medicines, which should include the following features:

- The pharmaceutical sector will be prioritized for industrial development.
- Dedicated funding will be available to provide the support for local entrepreneurs.
- Demarcation of industrial zones with high quality provision of essential services, and other infrastructural support.

Recommendation No. 19: National Task Force for Domestic Production

In pursuance of the preceding recommendation, the National Task Force for Domestic Production should be resuscitated, capacitated and provided with a mandate to pilot the development of policy and implementation strategies for the proposed pharmaceutical industrial plan.

Additionally, the following specific recommendations should be pursued.

Recommendation No. 20: Financial incentives

It is recommended that included among the targeted interventions by the government should be the following financial incentives:

- Financial support in the form of both working capital as well as long-term credit at favourable rates in comparison to commercial banks
- Special subsidized rates for the supply of key utilities such as electricity and water
- Reducing (or better, eliminating) duties on imported APIs, other raw materials and machinery
- Providing limited-term tax exemptions for local manufacturers to enable them to establish themselves in the market
- An appraisal and extension of the 15 percent preferential pricing concession to local manufacturers

Recommendation No. 21: Market access

It is recommended that the government facilitate market access to local manufacturers by implementing the following measures, among others:

- It should aim to secure a substantial portion of the institutional market for local manufacturers, as MSD is the biggest purchaser of medicines in Tanzania.
- It could also introduce a method of tendering that is restricted to local manufacturers, so as to increase their market share.
- It should apply the 15 percent price preference more vigorously.

Recommendation No. 22: Increasing South-South cooperation

The Government should strengthen South-South cooperation and, in particular, enter into collaborative agreements with countries such as India to provide technical assistance, skills transfers and support for GMP compliance, among others.

7.5 Research and Development and Innovation

Recommendation No. 23: Alignment with ANDI and DNDi

It is recommended that the following measures be adopted:

- Strengthening collaboration with ANDI on the Centres for Excellence work, and extending its scope to the training in various levels of technical skills for both the government sector and private industry
- Identifying new projects for studies on priority diseases in Tanzania

Recommendation No. 24: Investment in health research and development and innovation

It is recommended that the government give serious attention to increasing its investment in health-related research and innovation; strengthen the institutions with capacity to undertake research in critical areas; and drive its own research agenda for the benefit of all.

8. Way Forward

One method of implementing these recommendations might be through the agency of a high-level Intersectoral Committee, which will drive the process. If this mechanism is acceptable, the following steps may be suggested:

- Establishment of the Intersectoral Committee (ISC)
- Agreement on policy goals (five overarching goals)
- Identification of lead agencies in respect of each goal
- Time-frames for initial investigations
- Report back to ISC, and confirmation of the programme of action on policy coherence Implementation of the programme of action on policy coherence

In the final analysis, the project of attaining policy coherence requires the convergence of a number of factors: political will on the part of the government, and the commitment to drive an inclusive process of undertaking the alignment of all policies; sourcing the necessary financial and human resources to implement these policies in an ordered and harmonious manner; and the courage to make difficult but necessary decisions to advance the health of all Tanzanians.

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10. Annex

10.1 Tanzania National Action Plan for Inter-sectoral Policy Making

National Priority or Goal	Key policies and /or strategies	Institutional mechanisms or framework	Key stakeholders
<p>1. Increasing access to medicines and diagnostics within the public supply chain system</p>	<ul style="list-style-type: none"> • Medicines/Health policy • Procurement policy • IP policy • Health financing policy 	<ul style="list-style-type: none"> • Finalisation of the medicine policy • Review/update the essential medicine lists • Comprehensive Strengthening MSD operations • Promote and strengthen universal health insurance schemes • Promote utilisation of public health related TRIPS flexibilities 	<p>Ministry of Health (Pharmaceutical services unit, DPP/ Finance/ Trade/TFDA/ and MSD/PPRA/ COSTECH)</p>
<p>2. Promoting domestic pharmaceutical industries to manufacture medicines and aspire to meet WHO pre-qualification standards</p>	<ul style="list-style-type: none"> • Medicines/Health policy • Industrial policy • Trade policy • Tanzania Pharmaceutical Manufacturing Plan of Action • East African Community Regional Pharmaceutical Manufacturing Plan of Action • East African Community Common Market Protocol 	<ul style="list-style-type: none"> • Effective use of 15% preferential scheme by MSD • Tax exemption for raw packaging and • Strengthen association of pharmaceutical manufactures • Establish export processing zones for pharmaceutical products • Promote technology transfer within the region • Advocacy for promoting domestic pharmaceutical product • Expedite registration of domestic pharmaceutical products • Strengthening the National Task Force for Promotion of Domestic Pharmaceutical Industries 	<ul style="list-style-type: none"> • Ministry of Industry & trade • Ministry of Health and Social Welfare • Ministry of Finance • COSTECH • MSD • Tanzania Pharmaceutical Manufacturers Association • East African Community Pharmaceutical Manufacturers Association

National Priority or Goal	Key policies and /or strategies	Institutional mechanisms or framework	Key stakeholders
<p>3. Link R & Ds with pharmaceutical industries to promote production, innovation and technology transfer</p>	<ul style="list-style-type: none"> • Science Technology & Innovation policy • IP policy • IP strategies • Health Financing policy 	<ul style="list-style-type: none"> • Adoption of policy framework and guidelines to effectively implement public health related TRIPS flexibilities • Domestication of Public health related TRPS flexibilities within national laws • Enhancing pharmaceutical R & D capacity • Promotion and enhancement of the use of locally produced inputs including herbal or natural products for production of pharmaceutical products • Structuring and mobilizing resources for pharmaceutical innovation fund 	<ul style="list-style-type: none"> • Ministry of Science & Technology • Ministry of Industry & trade • Ministry of Health and Social Welfare • Ministry of Justice and Constitutional Affairs • COSTECH • NIMR • BRELLA • Intellectual Property Office



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