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# EAC COMMON MARKET IMPLEMENTATION

## IMPACT OF TECHNICAL REGULATIONS ON INTRA-REGIONAL TRADE

### The Experience of Ugandan Pharmaceutical Firms

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The preparation of this report has benefited from insights and information provided by the following institutions:

*Pharmaceutical Firms in Uganda*

**The USAID East Africa Trade and Investment Hub** (the Hub) boosts trade and investment with and within East Africa. It does this by deepening regional integration, increasing the competitiveness of select regional agricultural value chains, promoting two-way trade with the United States (U.S.) under the African Growth and Opportunity Act (AGOA) and facilitating investment and technology to drive trade growth intra-regionally and to global markets. The Hub supports the U.S. Government's presidential Feed the Future initiative. It is funded by the U.S. Agency for International Development (USAID). www.eatradehub.org

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# ACRONYMS AND ABBREVIATIONS

| | |
|---|---|
| CAGR | Compound Annual Growth Rate |
| CMP | Common Market Protocol |
| CTD | Common Technical Dossier |
| EAC | East African Community |
| FAO | Food and Agriculture Organization |
| GMP | Good Manufacturing Practices |
| MRH | Medicines Regulatory Harmonization |
| NDA | National Drug Authority |
| NMRAs | National Medical Regulatory Authorities |
| NTB | Non-Tariff Barrier |
| RPMPOA | Regional Pharmaceutical Manufacturing Plan of Action |
| SSA | Sub-Saharan Africa |
| TBT | Technical Barriers to Trade |
| TFDA | Tanzania Food and Drug Authority |
| TFDCA | Tanzania Food, Drugs, Cosmetics Act, 2003 |
| USAID | United States Agency for International Development |
| WHO | World Health Organization |
| WTO | World Trade Organization |

## ABOUT THE STUDY

Regulatory requirements are normally used for, among other reasons, to ensure consumer safety and information, product quality, environmental or animal/plant protection and to prevent deceptive business practices. They are also intended to facilitate competition by clearly defining product characteristics and quality assessment, and to establish minimum standards and safety requirements.

Products like pharmaceuticals may require a large number of standards to comply with. The complexity of these regulations and the administrative processes used to implement them can be significantly burdensome. The process of applying for licenses, paying fees and obtaining certificates for exports all contribute to the complexity that, in some cases, can inhibit firms from accessing markets or even force firms to exit markets.

This study has sought to review the impact that technical requirements and standards by Tanzania Food and Drug Authority (TFDA) has had on private sector pharmaceutical firms in Uganda.

This case study highlights the procedures and requirements companies must comply with to register products entering Tanzanian market and illustrates the impact of the requirements on private sector firms. The study reveals that to access the Tanzanian market, medicines certified by the East African Community (EAC) Partner States' institutions are subject to (i) lengthy, cumbersome and duplicative registration requirements; (ii) costly registration fees; (iii) discrimination (i.e. EAC products and manufacturers are not recognised as "domestic" in Tanzania Regulations) and (iv) a lack of recognition of their countries' standards.

One of the key objectives of the EAC is to create a regional market for goods and services produced by Partner States. For pharmaceuticals, like many other categories of goods, this objective has yet to be fully realized. Across the region, pharmaceutical producers face fierce competition from Asian producers. EAC Partner States should therefore consider taking concerted measures to protect and support the regional pharmaceutical industry.

The study recommends eliminating Tanzania's registration requirements and calls for (i) further harmonization of technical requirements and adoption of a common legislative framework on technical regulations; (ii) implementation of a Common Technical Dossier (CTD) to achieve mutual recognition; (iii) elimination of all technical barriers without compromising public health and safety; (iv) acceptance of World Health Organization (WHO) certificates of pharmaceutical products with statement on Good Manufacturing Practices (GMP) compliance issued by National Medical Regulatory Authorities (NMRAs) and (v) revision of Tanzania's definition of local or domestic manufacturer in related laws and regulations. These measures will not only reduce the time and costs associated with registration for the exporting country, but they will also eliminate barriers in access to medicine for the general population.

# OVERVIEW

The East African pharmaceutical consumption market is estimated at USD 1.765 billion, with an estimated compound annual growth rate (CAGR) of over 10% (2007–2014).[1] Kenya has the largest pharmaceutical market (USD 740 million), followed by Uganda (USD 450 million), Tanzania (USD 400 million), Rwanda (USD 100 million) and Burundi (USD 75 million). The fastest-growing market is Kenya, with an estimated year-on-year growth rate of 15%.

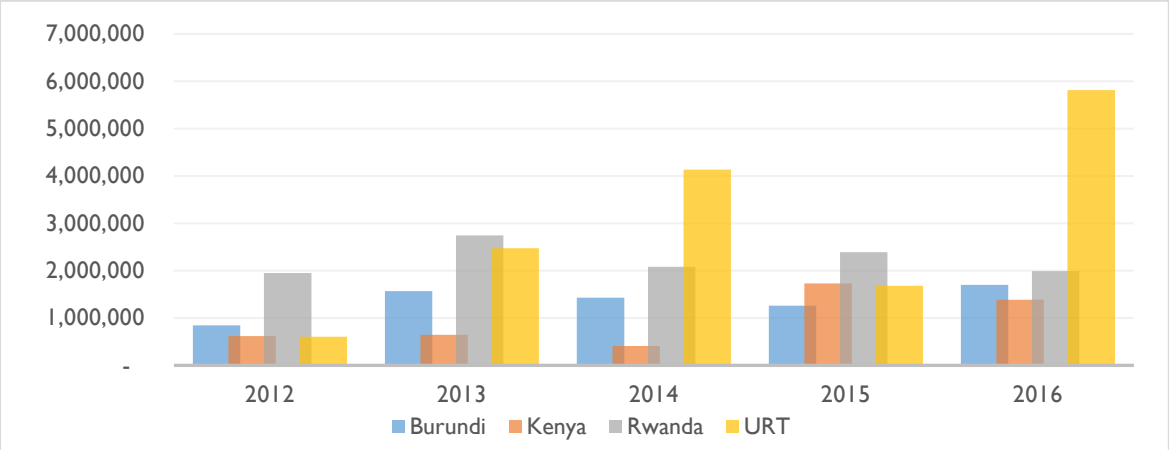
**Table 1. Overview of key pharmaceutical sector data for EAC countries**

| Countries | Burundi | Kenya | Rwanda | Tanzania | Uganda | EAC |
|---|---|---|---|---|---|---|
| Pharma market size (USD million, 2014) | 75 | 740 | 100 | 400 | 450 | 1,765 |
| Compound annual growth rate (CAGR) 2007 to 2014 | 12.85% | 15% | 16.36% | 9% | 8.50% | 12% |
| Market share of locally produced pharmaceutical drugs (% of overall market) | 3% | 30% | <1% | 12% | 20% | 20% |
| Market by segment | Generic 56% Branded 44% | Generic 62% Branded 38% | Generic 54% Branded 46% | Generic 54% Branded 46% | Generic 80% Branded 20% | Generic 60% Branded 40% |
| Number of local pharmaceutical manufacturers | 1 | 40 | 1 | 12 | 12 | 66 |
| Estimated number of direct jobs | 150 | 6,000 | 30 | 1,800 | 1,800 | 9,780 |

*Source: 2014 estimates (industry & associations)*

EAC export values show a rise from USD 46.7 million in 2006 to USD 84.7 million in 2015, with the largest share of export values from Kenyan local manufacturers, followed by Uganda. About half of the pharmaceutical exports from Kenya go to Uganda and Tanzania.[2] Uganda recorded the strongest rise in export values, from USD 1.4 million in 2006 to USD 25.6 million in 2016.

**Graph 1. Ugandan pharmaceutical export values to EAC (USD) 2012-2016**




*Source: COMTRADE Stats*

[1] 2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017 – 2027.
[2] South Centre, 2014, Regional pooled procurement of medicines in the EAC, https://www.southcentre.int/wp-content/uploads/2014/09/RP53_Regional-Pooled-Procurement-of-Medicines-in-EAC_EN.pdf

Products like pharmaceuticals may require a large number of standards to comply with. The complexity of these regulations and the administrative processes used to implement them can be significantly burdensome. The process of applying for licenses, paying fees and obtaining certificates for exports all contribute to the complexity that, in some cases, can inhibit firms from accessing markets or even force firms to exit markets.

The World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement seeks to ensure that technical regulations, standards and testing and certification procedures do not create unnecessary obstacles. The agreement does recognize countries' rights to adopt the standards they consider appropriate (e.g. standards to protect human, animal, or plant life or health; to safeguard the environment; or to meet other consumer interests).

EAC Partner States, as members of the WTO, are not prevented from taking measures to ensure that their national standards are met. But the agreement also encourages governments to apply international standards as a myriad of regulations can be a nightmare for manufacturers and exporters. In addition, whatever regulations countries use should not discriminate. Under the agreement, the procedures used to decide whether a product conforms to relevant standards must be fair and equitable, and any methods that would give domestically produced goods an unfair advantage are discouraged. The agreement also encourages countries to recognize each other's procedures for assessing whether a product conforms. Without recognition, products might have to be tested twice, first by the exporting country and then by the importing country.[3]

EAC Partner States have demonstrated commitment in promoting their pharmaceutical industry through the development of the two EAC Regional Pharmaceutical Manufacturing Plan of Action (EAC-RPMPOA).[4] These plans provide the framework upon which regional and national strategies are aligned in an effort to strengthen the sector. As part of implementation of the EAC Treaty provisions on Regional Cooperation on Health,[5] the EAC Secretariat, in collaboration with EAC Partner States NMRAs, established the East African Community Medicines Regulatory Harmonization (EACMRH) Programme[6] in 2012 to help EAC Partner States build effective medicines regulations and procedures through harmonization and regulatory capacity building. To date, the program has agreed on guidelines to facilitate timely assessments and approvals of medicinal product dossiers by the regulatory authorities for pre-market evaluation, registration and post-marketing review.[7] These guidelines set out harmonized procedures and requirements for the implementation of pharmaceutical products registration through established Common Technical Dossiers (CTDs) within the EAC NMRAs.[8]

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[3] World Trade Organization documents, http://www.wto.org
[4] First Plan of Action covered 2012 – 2016 and the Second Plan of Action covers 2017 -2027.
[5] Article 118 of the EAC Treaty
6 Implemented collaboratively by all the six (6) NMRAs in the region, namely Department of Pharmacy, Medicines and Laboratories (DPML) - Republic of Burundi, Pharmacy and Poisons Board (PPB) - Republic of Kenya, National Drug Authority (NDA) - Republic of Uganda, Pharmacy Task Force (PTF), Ministry of Health - Republic of Rwanda and Tanzania Food and Drugs Authority (TFDA) and Zanzibar Food and Drugs Board (ZFDB) - United Republic of Tanzania.
7 EAC Guidelines on submission of Documentation for Registration of Human Pharmaceutical Products, 2014.
[8] http://mrh.eac.int/

Nonetheless, the EAC Partner States continue to implement diverse legal requirements for registering drug products. According to a survey conducted by Center for Health, Human Rights and Development (CEHURD) in 2013, Ugandan respondents reported challenges penetrating the Tanzanian and Kenyan markets despite being under a regional integration arrangement.[9]

The EAC Partner States have also undertaken various measures and reforms to implement and comply with the EAC Common Market Protocol (CMP). According to the East African Common Market Scorecard 2016 great effort has been undertaken to eliminate non-tariff barriers (NTBs) to trade in the region; by December 2016, 113 NTBs had been resolved since 2009.[10] However, there have also been many new and recurring NTBs reported between 2008 and 2016. One such NTB is the requirement by TFDA for pharmaceutical companies exporting to Tanzania to register, re-label and retest certified EAC products.

### TANZANIA'S REGISTRATION, RELABELLING AND RETESTING REQUIREMENT

Tanzania requires all foods, drugs and cosmetics traded in Tanzania to be registered with TFDA. TFDA derives its mandate from section 5(1) of the Tanzania Food, Drugs, Cosmetics Act, 2003 (TFDCA). This provision confers upon TFDA the power to regulate the relevant products, including those from EAC Partner States.

The purpose of *registration* is to control the importation, manufacture, labelling, marking or identification, storage, promotion, selling and distribution of food, drugs, cosmetics, herbal drugs and medical devices or any materials or substances used in the manufacture of products regulated under the TFDCA. The registration requirement applies to all products regardless of their origin or whether they are certified in other EAC Partner States. Various regulations and guidelines are in place for the registration and importation of foods, drugs and cosmetics in Tanzania. These include:

1. Guidelines for the Importation and Exportation of Food, Revision No.3, November 2011;
2. The Tanzania Food, Drugs and Cosmetics (Regulation of Foods) Regulations, 2011;
3. Guidelines for the Importation and Exportation of Pharmaceutical Products and Raw Materials, January 2015; and
4. Guidelines for the Importation and Exportation of Cosmetic Products, November 2015.

Tanzania also requires *retesting* of all pharmaceutical and herbal drugs, poisons, cosmetics and food products. This is a compulsory requirement that importers must meet in order to be granted a registration permit that allows them to import their goods into Tanzania.

[9] CEHURD, 2013 Promoting Local Pharmaceutical Production in Uganda: Challenges facing Local Pharmaceutical Firms, Report of a Survey conducted in June 2013.
[10] The Status of Elimination of Nontariff Barriers In East African Community As of December, 2016

Tanzania also requires *relabelling* when the labels on imported products do not meet TFDA's labelling standards as provided under the labelling guidelines for respective products.[11]

### STATUS OF TANZANIA'S REGISTRATION REQUIREMENT AS A NTB

Tanzania's registration requirement has had a long history of reports in the EAC NTB monitoring framework with the EAC Regional Forum consistently recommending that Tanzania abolish this requirement with respect to EAC products.[12]

Presently, the NTB is reported as affecting all EAC Partner States. In Uganda, two companies, Mukwano Industries (U) Ltd and Samona Products (U) Ltd, reported this NTB for its effects, mainly on their cosmetics products.

**Table 2. Timeline and Status of TFDA Registration Requirement in EAC Time Bound Program on Elimination of NTBs**

| Year | Status as per EAC Time Bound Program Report |
|---|---|
| 2008 | Reported and indicated as resolved |
| 2012 | Reported as new NTB in December 2012 |
| 2013 | The EAC Standards Committee will meet to solve the issues related to standards |
| 2014 | The meeting of the East African Standards Committees deliberated on the NTB.<br>It urged Tanzania Bureau of Standards to adopt all the harmonized EAC Standards to ensure that there are no barriers arising from the Standards; and requested TFDA to carry out a review of product safety control systems in other Partner States for the purpose of creating confidence and facilitating trade within the EAC region and report back to the Committee by June 2015. |
| 2015 | The 18th meeting of the EAC regional forum on NTBs recommended that:<br>• EAC Secretariat should facilitate the composition of the technical expert team of food regulations to review the EAC Partner States' food safety systems and come up with the Recommendations to be undertaken in order to facilitate recognition of test certificates<br>• EAC Secretariat to assist in coming up with the Terms of Reference for the task force.<br>• EAC Secretariat to source funds for this exercise. |
| 2016 | The NTB is being considered internally in accordance with the Sectoral Council on Trade, Industry, Finance and Investment directive and a progress report will be availed to the next Forum. The meeting recommended that URT abolishes the requirement. |
| 2017 | The Meeting noted the need for harmonisation of SPS control measures as provided for in the EAC SPS Protocol, however also noted that Tanzania had not ratified the SPS Protocol which will delay the implementation of the Protocol. The meeting therefore recommended that the United Republic of Tanzania expedites the Ratification of the SPS Protocol. The meeting also recommended that the United Republic of Tanzania Mutually recognises quality marks from other EAC Partner States as provided for in the SPS Protocol. |
| 2018 | During the Bilateral meeting between Kenya and Tanzania held on 27th – 31st January 2018 in Mombasa, Kenya-Tanzania reported that they recognise quality marks on products from other Partner States and committed to ratify the EAC SPS Protocol by June 2018 |

*Source: Various Reports of the EAC Regional Forum on the Elimination of Non-Tariff Barriers and the Time Bound Programme*

## THE EXPERIENCE OF UGANDAN PHARMACEUTICAL FIRMS

The pharmaceutical industry in the EAC is growing at a fast pace. In 2016, Quintiles IMS estimated that the industry will grow approximately 12% annually over the next five years,

[11] www.tfda.go.tz
[12] Reports of The EAC Regional Forum on The Elimination of Non-Tariff Barriers

making it the region with the highest sales growth for pharmaceuticals in Africa.[13] This growth is due in part to increasing incomes and healthcare facilities within the region. Currently, the EAC's pharmaceutical industry is valued at approximately USD 5 billion, and has a total of 65 manufacturers.[14]

Uganda recorded the strongest rise in export values, from US$ 1.4 million in 2006 to US$ 25.6 million in 2016; 23% of this was reported to have been exported to the United Republic of Tanzania.

**Table 3. Uganda pharmaceutical export values (USD) 2012-2016**

| Year | Burundi | Kenya | Rwanda | URT | World |
|---|---|---|---|---|---|
| 2012 | 843,922 | 619,039 | 1,950,680 | 605,980 | 9,124,454 |
| 2013 | 1,569,350 | 644,110 | 2,744,794 | 2,475,605 | 10,618,271 |
| 2014 | 1,431,343 | 408,664 | 2,082,246 | 4,134,218 | 9,743,550 |
| 2015 | 1,260,812 | 1,729,130 | 2,391,309 | 1,680,603 | 12,280,717 |
| 2016 | 1,699,180 | 1,386,384 | 1,990,616 | 5,812,872 | 25,568,738 |

*Source: COMTRADE Stats*

In Uganda, all pharmaceutical firms must obtain licenses to manufacture, import and export drugs from the National Drug Authority (NDA), in accordance with the National Drug Policy and Authority Act Cap 206. In addition to the above licences, firms must register their products in Uganda. To operate in Uganda and obtain the necessary licences and registration, firms must comply with national standards, and/or WHO-issued standards as defined by NDA. Ugandan firms exporting to Tanzania must also register with Tanzania Customs (Tanzania Revenue Authority) and, in compliance with the requirements of TFDA, register all their products in Tanzania.

To access the Tanzanian market, Ugandan pharmaceutical firms that were interviewed during the study revealed that they undergo the following steps:

1. Expression of interest in the Tanzanian pharmaceutical market to TFDA;
2. TFDA then carries out a pre-registration Good Manufacturing Practices (GMP) inspection of the manufacturing plant;
3. Preparation of a product dossier for each product according to the "Guidelines on Submission of Documentation for Registration of Human Pharmaceutical Products" (see Table 5);
4. Payment of the applicable fees in support of the application;
5. Pursuant to the regulation that registration can only be done by a person who is resident or domicile in Tanzania, Ugandan pharmaceutical firms then hand over the

[13] Quintiles IMS (2016), Outlook for Global Medicines through 2021, EAC (2016), 1st International High Level Stakeholder Conference on Promoting Pharmaceutical Investment in the East African Community (EAC) Region, 2nd – 4th November, 2017, Nairobi, Kenya, Conference Booklet and Programme

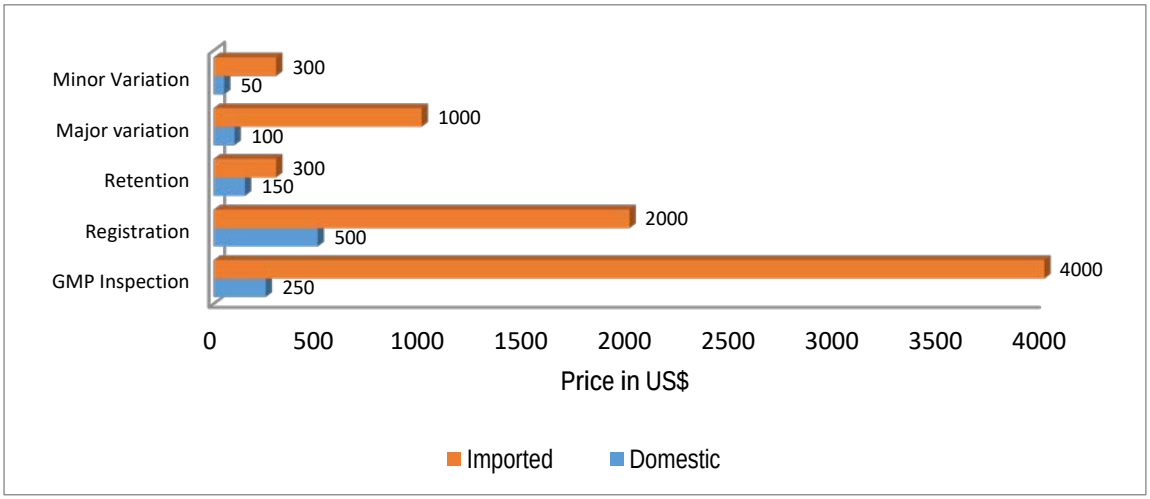
[14] TRALAC (2016) East African pharma companies missing out on fast growing $5 billion opportunity accessed at https://www.tralac.org/news/article/10778-east-african-pharma-companies-missing-out-on-fast-growing-5-billion-opportunity.html

dossier to a local agent, who in turn submits the application to TFDA and follows up in case of any queries.

According to the pharmaceutical firms, the registration process takes a minimum of 12 months if all the necessary documentation and information is submitted and no queries are raised by TFDA. This is in conformity with the "Guidelines on Procedural Aspects for Applications for Market Authorization of Medicinal Products" in Tanzania. However, if TFDA requests additional information and documentation, the approval process could take up to 24 months.

In accordance with the Tanzania Food, Drugs and Cosmetics (Fees and Charges) Regulations, 2015, the GMP inspection fee is USD 4,000. This fee is paid every three years. In addition to inspection fee, a registration fee of USD 2,000 must also be paid for each product to be registered. Finally a product retention fee of USD 300 is paid every year for each product in the market. These amounts are all more than three times what domestic manufacturers pay for the same services.

**Graph 2. Comparison of relevant fees for registration of pharmaceuticals (in USD) for Tanzanian (domestic) and EAC manufacturers (imported)**




*Source: The Tanzania Food, Drugs and Cosmetics (Fees and Charges) Regulations, 2015*

## EFFECTS OF THE REGISTRATION REQUIREMENT

### "Double Registration" Costs

According to Ugandan firms, their products are subject to the same registration procedures and requirements in Uganda as in Tanzania. Differences only arise in the approval time and amount of fees paid. In Uganda, pharmaceutical firms obtain faster approval and pay lower fees as local manufacturers. Moreover, registration is undertaken for the same purpose, to ensure that drugs meet the national and internationally agreed standards for quality, safety and efficacy. Essentially, Ugandan firms undergo "double registration," despite Uganda and Tanzania being part of the EAC and with commitments to the free movement of goods among the EAC Partner States.

**Table 4. Comparison of time and cost for registration of drugs in Uganda and Tanzania**

| | Uganda | Tanzania |
|---|---|---|
| Time | 1 month | 12 – 24 months |
| cost | GMP: $ 311<br>Registration: $ 200<br>Retention: $ 100<br>Change: $ 60 - $120<br>Notifications: $ 20 | GMP: $ 4000<br>Registration: $ 2000<br>Retention: $ 300<br>Change: $ 100 |

## High Registration Cost

Thus, the company has to incur costs in the form of GMP inspection fees, registration fees, retention fees, fees for any changes to product components, amounting to more than USD 5,000 per product in the case of new products and an annual minimum of USD 300 per product for old products.

There are additional costs associated with engaging a local representative/agent to submit and follow up on the registration process in Tanzania. Ugandan pharmaceutical firms have to identify an established pharmaceutical business in Tanzania, indicate the desired relationship with said agent and offer compensation. The nature of the relationship may be purely technical (in fulfilment of TFDA's requirement for a local agent), or may extend to marketing products. The offer is usually a given percentage of the consignment and the agent is paid per consignment.

The local agent requirement and categorization of EAC products as imports illustrates a departure from the EAC CMP commitments. Concerns abound as to why a manufacturer from an EAC Partner State would require a local agent (i.e. a Tanzanian resident) to facilitate the registration process when, within the context of the EAC integration, EAC nationals should not be discriminated against. Similarly, as a national of another EAC Partner State, the applicable fees must, at the very least, be uniform for Tanzanian products and products from other EAC Partner States in the spirit of regional integration.

## Lengthy, Burdensome Registration Process

Registering pharmaceuticals takes considerable effort. To comply with registration requirements, Ugandan pharmaceutical firms must compile all the necessary information for each individual product as part of the application dossier. The information alone requires a lot of time to compile, and the registration process is generally slow, taking a minimum of 12 months for new products. According to the firms, the market authorization's lengthy procedures are their biggest hindrance. While it is difficult to ascertain the loss suffered for each day the products are not on the market, such delays also translate into loss of market and revenue.

**Table 5. TFDA's comprehensive list of requirements for the registration of human medicines[15]**

| | |
|---|---|
| | **Module 1: Administrative Information and Product Information** |
| 1 | Cover letter |
| 2 | Comprehensive table of contents |
| 3 | Application form |
| 4 | Product Information i.e. Prescribing information - Summary of Product Characteristics; Container labeling; Patient information leaflet (PIL); Mockups and specimens |
| 5 | Information about the experts |
| 6 | Certificates of Suitability of monographs of the European pharmacopoeia (CEP) |
| 7 | Good Manufacturing Practice (GMP) |
| 8 | Good Clinical Practice (GCP) or Good Laboratory Practice (GLP) |
| 9 | Regulatory status i.e. Registration status from countries with Stringent Drug Regulatory Authorities (SDRAs); Registration status in EAC Partner States; List of countries in which a similar application has been submitted; and Statement on whether an application for the product has been previously rejected, withdrawn or repeatedly deferred in the EAC Partner States |
| 10 | Evidence of API and/or FPP prequalified by WHO |
| 11 | Manufacturing and Marketing authorization |
| 12 | Product samples |
| | **Module 2: Overview & Summaries** |
| 13 | CTD Introduction |
| 14 | Quality overall summary (QOS) i.e. Active pharmaceutical ingredient (name, manufacturer) and Finished Pharmaceutical Product (name, dosage form) |
| 15 | Nonclinical overview |
| 16 | Clinical overview |
| 17 | Nonclinical Written and Tabulated Summaries |
| 18 | Clinical Summary i.e. Summary of Biopharmaceutical Studies and Associated Analytical Methods; Summary of Clinical Pharmacology Studies; Summary of Clinical Efficacy; Summary of Clinical Safety; Literature References; and Synopses of Individual Studies |
| | **Module 3: Quality** |
| 19 | Body of data i.e. information on Active pharmaceutical ingredient, Finished pharmaceutical product and regional information |
| 20 | For Active pharmaceutical ingredient (API), information required is: |
| 21 | General information i.e. Nomenclature; Structure and General properties |
| 22 | Manufacture i.e. Manufacturer(s) (name, physical address); Description of manufacturing process and process controls; Control of materials; Controls of critical steps and intermediates; Process validation and/or evaluation |
| 23 | Characterization i.e. Elucidation of structure and other characteristics; and Impurities |
| 24 | Control of the API i.e. Specification; Analytical procedures; Validation of analytical procedures; Batch analyses and Justification of specification |
| 25 | Reference standards or materials |
| 26 | Container closure system |
| 27 | Stability |
| | *For Finished pharmaceutical product (FPP), information required is:* |
| 28 | Description and Composition of the FPP |
| 29 | Pharmaceutical development i.e. Components of the FPP; Finished pharmaceutical product; Manufacturing process development; Container closure system; Microbiological attributes; Compatibility |
| 30 | Manufacture i.e. Manufacturer(s) (name, physical address); Batch formula; Description of manufacturing process and process controls; Controls of critical steps and intermediates; Process validation and/or evaluation; |
| 31 | Control of excipients i.e. Specifications; Analytical procedures; Validation of analytical procedures; Justification of specifications; Excipients of human or animal origin; and Novel excipients |
| 32 | Control of FPP i.e. Specification(s); Analytical procedures; Validation of analytical procedures; Batch analyses; Characterization of impurities; Justification of specification(s) |
| 33 | Reference standards or materials |
| 34 | Container closure system |
| 35 | Stability |
| | *For regional information, details required are:* |
| 36 | Production documentation i.e. Master Production Documents |
| 37 | Analytical Procedures and Validation Information |
| | **Module 4: Non Clinical Study Reports** |
| 38 | Study Reports for Pharmacology, Pharmacokinetics and Toxicology |
| | **Module 5:Clinical Data Requirements** |
| 39 | Tabular Listing of All Clinical Studies |
| 40 | Clinical Study Reports i.e. Reports of Biopharmaceutic Studies; Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials; Reports of Human Pharmacokinetic (PK) Studies; Reports of Human Pharmacodynamic (PD) Studies; Reports of Efficacy and Safety Studies; Reports of Post-Marketing Experience if available; and Case Report Forms and Individual Patient Listings |

*Source: TFDA*

[15] TFDA (2015), *Guidelines on Submission of Documentation for Registration of Human Pharmaceutical Products, Doc. No. TFDA/DMC/MCER,* First Edition, January 2015

### Non-recognition of Certified Products

Tanzania's registration requirement also raises concerns about the commitment to mutual recognition and harmonization of standards within the region. The fact that Tanzania undertakes further registration to ensure the quality and safety of drugs suggests that there is no mutual recognition or harmonization of standards, which makes it necessary for Tanzania to have its own process.

Thus, the registration requirement only serves to restrict trade for "foreign" products. Effectively, companies within the EAC affected by this NTB have to surmount additional, cumbersome and burdensome procedures to register their products, which has an implication on cost and time.

## CONCLUSIONS AND RECOMMENDATIONS

The registration requirement by TFDA undoubtedly imposes costs on companies exporting to Tanzania in order to gain access to the market. These costs include a lengthy and cumbersome registration process; costly registration fees; and, in the event of delayed approval/registration, a loss of market revenue. This impedes the flow of goods across borders, a departure from the spirit of EAC integration and a violation of the WTO TBT Agreement. The requirement also raises concerns about the status of EAC manufacturers and products not being considered domestic in Tanzania and the non-recognition and/or harmonization of standards.

A key recommendation is for Tanzania to eliminate the registration requirement with respect to EAC products. While efforts are ongoing to address this requirement under the EAC Regional Forum on NTBs, the process must be fast tracked to minimize the time and cost of registration. Manufacturers from within the EAC typically undergo a similar registration process in their countries. Therefore, if manufacturers have approval from their home States, other EAC Partner States should recognize such registration as sufficient and allow for market authorization. EAC Partner States should further harmonize technical requirements and adopt common product registration application procedures and GMPs for pharmaceuticals.

To support the above recommendation, the EAC should harmonize drug registration policies and standards and also allow for mutual recognition. Mutual Recognition Arrangements will avoid the duplication of activities through enhanced collaboration, mutual trust/acceptance of equivalent technical regulations and improved information sharing. They can also implement common filing procedures with full mutual acceptability within the EAC. This will not only reduce the time and costs associated with registration for the exporting country, but will also eliminate requirements for re-testing or re-certification.

EAC Partner States should also accept WHO certificates for pharmaceutical products with a statement on GMP compliance issued by the NMRAs.

Finally, in eliminating the requirement for EAC manufacturers, Tanzania should revise the definition of "local" or "domestic" manufacturers and "residents" to include those originating from other EAC Partner States. This will eliminate the need for exporters from other EAC Partner States to engage a local agent to facilitate registration, reduce relevant fees for regional manufacturers and possibly allow similar incentives for regional manufacturers as with those afforded Tanzanian manufacturers.

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