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IMPACT OF TRADE AND TRIPS ON AFFORDABILITY OF MEDICINE IN TANZANIA

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ABSTRACT

To meet healthcare demands and costs, Tanzania depends largely on imports and financial aid from foreign countries. Current research analyses the impact of market competition on the cost and availability of medicine in Tanzania. Product approvals granted by Tanzanian drug regulatory authority were analyzed on the basis of exporting countries, molecules and therapeutic categories. The market competition among various countries was analyzed using UN trade statistics database 'Comtrade'. Our analysis revealed that India offers large number of competing vendors per molecule and has the highest average share in the product approvals granted in all major therapeutic categories. The analysis also reveals that most of the currently used second line therapy molecules that are essential for Tanzania are protected by patents and the country needs to consider utilization of TRIPS flexibilities to improve accessibility and affordability of medicine.

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INTRODUCTION: Currently Africa is afflicted with increasing morbidity and mortality rates due to chronic diseases and the continent has a very high burden of infectious diseases which account for around 69% of deaths on the continent¹. This perhaps is an indicator of non-affordability and accessibility of newer therapies. The World Health Organization (WHO) projects that over the next ten years, Africa will experience increase in death rates from cardiovascular diseases, cancer, respiratory diseases and diabetes². An estimated 80% of the regional health budgets have been allocated to communicable disease during the last decade^{3, 4}.

Tanzania is currently among the countries with a very high health burden. Approximately 5% of the HIV/AIDS population of Africa live in Tanzania⁵. The coverage of antiretroviral therapy (ARV therapy) among the people with advanced HIV infections is only 14%⁶ and the

country ranks 15th in the list of 22 high-burden tuberculosis (TB) countries in the world. Tanzania, in terms of population, is the 7th largest country in African region and 30th largest in the world. The country is among the 49 least developed countries (LDCs) of the world⁷.

It is a known fact that certain categories of products such as parenterals, anticancer drugs, and hormone preparations require dedicated facilities. The investments in such GMP compliant facilities are of the order 5 to 25 million, at the least.



The economy or market size of Tanzania cannot attract such huge investments. There are eight local manufacturers in Tanzania, all of them producing generic pharmaceutical products using imported active pharmaceutical ingredients (APIs)⁸. Of these only two meet the GMP requirements. These companies are mainly focusing on simple antibiotics, cough and cold preparations, analgesics, antipyretics, nutraceuticals etc. They lack know-how and capabilities for manufacturing technologically sophisticated products like injectables, Novel Drug Delivery Systems (NDDS) or advanced molecules etc.

The country, therefore, depends largely on imports to meet the healthcare demands. Tanzania imports about 70% of the national drug requirement⁸. Further the country largely depends on foreign aid for meeting its healthcare costs. A study by the International Labor Organization (ILO) has shown that during 2002–2006, donor funding contributed to 45% of the national health care system financing⁹. As per WHO statistics, the share of Government in the total expenditure on health was only 59%⁶.

Current research therefore, attempts to identify the impact of competition among various supplier countries and WTO TRIPS agreement on the cost and availability of medicine in Tanzania.

RESEARCH METHODOLOGY: All the Marketing Authorizations were collected from the online database of Tanzania Food and Drugs Authority (TFDA) and analysis of approvals granted for various molecules, products, companies and countries was done to identify major supplier countries and their product portfolio. Therapeutic category-wise analysis of approvals was also undertaken to establish the country and company focus in the market.

To analyze trends in the supply of medicines, the country's trade in formulations, bulk drugs, export & import statistics were collected from United Nations trade database 'Comtrade', under the list 'Pharmaceuticals and medicaments cluster'¹⁰.

Global Price Reporting Mechanism (PRM) database of WHO was used to identify the molecules supplied by various international agencies⁶. Secondary research was also carried out to identify relevance of TRIPS

flexibilities to Tanzania in improving accessibility and affordability of medicine.

During the research, several data validation and data checking steps were undertaken to ensure accuracy. Data were analyzed using spreadsheets (MS Excel). Results were cross-checked and data validation was performed.

RESULTS:

Pharmaceutical Product Competition in Tanzania: Analysis of product approvals granted by TFDA reveals that nearly 3,400 product approvals were granted by the country's regulator to 258 companies belonging to 42 countries. Asia received 45.29% of all approvals followed by Europe (27.37%) and Africa (25.08%). Among the countries that were granted product approvals, India received the highest number of approvals with a share of 39% followed by Kenya, Tanzania, Egypt and UK (**fig. 1**).

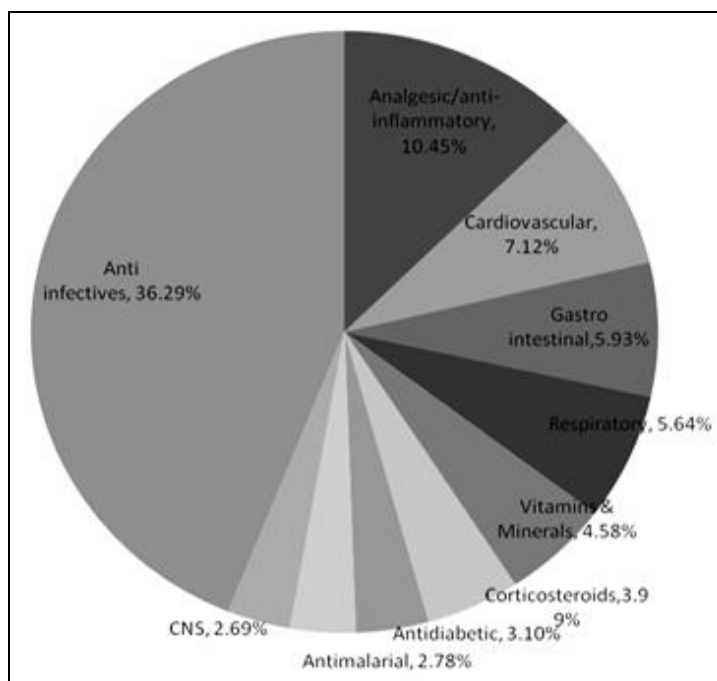


FIG. 1: COUNTRY-WISE PRODUCT APPROVALS GRANTED BY TFDA, TANZANIA (AS ON MARCH 2010)

It is found from the analysis that, product approvals of anti-infectives alone constituted 36.29% of all authorizations. Anti-infectives, analgesic/anti-inflammatory, cardiovascular, gastro-intestinal and respiratory drugs for around 65% of all approvals received (**fig. 2**).

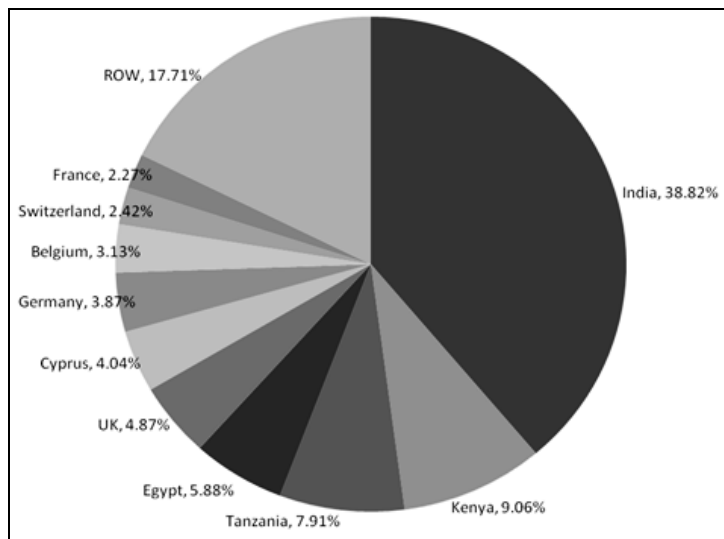


FIG 2: TOP TEN THERAPEUTIC CATEGORIES RECEIVING APPROVALS FROM TFDA (AS ON MARCH 2010)

India has the largest number of product approvals in all the top 15 therapeutic categories with the largest number of approvals in Anti-TB, anti-retroviral drugs, electrolytes, biologicals and gastro intestinal drugs (**table 1**). For several essential medicines (SEG and NEDLIT, 2010), India has a very high proportion of companies that were granted product approvals vis-à-vis rest of the world. For example, for Ciprofloxacin, India accounts for around 47.92% of companies that received approvals from TFDA, 37.84% in case of Diclofenac and 36.67% for Amoxicillin (**table 2**).

Due to this large number of vendors per molecule, cost of procurement from India was substantially lower than from the other countries.

The largest generic manufacturer of India viz., M/s. Cipla, the company responsible for revolutionizing anti-retroviral therapy ¹¹ holds the highest number of product approvals in Tanzania. The company has approximately 5% of the total approvals. Only three innovator companies viz., GlaxoSmithkline, Sanofi-Aventis & Bristol-Myers Squibb are present among the top twenty. Except GlaxoSmithkline, all other innovator companies are mainly focusing on lifestyle and non-communicable diseases such as cardiovascular, cancer, psychotherapeutics, anti-diabetics, etc.

Analysis of Pharmaceutical Imports of Tanzania: As per trade statistics available from UN Comtrade, in the year 2008 Tanzania imported around US\$ 198 million worth formulations (**table 3**) and bulk drugs from approximately 41 countries that have reported their trade statistics. Imports grew at a compounded annual growth rate of 23.24% during the five year period from 2004 to 2008. Exports were valued at US\$ 3.15 million in 2008. The market size is therefore estimated at around US\$ 270-290 million.

TABLE 2: MOLECULE-WISE NUMBER OF INDIAN COMPANIES VIS-À-VIS ROW

Rank	Molecule	Therapeutic Category	Number of Companies		Cost Per country (ROW)
			India	ROW	
1.	Ciprofloxacin		23	25	2.27
2.	Metronidazole		17	12	2.40
3.	Amoxicillin		11	19	1.90
4.	Ampicillin		11	15	1.67
5.	Ampicillin + Cloxacillin	Anti-infectives	8	12	2.00
6.	Ceftriaxone		8	10	1.43
7.	Clotrimazole		8	13	1.63
8.	Sulfamethoxazole + Trimethoprim		8	15	2.50
9.	Amoxicillin + Clavulanate		5	4	1.33
10.	Diclofenac		14	23	1.92
11.	Paracetamol	Analgesic/Anti-inflammatory	10	21	2.10
12.	Insulin	Anti diabetic	1	6	1.20
13.	Acyclovir	Anti viral	7	17	1.89
14.	Salbutamol	Respiratory	7	15	1.88
15.	Calcium	Vitamins & Minerals	10	20	2.00

Source: Authors research based on TFDA online database

TABLE 3: BILATERAL TRADE OF TANZANIA IN PHARMACEUTICALS (IN US\$ MILION)

	2004	2005	2006	2007	2008	CAGR
Export	0.86	1.23	1.15	2.87	3.15	38.28%
Import	85.85	116.33	124.69	216.70	198.05	23.24%

Source: UN Trade Statistics database 'Comtrade'

Analysis of major supplying nations of bulk drugs and formulations to Tanzania reveals that India is a major supplier of pharmaceuticals (formulations & bulk drugs combined) accounting for over 30% of the country's imports followed by France, Kenya, Switzerland and China. The imports from India have been growing at a rapid Compounded Annual Growth Rate (CAGR) of 35.09% during 2004-08. However, Europe accounts for 44.56% (**table 4**) of the country's pharmaceutical imports with three top European countries viz., France, Switzerland and UK accounting for up to 37%.

Asia is the second largest supplying region accounting for over 39% of the total country imports with India and China accounting for nearly 97% of the supply from this region.

India is not only the largest formulation supplier with a share of 28.81% but also the largest supplier of bulk drugs with a share of 59.68% (**tables 5 & 6**). Formulation imports from India are growing at a very high pace. Imports from Switzerland, China are also rapidly growing while imports from Belgium, USA and Germany are on the decline.

TABLE 3: REGION-WISE IMPORTS OF PHARMACEUTICAL PRODUCTS BY TANZANIA (IN US\$ MILLION)

Partner Region	2004	2005	2006	2007	2008	% Share	CAGR
EU	47.50	56.32	55.57	121.55	70.38	35.53%	10.33%
South Asia	13.43	22.40	32.04	39.66	59.95	30.27%	45.37%
Africa	14.30	14.30	15.32	23.31	30.63	15.46%	20.98%
Other European Countries	1.77	2.02	13.51	18.88	17.87	9.02%	78.13%
Asia (Excluding Middle East)	4.96	4.46	6.45	11.51	16.04	8.10%	34.07%
North America	3.46	16.34	1.21	1.39	1.52	0.77%	-18.56%
Middle East	0.06	0.21	0.27	0.24	1.16	0.58%	113.24%
Asean	0.30	0.19	0.26	0.11	0.43	0.22%	8.78%
LAC			0.06		0.06	0.03%	
Oceania	0.07	0.09	0.01	0.03	0.02	0.01%	-28.27%

Source: UN Trade Statistics database 'Comtrade'

TABLE 5: FORMULATIONS IMPORTS OF TANZANIA FROM VARIOUS PARTNER COUNTRIES (IN US\$ MILLION)

Rank	Partner Country	2004	2005	2006	2007	2008	CAGR	% Share	Cumulative % Share
1	India	11.08	20.14	30.40	36.04	54.71	49.06%	28.81%	28.81%
2	France	25.89	35.16	9.36	84.22	50.92	18.43%	26.81%	55.62%
3	Kenya	10.44	11.28	10.80	19.50	23.81	22.89%	12.54%	68.16%
4	Switzerland	1.77	2.02	13.51	18.88	17.87	78.13%	9.41%	77.57%
5	China	3.80	3.29	5.35	9.56	13.05	36.17%	6.87%	84.44%
6	United Kingdom	2.30	2.88	3.83	3.08	4.17	16.08%	2.20%	86.64%
7	South Africa	2.30	2.33	3.83	2.63	3.97	14.65%	2.09%	88.73%
8	Netherlands	3.10	3.45	3.78	2.59	3.62	3.95%	1.91%	90.64%
9	Belgium	8.49	8.25	31.94	25.47	3.52	-19.76%	1.85%	92.49%
10	Botswana	0.73	0.03	0.09		1.94	27.70%	1.02%	93.52%
11	Cyprus	0.97	0.86	1.51	1.76	1.82	16.90%	0.96%	94.47%
12	Denmark	0.72	0.49	1.09	0.73	1.52	20.66%	0.80%	95.27%
13	USA	3.38	16.25	1.01	1.05	1.52	-18.18%	0.80%	96.07%
14	Germany	2.71	0.96	0.83	1.02	1.29	-16.90%	0.68%	96.75%
15	Italy	0.97	0.87	1.15	1.00	1.25	6.56%	0.66%	97.41%
	RoW	2.97	3.13	2.79	4.57	4.92	13.44%	2.59%	100.00%

Source: UN Trade Statistics database 'Comtrade'

TABLE 6: BULK DRUG IMPORTS OF TANZANIA FROM VARIOUS PARTNER COUNTRIES (IN US\$ MILLION)

Rank	Partner Country	2004	2005	2006	2007	2008	CAGR	% Share	Cumulative % Share
1	India	2.16	2.09	1.51	3.20	4.86	22.53%	59.68%	59.68%
2	China	0.51	0.62	0.60	1.11	2.39	47.11%	29.26%	88.95%
3	Denmark	0.00	0.08	0.05	0.02	0.46	239.85%	5.69%	94.64%
4	Germany	0.20	0.08	0.02	0.06	0.12	-12.48%	1.41%	96.05%
5	South Africa	0.22	0.06	0.08	0.09	0.08	-21.76%	1.02%	97.07%
6	United Kingdom	0.15	0.02	0.06	0.02	0.07	-16.30%	0.90%	97.97%
7	Spain	0.06	0.06	0.00	0.06	0.06	-0.85%	0.68%	98.65%
8	Belgium		0.01			0.04		0.53%	99.18%
9	Malaysia	0.06	0.04	0.00		0.02	-18.91%	0.30%	99.48%
10	Kenya	0.01	0.03	0.01	0.01	0.02	9.07%	0.24%	99.72%
	RoW	0.86	1.86	1.09	0.01	0.02	-59.75%	0.28%	100.00%

Source: UN Trade Statistics database 'Comtrade'

Imports from Europe have been facing a formidable competition from India which has emerged as a major player by virtue of its chemistry, regulatory and compliance capabilities¹². India accounted for one out of every four Abbreviated New Drug Application (ANDA) approvals in the years 2007 and 2008, ranked first in total Type II active Drug Master Files (DMFs) with US Food and Drug Administration^{13, 14}. The country's manufacturing costs are 65% lower than those of North America⁶.

An interesting fact emerges from the analysis of average import price from various supplier countries

TABLE 7: SAVINGS ACHIEVED IN IMPORT BILL OF MEDICINES BY TANZANIA

Exporting Country	2007				2008			
	Qty. (mn)	Value (US\$ mn.)	Avg. Import Price/Unit	Savings in import bill (2007) (US\$ mn.)	Qty. (mn)	Value (US\$ mn.)	Avg. Import Price/Unit	Savings in import bill (2008) (US\$ mn.)
United Rep. of Tanzania	10.79	212.1	19.66		13.0	189.9	14.61	
India	5.02	36.04	7.18	62.63	6.37	54.71	8.58	38.41
France	0.05	84.22	1,748.5	-83.27	0.10	50.92	534.94	-49.53
Kenya	2.43	19.50	8.02	28.33	2.43	23.81	9.82	11.63
Switzerland	0.26	18.88	71.89	-13.72	0.28	17.87	64.13	-13.80
China	1.93	9.56	4.96	28.38	2.61	13.05	4.99	25.13

Source: Authors research based on United Nations trade database 'Comtrade'

Impact of TRIPS on Availability and Cost of Medicine:

It is a well-known fact that, patients suffering from diseases like HIV, AIDS, Cancer, TB develop resistance to first line drugs upon prolonged treatment, and therefore need arises for second line/higher line therapies¹⁵.

Our research revealed that currently in Tanzania, most of these second line/higher line therapies are protected by patents held by innovator companies. There are 98 molecules registered by TFDA, each by

(table 7). In 2008, the average value of imported pharmaceutical product (formulations) from India was around US\$ 8.58 per unit compared to Tanzania's average value of US\$ 14.61 per unit. This implies that the country saved approximately US\$ 6.03 per unit through generic imports from India which translated to a total savings of US\$ 38.41 million in 2008 and US\$ 62.63 million in 2007 in the import bill of Tanzania. On the other hand average unit price of imports from France were as high as US\$ 534.94 per unit and those from Switzerland are at US\$ 64.13 per unit.

one innovator company. All these are second line therapy drugs or Advanced molecules which are essentially required in the situation currently prevailing in Tanzania.

Out of these molecules the study of 25 molecules selected randomly from 7 different therapeutic categories, indicate that only 3 molecules pertaining to ARVs (2) and anti-malarial (1) are being supplied through global agencies (table 8).

TABLE 8: ANALYSIS OF AVAILABILITY OF SELECT INNOVATOR DRUGS IN TANZANIA THROUGH GLOBAL PROCURING AGENCIES

S. No.	Therapeutic Category	Active Ingredients	Brand Name	Manufacturer	Unit Price based on the Procurement by various International Agencies
1	Anti-HIV	Abacavir	Ziagen	GlaxoSmithKline	0.13
2		Lopinavir + Ritonavir	Kaletra	Abbott Place	0.14
3		Abacavir + Lamivudine + Zidovudine	Trizivir	GlaxoSmithKline	Not supplied by Global Agencies/NGOs
4	Antimalarial	Artemether + Lumefantrine	Coartem	Novartis Pharma	2.05
5		Atovaquone + Proguanil	Malarone	GlaxoSmithKline	
6	Antiasthma	Ambroxol + Guaiphenesin + Theophylline	Trisolvin	GlaxoSmithKline	Not supplied by Global Agencies/NGOs
7		Budesonide + Formoterol	Symbicort	AstraZeneca Pharmaceuticals	
8		Cefamandole	Mandol	Eli Lilly	
9	Antibiotic	Ampicillin + Flucloxacillin	Co fluampicil	Norbrook Laboratories Ltd	Not supplied by Global Agencies/NGOs
10		Cefazolin	Kefzol	Eli Lilly	
11		Cefepime	Maxipime	Bristol-Myers Squibb	
12		Cefprozil	Cefzil	Bristol-Myers Squibb	
13		Anastrozole	Arimidex	AstraZeneca Pharmaceuticals	
14	Anti-cancer	Cytarabine	Cytosar	Pharmacia & Upjohn	Not supplied by Global Agencies/NGOs
15		Goserelin	Zoladex	AstraZeneca Pharmaceuticals	
16	Cardiovascular	Felodipine	Plendil	AstraZeneca Pharmaceuticals	Not supplied by Global Agencies/NGOs
17		Fluvastatin	Lescol	Novartis Pharma	
18		Formoterol	Oxis	AstraZeneca Pharmaceuticals	
19		Fosinopril	Turbuhaler Staril	Bristol-Myers Squibb	
20		Hydrochlorthiazide + Valsartan	Co Diovan	Novartis Pharma	
21		Lacidipine	Lacipil	GlaxoSmithKline	
22		Pravastatin	Lipostat	Bristol-Myers Squibb	
23		Tadalafil	Cialis	Eli Lilly	
24	CNS	Valsartan	Diovan	Novartis Pharma	Not supplied by Global Agencies/NGOs
25		Paroxetine	Seroxat	GlaxoSmithKline	

Source: Authors' Research based on TFDA & Global Price Reporting Mechanism database, WHO

CONCLUSION: Currently Tanzania is laden with high health burden due to lack of domestic manufacturing capabilities or economic strength and hence is highly dependent on the imports to meet healthcare demands. Most of these second line/higher line therapies in Tanzania are protected by patents held by innovator companies¹⁶. It must also be noted that diseases like Cancer, Cardiovascular, Infectious, Metabolic disorders, etc., are as serious as HIV, malaria or tuberculosis. But currently, ARVs, anti-malarials and anti-TB drugs supplied by global NGOs are only first line drugs¹⁷. They are not providing high cost second line drugs due to their high costs of production¹⁸.

It therefore, appears that between encouraging drug discovery through market monopolies by innovator companies and saving lives, they have chosen the former. The TRIPS agreement provides three flexibilities to improve access for essential innovator drugs viz., parallel imports, compulsory Licensing and bolar provision. But, these safeguards are not applicable until they are written into national law of the corresponding country. TRIPS flexibilities are currently not included in the Tanzanian law and therefore the country is not able to make use of these flexibilities.

As Tanzania has already been granted exemption from complying with TRIPS agreement till 2016, it has the opportunity to promote domestic manufacturing of the molecules patented elsewhere in the world. But the country has not availed this advantage also till now and Tanzania has not issued any compulsory license (CL) till date. This is in sharp contrast to Canada which has issued 662 Compulsory Licenses so far.

In the light of the above findings, we suggest that Tanzania needs to consider the flexibilities in TRIPS agreement to lower the cost of medicines, especially for advanced/innovator molecules before this option becomes non-available. Perhaps India being the largest and the most economical supplier, it plays a key role in reducing the health care burden of Tanzania. The comments of UNITAID Executive Secretary Jorge Bermudez, that "If Indian companies cannot meet these demands of supplying the lifesaving medicines due to product patent, a lot of the progress we have made in the last seven years will be reversed"¹⁹ therefore assume relevance for Tanzania.

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