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The Viability of Local Pharmaceutical Production in Tanzania

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List of Abbreviations

API	Active Pharmaceutical Ingredient
ART	Anti Retroviral Treatment
ARV	Anti Retroviral Drugs
BCI	Business Climate Index
BEGECA	Beschaffungsgesellschaft für kirchliche, caritative und soziale Einrichtungen
BMZ	Bundesministerium für Wirtschaftliche Zusammenarbeit und Entwicklung – German Federal Ministry for Economic Cooperation and Development
BoT	Board of Trustees
CAMERWA	Centrale d'Achat des Médicaments Essentiels du Rwanda
CEO	Chief Executive Officer
CIPR	Commission on Intellectual Property Rights
COMESA	Common Market for Eastern and Southern Africa
DIE/GDI	Deutsches Institut für Entwicklungspolitik/German Development Institute
DNA	Deoxyribonucleic acid
DRA	Drug Regulatory Authority
DRC	Democratic Republic of Congo
EAC	East African Community
EACU	EAC Customs Union
ESTHER	Ensemble pour une Solidarité Thérapeutique Hospitalière en Réseau
ESTs	Expressed Sequence Tags
EU	European Union
FDA	Federal Drug Authority
GDP	Gross Domestic Product
GFATM	Global Fund for AIDS, Tuberculosis and Malaria
GMP	Good Manufacturing Practice
GTZ	Gesellschaft für Technische Zusammenarbeit
HAART	Highly Active Antiretroviral Therapy

HIV/AIDS	Human immunodeficiency virus / acquired immunodeficiency syndrome
HNP	Health Nutrition and Population
IPRs	Intellectual Property Rights
KfW	Kreditanstalt für Wiederaufbau
LDC	Least Developed Country
MDGs	Millennium Development Goals
MFIs	Micro Finance Institutions
MPR	Median Price Ration
MSD	Medical Stores Department
MSF	Médecins Sans Frontières
NAFTA	North American Free Trade Association
NCBI	National Center for Biotechnology Information
NCI	National Chemical Industries
NCTP	National Care and Treatment Plan
NGO	Non-Governmental Organisation
NHP	National Health Policy
NMP	National Medical Policy
NSGRP	National Strategy for Growth and Reduction of Poverty
NTB	Non-Tariff Barriers
OECD	Organisation for Economic Co-operation and Development
PEP	Post Exposure Prophylaxis
PFP	Private For-Profit
PIC	Pharmaceutical Inspection Convention
PNFP	Private Not-For-Profit
PNMLS	Programme National Multisectoriel de Lutte contre le Sida
PPP	Public Private Partnership
SADC	Southern African Development Community
SNPs	Single Nucleotide Polymorphisms

TB	Tuberculosis
TFDA	Tanzania Food and Drug Authority
TPI	Tanzania Pharmaceutical Industries
TRIPs	Trade Related Intellectual Property Rights
UNCTAD	United Nations Conference on Trade and Development
WHO	World Health Organisation
WTO	World Trade Organisation

Executive Summary

This study argues that there is a case for promoting the local production of pharmaceuticals in Tanzania. Especially the donor market in Tanzania itself is sufficiently big to accommodate Tanzanian producers and offers realistic options for a viable business. However, in regional or international markets, where Tanzanian producers have to compete with producers from India and China, their prospective success is at least questionable.

Considering the background of the TRIPs agreement, which allows Least Developed Countries (LDCs) like Tanzania to produce essential drugs without introducing pharmaceutical product patents until 2016, there seems to be an opportunity to build up a pharmaceutical industry, using this transition period. There are several possibilities of taking advantage of the transition period in order to ensure access to essential drugs. One of them is the promotion of local pharmaceutical production. An extensive study on the international background and the implementation of TRIPs flexibilities is to be published by the Secretariat of the United Nations Conference on Trade and Development (UNCTAD).[1]

Tanzanian producers are *formulating* active pharmaceutical ingredients (APIs) into Anti Retroviral Drugs (ARVs). That means they are importing the APIs and then formulate the combination and package the actual ARVs. The APIs that are needed and imported from China for the triple combination product which is to be manufactured by Tanzania Pharmaceutical Industries (TPIs) are off-patent. Thus, in this case the significance of the TRIPs agreement is not as relevant as anticipated.

The market size in Tanzania itself is large when it comes to the donor market. This “parallel” market is considered a “real” and very profitable market in the medium term.

There are two major local suppliers of the market: Shelys and TPI. Both have recognised and are aiming at the donor market. TPI is already producing ARVs (even though this could not be verified during the field study). All producers can participate in tenders issued by the government. Local producers enjoy a 15% preferential treatment and have to comply with Tanzanian Good Manufacturing Practices (GMP) standards. However, as no local producer complies with international standards yet, they are not eligible for international donor financed tenders, which are more profitable. Shelys is part of a Public Private Partnership (PPP) Initiative aiming at achieving international quality standards. The area of quality standards poses one of the three most significant challenges of local production and competitiveness of the pharmaceutical sector. German Development Cooperation (GTZ) can contribute to the improvement of quality standards, in particular through its PPP facility, but also through the facilitation of knowledge transfer or advisory services to the Tanzanian Food and Drug Regulatory Authority (TFDA).

The other main challenges are regional cooperation and human resource development. The regional market of the East African Community (EAC) is potentially big. To what extent Tanzanian producers will be able to meet foreign standards and consumer expectations in markets, where they have to compete both with attractive and well established third country producers (from India, China, etc.) and local producers enjoying preferential treatment through Medical Stores Department (MSD) tenders, is however unclear. The unused potential of regional integration, especially a regional approach to quality control by a common Drug Regulatory Authority (DRA), is huge.

Human resource development is highly relevant. Pharmaceutical companies have to recruit staff from India and Europe to be competitive. Even though a large majority of staff does not

[1] See Chapters 2 and 3.

need to be especially trained, it is hard to find personnel. This indicates that there is a lack of general education, as well as specialised work force.

1. Introduction

Life-saving drugs against HIV/AIDS are generally available, but not for all. The barriers to access essential medicines are various and diverse. They include high prices, anti-competitive restrictions such as patents, or reliance on importation, limited public financing and constraints in health service delivery. In 2001, in high-income countries, 500,000 patients took ARVs and fewer than 25,000 died; in Sub-Saharan Africa, fewer than 30,000 patients took ARVs and 2.2 million died.

The situation could become more severe with the implementation of the WTO agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). From 2005 on, all non-LDC World Trade Organisation (WTO) Member States are required to make available patent protection for pharmaceutical products. This includes India and China –major suppliers of generic medicines to Tanzania and other Developing and Least Developed Countries. Thus, developing countries and LDCs will now face additional challenges in obtaining essential medicines and active pharmaceutical ingredients.

LDCs are offered a legal loophole: they are exempted from the agreement and may produce generic, patent- free drugs without licence fees (as long as there are no or favourable patent laws in the respective LDC), whereas these drugs are patent-protected in other countries. This might be an opportunity for LDCs, such as Tanzania, to build up a local pharmaceutical industry and start producing essential generic drugs for national, regional and possibly international markets.

The objective of this study is to analyse the economic potential of pharmaceutical production of Anti Retroviral Drugs (ARVs) in Tanzania. This includes an analysis of the pharmaceutical sector in the country and the potential to export ARVs to the sub-region.

During the 1970s and 1980s, local pharmaceutical production capacity in East Africa was promoted by governments and international organisations for various reasons. The aim was to support the countries' self-sufficiency in medicines supply, to reduce imports and loss of foreign exchange, to improve the quality of medicines, to gain foreign exchange earnings and to create employment and gain national prestige. In the late 1980s, international organisations and donors stopped promoting domestic production. Unfavourable studies on feasibility and potential for local production in developing countries were the basis for this development. The establishment of viable local production and the production of quality pharmaceuticals at competitive prices was delayed by practical difficulties. Yet, there have been notable success stories from outside the region, such as Brazil, Thailand, Bangladesh or Cuba.

Today, perspectives of governments, donors and multilateral organizations are changing. It has been recognised that certain conditions, such as competitive pricing, a stable political climate, significant market share, and an appropriate product mix have to be met in order for the production of pharmaceuticals to be viable. Local production in Sub Saharan Africa can be financially viable. From the mid-1990s onwards, several factors have revived the issue of local pharmaceutical production in Developing Countries and in East Africa in particular. First of all, the global focus on priority diseases of HIV/AIDS and Malaria articulated in Millennium Development Goal (MDG) 5, has increased funding for medicines procurement from the international community. The debate on Intellectual Property Rights (IPRs) and access to medicines within the WTO generated awareness on the lack of domestic pharmaceutical capacity. Due to the deadlines and exemptions around the TRIPs agreement, there is growing concern over the post-2005 supply of raw materials and generic medicines from China and India and pressure on LDCs to take advantage of the deadline (analysed below).

It is difficult to assess the market for pharmaceuticals in East Africa, as date is not sufficiently available. According to the WHO, who is monitoring 46 countries in Africa, there are 38

countries who do have pharmaceutical industries, and eight who have none: Ethiopia produces an essential medicines mix by public and private means. Kenya has a big private sector with 37 local manufacturers who together produce Antimalarials, Antibiotics and other essential medicines, including ARVs. In Tanzania, there are eight manufacturers. Most of these eight produce penicillin, infusions and injectibles. So far, there is one manufacturer who produces ARVs: Tanzania Pharmaceutical Industries (TPI). The other major player, Shelys, may follow soon. This study focuses on the performance of these two main players, as the two examples can demonstrate the viability of local production in an LDC such as Tanzania.

Quality is an essential precondition for successful pharmaceutical production. Multilateral funding for procurement of HIV/AIDS, Tuberculosis (TB) and Malaria medicines generally requires medicines purchased to meet internationally recognized quality standards. Therefore, the Drug Regulatory Authorities (DRAs) play a significant role. They have to apply at least Good Manufacturing Practices (GMP) and have sufficient monitoring capacity in order to ensure the prudent production of pharmaceuticals. Often the capacity of DRAs in developing countries is low. A potential yet unused to strengthen regulation of pharmaceutical production in the East African region is the East African Community (EAC): at the moment, each member has individual standards and supervisory procedures. Harmonisation of standards and procedures would strengthen the DRAs.

An enabling environment is crucial for economic development in any sector and any country. In order to foster the development and growth of the pharmaceutical sector in East Africa, it is crucial to create and support an enabling environment, including infrastructure, trade relations, regulations etc. A common policy and strategy, national Medicines Policies with goals and objectives as well as National Industrial Development Plans and Investment Strategies are a necessary pre-requisite. Furthermore, an industrial and infrastructural framework, i.e., water, electricity, technological capacity, petro-chemical resources, complementary and support industries such as packaging, bottling, etc. are needed.

After an extensive chapter on the background regarding the legal implications of the TRIPs agreement, chapter 3 analyses the legal situation in Tanzania with regards to the Doha exemptions in particular. In chapter 4, the Tanzanian market is assessed, the main local suppliers of the market are introduced and the distribution channels are analysed. The other influencing factors are discussed in chapters 4.2 to 4.4: the role of regulatory authorities and standards in general and in Tanzania in particular, the overall enabling environment, and the significance of a qualified work force. Chapter 5 analyses the potential of the EAC regional market. In the last chapter, the main challenges are summarised and potential areas of intervention for German Development Cooperation are identified.

2. Background: The Agreement on Trade-Related Aspects of Intellectual Property Rights[2]

Resulting from the Uruguay Round of Multilateral Trade Negotiations, the WTO's TRIPs Agreement entered into force on 1 January 1995, as one of the pillars of the umbrella WTO Agreement.[3]

According to Article 7 of the TRIPs Agreement, "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." In addition, WTO Members may, when implementing TRIPs rules, "adopt measures necessary to protect public health" and other public policy objectives, "provided that such measures are consistent" with the provisions of the TRIPs Agreement (Article 8.1, TRIPs). The TRIPs Agreement is based on the assumption that the implementation and enforcement of IPRs minimum standards will encourage owners of intellectual property (IP) to transfer technologies to others (e.g. through the conclusion of licensing agreements). On the other hand, the evidence in this respect is inconclusive.[4] Many experts have emphasized that in order to promote technology transfer and innovation, IPRs need to be adapted to the respective country's level of development and technological capabilities.[5]

The TRIPs Agreement obliges members to provide for **minimum standards of IP protection** in their domestic legislation. Members may, but are not required to go beyond, such minimum standards. These minimum standards encompass the following IPR categories:

- Copyright and Related Rights
- Trademarks
- Geographical Indications
- Industrial Designs
- Patents

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[2] The sections on the international background and the implementation of TRIPs flexibilities are based on the more detailed "Intellectual Property Rights, Investment and Access to Medicines: the United Republic of Tanzania", Report by the Secretariat of the United Nations Conference on Trade and Development (UNCTAD), Geneva, 2006 (forthcoming) [hereinafter: UNCTAD Report (2006)].

[3] See Agreement Establishing the World Trade Organization and its annexes (Annex 1A: Multilateral Agreements on Trade in Goods; Annex 1B: General Agreement on Trade in Services; Annex 1C: Agreement on Trade-Related Aspects of Intellectual Property Rights; Annex 2: Dispute Settlement Understanding; Annex 3: Trade Policy Review Mechanism; Annex 4: Plurilateral Trade Agreements). All WTO agreements are available at http://www.wto.org/english/docs_e/legal_e/legal_e.htm.

[4] For an overview of different studies, see UNCTAD-ICTSD (2003): Intellectual Property Rights: Implications for Development. Policy Discussion Paper, Geneva, [hereinafter UNCTAD-ICTSD (2003): Policy Paper]: pp. 87/88. The UNCTAD-ICTSD Policy Paper is available at http://www.iprsonline.org/unctadictsd/policyDpaper.htm

[5] See, for example Kim, L. (2003):Technology Transfer and Intellectual Property Rights: Lessons from Korea's Experience. UNCTAD-ICTSD Issue Paper No. 2, Geneva, [hereinafter UNCTAD-ICTSD (2003): Issue Paper No. 2]; Maskus, K. (2004): Encouraging International Technology Transfer. UNCTAD-ICTSD Issue Paper No. 7, Geneva, (both papers are available at http://www.iprsonline.org/unctadictsd/projectoutputs.htm#top); IPR Commission: pp. 24 *et seq*. Concerns about broad monopoly rights and their impact on competition and innovation have also been expressed in developed countries; see, e.g. US Federal Trade Commission (2003): To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy. (executive summary online available at http://xml.coverpages.org/FTC-InnovationReportSumm.pdf).

- Layout-Designs (Topographies) of Integrated Circuits
- Protection of Undisclosed Information
- Control of Anti-Competitive Practices in Contractual Licences

WTO Members are obligated to "give effect" to the TRIPs provisions on minimum standards (Article 1.1, first sentence, TRIPs Agreement), i.e. to incorporate them into their domestic legal system and practice ("implementation"). As Members "shall be free to determine the appropriate method" of implementation (Article 1.1, third sentence), they may choose to either recognize the text of the TRIPs Agreement as part of their domestic legal system ("monist" approach) or adopt specific statutes or administrative rules to implement the Agreement ("dualist" approach).[6]

The above examples show that Members, when implementing the TRIPs provisions, have considerable **leeway**, as long as they respect the minimum standards expressly provided by the TRIPs Agreement. In essence, implementation of undefined TRIPs language will require members to strike a **balance between the exclusive right and public areas**. The exclusive right is promoted by the respective IPR at issue, and the area remaining outside the scope of exclusivity (i.e. the "public domain"). Governments will have to decide where the dividing line between these areas should be drawn, whether to promote broad exclusive rights and a limited public domain, or vice versa. Shifting the balance in favour of one of these will automatically reduce the scope of the other. The challenging task for Governments is to determine which approach is the appropriate one for their country's efforts to promote technological innovation and technology transfer, without at the same time obstructing other policies in such diverse areas as public health and access to scientific and educational materials.

The TRIPs Agreement for the first time at the multilateral level introduced the obligation to make patents available "for any invention, whether products or processes, in all fields of technology" (Article 27.1). Unlike many industrialized and developing countries in the past, WTO Members today may therefore in principle no longer exclude pharmaceutical products from patent protection,[7] but must provide the pharmaceutical industry with the possibility to be granted patents not only on pharmaceutical processes but also products.

A granted patent confers a monopoly position on its holder: the patent is a public authorization to exclude others, for at least 20 years, from the acts of making, using, offering for sale, selling, or importing a protected product.[8] Thus, a patented medicine may only be produced, sold, and imported by the patent holder or with his authorization. Third party producers or importers are therefore obligated to seek a license from the patent holder. As the use of the patented substance is subject to the patentee's authorization, unauthorized third parties engaging in reverse engineering of the product for commercial purposes risk patent infringement suits. The granting of pharmaceutical product patents may therefore entail considerable challenges for generic drugs producers.

This being said, a number of qualifications should be made. First, LDCs under TRIPs rules enjoy transition periods for the implementation of TRIPs obligations. According to these

[6] For details, see: UNCTAD-ICTSD (2005): Resource Book on TRIPs and Development, Cambridge University Press, [hereinafter UNCTAD-ICTSD (2005): Resource Book], Chapter 2 (especially pages 19/20 and 25-27). The UNCTAD-ICTSD Resource Book is online available at http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm

[7] For example, Switzerland excluded pharmaceutical products from patentability until 1977; India until 2005.

[8] See Article 28.1, TRIPs Agreement. Rights of importation, distribution, use and sale of a protected product may only be relied upon until they are "exhausted" (for details, see below). Comparable rights are conferred on the holder of a process patent, see Article 28.2, TRIPs Agreement.

transition periods, LDC Members are not obliged for the time being to make patent protection available for pharmaceutical products. This important qualification will be discussed in detail at the beginning of the following section on TRIPs flexibilities.

Second, for those LDCs not taking advantage of their transition periods, the obligation to make patents available does not necessarily mean that a patent will actually be granted for each patent application. A country's national patent office will have to examine whether the invention at issue (e.g. a pharmaceutical product) meets the three patentability criteria of novelty, inventive step and industrial applicability, and has to refuse to grant a patent if this is not the case.

Third, patents are territorial by nature; this means that a pharmaceutical product that is protected in country A does not enjoy patent protection in country B unless a national patent has actually been granted in country B. Pharmaceutical companies do not always seek patent protection in every country, due, *inter alia*, to a perceived lack of market size. Therefore, it is possible that in some countries, despite the existence of a national patent law, certain pharmaceutical substances remain off-patent and may be freely used, made and imported. Should the original inventor change his mind later on and seek patent protection, the application would be rejected for lack of novelty, as the substance at issue would have been available to the public before the filing of the patent application.

3. Public Health-Related TRIPs Flexibilities and their Implementation in Tanzania

3.1 Transition periods for implementation

According to a 2002 Decision of the TRIPs Council, based on the 2001 Doha Declaration on the TRIPs Agreement and Public Health, LDCs such as Tanzania are exempted until the 1st of January 2016 from implementing, applying or enforcing the TRIPs provisions on patents and the protection of undisclosed information with respect to pharmaceutical products.[9]

Notwithstanding this flexibility, Tanzania's Patents Act of 1987 makes patents available for both processes and products, without expressly excluding pharmaceutical products.[10] Prior to starting the manufacture of a given drug, generic producers therefore have to make sure that neither the final product nor any of its ingredients are patented in Tanzania.[11] Where a patent exists, the producer will in principle have to seek a voluntary license from the patent holder.[12]

The Tanzanian Government is free under WTO law to amend the Patents Act with a view to excluding, until 1 January 2016, pharmaceutical products from the protection through patents and undisclosed information. Alternatively, the Government may elect to authorize its authorities (such as administrative bodies or courts) to not enforce pharmaceutical patent rights until 1 January 2016.[13]

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[9] See: WTO (2001): Declaration on the TRIPs Agreement and Public Health. Doha Declaration WT/MIN/(01)/DEC/W/2 of 14 November 2001, paragraph 7 [hereinafter Doha Declaration], and the implementing Decision by the TRIPs Council (2002): Extension of the Transition Period under Article 66.1 of the TRIPs Agreement for Least-Developed Country Members for Certain Obligations with respect to Pharmaceutical Products. WTO document IP/C/25, 27 June 2002. [hereinafter Decision on the 2016 Extension]. Note that with respect to products other than pharmaceuticals, implementation of the provisions on patents and undisclosed information is waived until 1 July 2013. LDCs may also postpone implementation of other TRIPs categories of IPRs until 1 July 2013. See TRIPs Council (2005): Extension of the Transition Period Under Article 66.1 For Least-Developed Country Members. Decision of the Council for TRIPs of 29 November 2005, WTO document IP/C/40 of 30 November 2005. [hereinafter Decision on the 2013 Extension]. In the meantime, the only TRIPs provisions LDCs need to respect are Articles 3, 4 and five on national treatment, most-favoured nation treatment under TRIPs and certain WIPO-administered IPR conventions.

[10] See Articles 7 (1) and 8 of the Tanzanian Patents Act of 1987 [hereinafter Tanzanian Patents Act (1987)]. Article 13 authorizes the exclusion from patentability of "certain kinds of products, or processes" for a maximum period of ten years. For details, see the separate section below (on general exclusions from patentability).

[11] Pertinent information can be obtained from the national patent office. For a table showing the patent status of certain substances in selected countries (not including Tanzania, but EAC Members Kenya and Uganda), see Médecins Sans Frontières (MSF) (2003): Drug Patents Under the Spotlight. Geneva, Annex A:p. 28; reprinted in "Determining the Patent Status of Essential Medicines in Developing Countries", Health Economics and Drugs EDM Series No. 17, UNAIDS, WHO, MSF, Geneva, 2004:pp. 11-14.

[12] For more details on the negotiation of voluntary licenses, see below. Compulsory licenses provide an alternative, but in principle presuppose unsuccessful attempts to reach agreement on a voluntary license (see below).

[13] Two qualifications have to be made here: first, in respect of patents that have already been granted, it would seem advisable for the Tanzanian Government not to insist on their non-enforcement. This is independent of the legal situation and the issue of potential Government liability under constitutional principles on expropriation. Second, the Government would have to make available a mechanism for the filing of pharmaceutical patents ("mailbox") between 2013 and 2016. For details, see UNCTAD Report (2006).

3.2 Patentable subject matter

If Tanzania chooses to abstain from its right to use a transition period for the introduction of patent rights, pharmaceutical product patents will generally be available. However, certain subject matter may be excluded from patentability in the first place, i.e. considered ineligible for patent protection. Patent applications concerning such subject matter would then have to be rejected without even examining if the submitted invention meets the patentability requirements of novelty, inventive step and industrial applicability. The substances at issue may then be used by generic producers without the need for authorization from a patent holder.

According to the Patents Act, **substances existing in nature** may in particular be excluded from patentability. The extent to which naturally existing substances may be patented has some important implications for generic pharmaceutical production. Medicaments may entirely or partially consist of biological substances, including extractions from plants, algae and human proteins, and the results of genetic engineering.[14] The Patents Act does not define "discovery", thus leaving it open whether naturally occurring substances may be patented if isolated from nature. The Government under WTO rules has considerable discretion to provide for a more detailed definition in this respect.[15]

3.3 Patentability criteria

Subject matter which is not excluded from patentability is in general eligible for patent protection. However, inventions incorporating such subject matter will need to meet the three basic patentability criteria in order to be granted a patent right: novelty, inventive step, and industrial applicability.

3.3.1 Novelty

The TRIPs Agreement does not define novelty. According to traditional patent law prevailing in developed country jurisdictions, this requirement generally means that the information must not have been available to the public prior to the original application date (the priority date).[16] Everything available to the public before that date is considered as part of "prior art". Members are free to adopt strict standards of novelty, thus making it more or less difficult to obtain a patent on a given product or process. For instance, a strict novelty standard may require world wide novelty and the rejection of novelty in the cases of both written and oral disclosure to the public, as provided under Section 9.2 (a) of Tanzania's Patents Act.[17] A strict standard of novelty could also provide that:

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[14] See C. Correa, "Integrating Public Health Concerns into Patent Legislation in Developing Countries", The South Centre, 2000, pp. 15/16 [hereinafter South Centre, 2000].

[15] For details, see UNCTAD Report (2006).

[16] The priority date refers to the date on which a patent applicant files his first patent application for a given invention in any WTO Member. If the inventor files an application for the same invention in any other Member state within 12 months from the filing of the first application, the inventor will enjoy a right of priority for this "later" application (see Article 4 A. (1), and C. (1) of the Paris Convention for the Protection of Industrial Property, which is binding for WTO Members, Article 2.1, TRIPs Agreement). Competing applications on the same invention will thus be considered as lacking novelty, as the first application has already disclosed the invention to the public.

[17] By contrast, under U.S. law oral disclosure of an invention *outside* the United States does not destroy novelty. This relative concept of novelty has allowed the patenting in the USA of knowledge and materials used by indigenous communities abroad. See UNCTAD-ICTSD (2005): Resource Book: p. 359, referring to Correa.

- Even if the invention is not publicly available in a single document, but can be derived from a combination of publications, it is considered as part of prior art and therefore not new;[18]
- Even the theoretical possibility of having access to information renders it available to the public, whatever the means by which the invention was made accessible;[19]
- Information that has not been published in express terms, but that may be implied in expressly published information may also be regarded as prior art ("implicit teachings").[20]

3.3.2 Inventive step

The TRIPs Agreement does not define the notion of inventive step. Section 10 of the Tanzanian Patents Act has adopted the classical definition available in many developed country jurisdictions: an invention shall be considered as involving an inventive step if, having regard to the prior art, it would not have been obvious to a person skilled in the art on the date of filing or priority. This definition can be applied more or less strictly. The higher the requirements to meet the definition, the more difficult it is to receive a patent on a given substance, and the more likely it is that this substance will remain in the public domain, freely available for generic production.

The Patents Act does not make any specific provisions as regards inventive step in the area of pharmaceuticals. The Act could be amended to address issues such as the inventiveness of new pharmaceutical substances developed from existing medical products.[21]

3.3.3 Industrial applicability

This is the third and last requirement an invention needs to meet in order to be protected by a patent. As the objective of patent law is the promotion of technical and practical solutions, rather than the monopolization of theoretical knowledge, an invention has to be capable of industrial application. Again, the TRIPs Agreement provides no definition in this respect. The Patents Act in Section 11 employs the traditional concept used in European countries, stating that an invention is capable of industrial application if "according to its nature, it can be made or used, in the technological sense in any kind of industry, including agriculture, fishery and services". In other words, developments not leading to an industrial product cannot be patented. In the pharmaceutical context, this means that purely experimental inventions not producing any technical effect cannot be patented. One important implication is that research tools used by the pharmaceutical industry in the development of new medicines, such as expressed sequence tags (ESTs)[22] and single nucleotide polymorphisms (SNPs)[23] cannot be

[18] By contrast, the United States requires complete disclosure in a *single* publication to destroy novelty, despite the fact that a skilled person may have been able to derive the invention without effort from a combination of publications. See UNCTAD-ICTSD (2005): Resource Book: p. 359.

[19] This strict approach has been developed under European Patent Office case law (case T 444/88). See UNCTAD-ICTSD (2005): Resource Book: p. 359.

[20] See Correa(2000): p. 41, referring to European Patent Office practice.

[21] See UNCTAD Report (2005) for details.

[22] An EST is a tiny portion of an entire gene that can be used to help identify unknown genes and to map their positions within a genome, in a quick and inexpensive fashion. See National Center for Biotechnology Information (NCBI): http://www.ncbi.nlm.nih.gov/About/primer/est.html.

[23] SNPs are variations of a DNA sequence. Variations in the DNA sequences of humans can affect how humans develop diseases, respond to pathogens, chemicals, drugs, etc. As a consequence SNPs are of great value to biomedical research and in developing pharmacy products. See Wikipedia: http://en.wikipedia.org/wiki/Single_nucleotide_polymorphisms.

patented but remain available to generic producers. From this perspective, the current standard of the industrial applicability requirement under the Patents Act seems to be appropriate to avoid the monopolization of theoretical knowledge.

3.4 Exceptions to patent rights

Once a patent has been granted, the scope of the exclusive rights conferred may be limited for certain public interest reasons considered superior to the interests of the patent holder. For instance, national legislation may provide that the right to exclude others from the use of the patented substance should not prevent scientific research needed for the benefit of society as a whole and therefore exclude acts done for scientific research from the exclusive rights conferred by a patent.[24] Exceptions to exclusive rights have to be distinguished from exceptions to patentability: the latter exclude a given subject matter from protection and result in the non-granting of a patent (e.g. on substances as existing in nature, see above); by contrast, exceptions to exclusive rights as considered under this section apply after a patent has been granted.

The TRIPs Agreement does not provide for specific exceptions to granted rights; it rather provides a general clause on admissible exceptions (Article 30), stating that:

> "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

WTO Members are therefore free to provide more specific exceptions to patent rights, as long as the minimum requirements in Article 30, TRIPs Agreement, are respected.[25] National patents laws provide a variety of patent exceptions, some of which are of particular relevance in the public health context.[26]

The Patents Act in its Section 37 provides, *inter alia*, for the following exceptions to granted patent rights:

- the rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to **acts done for scientific research** (para. 1);
- the rights under the patent shall extend only to acts in respect of **articles put on the market in the United Republic** by the owner of the patent or with his express consent (para. 2);
- the rights under the patent shall be limited by the **duration of the patent term** (para. 4);
- the rights under the patent shall be limited by the provisions on **compulsory licenses** and **government use licenses** (para. 5).

3.4.1 The Scientific Research/Experimental Use Exception

The scientific research exception available under the Patents Act as quoted above seems to exclude those cases where commercial interest is one of the driving forces behind

[24] The Tanzanian Patents Act provides such exception in Section 37 (1), see below.

[25] For a detailed analysis of Article 30, TRIPs Agreement, see UNCTAD-ICTSD (2005): Resource Book, Chapter 23: pp. 430 *et seq*.; and Garrison, C.: Exceptions to Patent Rights in Developing Countries. UNCTAD-ICTSD Issue Paper No. 16, forthcoming [hereinafter Garrison].

[26] For an extensive review of long established practices and principles of patent exceptions and their implementation in both developed and developing country legislation see Garrison.

experimental activities. The Patents Act is in this respect stricter than some Organisation for Economic Co-operation and Development (OECD) country legislation, such as the German Patent Act, for example.[27]

3.4.2 The Early Working Exception

A patent confers upon its holder the right to exclude others from making, using, selling, etc. the protected product or process. The patent, however, does not authorize the right owner to put the patented product on the market. Such authorization may only be obtained from a specialized Government body, hereinafter referred to as "regulatory authority". In Tanzania, this is the Tanzania Food and Drugs Authority (TFDA). The procedures for obtaining marketing approval from the TFDA are completely independent of the procedures for patent application with the national patent office.

Obtaining approval from a regulatory authority for the marketing of a drug might take a considerable amount of time, sometimes up to several years.[28] Generic producers in order to obtain marketing approval might be required to use the substance of a patented drug for submission to the regulatory authorities, which will normally examine the bio-equivalence of the submitted material with the pharmaceutical test data submitted earlier by the first applicant for marketing approval (i.e. the "data originator", who often also holds a patent on the respective drug).[29] Regulatory approval processes may require substantial amounts of test production to demonstrate reliable manufacturing.[30] If the patent holder could use his exclusive right to prevent generic producers from using the patented substance for marketing approval purposes, a generic producer could only submit his request for marketing approval after the patent has expired. Considering the time required for the approval process, the generic drug could only be marketed quite some time after the expiry of the patent, thus extending, *de facto*, the exclusive position of the patented drug on the market. From a public health perspective, delayed market entry of generic competitors is likely to delay any possible decrease of drug prices.

This is the current situation under Tanzanian law. According to Section 35 (a) (i), the owners of Tanzanian product patents shall have the right to preclude any person from using the patented product. Such use would include the submission by generic producers of a generic drug incorporating a patented substance. The patent exceptions enumerated under Section 37 of the Patents Act (see above) do not include any express reference to the possibility to use patented substances for the purpose of requesting marketing approval before the expiry of the patent term ("early working" exception). Section 37 (1) provides that the rights under the patent shall extend only to acts done for "industrial or commercial" purposes. It would seem rather difficult to argue that the use by generic producers of a patented substance for marketing approval purposes does not serve any industrial or commercial purpose. While the immediate purpose is to receive marketing authorization, this is only done for the overall purpose of commercialisation of the (generic) pharmaceutical product.

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[27] See § 11.2 of the German Patents Act (Patentgesetz).

[28] For more details on the drugs approval process, see Pugatch, M. (2006): Intellectual Property, Data Exclusivity, Innovation and Market Access. In *Negotiating Health. Intellectual Property and Access to Medicines*, Earthscan, ICTSD, UNCTAD: pp. 97 *et seq*.

[29] In case the relevant national law provides for exclusive rights on the originally submitted data, regulatory authorities will even require generic producers to submit their own test data to prove the generic version of the drug meets certain quality standards. For more details on data exclusivity, see below.

[30] *Canada – Patent Protection of Pharmaceutical Products,* Report of the Panel, para. 7.45.

Thus, it would be advisable, from a public health perspective, to include an early working exception in the Patents Act.

3.5 Patent term

The exclusive rights conferred by a patent are only granted to the inventor for a limited period of time. After expiry of the patent term, third parties like generic producers may legally make, use, and sell the patented substance. According to Article 33, TRIPs Agreement, Members are obligated to provide for a term of protection of at least 20 years counted from the date of filing of the patent application. Section 38 (1) of the Patents Act only provides a patent term of 10 years after filing the application. According to paragraph two of this Section, the term of the patent may be extended for another five years, provided that a fee is paid and the patent holder or licensee proves that the invention is being worked[31] in the United Republic at the date of the request for patent term extension.

As pointed out above, Tanzania has until 1 July 2013 to implement the TRIPs obligations other than those specifically related to pharmaceutical products, for which the transition period ends on 1 January 2016. The term of protection generally available for any patent under the Patents Act will have to be adjusted to TRIPs minimum standards by 1 July 2013. For the time being, Section 38 (1) and (2) of the Patents Act on the term of the patent is inconsistent with the TRIPs Agreement, for the following reasons:

- The term of protection must not be less than 20 years. This does not exclude an obligation on the part of the patent holder to pay fees to maintain the term of protection.[32]
- Making the availability of a patent term extension dependent on local working of the patent could arguably be considered as inconsistent with the principle under Article 27.1, TRIPs Agreement that patents shall be made available without discrimination as to whether products are imported or locally produced.

3.6 Parallel imports

Pharmaceutical companies often sell their products at different prices in different areas of the world, depending to a large extent on what the market will bear. Parallel importers take advantage of the price difference between countries. They purchase certain IPR-protected products at low price in a low-price country and import them into high price countries, undercutting the local price set by the IPR holder. The low-priced products are imported in parallel to the official channels of distribution established by the IPR holder (in this context the holder of a pharmaceutical patent). It is important to note that parallel imports are not counterfeits; they are original products of the patent holder sold by him/herself or an authorized person on a given market, and purchased and subsequently re-sold by a third party. Upon the first sale of the patented product, the patent holder loses the right to control the further distribution and resale of that particular product; the idea being that through the first marketing, the patent holder has been sufficiently rewarded for his/her inventive efforts and his/her exclusive distribution rights in the product are therefore exhausted (commonly referred to in EU countries as "exhaustion doctrine", or "first sale doctrine" in the United

[31] According to Section 38 (3) of the Tanzanian Patents Act, "a patented invention is worked if the patented product is effectively made, or if the patented process is effectively used in the United Republic on a scale which is reasonable in the circumstances and importation shall not constitute working."

[32] See *Canada – Term of Patent Protection*, WT/DS114/R, Report of the Panel of 17 March 2000, para. 6.110.

States).[33] During the Uruguay Round of Multilateral Trade Negotiations, some developing countries adopted the position that exclusive distribution rights should also be exhausted in case the protected product is put on the market on the basis of a compulsory license, i.e. without the authorization of the patent holder.[34]

The first sale of a patented product could occur either in the country for which the patent has been granted, or abroad. Domestic marketing of the patented product will in any case exhaust the exclusive distribution rights. An important issue arises when the first marketing occurs abroad. In this case, the concept of "international exhaustion" prescribes that the distribution rights available under the domestic patent will be exhausted as in the case of domestic marketing.[35] By contrast, the concept of "national exhaustion" limits exhaustion to the domestic market and first sales outside the country for which the patent has been granted will not affect the existence of the domestic patent. Finally, the concept of "regional exhaustion" as practiced in the EU provides that first sales of the patented product in any EU Member State will exhaust a national patent; first sales outside the EU will not.

Thus, parallel imports are only possible if the patentee's distribution rights are exhausted in the country destined for importation. In the pharmaceutical context, where price differences between countries may be considerable, parallel imports constitute an important means to provide access to low-priced medicaments. In addition, they may provide an important source of affordable pharmaceutical substances needed by generic manufacturers for their own production.

For these reasons, the London-based, independent Commission on Intellectual Property Rights (CIPR) in a 2002 report recommended that developing countries seeking to promote access to medicines "should aim to facilitate parallel imports in their legislation."[36] Under the TRIPs Agreement, WTO Members are free to admit or to prohibit parallel imports in their domestic legislation.[37]

In Tanzania, parallel imports from abroad are not admitted (see the Patents Act in Section 37 (2)). The Tanzanian Government, should it wish to do so, is free to amend this provision, authorizing parallel imports of patented products.[38]

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[33] A patent confers upon its holder a bundle of different exclusive rights: the rights to exclude others from making, using, offering for sale, selling, or importing the patented product (Article 28.1, TRIPs Agreement). As a result of patent exhaustion, the patent holder only loses those exclusive rights related to the **distribution** of the particular product he has marketed; he may no longer exclude others from using, offering for sale, selling, or importing that particular product. By contrast, he may still exclude others from **making** the product: exhaustion does not affect his exclusive right in the invention as such (as opposed to the distribution of a particular product). Purchasers of patented products may therefore resell them, but not copy them for commercial purposes.

[34] See UNCTAD-ICTSD (2005): Resource Book: p. 102. Due to such fundamental differences in opinion, the TRIPs Agreement contains no binding definition of what constitutes "exhaustion".

[35] Under the international exhaustion doctrine, the first sale of a product abroad will only exhaust the domestic patent if the respective product is protected by a corresponding patent in the country of first sale. Otherwise, the patent holder enjoys no exclusivity in the country of first sale, thus the first marketing there cannot be treated as equivalent to the first sale on the domestic market. Note that the European Court of Justice has admitted parallel imports within EU Member States even where the product at issue was not patented in the (EU) country of first sale. See joint cases C-267/95 and C-268/95 *Merck & Co Inc. and others v Primecrown Ltd. and others* and *Beecham Group plc. v Europharm of Worthing Ltd*. of 5 December 1996.

[36] See CIPR (2002): Integrating Intellectual Property Rights and Development Policy. London: p. 42 (online available at http://www.iprcommission.org/graphic/documents/final_report.htm .

[37] This is at least the majority view and accepted practice among WTO Members. For a discussion of the issue, see UNCTAD-ICTSD (2005): Resource Book: pp. 92 *et seq*.

[38] For details, see UNCTAD Report (2006).

3.7 Compulsory licenses

A compulsory license is an authorization granted by the Government to a private party or a Government entity ("government use") to use an invention without the consent of the right holder. The right holder is generally not excluded from using his/her invention, but loses, for a certain period of time, his/her monopoly right. Both the patent holder and the compulsory licensee(s) have the right to exclude third parties from making and using the patented invention. The granting of compulsory licenses for private commercial use is provided under Sections 52-59 of the Patents Act, according to which the license is granted by a court. A non-voluntary license may also be issued under Section 61 by the Government, for exploitation by a Government agency or a third person designated by the responsible Minister.

The reason for the granting of a compulsory license is usually a perception by the Government that the patent holder cannot satisfy the market demand for a given product (for example in case of an emergency[39]) or that prices are excessive. Compulsory licenses are a traditional means in developed country legislation to assure competition and affordable prices of patented products. Some developed countries, such as Canada, used compulsory licenses in the past to promote the establishment of a national generic pharmaceutical industry.[40]

From a development perspective, compulsory licenses may be an important instrument both to promote the wider availability of medicines at affordable prices and to promote the establishment of a generic pharmaceutical industry. Key stakeholders in the public health debate have been stressing the importance of improved implementation of TRIPs flexibilities in respect of compulsory licensing.[41] Very often, however, the mere possibility of issuing a compulsory license will convince patent holders to enter into serious licensing negotiations. For example, the Government of Brazil by threatening the authorization of compulsory licenses has been able to secure the commitment on the part of large pharmaceutical companies to make drugs available at affordable prices.[42]

Moreover, excessive reliance on compulsory licenses may have negative effects in terms of discouraging foreign investors, whose cooperation may be needed by local producers. It is important to note that an expansive granting of compulsory licenses is politically very sensitive and should not be regarded as a substitute for a careful *pre-grant* patent policy. It seems preferable to limit the scope of patents to begin with, by exempting substances from patentability and applying strict patentability criteria (see above), rather than seeking to

[39] For example, the US Government in the fall of 2001 considered the production under compulsory license of the anti-anthrax drug Cipro, on which the German pharmaceutical firm Bayer holds a patent. Bayer and the U.S. Government finally came to an agreement enabling the low-cost mass production of Cipro.

[40] Canada changed its policy after the entry into force of the North American Free Trade Association (NAFTA) and the TRIPs Agreement. For details, see Reichman, J. / Hasenzahl, C. (2003): Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework Under TRIPs, and an Overview of the Practice in Canada and the United States of America. UNCTAD-ICTSD Issue Paper No. 5, Geneva (available at http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf) [hereinafter Reichman/Hasenzahl (2003)].

[41] See, for example, Jack, A. (2006a): WHO urges poor nations to push for cheaper AIDS drugs. The Financial Times (on-line issue), 16 August 2006 (referring to a top WHO official addressing the August 2006 International AIDS Conference at Toronto).

[42] See, for instance, Jack, A. (2006b): Cut-price HIV drugs drive may spur patents clash. The Financial Times (on-line issue), 10 August 2006 (referring to a 2005 agreement between the Brazilian Government and Abbott Laboratories to provide the second-line AIDS therapy Kaletra at a lower price than the company had originally planned).

curtail the scope of broad patents in the *post-grant* phase by means of highly politicised compulsory licenses.

Against this background, it seems advisable for Governments to provide the possibility of issuing compulsory licenses, but accompanied by a careful pre-grant patent policy and appropriate use of public health-related patent exceptions. All of these instruments should be considered of equal importance, rather than relying exclusively on one of them.

The Patents Act does provide for the possibility for the Government to issue compulsory licenses (Sections 54 and 61 of the Patents Act). A number of observations should be made in this respect:

- As in the case of the patent term extension (see above), the question arises whether the granting of a compulsory license for the failure to work a patented invention locally is compatible with the principle of non-discrimination under Article 27.1, TRIPs Agreement. It seems advisable for the Tanzanian Government to remove, by 1 July 2013 (date of mandatory compliance with most TRIPs obligations), the local working requirement as a ground for the granting of compulsory licenses under Section 52 of the Patents Act.
- The Tanzanian Government is free to introduce, in Sections 52 or 61, an express reference to anti-competitive behaviour and resulting excessive prices as a reason for the granting of a compulsory license.
- Section 55 (a) of the Patents Act neglects the right granted to WTO Members to waive the prior negotiations requirement in cases of a national emergency, other cases of extreme urgency or cases of public non-commercial use (Article 31 (b), TRIPs Agreement). In the public health context, this may be an important means of speeding up the availability of low-priced generic drugs.
- With the exception of public health-related compulsory licenses, compulsory licenses in Tanzania may in general only be granted by a court after a waiting period of four years after the date of filing of the patent application or three years from the grant of the patent, whichever period last expires (Sections 52 (1); 54 (2) of the Patents Act). Such requirement is not mandatory under TRIPs, which only mandates prior unsuccessful negotiations with the right holder.
- Under a new provision (Article 31*bis*) of the TRIPs Agreement, the obligation to remunerate the patent holder in exchange for the issuance of a compulsory license may be waived. This applies to cases where the products manufactured under the compulsory license are exported to countries lacking domestic pharmaceutical manufacturing capacities and remuneration is paid in the exporting country.
- Under the same TRIPs provision, a country member of a regional trade agreement which consists of at least 50% of LDCs may export pharmaceutical products produced or imported under compulsory license to all other member states of the regional trade agreement. If, for example, Tanzania imported patented drugs from India under compulsory license, it would be free to export part or all of these drugs to the other member states of the East African Community (EAC). If Tanzanian local manufacturers produced a drug under compulsory license, they would be authorized to export the entirety of this production to the other EAC member states, as opposed to general TRIPs rules.

3.8 The control of restrictive business practices

Local producers of pharmaceutical products in developing countries often depend on collaboration with pharmaceutical companies from developed or advanced developing countries. Many pharmaceutical substances needed for the production of anti-HIV/AIDS drugs will have to be imported, such as active pharmaceutical ingredients (APIs). To the extent that the foreign company holds a Tanzanian patent on one or more of these

substances, local producers may be interested in seeking a voluntary license from the patent holder. The terms of the license, i.e. the conditions under which the licensee may operate, are determined in negotiations between the licensor and the licensee.[43] The licensing terms are of considerable importance to the local manufacturer, as they can be more or less favourable to sustainable production. Licensors might be tempted to retain most of their protected technology and to reduce the licensee's role to the mere assembly of the product, without passing on significant know-how. Governments have limited powers to control such restrictive business practices. In general, it is up to the patent holder to decide to what extent he/she wishes to license the protected technology. However, there may be cases of abuse of IPRs, and in particular patents. The TRIPs Agreement grants Members the freedom to determine practices, in their domestic laws, which in particular cases may constitute IPR abuse, and to take the appropriate measures to control such practices (see Articles 8.2 and 40).

While the Patents Act in Section 48 lists 18 practices that may cause the responsible Government agency to refuse the registration of a licensing contract, this list does not contain all practices authorized under the TRIPs Agreement as potential sources of government intervention. Again, WTO law does not prevent the Tanzanian Government from completing the list provided under Section 48. [44]

[43] For some details on licensing negotiations, see UNCTAD Report(2006).

[44] See UNCTAD Report (2006) for details.

4. The National Market for Pharmaceutical Products in Tanzania

Several factors influence the feasibility of producing pharmaceuticals in a given country. Apart from the legal situation analysed above, the overall political situation is an important factor. Most importantly, access to active ingredients needed for the production or skilled labour and know how have an impact on the business potential. Also, the qualities of a given company, such as management, leadership within the company, assessment of market size, marketing etc, influence the feasibility and profitability.[45]

Governmental policies can have a significant impact on pharmaceutical production, such as trade policies and the efficiency of regulatory authorities. The financing of the health system as a whole is another crucial issue: no high prevalence LDC can afford to finance the treatment of all HIV infected people with ARVs. Therefore, donors play a significant role and are important actors that influence local markets or even represent a very significant parallel market.

The following factors are considered particularly important for the feasible production of ARVs in Tanzania:

1. The market must be big enough in order to reach economies of scale. In LDCs such as Tanzania the private market is usually small, but the market created by donors is significant.

2. An efficient regulatory authority. A pharmaceutical producer has to be in a position to prove the quality of its products. Ideally, the DRA supervises and advises the producers in order for them to comply with the set standards.

3. Access to investment capital

4. Enabling environment: an enabling environment is crucial for the establishment of any business. In this, case, it embraces the national drug policy, a national industrial development plan and investment strategy as infrastructure, water, electricity.

5. Qualified work force. Few, but highly qualified personnel are needed. The bulk of the work (packaging) can be done by unqualified staff.

4.1 The Market Size

In order for companies to achieve economies of scale the market must be big enough. There are no quantifiable indicators as to how big exactly the Tanzanian market has to be in order for local production to able to use economies of scale. In general, producers from LDCs face difficulties in achieving economies of scale. As they buy smaller amounts of the needed APIs, they usually pay higher prices for them. Competing companies from India and China have advantages because they already supply large markets in their home countries, can afford to buy APIs in large amounts and thus are in a position to take advantage of economies of scale.

Pharmaceutical markets in developing countries are segmented. Only a small minority of the population is insured. The majority has to pay privately for any medical treatment and medicine. There are three major buyers: chemists and medical doctors (private market), the state, and donors. The latter are particularly important in LDCs. The state and donor markets

[45] See Klaus Liebig (2006): Auswirkungen des internationalen Patentregimes auf die Medikamentenproduktion und den Zugang zu Medikamenten in LDCs. DIE, Bonn.

are attractive when it comes to large amounts of essential drugs, such as drugs against Tuberculosis, HIV AIDS and Malaria. Thus, the ARV market is attractive for producers because governments and donors purchase large amounts of ARVs over a long period of time.[46]

As outlined above, the market for pharmaceutical products in Tanzania is largely a government- and donor market. Tanzanian bidders enjoy preferential treatment when the tender is issued by the Tanzanian government. In such cases, they only have to comply with Tanzanian national standards set by the TFDA. The Medical Stores Department (MSD), in charge of the distribution of drugs, runs the tenders and gives a 15% preferential treatment for national suppliers.[47] Thus, Tanzanian producers have potentially a substantial advantage over international ones as long as the tenders are issued by the Tanzanian government and the purchase is not financed by donor money.

The vast majority of tenders are issued by international donors. Bidding for such tenders requires compliance with international standards (see Box 2). None of the Tanzanian producers complies with international standards yet. When the quality of drugs offered by the bidding firms is equal (i.e. complying with international standards), the price is the decisive factor. Chinese and Indian producers usually offer the cheaper prices, as they profit from economies of scale, often as a result of negotiations with donor financed NGOs or foundations, such as the Clinton Foundation.

Thus, an important precondition for drugs to access the donor market is the compliance with international quality standards. Achieving compliance with such standards requires extensive investments for Tanzanian pharmaceutical companies (buildings, capacity of staff etc.). Until today, not one African company has reached the WHO pre qualification status (an internally recognised standard) for their ARVs on the respective WHO list. Tanzanian producers have recognised the relevance of complying with international standards and are approaching the highly profitable donor market. As the tenders issued by international donors are very competitive, the incentives for local producers to achieve international quality standards are very high.[48] It has to be shown whether or not they will be able comply and once certified, to compete with Indian and Chinese imports.

4.1.1 Prevalence of HIV/AIDS and the National Demand for Anti Retroviral Treatment

According to Tanzania's National Care and Treatment Plan (NCTP), 2.2 million Tanzanians (out of a population of 34.5 million) above the age of 15 were estimated to be living with HIV in 2001.[49] By 2010, AIDS is expected to increase the death rate by more than 50 per cent and life expectancy to drop from 56 years to 47 years.

Only a small minority of Tanzanians (approximately 1,500-2,000 people mostly living in Dar es Salaam) can currently afford treatment with the "Highly Active Antiretroviral Therapy" (HAART), which has recently become available in the country.[50] Even though the cost of basic HAART therapy dropped to a price of currently $30 per month, or $360 per year, there

[46] See Liebig, Klaus (2006).

[47] In Tanzania domestic preference rate is 15%; viz during evaluation of financial offers 15% would be added to the financial quotations of foreign manufacturers when comparing them with the quotations of local manufacturers.

[48] Interviews with Chandra Sharma, CEO of Shelys and Ramadhan R. Madabida of TPI in Dar es Salaam, December 2005.

[49] See: United Republic of Tanzania: HIV/AIDS Care and Treatment Plan, 2003-2008. Business Plan 4.0, September 1, 2003: p. 13.

[50] See NCTP (2003): p.16.

is a substantial gap between the estimated number of people who need treatment and the few who can afford to pay for the drugs.[51]

The NCTP, drafted by the Ministry of Health with support from the Clinton Foundation, foresees to treat 423,000 people living with HIV/AIDS by 2008. In 2005 it was envisioned to treat 65,000 patients.[52] Due to the lack of number, quality and capacity of the ARV treatment sites throughout the country, only an estimated 20,000 patients were treated in 2005. The table below illustrates the comprehensiveness and ambition of the Plan.

Table 1: Highlights of the HIV/AIDS Care and Treatment Plan (cumulative numbers)

(numbers in '000s)	**2004**	**2005**	**2006**	**2007**	**2008**
Patients under treatment	16	65	151	274	423
HIV+ patients under care	65.4	260.6	604.8	1098	1692.2
Budget for drugs ($MM)	**6.6**	**25.5**	**67.6**	**138.4**	**237.1**
Total budget ($MM)	26	79.9	178.1	332.7	539.3
Certified facilities	23	78	141	204	247
Health care workers	459	1674	3632	6285	9299
Cost per patient	398	307	162	141	122

'Budget for drugs' is the largest category: US$ 237 million are to be spent over the five years of the initiative. 91% of this amount is used to purchase ARVs directly, while OI drugs and Post-Exposure Prophylaxis (PEP) for healthcare workers account for 9% and 0.1%. This includes distribution costs within Tanzania.[53]

The NCTP notes:

> Drug costs were computed using a current annual cost estimate for first-line ARVs of US$ 350 per patient, discounted 20% per year to account for expected downward pricing adjustments. It is anticipated that patients will migrate from the first-line ARV regimen to more expensive second and third lines, leading to an overall decrease drug cost per patient of about 9% annually. 2nd line treatments are patent protected and not being produced in the country or the region. The second-line regiment is assumed to start at $1,285/patient annually, again discounted 20% per year. Third-line regimens, not yet determined, were assumed to be 150% of second-line costs.[54]

The issue of patent protected 2nd and 3rd line treatments might pose a problem in the future, once the effects of the 2005 TRIPs deadline become prominent. Whereas the supply of off patent APIs will continue after 2005, that of innovative drugs, which will be needed eventually, is likely to change. Innovative drugs (such as 2nd and 3rd line treatments) may then become subject of compulsory licenses.[55] According to the CEO of TPI, compulsory

[51] Price reported at the Clinic for Sexually Transmitted and Infectious Diseases, Dar es Salaam, Feb. 2003.

[52] See: Care and Treatment Plan (2003): p. 1.

[53] See NCTP(2003): p. 16.

[54] See NCTP(2003): p. 16.

[55] See: Rovira, Joan (2006): Creating and Promoting Domestic Drug Manufacturing Capacities: A Solution for Developing Countries? In: Pedro Roffe, Geoff Tansey, David Vivas-Eugui: Negotiating Health. Intellectual Property and Access to Medicines: p. 234.

For a detailed analysis of the legal possibilities within the TRIPs agreement, refer to the UNCTAD Report (2006).

licenses will become necessary and will not be a bottleneck, as the Government of Tanzania is changing their patent legislation in order to include the necessary TRIPs flexibilities.[56]

Table 2: Cost of Drugs ($000)

	2004	2005	2006	2007	2008	Total
ARVs	6,048	17,323	38,467	64,570	89,669	216,068
Ois	388	1.498	3,535	6,186	8,927	20,535
PEP for HCW	57	47	41	37	35	217
PMPCT	59	61	63	65	67	314
Total	8,556	20,924	44,113	72,865	100,705	237,134

The figures outlined in the NCTP demonstrate that the donor and governmental market is large. So far, the drugs bought by the budget of the NCTP were imported from China and India. Depending on who funds the money, local manufacturers can participate in the tenders issued by the MSD. If it is government money, compliance with standards set by the TFDA is sufficient and thus chances for local manufacturers to win a tender are big due to the preferential treatment they are given. If the drugs are funded by a donor, US American FDA standards or European PIC-S standards have to be applied. As the majority of the drugs are funded by different bi- and multilateral donors, compliance with international standards is a crucial pre-requisite for Tanzanian manufacturers to access the national, regional and international market and stay in the market.

4.1.2 The pharmaceutical sector

To assess the capacity of the pharmaceutical sector in a given country, it is necessary to understand the complexity of drug production processes. The feasibility of domestic pharmaceutical production depends on the complexity and technological requirements of the different stages of the process of producing drugs. Joan Rovira distinguishes four categories:[57]

1. Chemical synthesis – manufacture of pharmaceutical products by chemical synthesis – the most sophisticated part of the process.

2. Fermentation – this includes the production and separation of medical chemicals, such as antibiotics and vitamins, from micro organisms.

3. Extraction – manufacturing of botanical and biological products by extraction of organic chemicals from vegetative materials.

4. Formulation and packaging – formulation of bulk pharmaceuticals into dosage forms such as tablets or syrups.

In 2000, no Developing Country had a sophisticated pharmaceutical industry (category 1). The high technological capacity required to produce APIs is concentrated in the industrialised world and a few emerging countries. India and China's emergence as generic manufacturers and major international suppliers of APIs is a remarkable trend. This was made possible by the lack of patent protection until 2005 and these countries' capacity for reverse engineering.[58]

[56] Interview with Ramadhan Madabida, CEO of TPI, December 2005.
[57] See Joan Rovira (2006): p. 234.
[58] See Joan Rovira (2006): p. 230/231.

Apart from understanding the complexity of the production process itself, it is helpful to know what type of companies are producing drugs and on what scale. In the HNP Brief of March 2005, Andreas Seiters distinguishes between four different types of pharmaceutical companies in developing countries:

1. Subsidiary companies of large multinational companies producing branded products for the local and regional market.

2. Generic manufacturers, operating globally (for example Cipla, Ranbaxy, Sandoz, Teva). Sales range from 0,5 to 5 billion US $. These companies are working increasingly with a globally integrated manufacturing strategy. Key parameters influencing investment decisions are access to main markets, costs, infrastructure, and skilled labour. Their core business is focused on developed markets in the US, Europe, and large middle income markets as India and China. Some have manufacturing operations in smaller developing countries or joint ventures with local companies. They offer a large portfolio of generic drugs at competitive prices and are capable of meeting global standards for quality – a prerequisite for their presence in the developed markets. A few of these companies have made significant investments in Research and Development and may turn into viable companies on the high value market for innovative drugs in the future.

3. Generic companies with predominantly national operations: Their main market is the country of residence, sometimes they export to nearby countries. The product range of these companies is typically based on off-patent drugs.

4. Small local companies, which produce a small scale of generic products for the national market and hardly meet GMP standards. Some of them are focussing on the informal sector, some on traditional medicine.

Some companies cut across all four categories.[59]

For the purpose of this study and in the Tanzanian context, the most interesting categories are category two and three. There are eight pharmaceutical manufacturers in Tanzania: The two largest players are Shely's Pharmaceuticals and Tanzania Pharmaceutical Industries (TPI). These two are the only producers that are relevant for this study. Others include Keko Pharmaceutical Industries, Interchem Pharma Ltd, and Mansoor Daya. There are also smaller producers such as Khanbhai, Janoowala and Mwanza Pharmaceuticals Ltd.

4.1.2.1 Shelys Pharmaceuticals

Shelys Pharmaceutical Ltd. belongs to the Sumaria Group, which started as a small family business in 1956. Today, it is one of the largest private sector Groups in East Africa. Sumaria Group has business interests in Plastics, Healthcare, Consumer Goods, Dairy and Agro-Processing, with manufacturing and distribution units in Tanzania, Kenya, Uganda, the Democratic Republic of Congo, Mozambique, the United Kingdom, Mauritius, Nigeria, Zambia, Malawi, Burundi, Madagascar, Rwanda, and Ethiopia. In East Africa, the Sumaria Group has more than 3500 employees.[60]

In Tanzania, 30% of the company's products are bought by the Medical Stores Department (comparison: in Kenya, none of the products are bought by a governmental agency). 70% of

[59] See Andreas Seiter (2005): Pharmaceuticals: Local Manufacturing, HNP Brief No 3, March 2005, World Bank, Washington, D.C.

[60] Interview with Chandra Sharma, CEO of Shelys, December 2005.

buyers are private pharmacies. Some products are exported to Kenya, Uganda, Zambia, and other countries.

Shelys Tanzania is based in Dar es Salaam. The company manufactures over 90 products in different therapeutic segments covering essential drugs that are required in the region (Pain and headache, cough and cold, anti malarials, vitamins, and antibiotics). Shelys has different manufacturing areas for both Beta-lactum and non Beta-lactum products. Beta Health Care Ltd., the leading OTC healthcare manufacturing company, based in Nairobi, is also a part of Shelys Healthcare business. According to the management of Shelys in Dar es Salaam, both plants are equipped with modern automatic equipments for both Solid & liquid orals preparations. Even though the authors could not visit any of the plans, it is confirmed in the auditing reports of BEGECA (*Beschaffungsgesellschaft für kirchliche, caritative und soziale Einrichtungen*) (see Box 1) that the production quality does not yet comply with PIC-S standards but is expected to by 2007.

According to Shelys' "Company at a Glance" paper, their future interests are in therapeutic areas like Anti Tuberculosis drugs, Anti Retroviral drugs, large volume parenterals, and Skin Preparations. Furthermore, the management is convinced that local production – regardless of TRIPs – related opportunities – is worthwhile due to the sheer market size for Malaria drugs, ARVs, TB drugs and medicines for other basic diseases affecting public health. This indicates that the company is geared towards the donor market, which will be in demand of drugs for these diseases in particular, as stated in MDG 5. It is the aim of Shelys to supply this market. As Shelys is a large market player in the entire region and has been manufacturing a number of drugs, it can be assumed that the ongoing manufacturing forms the economic basis for the investment in the manufacturing of the "essential" drugs (mainly ARVs), to be oruchased by government and donors.

Shelys' staff comprises mainly of Indian and British expatriates. Tanzanian staff is still the minority and it was mentioned by the CEO that this is a major problem. Shelys would prefer to employ Tanzanian staff, but the competency needed for pharmaceutical production is simply not available in the country. In total the company employs 800 people in Tanzania. Out of these, the majority are from India and the UK. The Tanzanian employees are unskilled and work in the packaging area, whereas the Indian and British staff is skilled.

Shelys roughly has a 50% Market share in Tanzania. They cover 400 Pharmacies, 4,000 *dukala dawas*, and 10,000 kiosks, all Government regional hospitals, referral hospitals, Pvt. Hospitals covering over 5,000 doctors. Shelys is working in a Public Private Partnership with the BEGECA, a Private Limited Company for Procurement for Church-related, Charitable and Social Institutions, supported by the German Government (see box 1).

Box 1: Public Private Partnership: Shelys-BEGECA

BEGECA procures goods and drugs for non-commercial, social, development-oriented institutions all over the developing world. It prefers to procure and distribute local products, because they are available within the region and they are often cheaper. BEGACA's main objective in East Africa is to deliver emergency aid to the crisis-affected areas in the Democratic Republic of Congo (DRC) and Sudan, but the local procurement of pharmaceutical products in this region is particularly difficult.

Despite the existence of a number of pharmaceutical manufacturers in the region, there is a constant lack of drugs that BEGECA can procure within the region. The core of the problem is the low quality and the absence of international standards of locally manufactured drugs. If the top companies in the region could improve their quality standards up to the level of PIC-S standards, the sustainable and swift delivery of drugs in the region could be improved substantially. But without international expertise, private companies will not be able to introduce and sustain such high standards.

This is the starting point of the BEGECA and GTZ public private partnership (PPP). The project supports seven selected pharmaceutical companies from Kenya and Tanzania, such as Shelys, in introducing and maintaining PIC-S standards in order to get access to international pharmaceutical markets. Shelys benefit through the Public Private Partnership project through regular inspections and trainings. After each inspection, the international inspectors who audit the production plant in Dar es Salaam once a year, using a regular cGMP checklist, hand over a list of issues that need to be improved in order to fulfil the standards. This list includes issues like required staff training or other investments.

As only companies who fulfil international standards are eligible to participate in international, donor-financed tenders, compliance is an important opportunity. Therefore, the perspective of compliance in itself is an incentive for a local firm like Shelys to participate in the project and finance the necessary improvements and investments in its company. For BEGECA, who finances the inspections, the benefit is that in the future they will be able to procure drugs in the region and thus avoid transport costs and delays. Finally, GTZ's PPP facility, which is partially financing the undertaking, has the objective to support the development of a sustainable pharmaceutical industry and improve the availability of essential quality drugs in the region.

Accordingly, expected impacts of the project include the access of local manufacturers such as Shelys to the non-profit pharmaceutical world market. Furthermore, Tanzanian and Kenyan GMP inspectors are enabled to support local manufacturers in maintaining the achieved standards, and NGOs active in health projects in the region will establish ways to sustainably procure affordable high quality drugs in the region.

In order to comply with the increasing market demands and international regulatory requirements, Shelys is building a new manufacturing plant in Dar es Salaam. The new plant, where ARVs will be produced, is built according to International Standards to meet the WHO-cGMP, US FDA and European PIC-S guidelines. It is the first plant in East Africa to use the latest European standard Modular Clean Room Panels against the conventional Brick walls. According to external auditors, Shelys will be able to comply with PIC/S standards by 2007.

4.1.2.2 Tanzania Pharmaceutical Industries (TPI) [61]

TPI is located in Arusha, in northern Tanzania. Founded in 1980 by the Tanzanian government, TPI was privatized in 1997, and is now owned by Tanzanian entrepreneurs as well as Tanzanian Investment Funds. The company produces a number of different products, ranging from aspirin to mouthwash, Allergy and Cough Syrups to medical kits (see table 3).

TPI is using a fixed-dose combination of three antiretroviral drugs developed by Thai pharmacist Krisana Kraisintu, who has already successfully transferred her technology to "Pharmakina", a pharmaceutical factory in Bukavu, in the DRC. TPI received the ARV production and marketing authorization for two fixed-dose combination products from the TFDA in December 2005. The applications for two additional ARVs are still being processed.

According to TPI, the production of ARVs has started last year and is ongoing. Before the production could start, the production plant had to be upgraded in order to be feasible for ARV production. This cost about US$ 1 million, including the capacity building of staff. The production plant in Arusha is considered to be one of the largest in the country. However, when the plant was visited at the end of January 2006, production was not ongoing. The quality of the current production, which re-strated after the visit, has not been assessed yet. The impression ist that a number of steps still need to be put in place before TPI complies with international GMP standards.

TPI, like Shelys, can be positioned between company type three and four. As a limited liability company TPI was incorporated in 1976 as a Government owned company. Production started in May 1980 originally under a Management Contract with "Ms Orion-yhtyama Oyi" of Finland and later under the management of National Chemical Industries (NCI). TPI was closed in 1994. In March 1997 the company was privatised and 60% of its shares were sold to a consortium of local Tanzanian entrepreneurs. The remaining 40% are owned by the government (see below).

Since privatisation, TPI's capacity utilization has doubled, the cost of production has been significantly reduced and the prices have come down. The table below is taken from TPI's business plan and illustrates the production performance of existing production lines (excluding injectables) on a single shift basis before and after privatisation.

Table 3: Average Production p.a. pre and post Privatisation

Products	**1983 – 1993 (Pre-Privatisation)**	**1998 – 2003 (Post-Privatisation)**
Tablets	141,738,000	695,981,830
Capsules	7,200,000	24,846,667
Syrups and Suspensions (100ml bottles)	80,950	1,947,500

TPI also has the vision to become a *Centre of Pharmaceutical Excellency*, not only in manufacturing quality and affordable medicines, but also in the acquisition and dissemination of knowledge and capacity building of regional expertise. This has not been specified or implemented yet but would be a very important initiative, given the current skills shortages.

[61] All information on TPI is based on interviews with TPI representatives, Dr. Krisana Kraisintu as well as the unpublished "Corporate Plan" by TPI. Furthermore, Action Medeor, in accordance with TPI, made available external auditing reports of TPI 2002-2005.

Options mentioned include building up linkages with pharmaceutical schools, university faculties, offer students on the job training, etc.

TPI formulates manufactures and markets pharmaceutical products. It imports the APIs, in particular those needed for the manufacturing of ARVs, from China, India, Vietnam and Europe and converts bulk pharmaceutical raw materials into tablets, capsules, syrups, etc. TPI has signed a Memorandum of Understanding with a Chinese company who will provide them with APIs for the next five years. The MoU covers the price, general collaboration, and the training of TPI employees. TPI is even planning to send staff to partner company, "Mchem", be trained in China.

The same Chinese company has just signed an agreement with the Clinton Foundation on the delivery of ARVs.[62]

TPI's marketing strategy targets the drug needs for Malaria, HIV/AIDS and Tuberculosis. At the moment, the company offers one dose per patient per month for US$ 20.[63] TPI is also aware of the Global Fund for AIDS, Tuberculosis and Malaria (GFATM), which might have influenced their decision to focus on drugs for these three diseases. Thus, drugs to be produced include antiretroviral and anti-malarial drugs, antibiotics and cephalosporines, in solid, liquid and injectable forms. As the financial performance of TPI has improved substantially over the past four years (see section below), without manufacturing and marketing ARV, it is assumed that those drugs that are not classified as "essential", i.e. not targeting HIV/AIDS, Malaria, and Tuberculosis, still form the backbone of TPIs production and provide the largest profit margin.

TPI is fully aware of the implications of the TRIPs agreement. The interest of the international donor community in local manufacturing of essential generic drugs is well known to the management. Thus, it is planned to actively participate in National Health campaigns such as the Malaria Control Programme and HIV/AIDS awareness campaigns.

There is an interest to export drugs to countries like Mozambique, Rwanda, Malawi, Zambia, Burundi and Democratic Republic of Congo. However, it is doubtful that the regulatory authorities of these countries will accept the quality of the imports, as they don't comply with international standards. Also, authorities in neighbouring countries might offer a preferential treatment to national suppliers.

The company has obtained substantial loans from Financial Institutions and Investments from two pension funds: the public service pension fund and national social security fund. A loan for working capital was obtained from Barclay's Bank. The governmentally sponsored loans could lead to a dependency that might not be desirable in the long run.

TPI have entered into a Technological Transfer Agreement with Dr. Krisana Kraisintu from Thailand. As mentioned above, Dr. Kraisintu had also successfully transferred her technology, i.e. her formulation for the manufacturing of ARVs, to Pharmakina in Bukavu, DRC. TPI and Dr. Kraisintu have agreed to co-operate and to transfer knowledge and know-how and all other information necessary, to support TPI in the production of ARVs. The cooperation is meant to include a practical training programme for TPI in areas of production and quality assurance over the next five years. Action Medeor, a German non-governmental organisation (NGO), has committed Euro 34,967 to partly meet the annual expenses for this cooperation. Furthermore, Action Medeor is planning to build up a GMP complying production plant for ARVs – including 2nd line treatments – in cooperation with TPI. This project is to be financed by an EU grant. The entire project is planned to be implemented

[62] Interview with Ramadhan Madabida, CEO of TPI and Krisana Kraisintu, technical advisor to TPI, 13th of January 2006.
[63] Interview with Ramadhan Madabida, Chief Executive Officer of TPI, in December 2005.

within 30 to 48 months, starting in December 2006. Dr. Krisana Kraisintu is supporting the project as a technical consultant.

4.1.3 Financial Performance

In the last years the company constantly had around 20% of its funding from shares outstanding. Around 30% of its income is held as reserves. TPI has issued preferable shares to augment its internal funding. As of November 2002 Public Service Pension Fund (PSPF) owns 1,500 million Tanzanian Shillings (TZS) preferred stock. 4,357.5 million TZS shares of preferred stock were purchased by the National Social Security Fund (NSSF) in July 2004. Thus, in 2004 the company increased the volume of preferred equity by 200%. The two governmental funds are also involved in granting two important loans in 2003 and 2004.

According to the 2002 annual report, the company went through a modernization process in 2001/2002. In both years TPI suffered severe losses and had to secure working capital for 2002 through a loan. In 2001 and 2002 TPI used external funds, a rehabilitation programme loan and the already mentioned working-capital loan to secure the financing of the modernization. Since it issued preference shares in 2004 the financing of the expansion was shifted towards internal funds.

The number of staff increased from 21 in 2001 to 81 in 2004 in order to meet production goals.

The analysis of TPIs financial performance shows that TPI was not profitable until 2002. Cost of modernization and debt from previous years led to an increase of indebtedness and high accumulative losses. But from 2003 onwards, TPI became increasingly profitable, accumulative losses slightly decreased and return on equity increased.

A four year survey is a very short time to evaluate TPI position, especially lacking a real benchmark to compare TPI with. But from the numbers given, it seems that the current expansion and modernization might lead to higher returns in the future.

4.1.4 Distribution Channels

The procurement and distribution of drugs to the hospitals and treatment sites is organised by the Medical Stores Department (MSD). The MSD is the main distribution channel for imported and locally manufactured drugs in Tanzania. It was created by an act of Parliament in 1993 with the objective to distribute good quality drugs and medical equipment throughout Tanzania.

Tanzania has a relatively well-developed basic healthcare delivery system. It is 61% government owned, with the remaining 39% run by NGOs, parastatal organizations, voluntary agencies, and the private sector. There are approximately 5,000 healthcare facilities, geographically distributed. 70% of the population live within five km of a facility and 90% within 10 km.[64] Services are organized on three levels, with six tertiary hospitals providing the most comprehensive care and predominately serving as referral hospitals. The secondary level consists of regional hospitals, while the primary level consists of dispensaries, health centres and district hospitals. Administratively, the health system is largely decentralized. The Ministry of Health has direct responsibility for the referral hospitals, and regulatory power over all health facilities, but facilities are independently run by the region or district. Zanzibar is administered independently.

[64] Ministry of Health (2002): Health Sector HIV/AIDS Strategy for Tanzania, 2003-2006. February 2002: p. 5.

Increasing HIV prevalence imposes pressure on the capacity and efficiency of Tanzania's healthcare system. The average HIV positive adult in Tanzania has an average of 17 illness episodes before death, leading to healthcare costs per patient which can be twice the Tanzanian GDP of US$478 per capita.[65]

As an autonomous department of the Ministry Of Health the MSD is supposed to operate on a commercial basis. It is responsible for its financial sustainability. MSD management reports to a board of trustees (BoT) composed of public servants, medical professionals and business people. MSD's commercial operations ideally provide funds sufficient for the maintenance and growth of the department without drawing upon outside resources.

MSD is in charge of maintaining and managing an efficient and cost-effective system of procurement, storage and distribution of approved essential drugs and other medical supplies required for use in Tanzania. It manages the whole drug supply chain. Order fulfilment levels are averaging 86% of ordered goods.

MSD advertises tenders for specific medical products and quantities and works in collaboration with the TFDA in verifying that all medical products selected, imported and sold are compliant with the laws and standards applied by the TFDA and the respective purchaser. How this cooperation and operationalisation is implemented in practice could not be analysed. Bids are received at a public meeting and further evaluated by MSDs Directorate of Pharmaceuticals and Technical Services. All decisions for final purchase and awards of contracts are made by the Medical Tender Board, which is usually attended by the Pharmaceutical Board, and MSD Management.

Upon approval of the bids, MSD's Directorate of Pharmaceuticals and Technical Services proceeds to contact the supplier and establish the parameters of the agreement including timing of deliveries, payment and delivery guarantees and once again verification of specifications and compliance. Upon receipt of goods at MSD, the product is stored in the central warehouses in Dar es Salaam and eventually brought to zonal warehouses or delivered in some cases directly to the health facilities. How smooth this process is in reality could not be found out. Due to the general infrastructure related problems of the country and the region, it can be assumed that there might be difficulties in transporting or refrigerating the drugs. None of the warehouses was visited, so that an assessment of their quality was not possible within the context of the present study.

MSD's network consists of eight zonal stores and a central office and warehouses in Dar es Salaam. Each zone is supposed to have all required facilities to handle all types of items including cold chain items. Again: to what extent the zonal stores are operational could not be verified. It is however assumed that there might be problems regarding the weak infrastructure, including lack of electricity, bad roads, lack of water supply, etc. which might prove as a challenge to warehouse operators and other actors in this process. Infrastructure related aspects are discussed in chapters 4.3 and 5.

4.2 Regulatory Authority

Manufacturing of pharmaceutical products is regulated by international standards. International standards are a pre-condition for worldwide trade with pharmaceutical products. National bodies (Drug Regulatory Authorities – DRAs) are responsible for licensing the production of medicines, controlling ongoing production and if necessary, the withdrawal of licences. They often face conflicting pressures by local and international industrial players and health policy makers.

[65] UNAIDS: Tanzania Country Report. NCTP: p. 15.

International standards include the "Good Manufacturing Practices (GMP) for medicinal products" of the EU, the "Code of Federal Regulations" of the American FDA and the "Pharmaceutical Inspection Convention" (PIC, see Box 2). All of them give recommendations. The producers themselves are responsible for the implementation of these recommendations. The national regulatory bodies inspect the producers on a regular basis and enforce the compliance with the international or, depending on the respective regulations, national standards. As will be discussed below, the Tanzanian DRA applies national GMP standards, which do not comply with international standards. In addition to that, the Quality Assurance Departments of producing companies conduct their own internal audits.

Box 2: Good Manufacturing Practices (GMP) and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S)

The WHO defines **Good Manufacturing Practices** (GMP) as "that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation".[66] GMP is a regulatory framework to ensure the correct manufacturing of pharmaceutical products.

The Pharmaceutical Inspection Convention (PIC) goes further. It aims at the mutual recognition of inspections, harmonisation of GMP requirements, uniform inspection systems, training of inspectors, exchange of information and mutual confidence. **The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S)** are two international instruments between countries and pharmaceutical inspection authorities, which provide together an active and constructive co-operation in the field of GMP. PIC/S aims at improving and harmonising GMP standards by focusing not only on the product, but on the entire process, including the capacity of the inspectors. It includes developing and promoting harmonised GMP standards and guidance documents, training competent authorities (in particular inspectors), assessing inspectorates and facilitating the co-operation and networking for competent authorities and international organisations. The purpose of PIC/S is to facilitate the networking between participating authorities and the maintenance of mutual confidence, the exchange of information and experience in the field of GMP and related areas, and the mutual training of GMP inspectors.

Drug Regulatory Authorities (DRAs) in Developing Countries are often described as weak and inefficient, sometimes even corrupt. In Africa, there is no DRA that effectively applies international inspection standards (i.e. WHO GMP standards or the standards of Industrialised countries, such as PIC/S). Both, regulators and manufacturers of drugs need to be supported in order to comply with international standards (Good Manufacturing Practice – GMP, PIC/S etc.).

The WHO is undertaking various measures to build capacity for international standards in good manufacturing practice, laboratory practice and in regulatory competence in order to create consensus on quality standards, which can be used by countries as a benchmark for their registration procedure.[67] Because of the strict interpretation of Article 39 of the TRIPs Agreement by the USA and Europe, access to the innovator's drug dossier is postponed by

[66] WHO Expert Committee on Specifications for Pharmaceutical Preparations (1992): Good Manufacturing Practices for Pharmaceutical Production. Technical Report Series No. 823. Annex 1. WHO Geneva.

[67] DFID Health Systems Resource Center (2004): Access to medicine in under-served markets, September 2004.

five years (US) and 8-11 years (EU).[68] Drug regulatory agencies therefore cannot rely on previously submitted data to assess the safety and efficacy of generic substitutes, which might prevent registration of drugs in a country.

Ignoring international standards in the medium or long term cannot be in a country's interest. To assure a certain quality of drugs and therefore require minimum standards is essential for the sake of people's health – independent of a country's level of income. DRAs are of essential importance to the development of the national pharmaceutical sector, since transparent regulatory systems are a precondition to reduce the unofficial supply of drugs and efficient processes of drug approvals are important to guarantee rapid delivery of drugs. 50% of the drugs provided in Kenya are assessed to be unofficial (substandard or illegal). In Tanzania and Uganda numbers are expected to be slightly lower. Proving quality of national products is furthermore important with regard to exports. Effective and efficient DRAs are therefore of high importance for a country's reputation and the marketability of its drugs.[69] The DRA should therefore not only inspect, but also – without compromising their independence - give feedback to producers so they can gradually improve quality.

As discussed in more detail in chapter 5, one of the problems in the East African Community is the fact that each member state has their own DRA and their own national standards. Thus, each new drug has to be approved by each DRA. In addition to this, extensive boarder controls pose a severe obstacle to trade.

In Tanzania, the TFDA is an independent regulatory body. Its registration office has to register all drugs, locally manufactured and imported ones. It is recommended to have an in-depth evaluation of the TFDA. This evaluation can be used by TFDA to improve its performance.

According to the TFDA itself, it has taken deliberate initiatives to assist local manufacturers in the production of quality essential drugs. To encourage local producers to improve the quality of their products, several workshops were held. The latest one, held in 2005, agreed on a national GMP action plan to be implemented by producers and supervisors. The agreement was that at the end of June 2005, the facilities complying with national GMPs will be fully registered. According to the TFDA concept paper, four pharmaceutical producers have complied with these GMP requirements in some of their production lines. Shelys reaches the national GMP standard at their Penicillin Plant, Keko (Penicillin Plant), Intechem-Moshi, and TPI-Arusha. The concept paper does not give information on the question of which production lines are registered.[70]

The TFDA's inspection of TPI's ARV production took two days. According to the TFDA and TPI, the inspectors applied Tanzanian GMP standards. TPI received a licence to produce ARVs. According to the interviewees at the TFDA, these GMP standards represent "minimum standards". As mentioned above, the production of ARVs by TPI was not ongoing in Arusha in January 2006, so that it is not possible to give any assessment of the quality of production. Clearly, the registration of ARVs has a priority in Tanzania and there might even be political pressure to foster local production.

The Government of Tanzania's National Medicine Policy of 2006[71] emphasises the need for efficient quality assurance. It foresees to establish a quality assurance system "to ensure that

[68] WTO TRIPs Agreement: Protection of undisclosed information, paragraph 3, Section 7, article 39;.

[69] This includes the application of guidelines, checking lists, standardized procedures for evaluation and application, quality manual, etc.

[70] TFDA Concept Paper of 2006. Unpublished document.

[71] United Republic of Tanzania, Ministry of Health and Social Welfare (2006): The National Medicine Policy. Tanzania Mainland.

medicines reaching the patient are safe, effective and of acceptable quality". According to the policy, the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce will apply in importing and exporting of medicines. Furthermore, the policy aims at strengthening the National Medicines Regulatory Authority (the TFDA). Other aspects of the policy in the field of regulation include:

- The establishment of Medicines Quality Control Laboratories
- The utilisation of "Accredited Regional Quality Control Laboratories"
- The enforcement of GMP regulations
- Strengthening of a market surveillance system at all levels of supply chain of medicines and related supplies
- The establishment of "a system aimed at preventing infiltration of substandard and/or counterfeit medicines in Tanzania"

The existence of the policy demonstrates how important the pharmaceutical sector is for the Tanzanian government. To what extent the individual activities can and will be implemented as part of an action plan remains to be seen. Where possible, wanted and considered sensible, stakeholders including donors, should support TFDA in its implementation. However, not all of the proposed activities are in line with other policies. It is essential to coordinate such activities in order to ensure the coherence of individual policy approaches, especially when it comes to demanding subsidies like soft loans and guarantee schemes for the promotion of the sector. Experience shows that for example targeted lending is not sustainable (see Chapter 4.3).

To conclude, Tanzanian regulatory authorities appear to be relatively strong. Whether or not the TFDA is stronger or more independent than in other countries in the region is hard to tell. It is obvious that there is still a lot to do. The overall positive picture derives from the fact that interview partners as well as the leadership of the TFDA (as illustrated by the concept paper) have a clear picture regarding the core problems, including the capacity of regulators and producers. If the TFDA wants to cooperate with all involved stakeholders, the producers in particular, but possibly also the donors, this cooperation could develop high leverage and be an important step in the right direction.

4.3 Access to Finance

Access to finance is an obstacle often mentioned when it comes to the economic development of any sector. Whereas the very small enterprises and economically active poor households often can be served by Microfinance Institutions (MFIs), the medium enterprises lack adequate access, as they need much higher loans for big investments and on a longer term. In East Africa, as in most other regions, start up capital is more difficult to access than working capital, as banks usually percieve start ups as high risk undertakings. Therefore, the investment capacity of medium enterprises is limited. However, this shortcoming can and should not be addressed by subsidised or any form of targeted lending, as demanded in a TFDA concept paper on local production of pharmaceuticals. Targeted lending approaches have failed in the past and would undermine the repayment morale in all sectors as well as any sustainable development of the financial sector in the country. The problem can only be addressed in a holistic and systemic approach, i.e. by strengthening the financial system as a whole. Any approach in this direction has to be coherent with policies aiming at the development of the financial sector.

The rationale of the TFDA concept paper is to encourage local investments by "harnessing locally available finances and to facilitate availability of capital for entrepreneurs involved in the manufacture of pharmaceuticals". The expectation of the authors of the concept paper is further that Government should issue guarantees for seed capital and expansion capital to industries manufacturing drugs. The understanding is that this would enable local industries

to expand and acquire new technologies in the country. Furthermore, the paper suggests that the Government should subsidize up to 5% of the interest charged by banks lending to pharmaceutical industries. As mentioned above, experience in various countries suggests that the finance sector needs to stay independent of governmental policies. Banks are profitable private businesses and should not be influenced by such directive policies. The subsidisation of interest rates is not recommendable, as it undermines the repayment morale of borrowers of all sectors. Financial services relevant for pharmaceutical producers are identical with those for other Small and Medium Enterprises (SMEs) who lack access to adequate financial services as well.

Subsidised and directed lending is not sustainable. Banks only offer such credit lines to specific sectors, if Government forces them to and in some cases, if Government finances the credit lines. Thus, profit oriented private banks are likely to withdraw from the subsudised sector and leave it to state-owned banks. Such a development undermines the growth of a sustainable financial sector. State interventions can also influence credit granting technologies of financial institutions: these credits are often granted on the basis of the respective sector or other factors that are not related to the business perfomamce (management, profotability) of the respective enterprise. If directed and subsidised creit lines were introduced in the pharmaceutical sector, other sectors, agriculture in particular, would be expecting similar measures. Furthermore, directed credit lines financed by Government, are taken from the budget of the country. Thus, funds are not available for other, more important tasks of the state.

A major structural bottleneck that destroys all incentives of banks to lend to SMEs is the availability of risk free and profitable treasury bills issued by the Central Bank. A Treasury (T -)Bill is a debt instrument issued by the Government in exchange for (mainly) Commercial Banks lending it money. T-Bills can be negotiated and traded freely in the market or rediscounted at the Central Bank as a last resort. The Central Bank may sell Treasury Bills on behalf of the Government, with a view to transferring spending power from the public to the Government. The advantage of this approach is that it becomes unnecessary for the Central Bank to print additional money to finance Government expenditure, thereby greatly reducing the inflationary effect of financing the government deficit. T-Bills are secure (risk-free), transferable and negotiable. They can be pledged as collateral and their rate of return is competitive. Any Commercial Bank can buy treasury bills sold by BoT, a rsik free and very profitable investment, much more attractive than investing in entrepreneurs of a given sector. To tackle this problem, the related macro economic issues need to be addressed.

For more details on the approach to Finance see the Finance Sector Concept of the BMZ.[72]

4.4 Enabling Environment

The overall political environment in Tanzania is stable and conducive. Trade related barriers are highly relevant, as active ingredients and machinery have to be imported. Transport costs, import taxes, electricity costs and other aspects related to a weak infrastructure are crucial for the production costs. The costs for setting up a business (administrative regulations, water, electricity,…) are very high. Obstacles related to trade and the weak infrastructure in the entire region are analysed in more detail in chapter 5.

The Tanzanian National Strategy for Growth and Reduction of Poverty (NSGRP), the framework for poverty reduction in Tanzania, addresses health issues. It is divided into three clusters: 1. growth and reduction of income poverty; 2. improvement of quality of life and

72 http://www.bmz.de/de/service/infothek/fach/konzepte/Finanzsystementwicklung.pdf#search=%22sektorkonzept%20Finanzsystementwicklung%20BMZ%22

social well being and 2. good governance. The health sector falls predominantly under cluster 2.

The Tanzanian government has recognised the significance of pharmaceutical production in the country. The National Medical Policy (NMP) of 2006, which is an integral part of the National Health Policy (NHP), aims at reducing the country's dependence on imported essential drugs to 50% (currently, 80% are imported). The goal of the NDP is to make quality essential pharmaceutical products available at affordable prices. Thus, the government seeks to provide an enabling environment for pharmaceutical manufacturers in the country.[73]

The TFDA has also developed a concept paperon the issue of local production of pharmaceuticals. Whereas it entails all major issues, it also stresses some areas that should be handled with care. The reference to targeted lending needs to be questioned in particular (see 4.3).

4.5 Qualified Work Force

There is a general lack of highly skilled human resources in Tanzania. The capacity and number of professional staff is very low, professionalism is only skin deep. There is a high demand for the development of local capacity (management as well as technical). However, according to some interview partners (Shelys and TPI), the need for highly qualified people is limited as the bulk of work (packaging) can be done by unqualified staff.

In 2002, Tanzania had 365 pharmacists or one pharmacists per 100,000 inhabitants (in Germany, there are 47,956 pharmacists or 580 per 100,000 inhabitants).[74] As in other sectors, the need for adequately trained human resources is a pre-requisite for the provision of reliable, professional and responsive pharmaceutical services. This includes staff with secondary education as well as tertiary education.

There is need for an increase in the number of pharmacists. This can be achieved by increasing the number of training institutions and by improving education in general. The National Medicines Policy quoted above addresses this issue and aims at developing adequate and competent human resources for its successful implementation. In its action plan, the NMP claims that "necessary steps will be taken to ensure that a sufficient number of pharmaceutical personnel are trained, recruited, deployed, developed and retained in the health system". Furthermore, "Public and private training institutions will be promoted and supported to ensure the production of adequate and suitably qualified pharmaceutical personnel".[75] If these ideas are taken up and implemented, it would be an important step in the right direction. Private entrepreneurs, such as Shelys and TPI as well as donors can contribute to this initiative.

[73] The United Republic of Tanzania, Ministry of Health and Social Welfare (2006): The National Medicine Policy (NMP). Tanzania Mainland.

[74] See: http://www.who.int/whr/2006/annex/06_annex4_en.pdf

[75] See: NMP

5. Regional Markets

Together with its neighbouring countries Uganda and Kenya Tanzania forms the East African Community (EAC). The Treaty for the Establishment of the EAC was signed in November 1999 and ratified in July 2000. The EAC Customs Union (EACU) Protocol is being implemented since January 2005. By 2010 the EACU will be fully fledged providing a common (3-band) external tariff to importers from third countries and no internal tariffs among the Partner States. Rwanda and Burundi are expected to join the EAC by end 2006.

The general WTO-Council's decision of 30th August 2003[76] provides special conditions for customs unions, which are composed of LDC members by majority. This is the case for EAC since Tanzania and Uganda (and also Rwanda and Burundi) are LDCs.[77] Paragraph 6 (i) of the decision forms a temporary waiver, which is valid until the TRIPS agreement is changed respectively[78]: One compulsory license is effective for the whole EAC. Once one EAC Partner State got a compulsory license, the generic drug can be exported within the EAC region, given it is consistent with the patent law of the importing country.[79]

Taking advantage of these regulations, from an economic point of view, the question still remains whether there is a competitive advantage for Tanzania in producing generic drugs at all – particularly towards other countries in the region.

The production of generic drugs is more efficient the longer the patent on the original drug is valid. Tanzanian producers of generic drugs could set their prices in the area between marginal costs and monopoly price. However, many essential drugs against HIV/AIDS (except ARVs of second generation) are already patent free. Developing countries, which are not classified as LDCs, like Kenya, can also produce them.[80] Non-LDCs are also allowed to produce patented drugs approved before 01.01.1995.

Because of its small market Tanzania's local production would be much better off using the opportunity of the regional EAC markets to exploit economies of scale. Missing economies of scale cause high marginal costs. The following chapter considers the potential trade volume of pharmaceutical goods in the East African region and analyses whether there are opportunities for export of ARVs from Tanzania to neighbouring countries. Because of their EAC-membership the analysis mainly focuses on Kenya and Uganda. Rwanda, Burundi, the DRC and Sudan are also taken into consideration.

5.1 Prevalence of HIV/AIDS and need for ART

Prevalence of HIV and therefore the need for Anti Retroviral Treatment (ART) is high in East Africa. Adult prevalence rates (15-49) range from around 6% in Uganda to around 11% in Tanzania (in 2004).[81]

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[76] See: WTO (2003): Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health – Decision of 30 August 2003. WTO Document WT/L/540, 2.9.2003.

[77] All five countries (Burundi, Kenya, Rwanda, Tanzania, Uganda) are WTO members.

[78] In December all WTO members agreed to include this exception into the TRIPS agreement as a new article 31. To make this new article come into force, parliaments of 2/3 of all members have to ratify the article by 01.12.2007. Before December 2007 the exception is automatically in force.

[79] If the importing country issues patents on drugs and a patent is registered on the respective drug, a different compulsory license is required.

[80] This counts even more for drugs against TB and Malaria.

[81] Data from WTO country profiles.

In ***Uganda***[82] in 2003, 350-880,000 people (0-49 years) were living with HIV/AIDS. The reported number of people receiving ARVs (15-49 years) was 63,896, of whom 10,600 were receiving free treatment via the Ministry of Health. WTO/UNAIDS assumed that treatment for 114,000 people was needed in 2004. The unmet need therefore concerns around 50,000 people.

By the end of 2004 the estimated number of people (15-49) living with HIV/AIDS in ***Kenya*** was 1,59 million. At that time treatment for 233,831 people was needed.[83] Only 38,000 people were provided with ARVs by June 2005, leaving an unmet demand of around 200,000 people in Kenya.

The number of HIV/AIDS patients in ***Rwanda*** was around 170,000 to 380,000 by 2003. Out of 39,000 people needing ARVs around one fourth (10,346) was receiving ART by the end of 2004.[84] The Rwandan government, supported mainly by the Clinton Foundation and the Global Fund (3rd round) has very ambitious plans to increase the number of treated people. However, since especially the prevalence rate in the rural areas continues to rise, the unmet need for ARVs in Rwanda can be assessed by over 30,000.

With about 170-370,000 people infected in ***Burundi*** the number of people in need for ART rose to 40,000 in 2004.[85] Only 5,050 people were estimated to receive treatment by that time, mainly by nongovernmental organisations. Despite the Global Fund's proposal (1 grant) and the government's ART targets of 25,000 by 2006, there is still an unmet need of 20-30,000 people in Burundi.

Particularly for ***Southern Sudan*** the HIV/AIDS prevalence rate is difficult to assess.[86] The estimated number of people living with HIV/AIDS in 2003 ranged from 120,000-1,300,000. Assessed need for ART at that time was 43,000 people. Only an estimated 400 people are receiving antiretroviral therapy, mostly through the non-public sector. This includes 100 people receiving antiretroviral therapy from military hospitals. The Global Fund is expected to provide ART to around 500 people. The government of Southern Sudan committed to provide ART to 40,000 people by the end of 2009. Because of the difficult circumstances in Southern Sudan there will still be an unmet demand of about 30,000.

The number of people living with HIV/AIDS in the ***DRC*** is estimated to be around 430,000-2,600,000 with 167,000 people in the need for ART.[87] The Global Fund, the World Bank and some bilateral donors support the national strategic plan including provision of ARVs. There is still a gap of unmet need of 80,000 people.

In order to identify the current and future regional unmet demand for ARVs, one has to take into account both changes in the prevalence rate (e.g. through increased or decreased protection or deaths) and in the provision of ARVs (through the Global Fund, local production and competitive international producers). According to currently available data unmet demand ranges from 200-300,000 in Kenya and Uganda without Tanzania and 400- 600,000 Kenya, Uganda, Rwanda, Burundi, DRC and Sudan respectively.

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[82] See: WHO: http://www.who.int/countries/uga/kn/rw/en/.

[83] See: WHO: http://www.who.int/countries/ken/en/.

[84] See: WHO: http://www.who.int/countries/rwa/en/.

[85] See: WHO: http://www.who.int/countries/bdi/en/.

[86] See: WHO: http://www.who.int/countries/sdn/en/.

[87] See: WHO: http://www.who.int/countries/cod/en/

5.2 Current drug market in the region

In East Africa the pharmaceutical industry is still at a very low stage of development. There is a big disparity between the three East African countries on the level of development in the pharmaceutical industry. Kenya is at the forefront in the number of established industries and has other supporting industries such as packaging, printing, pharmaceutical active ingredient wholesalers etc. While Kenya is the main exporter of pharmaceuticals into Uganda and Tanzania, the local Kenyan pharmaceutical production can only meet 30-35% of the national demand. In Uganda and Tanzania local production meets around 10% of the respective country's demand. Around 70% of drugs consumed in the region are imported from 3rd countries.

The five biggest producers of pharmaceutical goods in ***Kenya***[88] are Cosmos Ltd, Regal Pharmaceuticals Ltd, Elys Chemical Industries, Infusion Kenya Ltd and Universal Corporation Ltd. It is very difficult, however, to estimate their market share, since all of them keep information confidential. Currently only Cosmos Ltd (under voluntary license from GSK and Boerhinger) is producing ARVs, including ARV second line drugs like Coortem, Gancyclovir, Vancyclovir, etc. Universal Corporation is also planning to produce ARVs in the near future. Active ingredients are mostly imported from India. The main importers of ARVs into the Kenyan market are GSK, Philips Pharmaceuticals and Lords Care Ltd.

ART is mostly provided by the public sector (Kenya Medical Supply Agency). In 2005 only 8,000 people out of 38,000 are being treated through private facilities (private companies, hospitals and practitioners). For further 7,000 people drugs are planned to be purchased by the Global Fund.[89]

The 4-5 producers of pharmaceutical goods in ***Uganda*** are Kampala Pharmaceutical Industry, Rene Industry, Uganda Pharmaceutical Industry, Medipharm and Nec Health World – a Joint Venture/ government cooperation, which is not licensed yet, but is assumed to become the biggest producer in country. Currently none of them is producing ARVs. Kampala Pharmaceutical Industries plans to produce ARVs in the near future. For similar reasons as in Kenya, there is no data available about market shares. The biggest importers of ARVs into Uganda are, GSK, Cadila, Sanofi Aventis, Emcure and Rambaxy. APIs for essential drugs other than ARVs are mainly imported from China and India, but also from the DRC (Quinine, produced by Pharmakina).

Until 2004 ART in Uganda was largely confined to nongovernmental organisations, commercial providers and research and pilot projects. With the announcement of the government initiative to provide free treatment to people living with HIV/AIDS in 2004 the situation changed. Similar to Kenya, now private suppliers provide 20% of the drugs in Uganda, while National Medical Stores (for all Public/Government institutions) and Joint Medical Stores (for Christian aided health units and Government institutions) are assumed to supply around 80%. Among the private sector some companies provide antiretroviral therapy for employees[90]. Like in Tanzania, the awareness of TRIPS in Uganda is still rather limited;[91] so are the problems Ugandan factories are facing (lack of qualified staff, difficulties in meeting international standards).

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[88] In total there are 37 producers of pharmaceutical goods (anti-malarial, antibiotics, essential medicine, ARV) in Kenya.

[89] See: WHO country profiles.

[90] See: WHO country profiles.

[91] "TRIPS has not yet affected us", states a representative of the Ugandan National Drug Authority. Interview with Zaidi Mwondha at the WS on Pharmaceutical Production in Eastern Africa in Moshi, 30.01.-02.02.06.

One reason for the relatively advanced pharmaceutical industry in Kenya refers back to the political situation in the region in the1960s and 70s. While the pharmaceutical industry was pushed in Kenya by governmental incentives, Tanzanian private sector development was of little important to the socialistic regime and Uganda's dictator Idi Amin expelled Asian business people from the country. High cost and erratic supply of utilities like water and electricity hamper the development of the pharmaceutical sector in Tanzania until today. The cost of electricity in Tanzania is the highest in the SADC region. The supply of water is not reliable; its quality fluctuates periodically and in most cases does not meet drinking water standards.

The only pharmaceutical production plant in ***Rwanda***, Labophar, an autonomous unit under the Ministry of Health, does not produce ARVs. The Centrale d'Achat des Médicaments Essentiels du Rwanda (CAMERWA), a central autonomous body, is responsible for drug procurement and holds a monopoly given by the Rwandan Government for importation of ARVs for the public and the private sector. The provision of antiretroviral therapy is supported by ESTHER (Ensemble pour une Solidarité Thérapeutique Hospitalière en Réseau), Médecins sans Frontières, the United States Agency for International Development (USAID) and the Clinton Foundation. The population has access to ARVs in Rwanda through registered treatment sites[92] and is charged according to the household's income.

There is also no local production in ***Burundi***. While the Ministry of Public Health has just started to deliver antiretroviral therapy in hospitals, ART is mostly delivered by nongovernmental organisations through HIV/AIDS centres.

The most important pharmaceutical producer in the DRC is Pharmakina Bukavu, also the only producer of ARVs. Pharmakina has no second line production yet. APIs are imported from Mchem, China. Main importer of ARVs into DR Congo is CIPLA, which imports via the governmental organs like PNMLS ("Programme National Multisectoriel de lutte contre le Sida"). PNMLS has a structure on the exclusive rights of the importation and financing for public network. Access to health caring services in the DRC is generally very low – particularly in the East of the country.

The East African regional drug market is dominated by the public supply of ARVs. The regional local pharmaceutical industry is at a very infant state concerning ARV production. Potential Tanzanian exporters face competition through local producers enjoying domestic preferential treatment by the public suppliers and rather competitive (patented) ARVs subsidised by international foundations (like the Clinton Foundation, the Global Fund, etc.).

To what extent Tanzanian producers are able to bear this competition and bridge the gap in the market left by third non-LDC generic drug producers depends – apart from supply determining factors – on whether the regional (unmet) demand is characterised and reachable.

5.3 Unmet demand – Chances for export?

On average 75% (Kenya 60%, Uganda 85% and the United Republic of Tanzania 80%) of the medicines in the EAC market are imported.[93] At the same time there is still a significant unmet demand for ART (number of people needing ART minus number of people on ART) in the region. Whether this signifies a market for Tanzanian ARVs is unclear. Various factors like a national (enabling) environment and demand driven conditions play a role.

[92] Both public and private treatment sites need to register with TRAC.

[93] See AICC Workshop for EAC Partner States legal, trade and pharmaceutical experts and manufactures of essential medicines on the review of national patent laws and WTO TRIPS flexibilities, 22-23 February 2005, Arusha, Tanzania.

In order to analyse the exportability of Tanzanian pharmaceutical products beside supply related factors one has to take the following aspects into consideration: the regional demand for Tanzanian pharmaceutical products concerning affordability and acceptability of drugs and *how* local producers are able to meet it. This includes geographical and physical accessibility and standards. In the following the study refers to regional demand including price sensitivities. Subsequently possible barriers to accessibility will be discussed. The discussion focuses on prices and price sensitivity, regulation, transportation and storage as well as on trade barriers.

5.4 Prices and price sensitivity

Prices of pharmaceuticals are not entirely derived from the demand and supply mechanism, but depend on different variables.[94] It is difficult to compare drug prices worldwide. Prices vary among countries and even in one country the same medicine is sold at different prices to the public, private not-for-profit (PNFP) or the private for-profit (PFP).[95]

WHO defines affordable prices to be one out of four key factors affecting access to essential medicines (beside rational selection and use of medicine, sustainable financing and reliable health and supply systems). Developing countries appreciate low prices through the international health organisation's bulk purchasing system. But in many cases the drugs do not reach consumers because of corruption, incompetence and theft along the chain. Kenya's prices used to be amongst the highest in Africa. In 2000 Kenyan drug prices even exceeded the Europe's. Uganda, unlike Kenya, did not permit patent monopolies leading to relatively lower drug prices. The main reason for high prices of medicines in East Africa was a lack of generic competition.[96]

Because of widespread disease in East Africa, a large percentage of health budgets (around 40-60%) is spent on drugs.[97] Around 50-90% of the spending is estimated to be on drugs only.[98] Spending on drugs is mostly on the "out of pocket" basis due to lack of social security. Taking into account East Africans' low purchasing power, consumer's price awareness is high. Consumers' influence on drug prices, however, is still rather limited due to the ample need for drugs in the region and relatively small competition on the drug markets. In other words: Up to a certain threshold, price elasticity of demand on drugs is >1, above that price-level it is <1.

Tanzanian drugs have not made an impact on the Kenyan market so far.[99]

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[94] Oclay, M./Laing, Richard (2005): Pharmaceutical Tariffs: What is their effect on prices, protection of local industry and revenue generation? , May 2005: p. 8.

[95] Myhr, K. (2000): Price Survey East Africa, Norway; online available at: http://www.accessmed-msf.org/upload/ReportsandPublications/3920012349208/East%20Africa.pdf

[96] The data freely accessible on HAI's web site for international price comparisons (www.haiweb.org/medicineprices) does not provide for recent data on ARVs. In order to get valid results, one should only compare median price ration (MPR), if identical or very similar basket of medicines is compared.

[97] Developed countries spend around 20% of their health budget on drugs; WHO (2001): World Health Report.

[98] See: WHO (2000): World Health Report.

[99] Interview with R. Dhanani, Universal Cooperation LTD and A. Rahemtulla, Kam Pharmacy LTD, WS on Pharmaceutical Production in East Africa, Moshi, February 2006.

For the last two years, drug prices in Kenya have been dropping significantly. There is no price change identified, however, which could be seen in relation to the TRIPS arrangement, effective since 1st January this year.
Opinions differ whether the still relatively more expensive drugs in Kenya (compared to Uganda or Tanzania) could mean a comparative advantage in prices for Tanzanian producers. According to Kenyan businessmen, most drugs produced in Tanzania have an unfavourable reputation on the Kenyan market. Depending on income groups, the Kenyan demand for branded drugs (mainly from India, China, Malaysia, and Cyprus) ranges between 30-60%. This means that in terms of price elasticity, Tanzanian drugs are treated as inferior goods and are therefore associated to a negative income elasticity of demand to a certain consumer-group (relatively high-income): The higher the consumer's income the smaller his demand on generic Tanzanian drugs.

Tanzanian producers therefore first have to focus on low-income groups' demand in the Kenyan and Ugandan market. Along with increasing generic competition, competitive pricing gains in importance. At the same time, however, increased quality – in line with international standards – is essential for gaining market share in the region.

To what extent Tanzanian producers will be able to meet foreign standards and consumer expectations in non-donor-markets, where they have to compete both with attractive and well established third country producers (from India, China, etc.) and local producers enjoying preferential treatment through MSD tenders[100], remains to be seen.

5.5 Regulation

As in most low and middle-income countries the pharmaceutical market in the East African region is poorly regulated.[101] National regulation authorities are inadequately resourced, lack institutional performance and have weak monitoring systems.

While Tanzania and Uganda's DRA are independent, the Kenyan regulation authority is part of the national Ministry of Health and only the Ugandan authority does not receive government subsidies, but depends on fees for regulatory services and grants.[102] DRAs often face conflicting pressures by local and international industrial players and health policy makers.

In theory any drug for export needs to be registered by the regulatory authority in the importing country. Most African countries require registration, which usually involves submission of a GMP inspection report, a technical dossier and a registration fee of $500-1000. Several Indian generic companies have already registered or submitted applications for registration in African countries.[103]

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[100] In Tanzania domestic preference rate is 15%; viz during evaluation of financial offers 15% would be added to the financial quotations of foreign manufacturers when comparing them with the quotations of local manufacturers.

[101] For instance medicine distribution categories differ between East African countries; Especially clinical trials and regulation of traditional medicines are week in all countries; See: Council of Ministers (2006): 11th Council of Ministers on April 2006; Arusha, Tanzania. Report of the meeting on harmonisation of medicines regulation in the EAC Partner States, Kampala, 19-21 December 2005.

[102] Tanzania's and Uganda's DRA recruit there own staff.

[103] In Tanzania Ranbaxy and Cipla are registered, whereas Cosmos, Hetero, and Aurobindo have applied for licences and are pending; See: WHO (2005): The Regulatory status of Antiretroviral Drugs Database. Online Available at: http://ftp.who.int/htm/AMDS/drugsdatabase.pdf

In Tanzania, ARVs produced by TPI have been approved, whereas they have not been approved in a foreign country yet.[104]

There is no formal DRA in ***Kenya***. The parastatal pharmacy and poison's board is currently responsible for the drug regulation in the country, but its quality control lab is not legally enacted. The process of registration for a foreign importer into the Kenyan market usually takes around 6-9 months, assuming all information is correct. Formally, however, there is no time limit on applications. A fee of $1,000 per product is required, which lasts five years.[105]

In terms of its statistical database and reliability of its measurements, the ***Ugandan*** National Drug Authority enjoys best reputation in the East African region. The process to get on the national register takes between 6 and 12 months for generic and new drugs respectively. Up to now no voluntary license is issued in Uganda.

There is no functional DRA in ***Rwanda***, yet, but quality controls according to requirements of national treatment guidelines are undertaken by CAMERWA. Preference is given to generic medicines as long as they are cheaper and comply with quality requirements (WHO prequalified, where possible).

The drug market in ***Congo*** is currently rather deregulated. Only in the East, which is partly covered by cooperations and NGOs, donors supply regular drugs. No functional DRA is in place and the market is dominated by grey importation.

Not being coordinated on the regional level, national regulation authorities hamper East African trade flows significantly. Each time medicine passes a border, the registration process has to start from the beginning, trade flows are delayed and intraregional trade becomes less beneficial. Tanzanian importers into neighbouring markets, however, not only would have to meet the target country's national standards in order to compete with other importers and preferred local producers (generic tender procedures usually include domestic preference rates between 10-15%).

As illustrated in the Tanzania chapter, there is a parallel and significant drug market created by donors in each country. In order to be eligible for tenders by PEPFAR, the Clinton Foundation and other international multi- and bilateral donors or international NGOs, locally produced ARVs have to be FDA approved and compete with highly subsidised drugs.

Since 2001, the process of regional EAC-wide collaboration among national agencies to carry out drug registration reviews is ongoing. However, harmonisation has not proceeded very far yet. Political reasons, protectionism and fear of sovereignty loss are probable reasons for that.[106] To what extent the five-year strategic plan, which was issued last year, will be implemented remains unclear. Developing a shared technical framework would mark a first step to kick-off the complex harmonisation process in order to form an EAC Food and Drug Regulatory Authority – one of the ambitious objectives within the five-year plan.

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[104] By June 2005: GMP and appropriate registration requirements.

[105] GSK and Boerhinger have issued voluntary licenses to Kenyan companies.

The following patents are currently valid in Kenya: GSK (Zidovudine, expires 2006; Zidovudine + Lamivudine, expire 2014; Lamivudine, expires 2010), Boerhinger (Nevirapine, expires 2010), Abbot (Nelfinar, expires 2014).

[106] After the first EAC meeting of Medicine Regulation Authorities in June 2001 it took almost four years until the second meeting took place in February 2005, where TORs for the situation analysis were developed; Report of the meetig on harmonisation of medicines regulation in the EAC Partner States, Kampala, 19-21 December 2005.

Political will and legislative capacity to reform national drug legislation in line with national law on intellectual property (IP) and staff capable to implement such reforms are crucial preconditions to overcome inefficient national regulations. The current national regulations pose significant non-tariff barriers in the East African region. Pressure from the EAC Council of Ministers could provide new dynamics to the process. Uganda could play a leading role in the regional harmonisation process.[107]

5.6 Regional Enabling Environment

5.6.1 Transportation and Storage

Costs of transport form one important issue of production costs. Main parts of the inputs needed by the pharmaceutical industry in LDCs – concerning both machines and ingredients – have to be imported. Infrastructure, taxes and electricity costs therefore play a crucial for the competitiveness of the pharmaceutical industry in Tanzania. At the same time transportation and storage is one key factor in determining intra-regional trade conditions in East Africa and the development of the region. For freight transport three distinctive markets can be drawn, namely intra-regional, inter-regional and transit freight transport. These markets are generally liberalized in Tanzania.

The road network totalling about 85,000 km is still the dominant transport mode, accounting for 60-70% of total internal traffic flows.[108] Since the length of paved roads remains very small regarding Tanzania's country size, they constitute a geographical barrier to drug accessibility. Kenyan drug sellers even state that imports from Asia into Kenya are more efficient concerning transport than imports from Tanzania.

Also railways, in a similarly bad condition, play an important role in the country's overall transport system, mainly for bulk commodities between Dar es Salaam and centres in rural areas and transit traffic to the landlocked regional countries (Zambia, Malawi, DRC, Burundi, Rwanda and Uganda). The two international airports and over 60 domestic airports and air strips are less important regarding trade in pharmaceuticals.

Development of road network infrastructure has been prioritised and road expenditures increased significantly in each member state during the last five years. The length of roads reconstructed in Kenya and Uganda between 2003 and 2006 is three times longer than the one which was upgraded during the five years before (1998-2003) – in Tanzania it is even five times longer.[109] Tanzania is ahead of Kenya and Uganda in establishing accountable, autonomous road authorities with private-public participation. It was also the first in implementing coherent and transparent road funding policies that ensure adequate flow of funds on full cost recovery basis.[110]

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[107] The next step of the East African integration process is the development of a Common Market with free movement of capital and labour. Currently even the ability of businesses to operate freely within the UR of Tanzania is limited. Businesses operating in Zanzibar has to register as foreign business in mainland Tanzania and vice versa.

[108] "Analysis of enforcement of laws and regulations that govern road transport industry in East Africa, TechnoServe", February 2001.

[109] This includes the length of gravel/earth roads upgraded to bitumen standards and the length of bitumen surfaced roads rehabilitated/reconstructed; East African Road Network Project (2006): Project Progress Indicators Tanzania , Annex 10, May 2006.

[110] The levy of $0.80 per liter of fuel in Tanzania and Kenya leads to an amount of $80 and $100 millions respectively for road maintenance. There is no levy on fuel in Uganda. Annually around $60 million is spent on road maintenance by treasury. Regarding the country size and length of road

Tanzania's ambitious plans have to be seen in the framework of its current situation. There is no tarmac road connecting Dar es Salaam directly with Musoma and Mwanza at Lake Victoria, the highest populated region in Tanzania. Transport of cargo from Dar es Salaam transfers via Nairobi passing the border twice and covers the double distance in order to reach Mwanza. Beside the loss of time and money, products are more likely to be damaged the longer and more complicated the transport.

30-35% of East African population is living in the Lake Victoria Basin, where the HIV prevalence rate is above the average country rate. The planned road network through Tanzania connecting Dar es Salaam with the Lake Victoria Basin and circling the Lake should reach 80% of people of the Basin Its reconstruction is planned to be finished by the end of 2008. Once in place it is expected to boost Tanzania's access to the Ugandan market.[111] The port of Dar es Salaam is presumably gaining importance towards Mombasa and increased competition between the two main ports could lead to reduced prices of pharmaceutical goods in the East African region.[112]

Indicators for future planning like the value of construction contracts completed or in progress are promising for all EAC members.[113] Concession is agreed on with private partners about the railways running next to the rehabilitated road network. In the middle and long term railways will probably form a competitive alternative for cargo transport.[114]

Appropriate storage is a prerequisite for trade in products, where pharmaceuticals require high standards. Traders' complaints address to inadequate buildings, power cuts and low quality of water. Tanzania does badly in this regard – also compared to neighbour countries. Most Tanzanian households still have no access to electricity and water. And even if provided, periodical power cuts and irregular water inflow are common.[115] For maintaining a "cold chain system", which is essential for producing and trading drugs the supply of appropriate housing, water and power are key challenges yet to be met.[116]

High transport costs are not only related to infrastructure, but also to border crossing delays, police road blocks, etc. To what extent they hamper intraregional trade in East Africa, will be discussed in the following chapter.

5.6.2 Trade barriers

Since 01.01.2005, EAC is in the process of implementing a Customs Union including the reduction of internal tariffs and agreement on a common external tariff. There is no import

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network, Tanzania spends less in road maintenance than Uganda and Kenya. Interview with EAC Civil Engineer, May 2006.

[111] Mutukula (Tanzanian border to Uganda) is expected to enhance importance towards Malaba and Basai (Kenyan border to Uganda) –currently the main entry points into the Ugandan market.

[112] Mombasa and Dar es Salaam are the only ports in East Africa, which play a significant role in maritime shipping. Smaller sea ports in Tanzania are in Zanzibar, Tanga and Mtwara; in Kenya in Lamu, Malindi, Kilfi and Shimoni.

[113] East African Road Network Project (2006): Project Progress Indicators Tanzania+ , Annex 10, May 2006.

[114] Interview with EAC Economist (Transport), May 2006.

[115] Ministry of Planning, Economy and Empowerment, The Poverty Eradication Division (2005): Poverty and Human Development Report 2005.Dar es Salaam.

[116] Interview with EAC Health Coordinator, May 2006.

duty on pharmaceutical goods in the EAC regarding both internal trade and trade with third countries.[117]

Intraregional trade in the EAC is still very limited. This is particularly the case for pharmaceutical goods. Both Uganda and Tanzania are net importers of Kenyan goods.[118] Out of all pharmaceuticals imported into Tanzania, 8-9% is imported from Kenya. Uganda's share of imports into Tanzania is negligibly small, (around 0.023%) and so is Uganda's share of Tanzanian exports of pharmaceutical goods. Overall only 0.1% of all Tanzanian exports are related to the pharmaceutical sector.[119]

Non-Tariff Barriers (NTBs) are a big – if not the main – hurdle to intraregional trade in East Africa just as to trade with third countries and to the attraction of foreign capital to the region. For the private sector, NTBs represent an additional cost factor and can even lead to complete loss of markets or customers. As a pragmatic way to overcome them both business and public sector officials responsible for enforcing trade related requirements tend to resort to corrupt practices. The EAC Sectoral Council on Trade, Finance and Investment (meeting in August 2005) considered and resolved a number of NTBs and directed the Partner States to act accordingly. A systematic approach to meet NTBs was initiated by the East African Business Council (EABC) by identifying main NTBs in the region and establishing a monitoring mechanism for their reduction.[120] During consultations East African stakeholders agreed to tackle on the following eight problem clusters: Customs documentation, Immigration, Inspection-quality, Police road blocks, Varying Trade Regulations, Varying transiting procedures, Business registration and licensing procedures, Duplicated functions of agencies.[121] Customs documentation (the administration of duties and other taxes) was ranked top among the existing NTBs identified. Limited customs open hours and intransparent regulations and procedures (long after relevant rules have been officially harmonised) just as time-consuming off- and re-loading container are hindrances to faster movement of goods across borders. Pharmaceuticals as perishable products are mainly affected by these circumstances. Thereafter, most NTBs on pharmaceuticals are related to standards and quality controls.

A new import inspection procedure e.g. (implemented by Kenya in July 2005) requires imports to be accompanied by a quality inspection certificate from an internationally accredited laboratory. Police officers frequently stop commercial vehicles.[122] Different load and vehicle mass specifications between Kenya and Uganda (Common Market for Eastern and Southern Africa (COMESA) axe load specifications) on the one hand and Tanzania

[117] Tanzania pleaded for an import duty of 10%, but could not prevail towards Kenya and Uganda. The Sectoral Council on Trade, Finance and Investment decided on the amendment rates on pharmaceuticals to 0% (also for sanitary towels and tampons), which was adopted by the 11th Council of Ministers on April 2006, Arusha.

[118] Considering all imports in 2003: Kenya imports only 3.22% from EAC, whereas Tanzania and Uganda import 5.25% (4.97%) and 26.84% (26.05%) from EAC (and from Kenya) respectively; See: Stahl, H.M. (2005): East African Community Customs Union Tariff Liberalisation impacts in Perspective. EAC

[119] Source: EAC Statistic Database May 2006 (Dataset 2004/2005).

[120] In the Business Climate Index (BCI) Survey 2004, covering 500 companies and 150 government executives, nature and scope of NTBs are identified and classified in six clusters. Consultations about how to address them took place between August and December 2005.

[121] Government policies and government participation in trade were mentioned in the report as an additional category, under which NTBs may be experienced, but where no specific NTBs were identified. Specific NTBs under this category could include government procurement policies, systems of taxation, macroeconomic policies, rules of origin, etc.

[122] Although they are officially only allowed to stop commercial vehicles at road blocks based on more than 52% proof that goods being transported are suspicious.

(SADC load specifications) on the other hand undermine agreements on tariff reduction, since they limit transit traffic within the region. Finally various government bodies involved in import and export inspections and certification procedures prevalently do not collaborate or have not established laboratories at many entry and exit points.

Industrialised countries often justify NTBs to safeguard health, safety and security of human beings and animals and protection of home industries. In the East African region, the integration process (including liberalisation of national markets towards a common regional market) is strongly supported by the top political level of the Partner States, whereas local industry and bureaucracy in the same countries fearing loss of power and influence might have an interest in maintaining or even adding tariff barriers.

The gravity of specific NTBs was found to be quite consistent among the East African countries and so was the incidence of NTBs across sectors.[123] Tanzanians and Ugandans compared to Kenyans are more optimistic about future progression in addressing barriers to trade and among them governments are more optimistic than the business sector. One could interpret these results as government's intention to consequently remove trade barriers. Close cooperation of public and private sector is crucial in this regard e.g. through an effective dialogue mechanism.

[123] See: BCI (2004).

6. Conclusions and Recommendations for German Development Cooperation

The study shows that production of pharmaceutical products in Tanzania is on the rise and can become viable in the long term. Even though the overall drug market is rather small, public health related drugs have a significant market, largely a donor market. Regarding the manufacturing of ARVs in Tanzania by established producers like Shelys and TPI, for the Tanzanian (and donor-) market, there is hardly any risk involved. Especially if India – due to the TRIPs agreement – is not exporting ARVs to Tanzania anymore, producers in Tanzania have a big advantage.

The issue also seems high on the agenda of Tanzanian policy makers and is in line with the national poverty eradication plan. However, there are a number of challenges that have to be addressed. In general, it has to be noted that in some cases, it might still more cost effective to import the drugs from India and China than to produce them locally. The fact that India has 70 US approved production plants (compare: 40 in the UK) where APIs and ARVs can be produced, must not be ignored. In Tanzania, the adaptation of certain legal issues, as outlined in chapter 3, the lack of adequate and internationally recognised quality standards, the unused potential of regional cooperation, the weak infrastructure in the region and the lack of adequately trained human resources are the most significant challenges of economically viable pharmaceutical production. What role can (German) Development Cooperation, in close coordination with all relevant stakeholders, play in addressing them?

Some of the legal issues to be addressed include the approach to parallel imports: In Tanzania, parallel imports from abroad are not acknowledged. The Tanzanian Government could easily amend this provision, authorizing parallel imports of patented products. International multi- and bilateral donors can, where in demand, give specific legal advice with regard to the patent laws in Tanzania.

If Tanzanian producers could comply with international quality standards, they could participate in tenders issued by the donor community in the country and the region. As shown in chapter 4, the donor market is very big. The two major producers are aiming at that market and one is close to complying with international quality standards (PIC). The Public Private Partnership described in Box 1 can be seen as an excellent initiative. In addition to building the capacity of a company, the capacity of the TFDA needs to be strengthened. Both, regulators and manufacturers of drugs need to be supported in order to comply with international standards. The development of transparent and ideally EAC-harmonised processes and quality standards would be an essential added value to the pharmaceutical market in Tanzania and in the region. It is also a first and necessary step towards the international market.

Whereas the TFDA is considered to be relatively strong, only a thorough analysis – if wanted by the TFDA – can give a realistic picture of their capacity and demand for capacity building. If the TFDA wants to cooperate with all involved stakeholders, the producers in particular, but possibly also the donors, this cooperation could develop high leverage and be an important step in the right direction, also for German Development Cooperation.

If quality standards could be harmonised with those of the other EAC members, this would be an important first step towards a common DRA. Regional harmonization would strengthen the sector significantly. As illustrated in chapter 5, non-tariff trade barriers are a major obstacle to the development of the pharmaceutical sector and the entire region. Furthermore, regional cooperation could facilitate economies of scale. For example, Joan Rovira points out that the COMESA, Africa's large free trade block, made up of 20 countries, applied at the WTO for the right to produce ARVs and to treat COMESA as one region, so that drugs

manufactured in one member state can be sold throughout the region.[124] This and several other examples show that a regional approach is more sustainable than several national ones. Maybe there is a case for information exchange between COMESA and EAC.

A regional approach could prove more economically viable and more sustainable than national ones but obviously a number of additional factors need to be taken into account, such as mutual recognition of standards and quality controls as well as the need to control re-exportation to third countries.

There is a severe lack of human resources in Tanzania. The capacity and number of professional staff – management as well as technical – is low, professionalism is only kin deep. Therefore, there is a big demand for the development of local capacity in the field of human resource development; German Development Cooperation has a role to play. Through its extensive network it can facilitate technology transfer and South-South cooperation. Furthermore, initiatives by players in the private and public sector can be supported, where feasible. For example, trainings for pharmaceutical assistants or supervisors of the TFDA can be supported.

[124] See Joan Rovira (2006): p. 238.

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