

Asian Drug Import, Local Production, and Regulatory Capacity in Tanzania, 1970–2005

Peter Ernest Mangesho
National Institute for Medical Research
Amani Medical Research Centre
Muheza, Tanzania
peter.mangesho@nimr.or.tz

Christoph Gradmann
Department of Community Medicine and Global Health
Institute of Health and Society
University of Oslo
christoph.gradmann@medisin.uio.no

DOI: 10.53228/r27z5902



This work is licensed under a Creative Commons Attribution 4.0 International License.

Abstract

By the mid-2000s the contribution of Tanzania's pharmaceutical industry to local drug circulation was low compared to imports, with the latter mostly coming from India. The situation had mainly stayed the same since independence in 1961, despite a political desire to develop a local, self-sustaining drug supply pipeline. However, global developments affecting the pharmaceutical industry in the late 20th century around drug quality, safety, and availability to the majority of the poor of the Global South would later galvanize different actors, led by the World Health Organization (WHO), to respond. Among the interventions was the introduction of a set of evolving regulations, codes, and guidelines known as Good Manufacturing Practices (GMP). An archive located at the Tanzania Medicine and Medical Devices Authority (TMDA) provides a first-hand account, presented here for the first time, of the entanglements between selected local manufacturers and the regulator as GMPs were introduced into the country in the late 1980s. The TMDA archive's files offer insights into the response of local manufacturers in this early period of GMP's implementation. The archive facilitates a study of how the introduction of GMPs should be seen in connection with global economic and political events when, around 1990, the country's socialism-inspired policy of health and drugs provision was challenged by mandatory global free markets that rescinded governments' monopoly within the sector. The paper argues that while GMPs were a vital regulation to ensure drug quality and safety, their introduction caught local manufacturers off guard and stifled local drug production capacity while offering a favourable opportunity for imports, mainly from India, to dominate the markets, as the same rules did not initially apply to them locally. However, GMPs did offer an opportunity for the country's drug regulatory infrastructure to be strengthened.

Keywords: drug manufacturing, Tanzania, pharmaceutical regulation, Good Manufacturing Practices

Introduction

Scholars of pharmaceutical manufacturing in Africa have argued that by 2005, the sector was booming, following tumultuous transitions from a mostly state-controlled economy to a market-based one (Banda et al. 2016). Out of 46 African countries known to produce medicines within their borders, about 37 were documented as engaging in some form of drug manufacturing activities. The latter includes manufacturing active pharmaceutical ingredients (APIs), the production of finished dose forms, and the reformulation of products, packaging, and labelling (Berger et al. 2010). The market size of Tanzania for the years 2004–2005 was estimated at \$110 million. In this market, local manufacturers generated 29% of pharma supplies, while 71% (78 Million USD), including APIs, came from imports (Chaudhuri et al. 2010). These imports mainly originated from Asian countries, especially India and China (Chaudhuri et al. 2010). Moreover, a dedicated agency to regulate and oversee the manufacturing and flow of drugs and food in the country, the Tanzania Food and Drug Authority (now known as Tanzania Medicine and Medical Devices Authority), was formed in 2003 after decades of reforming the local pharmaceutical industry and its regulations (TFDA 2013).

The history of Tanzania's healthcare services, including of local pharmaceutical manufacturing, must be understood in the context of its postcolonial social and economic development trajectory, in which colonial powers left behind a seriously underdeveloped country, with parts of the health system also very unevenly developed (Edward and Lindner 2024; Green 2014; Schneider 2014; Turshen 1977; Young 1986). Tanzania's answer to this challenge was to pursue a socialist-oriented development strategy known as Ujamaa, led by President Nyerere, that emphasized self-reliance and collective ownership, which became a necessary part of nation-building following the 1967 Arusha Declaration (Nyerere 1967).

As Tanzania moved from being underdeveloped to becoming a developed nation, health policy aimed at providing free health care for all and at redressing the colonial legacies of inequality in social services (Abel-Smith and Rawal 1992; Banda et al. 2016; Tarimo 1978; Vogel and Stephens 1989). The government committed to managing all its major social services, especially in education and health, through a systematic centralization process. This included developing its own local pharmaceutical supply capacity, aiming to make essential drugs available and at a lower price (Mbwasi et al. 2023; Munishi 1991).

The historical development of Tanzania's pharmaceutical industry is not unlike that of other developing countries, especially in Africa. The rise and decline of African drug manufacturing has been a subject of scholarly interest for many years, often approached from the vantage point of Africa's industrial development in a globalized world (Banda et al. 2016; Baxerres and Cassier 2021b; Chaudhuri et al. 2010; Chorev 2019a, 2019b; Vogel and Stephens 1989). However, the specific focus of research on Tanzania's pharmaceutical production trajectory has been the recent neo-liberal era, and specifically manufacturing companies or disease programmes such as those relating to HIV/AIDS (Chorev 2019a; Munishi 1991; Tibandebage et al. 2016). Few studies have emphasized the role of policy, regulation, and how they have shaped the course of Africa's drug manufacturing field (Gray 2013; Kanji et al. 1992; Tibandebage et al. 2016; Wangwe et al. 2014). This paper follows the evolution of Tanzania's pharmaceutical manufacturing sector as the country strived to become self-sufficient in drug supplies and overcome dependence on imports from the late 1970s to the early 2000s. In doing so, it looks at how regulatory deliberations by government actors grew in connection with new global forms of pharmaceutical manufacturing and trade.

Wangwe et al. (2014) divides post-independence industrial growth into three phases: 1) industrial development in the mixed economy (1961–66), 2) state-led import substitution and industrialization (1967–85), and 3) the period of de-industrialization under structural adjustment programmes and associated policy reforms (1986–95). We concur with Wangwe and colleagues that the development of pharmaceutical manufacturing in Tanzania is best understood through these phases, as each had a unique impact on the sector's trajectory. An efficient pharmaceutical production, distribution, and supply system that catered equally for all Tanzanians was almost non-existent after the colonial period (Banda et al. 2016) nor were there adequate regulatory controls. This was the case in most developing countries in the 1960s and 1970s (Kanji et al. 1992).

Despite the government's ambitious plans to become self-sufficient in drug production by investing in the drug manufacturing sector in the late 1970s and early 1980s, concerns emerged both locally and globally about drug availability, supply, and, most notably, the quality and standardization of both imported drugs and those produced locally (Mhamba and Mbirigenda 2010; Munishi 1991; Yudkin 1980). These concerns are reflected in the country's minimal pharmaceutical regulation capacity at the time. Some local regulations existed, but little is known about how they shaped local manufacturing and its outcomes before and during the liberalization period of the late 1980s and 1990s (Fimbo et al. 2024). Through archival and published documentary sources, this paper looks at the contributions of an evolving set of pharmaceutical manufacturing guidelines on the development of Tanzania's pharmaceutical manufacturing sector. It also looks at how global and local pharmaceutical policies played out and how, ultimately, investment in pharmaceutical manufacturing technology became inevitable (Pourraz et al. 2022). Most importantly, this paper contends that the implementation of Good Manufacturing Practices (GMP) regulations in Tanzania significantly impeded the development of local pharmaceutical manufacturing ambitions. This, at a juncture when governmental oversight of pharmaceutical markets was decreasing, suggests a potential conflict between drug quality assurance initiatives and the growth of the local drug industry.

Global history of Good Manufacturing Practices (GMPs)

GMPs are an evolving set of regulations, codes, and guidelines agreed upon by international organizations, institutions, pharmaceutical industries, and national regulatory authorities that inform the consistent production of pharmaceutical products to the quality standards appropriate for their intended use, as per the World Health Organization (Immel 2001; WHO 1975, 1992). These 'good practices', elsewhere referred to as "the bedrock of quality assurance in the pharmaceutical industry" (Sangeda et al. 2024), are based on the principle that the quality of drugs ought to be embedded into products from the beginning of production and before they reach the market. GMPs first arose in response to catastrophic and tragic incidents that befell the global pharmaceutical industry in the 20th century, notably in Western countries. They included numerous side effects, deaths, and the births of malformed children due to contamination, to insufficient testing of drugs, or to malfunctioning vaccines, among other issues (Ballentine 1981; Dally 1998; Immel 2001; Parle and Wimmelbucker 2020; Rågo and Santoso 2008). Such events catalysed the development of a series of drug regulations aimed at protecting drug consumers in the developed countries. Regulators there demanded that drug companies provide strict evidence of efficacy and safety (through clinical trials, for example) before marketing prescription drugs (Daemmrich 2004; Greene 2011).

As control pressures increased from the 1960s onwards, this, in turn, affected sales for the big drug manufacturers. In response, companies could shift their marketing strategies and target countries with weaker laws and regulations, a practice termed ‘drug dumping’ (Baxerres and Cassier 2021a; Greene 2011; Silverman et al. 1982; Pourraz et al. 2022). The receiving countries, of which the majority were newly independent, including Tanzania, lacked the necessary policies and infrastructures to assess quality; they became the recipients of drugs many of which were inessential, hazardous, did not meet the same high standards of efficacy and safety as in the source countries, or were no longer in use there (Mamdani 1992; Yudkin 1978, 1980).

As these challenges embroiled the pharmaceutical industry in the 1960s, 70s, and early 80s, they galvanized efforts primarily by global organizations to facilitate the formulation of policies that would protect customers in both northern and developing countries who were at the mercy of the marketing strategies of multinational drug companies. Though useful, efforts by individual governments of developing countries to curb the powers of multinational companies needed to be revised, as they often led to conflicts with drug suppliers and their agents (Abraham 2008; Mamdani 1992). There were also efforts from UN agencies such as the United Nations Conference on Trade and Development (UNCTAD), the United Nations Industrial Development Organization (UNIDO), and the United Nations International Children’s Emergency Fund (UNICEF), led by the World Health Organization (WHO), where a special unit dedicated to pharmaceutical policy development was created in 1975 (Kanji et al. 1992). Together, they supported the development of global and national policies to support local drug manufacturing and ensure access to essential medicines of good quality and at affordable prices, mostly in the form of generics. The Action Programme on Essential Drugs for developing countries, was started in 1975 (formally established in 1981), followed by the declaration of health care delivery for all during the International Conference on Primary Health Care in Alma-Ata in 1978. Both policies identified access to safe and affordable drugs among their criteria. The GMPs were embedded in these policies as a necessary aspect of protecting drug consumers through ethical pharmaceutical manufacturing (Cueto et al. 2019).

As a consequence of these international developments, Tanzania, like other developing countries, repealed its older drug laws and formulated the Pharmaceuticals and Poisons Act, Act No. 9 of 1978. Section 3 of the Act established the Pharmacy Board to oversee and regulate the manufacturing, importation, labelling, marking, storage, and sale of pharmaceuticals and substances used to manufacture medicines in Tanzania (TFDA 2013). However, this did not, in itself, advance drug production; most of the essential drugs required still came from Western European countries.

This paper argues that the introduction of GMPs indirectly slowed the socialist government’s ambitions under President Nyerere to establish a local pharmaceutical industry to achieve self-sufficiency in pharmaceuticals. While the introduction of GMPs directly contributed to the strengthening of the local regulatory body, it challenged local drug industries. This effectively incentivized the importation of cheap drugs, mainly from India. These rapidly entered local circulation, facilitated by the rapid growth of India’s pharmaceutical manufacturing capacity at the time (Chaudhuri 2005; Joseph 2015). In the following, we describe how Tanzania’s drug quality regulations evolved through the implementation and the enforcement of GMPs, and how manufacturing companies responded, from market authorization to GMP policies. We argue that local manufacturers faced more than just competition from cheap imported cheap drugs. Rather, the challenge of adhering to global drug quality standards caught local manufacturers off-guard and had significant implications for Tanzania’s plans to expand its drug manufacturing capability and become self-sufficient.

The archive: Sources and methods

The archival material for this study was found at the Tanzania Medicine and Medical Devices Authority (TMDA). Its archive contains boxed files of TMDA's daily activities from its different units. Most of the archived material begins in the period immediately before the formation of the Tanzania Food and Drug Authority (TFDA) in 2003. It would seem that the conduct of the Pharmacy Board commenced around 1995. Inquiry on the whereabouts of other files met with a roadblock and we were informed that many files may have been lost when the new offices in Dar Es Salaam were constructed between 1995 and 1998.

However, importantly for us, there are a few files that reach further back in time, dealing with local drug manufacturing since the late 1970s. Four files covering local companies were particularly interesting for a history of antibiotics production in Tanzania. They cover Mansoor Daya Chemicals Limited (Daya, hereinafter), Tanzania Pharmaceutical Industries (TPI), and Shelys Pharmaceuticals limited. Another local company, Interchem Pharma Limited (Interchem), whose file was also intact, started soon after liberalization in 1988. Daya, Shelys, and Interchem are family-owned private companies, unlike TPI (Sutton and Olomi 2012). In this study we have limited our review to two company files, Mansoor Daya Chemicals Ltd and Interchem. To a lesser extent, we refer to Shelys Pharmaceuticals' file for context.

The file on Mansoor Daya Chemicals is the oldest one, dating as far back as 1976, while the Interchem file starts from 1985. Documents in the Daya file show that the company has been manufacturing pharmaceutical products since 1965.¹ However, on its own company profile website, the company claims to have been around since 1962. Material on Daya and Shelys relates to three pharmaceutical acts and three drug regulations (Pharmacy and Poisons Ordinance (Cap. 416) of 1937; the Pharmacy and Poisons Rules, 1970; the Pharmaceuticals and Poisons Act of 1978; the Pharmaceutical Regulations, 1980, 1990, and 2000; and the TFDA Act of 2003).

The files in these folders principally contain correspondence between the Regulator, the Pharmacy Board, and the manufacturing companies. They need to be read as files reflecting the interest of a nascent drug regulation authority in a situation where both the production of drugs and their regulation were insufficient. Topics addressed in these exchanges cover the submission of drug formulations, requests for drug production permits, responses to production queries, GMP inspection appointments and reports, requests to manufacture human and veterinary drugs, company collaborations with foreign entities, and requests to import pharmaceuticals and raw materials, among others. Very intriguing correspondence in all these company files concerns the initiation and implementation of GMPs from the late 1980s, where inspectors began to reference them in their reports, however leniently, and throughout the 1990s and onwards, where they became stricter and more decisive in their conclusions. Additional data from the Tanzania Revenue Authority depicting local pharmaceutical production and importation were incomplete. However, those that were secured offer valuable insights about budget estimates for medical production and supplies, and the values of pharmaceutical products imported from other countries, including Europe and India, which can contribute to an understanding of the sector.

These archives provide an intimate look at the exchanges between regulators, the pharmacy board, and pharmaceutical manufacturers in Tanzania. Through these archival materials², sup-

¹ www.mdchemicals.com (accessed June 14, 2023)

² The material in this paper could benefit from supplementary company archival material. We submitted formal requests but did not receive any response until the fieldwork period ended.

plemented by other guidelines and published and unpublished sources, this paper shows how the regulator and the pharmaceutical companies negotiated and renegotiated the GMPs' introduction and subsequent implementation from the late 1980s up until 2003. It further discusses the consequences of this process and its implications for the development of the local pharmaceutical manufacturing industry and its regulation.

Drug production by notification

To properly situate the GMP policies and how they impacted local pharmaceutical manufacturing and its regulation, it is important to ascertain what regulatory practices existed before and after 1978. The main pharmaceutical laws in Tanzania were the Pharmacy and Poisons Ordinance Cap 416 of 1937, the Food and Drugs Ordinance Cap 93 of 1937, and the Dangerous Drugs Ordinance of 1937. Before the enactment of the Pharmacy and Poison Act 1978, the colonial Pharmacy and Poison Ordinance Cap 416 (Pharmacy and Poison Rules 1970) enforced drug laws through the Pharmaceutical Unit, which was headed by a Registrar. The registrar was part of the Pharmaceutical Unit, under the Ministry of Health. A Pharmacy and Poisons Board (PPB) existed, led by a Registrar.

The regulatory practice involved in assessing eligibility for drug manufacturing was that drug manufacturers applied for a licence of the products they intended to produce to the registrar of the PPB. The licence application was to be accompanied by a list of all the products, including information on and formulae of the different preparations, drugs, and medicine manufactured, according to either British Pharmacopoeia or United States Pharmacopeia specifications. This would be accompanied by proof or an explanation of how they planned to ensure the products met quality standards by submitting quality control certificates from their own companies, among others.³ This was the model for licencing drug production by notification that existed before the introduction of the GMP guidelines.

The licence application review process itself, in practice, involved each board member commenting on the application by writing on the file whether they agreed or disagreed, and by signing. All comments were forwarded to the registrar for recommendation of a licence after considering the number of comments from members. The board members came from departments across different sectors and ministries. They included a pharmacist from the Muhimbili Medical Centre (MMC), a livestock development officer, representatives from the Division of Pharmaceutical Sciences, the Traditional Medicine Research Unit, and the Faculty of Medicine at MMC, a representative from the Ministry of Agriculture, , the director of the government-operated Keko Pharmaceuticals, a pharmacy operator, and a legal officer from the Attorney General's Chamber.⁴

Interestingly, not all board members agreed with the licence applications submitted, but such disagreement was of little consequence. For instance, there were concerns about quality control regarding the certificates submitted. This was because it was the manufacturers themselves who produced their own certificates. For example, one of Mansoor Daya's applications was reviewed by the Board and it demanded proof of how his company ensured that his products are of quality.⁵ Mr Mansoor Daya, the owner, who was also a chemist and head of production,

³ License Application, December 13, 1976, MDC 340: DA/105/124/06/7, TMDA, Dodoma.

⁴ Registrar to board members, "An inspection visit to M/S Shelys Ltd on Friday the 7th May 1982", April 30, 1982, Shelys 365 DA/05/124/16/11, TMDA, Dodoma.

⁵ Registrar, Pharmacy and Poisons Board to Mansoor Daya Chemicals February 18, 1977, MDC 340: DA/105/124/06/8, TMDA, Dodoma.

issued quality testing laboratory certificates upon this request.⁶ The file shows these had been done at the company's laboratory. While other board members approved the application straightforwardly, the board secretary, commenting on the application, had a different view. Apart from acknowledging the certificates submitted by the applicant, the member of the Pharmacy and Poisons Board wished the Board could be in a position to ascertain the quality of the drugs and confirm the certificates submitted by the company. However, he rather defeatedly acknowledged that this would only have been possible if the Board operated its own lab.⁷ This opinion highlights the technical inability of the Board at the time to independently verify submissions of quality by local manufacturers.

Following the enactment of the 1978 Pharmaceutical and Poisons Act, and its associated Pharmaceuticals and Poisons Regulations of 1979, there were some slight changes in the conduct of the newly formed Pharmacy Board. Drug manufacturers were now required to submit an application that included an assessment from an independent laboratory. The results were provided to the Board for decision making. In all the files reviewed, this independent analysis seems to take place at the time a company intends to manufacture pharmaceuticals for the first time⁸. It is only in 1981 that for the first time we witness a rather detailed list of criticisms internally raised by a board member to fellow members. The member was concerned with the credibility of the formulations submitted by the Daya company and felt the Board did not adequately respond. The board member considered this inaction unpatriotic on the part of the Board, whose obligation, he reminded everybody, was to protect the health of people.⁹ He objected to issuing a licence until Daya provided the specifications (quality standards proposed and justified by the manufacturer) which the drugs conformed to and also submitted copies of the methods of analysis used in assaying the formulations. He proposed to randomly select samples from the market and the factory and send them to government chemists (and other established labs) for verification. Further, in what seems to illustrate a spirit of self-criticism, he suggested that the Board should provide procedures to its members, guiding them on how to evaluate the applications. He also proposed that designated inspectors should analyse drug samples to provide unbiased reports as a basis for approvals or rejections. In addition, the board member felt that committee members were not doing enough with regard to ensuring the proper and smooth implementation of the 1979 Act, by not circulating applications early and promptly and by not ensuring that members' opinions on applications were taken into consideration. In fact, regardless of the substantial concerns of individuals, these licences were approved, since the Board decided on the issuance of permits through voting.¹⁰

Physical inspections of manufacturing premises before GMPs were implemented only took place at factory inaugurations, when a company was starting production for the first time. Further, these inspection visits, by a select four Inspection Committee members, who were also members of the Pharmacy Board, were facilitated by manufacturing companies themselves by providing transport to board members, as instructed by the Registrar.¹¹ Inspections of premises

⁶M.S. Daya to Pharmacy and Poisons Board, February 24, 1977, MDC 340: DA/105/124/06/11, TMDA, Dodoma.

⁷License Application Review Discussions Minutes, February 15, 1977, MDC 340: DA/105/124/06/2, TMDA, Dodoma.

⁸Registrar, to Chief Government Chemist, "Analysis of Sample of Pharmaceutical Products", May 1, 1982, Shelys 365 DA/05/124/16/12, TMDA, Dodoma.

⁹License Application Review Discussions, Minutes June 8, 1981, MDC 340: DA/105/124/06/5.

¹⁰In the absence of regulations and associated guidelines the Board would directly quote from the 1978 Act, which contain provisions but not the specifics of how to go about those provisions systematically and judiciously.

¹¹Registrar to Director, Shelys Ltd., "Registration of Premises for Pharmaceutical Manufacturing Purposes", Au-

were limited to the observation and assessment of four areas. These aspects were (1) premises (cleanliness, space), (2) equipment (machinery for production and for quality control), (3) personnel (production department and quality control), and (4) reference books. The language of the reports documented flawless premises and well-observed procedures. For example, they include statements such as “premises have general cleanliness outlook”, “premises are spacious enough”, “necessary machines present”, “heads of production and quality production are experienced”, and “reference books are kept”.¹² An inspection report before the issue of a business licence for the manufacture of chloroquine, paracetamol, and aspirin tablets in 1984 was concluded in two sentences: “The visit to the factory was conducted on 1984-08-24, and the team observed that the factory was in order in terms of space and other facilities for the production of the said pharmaceuticals. The team, therefore, recommends that a business licence be granted.”¹³

After 1978, the archival material testifies to the board members’ frustration in their attempts to implement verifications of medicine ingredient samples. The board was incapable of acting decisively without evidence but could hardly produce any. Failure to independently assess quality was a critical problem for the Board in effectively ensuring the quality and standard of drugs. This incapacity echoed the local poor technology level of the time and the inadequate infrastructure for supporting in-house quality and safety testing. As a result, it appears that private and even public manufacturers enjoyed a certain degree of freedom in production and market access during this period. For example, documentation from the Tanzanian Parliament on budgetary estimates for medical production and supplies between 1973 and 1980 (1973, 1976, 1978, 1979 and 1980) indicates an upward trend in allocating resources to boost domestic medical production between 1973 and 1980, with budget estimates of more than 3 million shillings in 1973 rising to almost 13 million shillings by 1980 (Table 1).

Table 1: Budget estimates for medical production and supplies in Tanzania 1973–1980

Year	Estimated values (TZS)	Estimated values (USD) ¹⁴	Estimated values today (USD) ¹⁵
1973	3,212,200	446,138.89	450,203.22
1976	5,430,900	648,078.76	648,310.85
1978	11,047,200	1,432,840.47	1,432,468.88
1979	11,252,200	1,368,880.78	1,369,380.55
1980	12,581,400	1,534,317.07	1,534,878.61

gust 15, 1984, Shelys 365 DA/05/124/16/25, TMDA, Dodoma.

¹² A report on the inspection of the premises of M/S Shelys Ltd intended for the manufacture of pharmaceuticals, May 11, 1982. Shelys 365 DA/05/124/16/10, TMDA, Dodoma.

¹³ An inspection visit to Shelys Pharmaceutical Factory, August 24, 1984, Shelys 365 DA/05/124/16/26, TMDA, Dodoma.

¹⁴ TZS to USD Official Exchange Rate (Annual Average) – International Monetary Fund (various years). *International Financial Statistics (IFS)*. Washington, D.C.: International Monetary Fund

¹⁵ The amount depicts an estimate of the value of the USD, from today’s market BOT website: <https://www.bot.go.tz/> (accessed September 26, 2025).

The files holding the Mansoor Daya communications show the company was active, submitting applications to the Board for permission to manufacture pharmaceuticals, including applications for permits for the importation of pharmaceuticals and raw materials from 1981 up to 1989.^{16,17,18} Its business seemed to flourish in those days as it supplied products to the local market and the East African region. The company exported its products to Rwanda, Burundi, the Democratic Republic of the Congo (formerly Zaire), and Zambia.¹⁹ Amid this steady stream of renewals of manufacturing licences, something is missing: there are no directives regarding the reinspection of premises and or ensuring quality of manufacturing, although these were required by law between 1983 and 1987. Neither does the Board submit samples from the company to the government chemist for analysis.²⁰ Instead, Daya submits applications and they are approved without further ado.

The beginnings of GMPs and the promise of successful local pharmaceutical production

In the 1980s, the decade of structural adjustment programmes, the World Bank undertook a review of Tanzania's sector-wide population, health, and Nutrition services. This review, from 1988, has to be read against the backdrop of the Tanzanian government's mid-1986 medium-term policy reform, the Economic Recovery Program (ERP) (World Bank 1989). The review was intended to shape the country's health sector for the 1990s to align with the ERP, which included building a dynamic private sector following the introduction of structural adjustment programmes (Gray 2013; van der Hoeven et al. 1994; Wagao 1992). The local pharmaceutical manufacturing industry was among the sectors reviewed. It is important to highlight here the political and economic challenges the country was facing to understand these developments. The impact of the global economic downturn from the mid-1970s to the late 1980s was felt locally. It was increased by the costly war with Uganda in 1978/79 and the breakup of the East African community, which disrupted the regional market, thus seriously affecting the availability of consumer goods, including drugs. External debt rose, impacting import and export substitutions, and the currency devalued. The government's ability to finance the importation of pharmaceutical products waned significantly (Bech et al. 2013; Lugalla 1995; Tibandebage et al. 2016). This was mentioned in a letter from Daya to the Pharmacy Board in 1983, complaining to the Registrar about the importation restrictions imposed on the company, which were affecting the supply of ingredients they needed to manufacture medicines.²¹

Amid this crisis, the involvement of the World Bank to appraise the health sector did not come as a surprise. The role of the World Bank in re-engineering the delivery of health care across developing countries, for example by encouraging privatization and the introduction of user fees, is well documented (Bech et al. 2013; Tichenor et al. 2021). It came in conjunction with the unpopular structural adjustment programmes. For Tanzania's health system this meant the amendment of the laws which had previously disallowed private practice, the reintroduction of private for-profit medical practice (MOH 1991), and cost-sharing of previously free public health services, among other policies. In the World Bank review, four major local

¹⁶ Manufacturing License Application, January 20, 1981, MDC 340: DA/105/124/06/22, TMDA, Dodoma.

¹⁷ Manufacturing License Application, January 6, 1989, MDC 340: DA/105/124/06/45, TMDA, Dodoma.

¹⁸ M.S. Daya to J.E. Chiliko, Registrar, March 1, 1983, MDC 340: DA/105/124/06/32, TMDA, Dodoma.

¹⁹ M.S. Daya to J.E. Chiliko, Registrar, March 7, 1983, MDC 340: DA/105/124/06/29, TMDA, Dodoma.

²⁰ Section 57 (1) and Section 52 of the 1978 Act.

²¹ M.S. Daya to J.E. Chiliko, Registrar, March 7, 1983, MDC 340: DA/105/124/06/29, TMDA, Dodoma.

pharmaceutical manufacturers were assessed (World Bank 1989). The review was critical of all four companies, describing a dismal situation in local pharmaceutical production capabilities. Generally, all local pharmaceutical manufacturing companies were viewed as using unsophisticated technology, suffering from low utilization of production capacity, and therefore requiring extensive rehabilitation and improvement of their plants. Companies lacked robust quality control systems (quality testing of products, poor quality control results). They also lacked proper testing of medicine quality, faced serious shortages of raw and packaging materials, and lacked air-conditioned rooms and spare parts. Daya was singled out for having particularly inadequate plant space. The report highlighted that insecticides were manufactured in the same building as drugs for human consumption, which the report remarks as “a very dangerous practice which should not be permitted.”²²

The World Bank review seems to have formed part of the basis for implementing and unleashing GMPs without mentioning the term. Following this report, several international and national documents on the pharmaceutical sector were produced. For example, a WHO review of the Pharmacy Board generated a comprehensive report on important procedures to be followed in the registration of pharmaceuticals (Kristinsdottir 1991). Among others, it proposed that any manufacturer applying for registration should be required to provide evidence that showed compliance with the WHO’s GMPs. This could only be attained following an approval certificate issued by an inspection committee of the regulatory authority. The report further recommended the updating of the legislation (the Pharmaceuticals and Poison Act 1978 and the 1990 regulations) to ensure that this requirement was explicitly stipulated in the Act.

Locally, a National Health Policy (NHP) was formulated in 1990 (MOH 1990), followed by the National Drug Policy (NDP) in 1991. The connection between the NDP and promises of local industrial support is obvious in both documents, only faintly echoing the previously prevailing, but crumbling, socialist ideals. The NHP categorically states, “The main objective of this policy is to encourage the growth of local public and private pharmaceutical industries in order to enhance self-reliance in the production of essential drugs” (MOH 1991). For its part, the NDP (1991) aimed to develop and support the national pharmaceutical industries with a view to increasing local production, thus encouraging self-reliance (MOH 1993). To do this, it promised to ensure the necessary protection until the local drug manufacturing industries matured to full competitiveness. The NDP further emphasized the need to do away with imported drugs from outside the region to support the local production of drugs and related APIs to achieve optimal self-reliance.

The restructuring of the local pharmaceutical sector also gained political support. During the 1991/1992 parliament session, when presenting the Ministry of Health Budget estimates, the then Minister of Health, Professor Philemon M. Sarungi, widely supported these new multilateral directives and endorsed the introduction of GMPs and their elements, such as drug quality inspection, certification to international standards, and drug quality assessment by local accredited laboratories (MOH 1991). He further emphasized that no drugs should be imported unless there was a deficit. This was a clear indication of the government’s intention to protect the local industry and boost local capacity.

However, the promotion of the local pharmaceutical industry and of GMPs were seemingly in friction with one another, to the detriment of the former. The speech was, in the same year, followed by probably the first official documentation developed to translate various elements of the Tanzania National Drug Policy of 1991 into practice, in the form of a Pharmaceutical

²² World Bank Health Section Review, 1988, MDC 340: DA/105/124/06/45.5, TMDA, Dodoma.

Master Plan for 1992–2000, launched in 1993 (MOH 1993). Key aspects of the plan included drug regulation matters, registration and inspection, and the production of essential drugs by the local pharmaceutical industry, now under GMP.

Overall, between 1992 and 2002, we see improvement in the pharmaceutical board structure and regulation implementation. Before this restructuring, the Pharmacy Board was composed of only four sections: Medicine Registrations, Inspections, Laboratory Services, and Drug Information, with heads of sections reporting to the Registrar.²³ The restructuring included the Board now being composed of 12 appointed members, whose operations were undertaken by a secretariat organized into six departments: Registration of Premises, Drug Registration, Drug Inspection, the Drug Quality Control Laboratory (launched in 2000), and the Drug Information Department and Registration of Pharmacists. The Board established six technical committees (TCs) to advise it on technical matters. They included Pharmacy, Drug Inspection, Drug Registration, Drug Quality Control Laboratory, Veterinary Drugs, and Drug Information (TFDA 2013).

Responding to GMPs in practice

In essence, GMPs received the full backing of the government, and they were seen in its plans as an important contribution to improving its local pharmaceutical industry. However, their introduction became entangled with global economic circumstances whereby the country unwillingly opened its doors to free market-based policies after years of socialism. As such, the GMP guidelines demanded a rapid change in drug manufacturing culture and infrastructure in order for the post-independence socialist leadership to fully realize its promise of self-reliance, with a robust manufacturing industry that included a vibrant pharmaceutical manufacturing sector that would dominate drug imports. How this was to be achieved depended very much on the readiness of the existing local pharmaceutical industry, which is what we turn to now. Specifically, we will look at Mansoor Daya and Interchem.

Mansoor Daya

The World Bank report was sent to the respective companies that were assessed. Daya responded to the Pharmacy Board Registrar with a letter of protest.²⁴ In this letter, the owner Mr Daya denied many of the issues raised, such as cross-contamination issues, the combining of insecticide and human drug production sites, and problems of quality control. To further argue his case, he claimed that the company had sent its products abroad (to the UK) for quality tests regularly. He rejected the accusations by pointing the finger at the Board for failing to set adequate standards for pharmaceutical industry. He ended the letter by demanding that the World Bank respond by producing a corrected version to give a true picture of his factory.

Considering the World Bank report and Daya's letter of response to the board, it was clear that the yardstick used by the World Bank to assess the local plants was informed by the GMPs as an emerging global standard, based on a very different approach than previously, when notification by producers had been the norm. Daya's reaction could be justified, since

²³ Some sections, such as Drug Information, were operated from and by the pharmacy department of the Muhimbili Medical Centre 1986, through a programme known as Tanzania Drugs and Toxicology Information System (TADATIS). Laboratory analysis was still implemented by the government chemist until the Board constructed its own lab (built 1994–1998, inaugurated in 2000).

²⁴ M.S. Daya to the Registrar, Pharmacy and Poisons Board, February 21, 1989, MDC 340: DA/105/124/06/46, TMDA, Dodoma.

the company was yet to be informed about the major changes that this implied for them. Amid this fracas, the Pharmacy Board inspected Daya on February 18, 1992 and produced a report.²⁵ Compared to the previous reports, this one was different in substance, length, and tone. The preamble categorically stated that the inspection was “carried out in accordance with WHO Good Manufacturing Guidelines and as outlined in the Pharmaceuticals and Poisons Act 1978, regulations of 1990”.²⁶

Overall, the report revealed many inadequacies, echoing what the World Bank had reported. Compared to the World Bank report, it was more incriminatory. Seemingly ordinary but important GMP aspects were also raised, such as dress codes and tea preparation in the lab area. The company was then ordered to solve the problems raised immediately and was given notification of re-inspection after three months, a rather minimal timeframe to accomplish all the requirements realistically.²⁷ When it applied to the Pharmacy Board to renew its license on January 4, 1993, the Board followed up on March 15, 1993 with a rather short, itemized letter, which refers back to the previous report by issuing concrete recommendations on areas that ought to be rectified as soon as possible, including the restructuring of the company’s plant, an activity that required massive investment over time.²⁸

There is little doubt that these detailed inspections reflected the introduction of GMPs by the WHO. They were unlike the previous notification practices, where we only saw applications for licences to manufacture and the granting of permits by voting. Now the regulation and control of pharmaceutical production was tightened. In 1992, the WHO Expert Committee on Specifications for Pharmaceutical Preparations had published guidelines for the inspection of pharmaceutical manufacturing according to GMPs for national regulatory authorities as a means to strengthen and facilitate the implementation of the WHO Certification Scheme (WHO 1992), giving local authorities a new lever to use.

It is impossible to say whether Mansoor Daya submitted any letter of response to the Pharmacy Board on the critical assessment of his factory based on GMPs, as the company did following the World Bank assessment report. There is no such response in the archive. However, the file contains two further licence application submissions for manufacturing pharmaceuticals to the Pharmacy Board, one from January 1994²⁹ and one from January 1995.³⁰ The file does not contain communication from the Board to evaluate whether the irregularities identified were addressed. But from these two submissions, we can infer that production continued regardless. After the application to manufacture drugs submitted in 1995, the folder was silent until August 1998 when the Pharmacy Board initiated a communique to all pharmaceutical dealers (retail, wholesale, and manufacturers) to abide by regulations by displaying original certificates of their registration. The letter also signals the incoming of a new Registrar.³¹

²⁵ Inspection report, Mansoor Daya Chemicals Ltd, February 1992, MDC 340: DA/105/124/06/53, TMDA, Dodoma.

²⁶ Inspection report, Mansoor Daya Chemicals Ltd, February 1992, MDC 340: DA/105/124/06/53, TMDA, Dodoma.

²⁷ Before GMPs inspections were implemented when a pharmaceutical factory was being set up.

²⁸ L.R. Mhangwa to Mansoor Daya Chemicals Ltd., March 15, 1993, MDC 340, DA/105/124/06/55, TMDA, Dodoma.

²⁹ Application for Manufacture of Pharmaceuticals, January 4, 1995, MDC 340, DA/105/124/06/56, TMDA, Dodoma.

³⁰ Application for Manufacture of Pharmaceuticals, January 4, 1995, MDC 340, DA/105/124/06/57, TMDA, Dodoma.

³¹ M. Ndomondo, Registrar PB, to all pharmaceutical dealers, August 14, 1998, MDC 340, DA/105/124/06/ 58, TMDA, Dodoma.

To sum up Mansoor Daya's journey up to 1990, one could say that the company was functional, serving its market and earning money, but the wind of change now blew in its face. Before the arrival of GMPs, private pharmaceutical production was a profitable venture for the few local companies that existed. This is the story told by the uninterrupted flow of pharmaceutical licences Daya received before GMPs began to be implemented. The World Bank report summarizes this period well by arguing that since there was a huge national demand for drugs in the 1980s, foreign currency shortages raised demand locally, impacting their prices (World Bank 1989). The drugs, including those manufactured by private companies, were exclusively purchased by Central Medical Stores (CMS) and the National Pharmaceutical Company (NAPCO). Hence marketing and promotion costs were presumably small. It was assumed that such a situation most likely contributed to companies ignoring quality assurance and control. Further, some structural advantages offered themselves to these companies. They did not incur research and development costs, since most formulations were freely supplied, and the government abolished the 100% import duty on all active drugs and raw materials (World Bank 1989).

Interchem narrative

Compared to Daya, Interchem, owned by a local African family, was a latecomer in the pharmaceutical manufacturing sector. Mr Benjamin M. Mengi, its first Director, seems to have seized an opportunity brought in by the liberalization policies of the late 1980s that allowed private capital to flourish. A significant contrast to MS Daya, Interchem entered the pharmaceutical manufacturing sector as a novice with no experience either in pharmaceutical manufacturing or in the business part of it. It was, however, part of the IPP conglomerate that included large media interests in print and television, as well as beverages, among other products (Tibandabage et al. 2016). To pursue such an undertaking was to venture into unknown waters. To navigate this period, the files show that Interchem received technical cooperation from a local consultant to formulate and manufacture drugs and recruit personnel as far back as September 1985, suggesting that the company began preparations a while earlier.³² The company applied to manufacture human and veterinary drugs in September 1988.³³

Interchem was first inspected by the Pharmacy Board on January 21, 1989³⁴, the same year the World Bank review report quoted above was officially published. It commenced production of veterinary medicines afterwards. The second inspection was conducted in February 1991³⁵, after they submitted their second application to produce human medicines, which suggests an increase in confidence based on their experience in veterinary production and various investments made: "Having successfully manufactured veterinary pharmaceuticals since 1989, we wish to apply for permission to manufacture pharmaceuticals for Human use namely (...) at the moment we feel we can satisfactorily manufacture intended products as per Good Manufacturing Practice regulations."³⁶ The emphasis on GMPs suggested that awareness of these requirements had reached the company management. In fact, GMPs had just been included in the Pharmaceutical and Poison Regulations of 1990 and Interchem was paying attention.

The results of the two initial inspections are an interesting read. At best, they suggest leniency and consideration of the start-up. The language used in the reports was uplifting and full

³² N. Njau to B.A. Mengi September 26, 1985, IPL 359, DA/05/124/08/11, TMDA, Dodoma.

³³ Application for Manufacture of Pharmaceuticals, IPL 359, DA/05/124/08/2, TMDA, Dodoma.

³⁴ Inspection Report: Manufacture of Veterinary Medicine by M/S Interchem Pharm. Ltd, IPL 359, DA/05/124/08/5 TMDA, Dodoma

³⁵ Inspection Report of Interchem Pharma Ltd, February 12, 1990, IPL 359, DA/05/124/08/25, TMDA, Dodoma

³⁶ B.A. Mengi to Registrar, Pharmacy Board, January 7, 1991, IPL 359 DA/105/124/08/24, TMDA, Dodoma

of praise: “The standards achieved are very good”. Comments were made on seemingly trivial issues to pharmaceutical manufacturing requirements and were rather soft in their wording: “The toilet facilities are adequate but situated far from the changing room”, “The premises outside the factory seemed to impress the inspectors very much”, “The surrounding area was well tended with flowers and well-cut green lawn” – although they further note a lack of relaxation facilities, such as seating areas, under the tree shades “so that workers can get fresh air during coffee/tea or lunch breaks”. Some criticisms pertained to the storage facilities: “There was no separate cold area for storage of inflammables and alcohol”. In general, both reports ended with both flattering and encouraging comments.³⁷

Taking into account the GMP requirements, both inspections were light. This was probably because the factory was only just starting and the GMP framework was little known. However, there was a dramatic turn with the third inspection in February 1992. In this report’s introduction, the authors made it known what guided the inspection: “The inspection was carried in accordance with the WHO Good Manufacturing Guidelines, and as stipulated in the Pharmaceuticals Act, 1978, Regulations 1990”.³⁸ The language in the report changed dramatically, and the directives were given as orders rather than advice, as had been the case in the previous reports. For each item listed, the report raised strong criticisms. For example, it noted failure to prove expiration dates assigned to products and the absence of so-called stability studies: “The team directs stability studies be instituted immediately”. The sanitary section, softly judged in the previous reports, was now deemed disqualified because there were not enough toilets. Further, the company had to address a minimum of 24 procedures straightaway, including improvement of quality control practices. The management was directed to the WHO GMP guidelines for guidance. The re-inspection visit interval was shortened from 12–18 months to three months. The management was instructed to conform to the regulations within that period.

All these requirements certainly put the brakes on the company’s plans and tremendously slowed down Interchem’s pharmaceutical manufacturing ambitions, as they demanded substantial investment. In contrast to Daya, however, Interchem had arrived on the market as a newcomer and as far as regulations were concerned it responded with compliance. The controls were rapidly upgraded, and there were no attempts to negotiate, as evidenced by the files’ silence in response to the Pharmacy Board regarding these inspection reports. The details in each new report also reflected the expanding capacity of the Board in terms of the length, scrutiny, and depth of the recommendations. Three inspectors are also involved, instead of the one mentioned in the first report. From the company’s perspective, this seems to have worked. Interchem submitted licence applications in November 1993,³⁹ and an application for renewal in August 1995,⁴⁰ suggesting it continued production. After that, similar to Daya, the Interchem file also went silent, with no correspondence between Interchem and the Pharmacy Board until August 1998.

³⁷ Inspection Report of Interchem Pharma Ltd, February 12, 1990, IPL 359, DA/05/124/08/25, TMDA, Dodoma.

³⁸ Inspection Report of Interchem Pharma Ltd, February 12, 1990, IPL 359, DA/05/124/08/28, TMDA, Dodoma.

³⁹ Application for Manufacture of Pharmaceuticals by Interchem Pharma Ltd, November 8, 1993, IPL 359, DA/05/124/08/32, TMDA, Dodoma.

⁴⁰ Application for Manufacture of Pharmaceuticals by Interchem Pharma Ltd, November 8, 1993, IPL 359, DA/05/124/08/34, TMDA, Dodoma.

The incoming Registrar and the hastening of GMP implementation

The Pharmacy Board gained a new Registrar, an experienced pharmacist, Ms Margaret Ndomondo-Singonda⁴¹, in 1998 (TFDA 2013). Her ascendancy to the position coincided with major restructuring happening across government parastatals, which touched upon the Board itself, which was then still part of the Pharmaceutical Unit of the Ministry of Health. This restructuring was made possible by the Executive Agencies Act, Cap 345 of 1997, which came in as part of the structural adjustment programmes that recommended restructuring of some government departments (into semi-independent government agencies), especially those serving clients and the public in the markets, so as to bolster the provision of services to the public (Mbwasi et al. 2023).⁴²

In the wake of Ms Ndomondo-Singonda's arrival, the files now show a drastic change in the communication style between the regulator and the manufacturers, as far as GMPs were concerned. Essentially, her arrival seemed to drastically upped the GMPs implementation. For instance, most of the communications to pharmaceutical manufacturers now had to do with the GMPs. Directives on their implementation were issued, now routinely accompanied by pointing out that legal actions would be pursued if they were not followed. During this period, there was a strong determination to have manufacturers comply with the GMP framework without further delay. For example, the new Registrar's second letter to all manufacturers, titled "Follow-up inspection of GMPs" of [date], was a reminder about a circular issued on April 13, 1999 that had instructed manufacturers to comply with the GMPs' specific requirements within a defined period.⁴³ The circular came against the backdrop of "The Guidelines for Good Manufacturing Practices Order, 1999 Regulations" and was preceded by a sensitization workshop for all pharmaceutical manufacturers. This workshop was informed by a baseline survey conducted in 1998 to assess the status of compliance with GMP requirements since their introduction. The Board then conducted a re-inspection of all manufacturers between April and October 2000 to re-evaluate compliance with the inspectors' propositions that they had received in 1998. The inspection evaluated seven pharmaceutical manufacturing plants, including three "extemporaneous preparation units". Seven key aspects related to GMPs were evaluated, including personnel, premises, warehouse, production area, equipment, documentation, and quality control (Board 2000).

The conclusions from that report showed that producers had yet to comply with GMP, but the issues identified varied in severity. Three broad recommendations were issued by the inspectors to the companies. First, two manufacturers were reported to have tried to conform to GMP requirements and were ordered to resolve them. Secondly, three companies, including Daya and Interchem, were ordered to stop manufacturing pharmaceuticals until the major deficiencies found were addressed. Interchem, in addition, was told not to submit licence applications until all irregularities identified were addressed. Two companies were considered to have totally failed and it was recommended to revoke their licences altogether (Pharmacy Board 2000).

⁴¹ At the time of taking up the role, she was already Chief Pharmacist at the Ministry of Health.

⁴² The proposed new law, known as the Food, Drugs and Cosmetics Bill 2002, underwent its first reading in parliament in the same year. Its enactment was expected in 2003. To that effect, the Tanzania Food Drugs and Cosmetics Authority (TFDA) was later formed under the Tanzania Food, Drugs and Cosmetics Act, Cap 219 of 2003 (repealing the Pharmaceuticals and Poisons Act No. 9 of 1978 and The Food (Control of Quality) Act, No. 10 of 1978. Ms Ndomondo-Singonda came in to spearhead this transition, leading a team of eight experts constituted in 2000 to coordinate the establishment of TFDA. She went on to become its first Director from 2003 until 2010.

⁴³ Follow up "Inspection of Good Manufacturing Practice" letter, January 17, 2000, IPL 359, DA/05/124/08/41, TMDA, Dodoma.

This was the first time since the introduction of GMPs in the early 1990s that local pharmaceutical companies had been compelled to stop production. In other words, the GMP policy had facilitated a halt in the local production of pharmaceutical materials by some companies. Instituting a new production culture that required sophisticated technological advancements, the introduction of GMPs caused most private production companies in Tanzania to succumb. The inspection report, interpreted in light of the journey Interchem and Daya had embarked on since their first registration, shows how local companies still had a mountain to climb to reach the promised land of local drug abundancy, and GMPs were, in large part, roadblocks on their way. Note that it took Interchem ten years to even begin to fulfil the GMPs. Astonishingly, compared to Interchem, Daya, who had been in the game for many years, seems to have performed even more poorly, indicating that when it came to GMPs, experience did not matter most. Rather, substantial investments were immediately required if local manufacturers could successfully compete with the drug imports that were flooding the country at the same time, a situation we elaborate on further below.

GMP frustrations

As the rollout of GMPs continued, so did the pressure on the companies' ability to continue production. The communication from manufacturers to the Board attests to this, and the challenges to continuing production became obvious as the companies took steps to conform to the GMPs. For example, in October 2000, Interchem had submitted a layout plan for its intended penicillin plant, and had then been waiting for a response for almost six months after claiming to have addressed GMP inspection report issues raised by an inspection conducted by the Board in April 2000. Interchem seemed to believe that the regulator was intentionally dragging its feet and instructed the Board to speed up its approval of the plans:

Interchem Pharma Ltd is very well aware of instructions which have been issued by the board as far as the implementation of GMP is concerned. Our detailed business plan for implementation of GMP was forwarded to your office through our letter with reference no [...] on 16th October 2000 [...] We had submitted to your office a sketch of the Penicillin's Plant for your comments and approval before we could initiated [sic] the refurbishment project. I am again forwarding to your office a **detailed refurbishment plan for the whole plant which is intended to solve, once and for all, the deficiencies noted in your report ie. The flow of production activities and air handling system.** This plan **MUST BE APPROVED** from your side for us to chart out the implementation process, thought in a phased manner. (emphasis in the original)⁴⁴

The letter from Interchem sums up well the ten years since the introduction of the GMPs as advised by the WHO. It not only echoes their mainstreaming, but even more, it positively reflects on the evolution of the Pharmacy Board, as a regulatory authority, as a driving force in the implementation of pharmaceutical manufacturing regulation at the time. The archives we studied contain numerous documentations of plans to regulate the quality, safety, and efficacy of food, medicines, cosmetics, and medical devices under a newly executive agency.

⁴⁴ P. Rite, Interchem Pharmacist, to the Registrar, Pharmacy Board, March 27, 2001, IPL359: DA/105/124/08/43, TFDA, Dodoma.

Consequences: Local GMPs, drug importation and the strengthening of regulation

Rapid gains in the strengthening of drug regulations, including drug manufacturing in line with GMPs, seem to have been made immediately before TFDA was officially launched as an autonomous agency in 2003. When Ms Ndomondo-Singonda joined the Board as a Registrar in 1998, there were only 32 staff. That number had reached 51 by 2002 (MOH 2002). The centrality of GMPs as a prerequisite for manufacturing pharmaceuticals is further evidenced in regulations made between 1978 and 2001. Of only eight regulations made under the Pharmaceutical and Poisons Act No. 9 of 1978 to facilitate the regulation of medicines, the Guidelines for Good Manufacturing Practices Order of 1999 is one of them, one year after Ms Ndomondo-Singonda became Registrar (TFDA 2013). The introduction to the 2002 Pharmacy Board Annual Report states that the Good Manufacturing Practices (GMP) status of local manufacturers has been upgraded, meaning that their capacity to conduct GMPs has also increased. The board now not only ensures manufacturers' compliance with GMPs but also offers practical guidance to local pharmaceutical manufacturers to help them upgrade their level of compliance with GMP requirements (MOH 2002).

By the end of the 1990s, the Pharmacy Board had become increasingly worried by a growing number of imported pharmaceuticals against the backdrop of poor local drug production capacity. Indeed, at its 53rd board meeting on August 17, 2000 the Board tabled recommendations for new guidelines for the importation of pharmaceuticals. The introduction to the guidelines recognized the opportunities brought by the free market economy that had paved the way for liberal market policies and that had brought about a dramatic increase “in the number of persons and companies that opted to deal with pharmaceuticals”, noting that the number of importers, wholesalers, and retailers had significantly increased. The introduction further admitted that the importation of pharmaceuticals did not match the capacity of local pharmaceutical manufacturers to increase production for one particular reason, the GMPs themselves: “Local pharmaceutical manufacturers who have the capacity to manufacture drugs according to Good Manufacturing Practice (GMP) as recommended by the World Health Organization (WHO) have gone down giving more room for imports from overseas” (Pharmacy Board 2000). This admission is supported by the Pharmacy Board's increased capacity to conduct GMP inspections both locally and abroad. By the end of 2002, a total of 54 manufacturing plants were inspected under the GMP framework, of which 49 were overseas (India, China, Korea, Kenya, and Zimbabwe) and only five were local (MOH 2002). These numbers clearly point to trends in importation, with more manufacturers from abroad importing more drugs than local players could deliver.

Indirectly conveyed, the Board acknowledged that GMPs had emerged as an obstacle for local manufacturers seeking to supply the domestic market with pharmaceuticals, despite the government's policy, established in 1990, of prioritizing local capacity. Nevertheless, the enforcement of GMP regulations on local manufacturers by the Board inadvertently facilitated the influx of imported pharmaceutical products into a market characterized by weak regulatory oversight. For instance, while the GMP framework was being implemented within the country, imported pharmaceuticals were not subjected to Tanzania GMP inspections until much later (Pharmacy Board 2000). Further ahead, in the introduction to the guidelines for importation mentioned above, the Pharmacy Board directly admitted to the fact that it had become difficult for them to effectively deal with the irregularities in the importation of pharmaceuticals into the country.

Data obtained from the Tanzania Revenue Authority Annual Trade and Statistics Reports for the years 1976–1988 show an upward trend in the quantities and corresponding values of pharmaceutical products imported into Tanzania during that period (Tanzania Revenue Authority 1977, 1980, 1999a, 1999c). The report highlights a surge in the volume of pharmaceutical imports from 1980 to 1998. Specifically, while 3,104 tons of imports worth approximately 260 million shillings were recorded in 1980, this amount skyrocketed to 130,603 tons in 1995, with a value close to 27 billion shillings (see Table 2). This surge provides further evidence to support the Pharmacy Board’s concerns regarding the declining capacity of local manufacturers to meet domestic market demands and the increase in dependency on imports.

Table 2: Pharmaceutical products directly imported to Tanzania from other countries⁴⁵

Year	Quantity imported (tonnes)	Values of direct imports (Tanzania shillings (TZS))	Values of direct imports (USD)
1976	2,582	121,961,572	14,553,886.87
1977	3,568	144,644,677	17,448,091.31
1979	4,788	205,656,763	25,019,070.92
1980	3,104	259,202,846	31,610,103.17
1995	13,603	30,711,919,591	53,434,337.1
1998	17,047	26,811,858,838	40,338,602.37

Concerning the transition to dependence on pharmaceutical products from Asia, it is noteworthy that by 1995, a significant portion of pharmaceuticals continued to be imported from Europe. According to the Tanzania Revenue Authority (1999b, 1999c), Tanzania imported a total of 17,919 tonnes of pharmaceuticals in 1995, from Europe (Table 3), and 5,781 tons originated from India (Table 4).

Table 3: Pharmaceutical products directly imported to Tanzania from Europe in 1995 and 1998

Year	Quantity imported (tonnes)	Imported values (TZS)	Imported values (USD)
1995	17,919	19,403,270,525	33,758,908.98
1998	2,914	10,813,112,278	16,268,392.25

By 1998, within a short span of three years, the volume of pharmaceuticals imported from Europe decreased to 2,914 tonnes, whereas imports from India rose to 12,320 tons (refer to Table 4).

⁴⁵ Tanzania Revenue Authority (TRA), *Annual Trade Statistics Report of Tanzania, 1977* (Dar es Salaam: Tanzania Customs and Excise Department, 1977), 41–45. See also TRA, *Annual Trade Statistics Report of Tanzania, 1980* (1980), 63–67; TRA, *Annual Trade Statistics Report of Tanzania, 1995* (1999), 97–104; TRA, *Annual Trade Statistics Report of Tanzania, 1998* (1999), 75–81.

Table 4: Pharmaceutical products directly imported to Tanzania from India in 1995 and 1998

Year	Quantity imported (tonnes)	Imported values (TZS)	Imported values (USD)
1995	5,781	6,609,209,434	11,499,076.89
1998	12,320	7,063,538,733	10,627,136.37

Ultimately, this paper argues that while local manufacturers were striving to comply with stringent GMP requirements, this put importers of mainly Indian-sourced pharmaceuticals in an advantageous position, allowing them to flourish at the expense of local manufacturers. Effectively, the government's local industry protection drive was limited by the lack of local capacity to comply with GMPs as per the timetable given to do so. It should be recalled that while local manufacturers were subjected to GMPs from the 1990s onwards, the 1990 pharmaceutical regulations document did not allow for GMP inspections of pharmaceutical industries abroad, practically shielding importers from scrutiny by the authorities in the countries they imported into. This was not considered until the early 2000s, when the budget proposal to do so was first tabled at a regular Board meeting. It meant that while local pharmaceutical companies were striving to comply with GMPs, imports gained the upper hand. It is, therefore, safe to assume that the tightening of regulations requiring local manufacturers to comply with GMPs facilitated the flooding of the local market with imported pharmaceutical products, increasingly from India.

Economists have recently argued that an improved local supply of consistently produced drugs is a non-negotiable option for improved accessibility and assurance of supply in Tanzania (Chaudhuri et al. 2010). This might be desirable, but it is not what happened in history. Instead, the gaps in the regulations at the time allowed Indian manufacturers to take advantage of them (Chaudhuri et al. 2010; Chaudhuri et al. 2005; Joseph 2015). These authors suggest that manufacturers from India were believed to have used regulatory and administrative loopholes to supply both standard and substandard drugs to the Tanzanian market. These companies strategically concentrated in 'unregulated markets' to conduct their business. Based on a historical analysis, 'loophole' is not the best term to describe what happened. Instead we argue that the introduction of GMPs in Tanzania created a situation where importers were privileged. Some parallels can be drawn here from the local cases we have studied, showing foreign drug companies exploiting a gap in the market created by the introduction of GMPs; other developing countries, mostly in the Global South, saw comparable events (Greene 2011; Yudkin 1978).

The final step to tightening GMPs came when the Pharmacy Board, during an extraordinary board meeting on February 16, 2001, tabled a proposal to amend the pharmaceutical and poison regulations of 1990 (Pharmacy Board and Ministry of Health 2001). The first point on the agenda proposed that all pharmaceutical manufacturing arrangements were to be made in line with GMPs and this was to form the basis for issuing licences for manufacturing operations. In other words, licences could be issued and drug production could commence if the Board was satisfied that the company was GMP compliant. At the same meeting, the Board also proposed granting authority to any business person to export pharmaceuticals. This had previously been assigned to local manufacturers alone, but the amended 1990 regulations now allowed importers to export their products to regional markets. Allowing the export of drugs by importers further damaged local manufacturers, who had hitherto boosted their earnings through exports into the existing and thriving regional markets.

Conclusions

Damaging to local business as it was, the introduction of GMPs directly contributed to the strengthening of the local regulatory authorities (Baxerres and Cassier 2021a; Pourraz et al. 2022). This pertinent aspect was evident in the archives in terms of the quality and number of reports produced by the regulatory authority in the course of GMP implementation from the early to late 1990s. Drug regulators from the Board had to be oriented about GMPs and this necessitated technical capacity investment. This was made possible by the support the Pharmacy Board received from the WHO when the GMPs became an official policy and was adopted by the government in the 1980s and 1990s (WHO 1985). The late 1990s saw rapid efforts to spearhead policies, build infrastructure, and strengthen human and laboratory capacity, leading to the establishment of the TFDA in 2003 by an Act of Parliament (Fimbo et al. 2024). This capacity strengthening and the latter determination to ensure that only quality drugs were imported meant the need to conduct GMPs for overseas companies, a breakthrough that only came in 2002. It thus did not come as a surprise when the first GMP inspections conducted in Asian manufacturing companies and those in other African countries found that some were not complying with GMPs.⁴⁶ Yet these drugs were imported and consumed locally even when local companies were being ruthlessly grilled over GMPs throughout the 1990s. By the time the TFDA was officially inaugurated in 2003, there were only two pharmaceutical companies that were GMP compliant, out of eight (Mhamba and Mbirigenda 2010)⁴⁷. It is unfortunate to note that GMPs are still one of the main obstacles to the growth of local pharmaceutical manufacturing to date, as documented in a recent study (Mhando et al. 2025).

This study traced the trajectory of global pharmaceutical policy with a focus on GMPs from their global origins to their rollout in Tanzania through the archives of the Tanzanian Drug Regulatory Authority. The files depict how drug manufacturers were caught off-guard when the regulations were introduced. Regulations arrived at a time when the country was undergoing major socio-economic reforms, from a government-led and protectionist economy to a liberalized import regime and an import-dependent economy (Tibandebage et al. 2016). In practice, this allowed for foreign-produced drugs to flood the country, ultimately meaning that the political promise of local drug manufacturing remained unfulfilled. The global GMP framework had evolved to ensure that high-quality drugs were produced, in response to negative experiences in markets in high-income countries. Such initiatives damaged industries in the South. The archives consulted show that in the decline of local pharmaceutical manufacturing from the 1980s up to 2000, which in the literature is heavily linked to global economic crises, the introduction of GMPs played a decisive role. Rather than technology, economy, and regulation being the determining forces of industrial decline in Tanzania in the post-liberal era (Chorev 2019b; Tibandebage et al. 2016), the role of regulation in the form of GMPs was also evident prior to the effects of a market economy in general terms. Effectively, the change in drug regulations and guidelines has to be considered the driving force behind the technological change at the time. Without the change in regulations, there was no incentive to invest in any drug technological development. The funds for that, however, were missing in the general economic malaise of these years. As the entanglements between local manufacturers and regulators continued, they thus paved the way for market domination by imported drugs.

⁴⁶ Director General, Inspection of Pharmaceutical Premises 2004, GMP INSPECTION OVERSEAS 357: DA105/127/04/07, TMDA, Dodoma. [20220914_144301]

⁴⁷ These were Tanzania Pharmaceutical Industries (TPI) and Shelys Pharmaceuticals. Both achieved compliance largely through funding from development partners.

Acknowledgments

We gratefully acknowledge the financial support of the Research Council of Norway (SAMKUL programme) for this study. We express our sincere appreciation to the Director General of the Tanzania Medicines and Medical Devices Authority (TMDA) for granting access to the archives in Dodoma. We thank TMDA staff, Dr Danstan Hipolite Shewiyo, and Mr Chrispin Mesiaki Severe for their institutional navigation support and for sharing insights into the numerous regulatory aspects of medicines in Tanzania and beyond. We are grateful to the two anonymous reviewers for their constructive feedback. We also thank our colleagues at the Department of Community Medicine and Global Health, as well as participants in the research project “From Asia to Africa: Antibiotic Trajectories across the Indian Ocean” (FAR), whose discussions enriched this article. Finally, we thank the Director General of the National Institute for Medical Research (NIMR) for granting permission to publish this article.

References

- Abel-Smith, Brian, and Pankaj Rawal. 1992. “Can the Poor Afford ‘Free’ Health Services? A Case Study of Tanzania.” *Health Policy and Planning* 7 (4): 329–341.
- Abraham, John. 2008. “Sociology of Pharmaceuticals Development and Regulation: A Realist Empirical Research Programme.” *Sociology of Health & Illness* 30 (6): 869–885.
- Ballentine, Carol. 1981. “Sulfanilamide Disaster.” *FDA Consumer Magazine* 5.
- Banda, Geoffrey, Samuel Wangwe, and Maureen Mackintosh. 2016. “Making Medicines in Africa: An Historical Political Economy Overview.” In *Making Medicines in Africa: The Political Economy of Industrializing for Local Health*, edited by Maureen Mackintosh, Geoffrey Banda, Paula Tibandebage, and Watu Wamae, 7–24. Palgrave Macmillan.
- Baxerres, Carine, and Maurice Cassier. 2021a. “Introduction: Pharmaceutical Markets in the Global South: Shaped by History and Multiple Regulations.” In *Understanding Drugs Markets: An Analysis of Medicines, Regulations and Pharmaceutical Systems in the Global South*, edited by Carine Baxerres and Maurice Cassier, 1–26. Routledge.
- Baxerres, Carine, and Maurice Cassier. 2021b. *Understanding Drugs Markets: An Analysis of Medicines, Regulations and Pharmaceutical Systems in the Global South*. Routledge.
- Bech, Margunn M., Yusufu Q. Lawi, Deodatus A. Massay, and Ole B. Rekdal. 2013. “Changing Policies and Their Influence on Government Health Workers in Tanzania, 1967–2009: Perspectives from Rural Mbulu District.” *International Journal of African Historical Studies* 46 (1): 61–103.
- Berger, M., J. Murugi, E. Buch, C. IJsselmuiden, M. Moran, J. Guzman, M. Devlin, & B. Kubata. 2010. “Strengthening Pharmaceutical Innovation in Africa.” Council on Health Research for Development (COHRED). New Partnership for Africa’s Development (NEPAD).
- Chaudhuri, Sudip. 2005. *The WTO and India’s Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries*. Vol. 16. Oxford University Press.
- Chaudhuri, Sudip, Maureen Mackintosh, and Phares G. M. Mujinja. 2010. “Indian Generics Producers, Access to Essential Medicines and Local Production in Africa: An Argument with Reference to Tanzania.” *European Journal of Development Research* 22 (4): 451–468.

- Chaudhuri, Sudip, William Wade, and Christopher Forsyth. 2005. *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries*. Oxford University Press.
- Chorev, Nitsan. 2019a. *Give and Take: Developmental Foreign Aid and the Pharmaceutical Industry in East Africa*. Princeton University Press.
- Chorev, Nitsan. 2019b. "Making Medicines in Kenya, Tanzania, and Uganda in the AIDS Era: Toward a Sociology of Developmental Foreign Aid." *Sociology of Development* 5 (2): 115–146.
- Cueto, Marcos, Theodore M. Brown, and Elizabeth Fee. 2019. *The World Health Organization: A History*. Cambridge University Press.
- Daemmrich, Arthur A. 2004. *Pharmacopolitics: Drug Regulation in the United States and Germany*. Chemical Heritage Foundation.
- Dally, Ann. 1998. "Thalidomide: Was the Tragedy Preventable?" *The Lancet* 351 (9110): 1197–1199.
- Edward, Frank, and Ulrike Lindner. 2024. "Health Infrastructure Planning in Tanzania, 1961–1980s." *Zamani: A Journal of African Historical Studies* 1 (1): 83–114.
- Fimbo, Adam M., Hiiti B. Sillo, Alex Nkayamba, Sunday Kisoma, Yonah Hebron Mwalwisi, Rafiu Idris, Sarah Asiimwe, Patrick Githendu, Osondu Ogbuaji, and Linden Morrison. 2024. "Strengthening Regulation for Medical Products in Tanzania: An Assessment of Regulatory Capacity Development, 1978–2020." *PLOS Global Public Health* 4(10): e0003241.
- Gray, Hazel. 2013. "Industrial Policy and the Political Settlement in Tanzania: Aspects of Continuity and Change since Independence." *Review of African Political Economy* 40 (136): 185–201.
- Green, Maia. 2014. *The Development State: Aid, Culture & Civil Society in Tanzania*. Boydell & Brewer Ltd.
- Greene, Jeremy A. 2011. "Making Medicines Essential: The Emergent Centrality of Pharmaceuticals in Global Health." *BioSocieties* 6 (1): 10–33.
- van der Hoeven, R., F. P. M. van der Kraaij, and Netherlands Ministerie van Buitenlandse Zaken. 1994. *Structural Adjustment and Beyond in Sub-Saharan Africa: Research and Policy Issues*. Ministry of Foreign Affairs (DGIS).
- Immel, Barbara K. 2001. "A Brief History of the GMPs for Pharmaceuticals." *Pharmaceutical Technology* 25 (7): 44–53.
- Joseph, Reji K. 2015. *Pharmaceutical Industry and Public Policy in Post-Reform India*. Routledge.
- Kanji, Najmi, Anita Hardon, Jan Willem Harnmeijer, Masuma Mamdani, and Gillian Walt. 1992. *Drugs Policy in Developing Countries*. Zed Books.
- Kristinsdottir, G. 1991. "Registration of Pharmaceuticals, Tanzania: Action Programme on Essential Drugs and Vaccines." WHO Report (WHO/DAP/92.12)
- Lugalla, Joe L. P. 1995. "The Impact of Structural Adjustment Policies on Women's and Children's Health in Tanzania." *Review of African Political Economy* 22 (63): 43–53.

- Mamdani, Masuma. 1992. "Early Initiatives in Essential Drugs Policy." In *Drugs Policy in Developing Countries*, edited by Najmi Kanji, Anita Hardon, Jan Willem Harnmeijer, Masuma Mamdani, and Gillian Walt, 1–23. Zed Books.
- Mbwasi, Romuald, William Reuben, William Mfuko, and Zarina Shamte Madabida. 2023. "Health Commodities Supply Chain." In *Primary Health Care in Tanzania through a Health Systems Lens: A History of the Struggle for Universal Health Coverage*, edited by N. A. Kapologwe, J. T. Kengia, E. van Praag, J. Killewo, and A. Kalolo, 104–123. CABI.
- Mhamba, Robert M., and Shukrani Mbirigenda. 2010. "The Pharmaceutical Industry and Access to Essential Medicines in Tanzania." Institute of Development Studies, University of Dar es Salaam, Equinet Discussion Paper 83.
- Mhando, Frank, Hassan Tearish Berenge, Jianying Yue, Emmanuel Makundi, Hamisi M. Malebo, Shasha Tao, Anita Munubi, Abdallah Mkopi, Omary Juma, and Guanqiao Li. 2025. "Challenges and Solutions for Local Pharmaceutical Production in Tanzania." *Voice of the Publisher* 11 (2): 318–331.
- MOH. 1991. *Speech of the Minister of Health His Excellence Prof Philemon M. Sarungi (MP) on Estimates and Expenditure for 1991/1992 Financial Year*. Dar es Salaam: Ministry of Health.
- MOH. 1993. *The Tanzania National Drug Policy, The Masterplan for the Pharmaceutical Sector 1992–200- Tanzania Mainland, Hospital Therapeutic Committees*. Dar es Salaam: Ministry of Health.
- MOH. 2002. *Pharmacy Board Annual Report: January–December 2002*. Dar es Salaam: Ministry of Health.
- MOH. 1991. *Private Hospitals (Regulation) Amendment Act 1991*. Dar es Salaam: Ministry of Health.
- Munishi, Gaspar K. 1991. "The Development of the Essential Drugs Program and Implications for Self-Reliance in Tanzania." *Journal of Clinical Epidemiology* 45: 7–14.
- Nyerere, Julius K. 1967. *After the Arusha Declaration: Presidential Address to the National Conference of the Tanganyika African National Union Mwanza, 16th October, 1967*. Ministry of Information and Tourism.
- Parle, Julie, and Ludger Wimmelbücker. 2020. "'These Are the Medicines That 'Make' Monsters': Thalidomide in Southern Africa, 1958–1962." *Social History of Medicine* 33 (3): 898–923.
- Pharmacy Board. 2000. *54th Board Meeting*. Dar es Salaam.
- Pharmacy Board and Ministry of Health. 2001. *Extra Ordinary Board Meeting: Report*. Dar es Salaam.
- Pourraz, Jessica, Claudie Haxaire, and Daniel Kojo Arhinful. 2022. "Strengthening National Pharmaceutical Regulation through Local Production." In *Understanding Drugs Markets: An Analysis of Medicines, Regulations and Pharmaceutical Systems in the Global South*, edited by Carine Baxerres and Maurice Cassier, 29–51. Routledge.

- Rägo, Lembit, and Budiono Santoso. 2008. "Drug Regulation: History, Present and Future." In *Drug Benefits and Risks: International Textbook of Clinical Pharmacology*, edited by Chris J. van Boxtel, Budiono Santoso, and I. Ralph Edwards, 2nd edition, 65–77. IOS Press.
- Sangeda, Raphael Zozimus, Chimpaye Julius Ndabatinya, Maganga Bundala Maganga, Emmanuel Alphonse Nkiligi, Yonah Hebron Mwalwisi, and Adam Mitangu Fimbo. 2024. *Good Manufacturing Practice Inspections Conducted by Tanzania Medicines and Medical Devices Authority: A Comparative Study of Two Fiscal Years from 2018 to 2020*. Journal of Pharmaceutical Policy and Practice 17 (1): 2399722.
- Schneider, Leander. 2014. *Government of Development: Peasants and Politicians in Postcolonial Tanzania*. Indiana University Press.
- Silverman, Milton, Philip R. Lee, and Mia Lydecker. 1982. "The Drugging of the Third World." *International Journal of Health Services* 12 (4): 585–596.
- Sutton, John, and Donath Olomi. 2012. *An enterprise map of Tanzania*. Vol. 3. International Growth Centre in association with the London Publishing Partnership.
- Tanzania, Parliament of. 1973. "Hansards: Twelve Session, 16th Sitting, 30th June 1973." Dar es Salaam.
- Tanzania, Parliament of. 1976. "Hansards: Twelve Session, 10th June, 1976." Dar es Salaam.
- Tanzania, Parliament of. 1979. "Hansards: Tenth Session, 30th June, 1979." Dar es Salaam.
- Tanzania, Parliament of. 1980. "Hansards: Nineteenth Session, 18th Sitting, 9th July, 1980." Dar es Salaam.
- Tanzania Revenue Authority. 1977. *Annual Trade Statistics Report of Tanzania – 1977*. Dar es Salaam: Tanzania Customs and Excise Department.
- Tanzania Revenue Authority. 1980. *Annual Trade Statistics Report of Tanzania – 1980*. Dar es Salaam: Tanzania Customs and Excise Department.
- Tanzania Revenue Authority. 1999a. *Annual Trade Statistics Report – 1998*. Dar es Salaam: Tanzania Customs and Excise Department.
- Tanzania Revenue Authority. 1999b. *Annual Trade Statistics Report of Tanzania – 1995*. Dar es Salaam: Tanzania Customs and Excise Department.
- Tanzania Revenue Authority. 1999c. *Annual Trade Statistics Report of Tanzania – 1999*. Dar es Salaam: Tanzania Customs and Excise Department.
- Tarimo, Eleuther. 1978. "Health and Self-Reliance: The Experience of Tanzania." *Developmental Dialogue* 1: 35–40.
- TFDA. 2013. *Ten Years of Regulating Food, Medicines, Cosmetics and Medical Devices: Milestones Attained (2003–2013)*. Dar es Salaam.
- Tibandebage, Paula, Samuel Wangwe, Maureen Mackintosh, and Phares G. M. Mujinja. 2016. "Pharmaceutical Manufacturing Decline in Tanzania: How Possible Is a Turnaround to Growth?" In *Making Medicines in Africa: The Political Economy of Industrializing for Local Health*, edited by G. Banda, M. Mackintosh, P. Tibandebage, and W. Wamae, 45–64. Palgrave Macmillan.

- Tichenor, Marlee, Janelle Winters, Katerini T. Storeng, Jesse Bump, Jean-Paul Gaudillière, Martin Gorsky, Mark Hellowell, Patrick Kadama, Katherine Kenny, and Yusra Ribhi Shawar. 2021. “Interrogating the World Bank’s Role in Global Health Knowledge Production, Governance, and Finance.” *Globalization and Health* 17 (1): 1–12.
- Turshen, Meredith. 1977. “The Impact of Colonialism on Health and Health Services in Tanzania.” *International Journal of Health Services* 7 (1): 7–35.
- Vogel, Ronald J., and Betsy Stephens. 1989. “Availability of Pharmaceuticals in Sub-Saharan Africa: Roles of the Public, Private and Church Mission Sectors.” *Social Science & Medicine* 29 (4): 479–486.
- Wagao, Jumanne H. 1992. “Adjustment Policies in Tanzania, 1981–9: The Impact on Growth, Structure and Human Welfare.” In *Africa’s Recovery in the 1990s: From Stagnation and Adjustment to Human Development*, edited by Giovanni Andrea Cornia, Rolph van der Hoeven, and Thandika Mkandawire, 93–115. Springer.
- Wangwe, Samuel, Donald Mmari, Jehovanes Aikaeli, Neema Rutatina, Thadeus Mboghoina, and Abel Kinyondo. 2014. *The Performance of the Manufacturing Sector in Tanzania: Challenges and the Way Forward*. WIDER Working Paper.
- WHO. 1975. “Twenty-Eighth World Health Assembly, Geneva, 13–30 May 1975: Part I: Resolutions and Decisions: Annexes.” Geneva: World Health Organization.
- WHO. 1985. “Conference of Experts on the Rational Use of Drugs: Report by the Director-General.” Geneva: World Health Organization.
- WHO. 1992. “WHO Expert Committee on Specifications for Pharmaceutical Preparations: TRS 823 – 32nd Report.” Geneva: World Health Organization.
- World Bank. 1989. *Tanzania – Population, Health and Nutrition Sector Review*. Washington, D.C.
- Young, T. Kue. 1986. “Socialist Development and Primary Health Care: The Case of Tanzania.” *Human Organization* 45 (2): 128–134.
- Yudkin, John S. 1978. “Provision of Medicines in a Developing Country.” *The Lancet* 311 (8068): 810–812.
- Yudkin, John S. 1980. “The Economics of Pharmaceutical Supply in Tanzania.” *International Journal of Health Services* 10 (3): 455–477.