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REGULATION OF INDIAN-MANUFACTURED MEDICINES IN ZANZIBAR A REVIEW OF ZFDA REQUIREMENTS FOR REGISTRATION, IMPORTATION, QUALITY ASSURANCE AND POST-MARKET SURVEILLANCE

***Habibu Masoud Khalfan, Salim Omar Suleiman, Khalda Mmaka Hamad, Dr. Hitesh Vekariya.**

Department of Pharmacy, RK University, Gujarat, India.

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***Corresponding Author: Habibu Masoud Khalfan**
Department of Pharmacy, RK University, Gujarat, India.

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ABSTRACT

Background

When medicines move from one country to another, the requirements of the country of manufacture must be considered alongside those of the destination country. Indian-manufactured medicines supplied to Zanzibar must comply with applicable manufacturing requirements, the requirements of the Zanzibar Food and Drugs Agency (ZFDA), and relevant East African Community (EAC) regulatory cooperation arrangements.

Objective

This review examines the requirements governing the registration, importation, quality assurance and monitoring of Indian-manufactured human medicines supplied to Zanzibar. It focuses on the relationship between Indian Good Manufacturing Practices (GMP) and ZFDA requirements.

Methods

Publicly available documents from the ZFDA, the Government of India, the Central Drugs Standard Control Organization (CDSCO), the EAC and the World Health Organization (WHO) were reviewed and compared. Relevant studies on medicine registration, marketing authorization, importation requirements, GMP, quality assurance, medicine safety and post-market surveillance were also examined.

Results

The documents describe requirements for marketing authorization, medicine registration, manufacturing-site inspections, importation, storage, pharmacovigilance, post-market surveillance and product recalls. The EAC Medicines Regulatory Harmonization (EAC-MRH) initiative supports collaboration, shared assessments and regulatory capacity development. The review highlights the

importance of distinguishing manufacturing requirements from Zanzibar's market-entry requirements and identifying the requirements applicable to each medicine.
Ensuring the quality of Indian-manufactured medicines supplied to Zanzibar requires consideration of the applicable requirements in both India and Zanzibar throughout the product lifecycle. Understanding how these regulatory frameworks interact, together with the support provided by the EAC, can help protect medicine quality and patient safety. Further analysis of current regulatory instruments is needed to clarify country-specific expectations and identify any gaps in the available evidence.

KEYWORDS: Zanzibar; ZFDA; Indian-manufactured medicines; pharmaceutical regulation; quality assurance; post-market surveillance.

1.INTRODUCTION

Having medicines that're safe, useful and of good quality is a basic part of public health. Keeping the medicine quality high needs regulation at every step of the product life from making and developing the medicine to registering the medicine, importing the medicine, storing the medicine, distributing the medicine and checking the medicine after it reaches the market. These rules are especially important when medicines are made in one country and sent to another, because the rules that control manufacturing in the exporting country and the rules that allow marketing in the importing country have different goals.

India is a worldwide supplier of generic medicines and pharmaceutical goods to markets around the world including African nations. Medicines made in India can help make medicine more available and cheaper. The assurance of medicine quality depends on proper manufacturing standards, trustworthy product records, review by regulators and ongoing monitoring after the medicine reaches the destination market. Meeting Good Manufacturing Practices (GMP) in the country where the medicine is made gives proof of manufacturing quality but the medicine cannot be sold or brought into another country automatically.

In Zanzibar, the Zanzibar Food and Drugs Agency (ZFDA) oversees regulation of medicines and related work under its authority. This includes registering products, controlling imports, inspecting facilities, tracking medicine safety and watching medicines after they hit the market. Medicines that are meant for Zanzibar must be looked at with the rules that cover marketing permission, checks of manufacturing sites, import rules, storage, distribution and handling of quality or safety problems. Knowing these rules matters a lot for makers, importers, distributors and other people who help bring medicines from India to Zanzibar.

In India making medicines is controlled by the Drugs and Cosmetics Act and Rules which include the updated Schedule M rules about Good Manufacturing Practices (GMP) and quality systems. These rules set the controls for making medicines and the systems that keep product quality steady.
However, following rules and getting permission in the destination country are two different regulatory matters. A medicine that follows GMP rules still might need to meet ZFDA rules before it can be sold legally in Zanzibar. The exact duties depend on the laws, regulations, type of product and the way approval is sought at the time the application is made.

Regional cooperation is also a part of the regulatory picture. The East African Community Medicines Regulatory Harmonization (EAC-MRH) Programme encourages teamwork among the national medicines regulators in the region by doing things like shared reviews, common technical rules and helping build skills. These ways can help make regulatory steps uniform and faster across the area. Still a regional review or agreement does not automatically replace every permission or import rule. The exact route and legal power of any step must be checked for the particular medicine and the destination market.

Even though earlier work has looked at medicine regulation GMP rules and regional harmonization a review that links these topics to medicines made in India for Zanzibar is still needed. Specifically, how manufacturing rules ZFDA market entry rules and after-market quality checks connect at each stage of the medicine life cycle must be studied. Knowing these links clearly can separate rules that are already set from places that need checking of up-to-date official papers. The review can also point out points for people who want to help meet rules and keep quality medicines available.

Therefore, this review looks at the available rules that apply to medicines made in India for Zanzibar. The review looks closely at four areas: permission to sell and register the medicine, rules for importing the medicine, quality checks in manufacturing and GMP and watching the medicine after it reaches the market. The review also looks at how EAC-MRH works in teamwork and how it is different from national duties. By putting together rules and useful research papers the review wants to give a clear picture of the rule set spot key spots that need a check of the medicine or the latest documents and show what matters for keeping quality in the whole medicine supply chain.

2. METHODS

2.1 Study Design

The study used a narrative review and regulatory document analysis to look at the rules that govern Indian-manufactured human medicines that are meant for the Zanzibar market. The study looked closely at how the manufacturing standards in India match up with the rules in Zanzibar and how the wider regional medicines regulations fit. The study was set up to gather and combine available regulatory information and did not try to judge how well regulators enforce the rules.

2.2 Information Sources

The study gathered information from regulatory sources that are available to the public and from peer-reviewed scientific papers. Official sources were the Zanzibar Food and Drugs Agency (ZFDA), the Government of India, the Central Drugs Standard Control Organization (CDSCO), the Ministry of Health and Family Welfare, the East African Community (EAC) and the World Health Organization (WHO). Scientific papers were found on PubMed, PubMed Central (PMC) and on publisher websites.

2.3 Search Strategy

The study carried out targeted searches that used combinations of keywords and related terms. The main search ideas were "Zanzibar " "ZFDA," "medicine registration," "marketing authorization," "medicine importation " "Good Manufacturing Practices," " quality assurance," "pharmacovigilance," and "post-market surveillance." Searches about regulations used terms like "India," "Schedule M " "GMP," and "pharmaceutical regulation." EAC-related searches used terms such as "EAC Medicines Regulatory Harmonization," " assessment," "regulatory harmonization," "GMP inspection," and "pharmacovigilance." The study looked at regulatory repositories to find legal instruments and guidance documents. The study also checked the reference lists of publications when those reference lists could point to more sources. The study performed source discovery on 17 October 2026.

2.4 Eligibility Criteria and Source Selection

The study considered a source only if it talked about at least one of the main areas of the review: medicine registration and marketing authorization in Zanzibar, importation requirements, Indian pharmaceutical manufacturing standards, GMP inspection, pharmaceutical quality assurance, post-market surveillance, pharmacovigilance or EAC regulatory harmonization. The study gave priority to documents based on who issued them how relevant they were to the review question, their legal or regulatory status and how up-to-date they seemed. The study chose peer-reviewed publications that were relevant to Zanzibar’s development, regional harmonization or pharmaceutical quality assurance. The study left out sources that did not give information for the review objectives. When the study talked about requirements, the study treated official instruments as the main evidence. The study used guidance and published studies to give technical background and explain changes in regulatory systems. The study noted that finding a document in a repository alone was not enough to prove the exact legal duties that document contains.

2.5 Data Extraction and Regulatory Analysis

The study arranged the information into four main categories:

- Registration and marketing authorization
- Importation and related regulatory controls
- GMP and pharmaceutical quality assurance and

- Post-market surveillance and pharmacovigilance.

The study looked at EAC harmonization as a theme that cuts across all categories and is important for regional cooperation and regulatory assessment. For each source the study checked who issued it, what topic it covered, what it was meant for, how it applied to Indian-manufactured human medicines and how it related to the Zanzibar market. The study looked at manufacturing requirements separately from ZFDA market-entry requirements so that it would not treat source-country GMP compliance as the same as destination-country marketing authorization. The study considered harmonization mechanisms in the context of national regulatory duties and made sure to verify the correct path for each product.

2.6 Synthesis and Limitations of the Method

The study summarized the findings in a way to spot the main regulatory requirements, how the Indian and Zanzibar regulatory frameworks interact and what issues need extra checking, against current official documents. The study did not do any data collection talk to regulatory officials run laboratory tests or do an independent review of how well regulation is enforced.

As a narrative review the study was not set up to be a systematic review or meta-analysis. Because of that the study’s results rely on how many sources can be found, how easy they're to get and how up-to-date they are.

3. Literature Review and Regulatory Analysis

3.1 Evolution of Medicine Regulation in Zanzibar

A medicines regulatory system is essential for protecting public health by ensuring that medicinal products meet appropriate standards of quality, safety and efficacy. Regulatory authorities perform interconnected functions, including product registration, manufacturing-site inspection, control of importation monitoring of product quality and surveillance of adverse drug reactions. The effectiveness of these functions depends on a legal framework, institutional capacity, qualified personnel and access to reliable regulatory information.

Simai et al. (2024) In their study **A 20-year evidence-based experience of the evolving medicine regulation in Zanzibar** examined the development of Zanzibar medicines system through a review of regulatory documents and assessments of institutional capacity. Their findings described improvements in legal provisions organizational arrangements, strategic planning, quality management and regulatory infrastructure. The study also identified continuing challenges that require attention to sustain development and strengthen cooperation with regional and international institutions.

This study provides background for understanding the present regulatory environment in Zanzibar. However, its principal focus is the development and institutional capacity of the Zanzibar Food and Drugs Agency (ZFDA) rather than a detailed comparison of requirements applicable to medicines manufactured in India. Consequently, its findings provide a foundation for examining the system but do not independently establish the complete requirements for registering, importing and monitoring a particular Indian-manufactured medicine.

The ZFDAs Department of Medicine and Cosmetics identifies medicine registration, importation and exportation pharmaceutical inspection, pharmacovigilance and post-market surveillance among its functions. Its accessible guidance repository also contains documents addressing marketing authorization, pharmaceutical importation, manufacturing-site inspection, storage and distribution and the recall and disposal of unfit medicinal products [1,2]. These documents demonstrate the breadth of activities relevant to medicine quality throughout the product lifecycle. Nevertheless, the precise obligations applicable to a product must be established from the relevant legislation, current guidelines and authorization pathway.

3.2 Regional Medicines Regulatory Harmonization in the East African Community

Harmonization is an important strategy for strengthening medicines regulation in regions where countries share public-health priorities but have differing regulatory capacities and resources. Through the adoption of technical requirements, collaborative assessments and joint inspections participating authorities can share expertise reduce duplication and improve the consistency of regulatory processes.

Ndomondo-Sigonda et al. (2020) In their overview of the East African Community Medicines Regulatory Harmonization (EAC-MRH) initiative described the programme as an approach to improving access to safe, effective and quality-assured medical products. The initiative, launched in 2012 sought to harmonize requirements, guidelines, standards and assessment procedures among participating national medicines regulatory authorities. Its approach emphasized collaboration while maintaining assessment of product quality, safety and efficacy.

Mashingia et al. (2020) Subsequently evaluated the eight years of the EAC-MRH initiative documenting progress in collaborative medicine assessment, regulatory capacity development and joint manufacturing-site inspections. Their review reported improvements in assessment timelines during the initiatives implementation and highlighted the contribution of shared technical procedures to regional regulatory development. However, the authors also identified challenges involving financing, differences in national regulatory capacity and the need for greater transparency and coordination.

Further evidence was provided by Ndomondo-Sigonda et al. (2021) [10] Who investigated the contribution of harmonization to strengthening national regulatory capacity in the EAC. Their study examined performance, registration systems and inspection functions emphasizing the importance of harmonized guidelines, joint dossier reviews, manufacturing-site inspections, information sharing and cooperation between regulatory authorities. These findings suggest that harmonization can strengthen capacity and support more efficient regulatory decision-making.

Recently, Ngum et al. (2025) Examined the EAC-MRH joint review process and proposed improvements to regional assessment and inspection arrangements. Their analysis emphasized the importance of coordination between participating authorities and the uptake of recommendations by national regulatory agencies. This highlights a distinction between a collaborative scientific assessment and the national regulatory decision that determines whether a product may be authorized in a particular market.

Collectively these studies demonstrate the value of regional cooperation in improving regulatory capacity and reducing duplicated work. However regional harmonization should not automatically be interpreted as eliminating legal requirements. For medicines intended for Zanzibar the applicable procedure must be established by examining ZFDA guidance and the legal effect of the relevant regional process. This distinction is particularly important when assessing manufactured medicines because the existence of an EAC-related assessment or recommendation does not by itself establish every national registration or importation obligation.

3.3 Indian Good Manufacturing Practices and Pharmaceutical Quality Assurance

Good Manufacturing Practices (GMP) constitute a component of pharmaceutical quality assurance. They establish requirements for controlling manufacturing operations, personnel, premises, equipment, documentation, materials and quality systems to support the production of medicines meeting established quality standards. GMP compliance is therefore relevant not to the manufacturer but also to regulatory authorities evaluating products intended for their respective markets.

In India pharmaceutical manufacturing is governed by the provisions of the Drugs and Cosmetics Act and Rules including the revised Schedule M requirements notified through G.S.R. 922(E) on 28 December 2023 [3]. The revised requirements address GMP and pharmaceutical quality systems. Are relevant to the evaluation of manufacturing controls and product quality. Their application to manufacturers must be considered alongside the applicable implementation provisions and subsequent official notifications.

The relevance of GMP compliance to Zanzibar lies in its role as evidence of manufacturing quality. However, manufacturing compliance and marketing authorization address regulatory questions. GMP

assessment concerns whether manufacturing facilities and processes comply with quality requirements whereas marketing authorization involves the regulatory evaluation of a medicinal product for its intended market. Consequently, evidence of compliance with manufacturing standards should not be treated as a substitute for the applicable ZFDA authorization.

The ZFDAs EAC GMP Compendium explains that pharmaceutical GMP inspections may apply to both overseas manufacturing facilities. It also describes the use of EAC guidance for pharmaceutical manufacturing and GMP inspection [7]. This is directly relevant to manufacturers seeking to supply medicines to Zanzibar because the overseas location of a manufacturing facility does not by itself remove the need to consider the destination authority's applicable inspection and compliance requirements.

The relationship between GMP requirements and ZFDA manufacturing-site expectations should therefore be assessed using the operative documents from both jurisdictions. Such an assessment should distinguish quality principles from specific regulatory obligations, including the evidence required to demonstrate compliance and the procedures applicable to overseas manufacturing facilities. Where the documents differ in scope or terminology the differences should be described than assuming equivalence.

Although GMP provides a foundation for quality assurance quality must also be maintained after a medicine leaves the manufacturing facility. Storage conditions, transportation, distribution practices, product handling and the management of deviations or quality complaints can influence the condition of a product before it reaches the patient. Source-country manufacturing controls and destination-country oversight should consequently be understood as components of a broader quality-assurance system.

3.4 Marketing Authorization and Importation Requirements in Zanzibar

Marketing authorization is a regulatory mechanism through which an authority evaluates whether a medicinal product satisfies the requirements applicable to its intended market. Depending on the product and applicable regulatory pathway the assessment may involve quality information, manufacturing details, evidence of safety and efficacy product information and supporting administrative documentation. The precise requirements must be established from the regulatory instruments rather than inferred from general international practice.

The ZFDA publishes a Compendium of Guidelines for Marketing Authorization of Medicinal Products and separate guidance addressing medicine registration and related regulatory procedures. Its accessible repository also includes guidance on non-routine registration procedures and the renewal of

marketing authorization [1]. These resources provide a basis for examining the regulatory pathway applicable to medicines intended for Zanzibar.

The distinction between product authorization and manufacturing-site compliance is important in this context. A manufacturing facility may operate under a GMP framework but this does not independently demonstrate that every medicine produced at that facility has received the necessary authorization for the Zanzibar market. Similarly the registration of a product should not be assumed to establish that every shipment automatically satisfies importation requirements.

Importation represents a stage of regulatory control. The ZFDA publishes guidance on the importation and exportation of pharmaceutical products [6] reflecting the importance of oversight beyond the product-registration stage. An assessment of the pathway should therefore examine the applicable responsibilities of manufacturers, authorization holders, importers and distributors together with the documentation and permits required for the particular transaction.

For Indian-manufactured medicines these requirements create a relationship between the exporting and importing jurisdictions. Indian regulatory documentation may contribute to the evidence for assessment in Zanzibar but its acceptability and regulatory significance must be determined under the applicable ZFDA requirements. A practical analysis should therefore distinguish the evidence generated in India from the permissions required for marketing and importation in Zanzibar.

A further consideration is the role of reliance and regional cooperation in decision-making. Collaborative or reliance-based procedures may support efficient assessment when their eligibility criteria and conditions are satisfied. Nevertheless, the applicable pathway, documentation requirements and legal effect of a regulatory decision must be verified from the current ZFDA instruments before conclusions are drawn about a specific product.

3.5 Post-Market Surveillance and Pharmacovigilance

Regulatory oversight continues after a medicinal product has entered the market. Post-market surveillance and pharmacovigilance help authorities identify quality defects, suspected adverse reactions and other problems that may not be fully apparent before authorization. These activities support the continued evaluation of product safety and quality under conditions of use.

Simai et al. (2024) Described improvements in Zanzibar's framework, including the development of pharmacovigilance and post-marketing surveillance activities. Their findings illustrate the importance of strengthening systems beyond the initial establishment of registration procedures. Continued improvement in surveillance institutional capacity and cooperation remains important, for maintaining public-health protection.

The ZFDA publishes documents addressing its post-market surveillance programme and guidance covering 2024–2027 [8,9]. These documents also address pharmacovigilance, storage and distribution controls, and the management of medicinal products that are not fit for use [1,2]. Together, they indicate that post-market monitoring involves several complementary activities.

For medicines manufactured in India and supplied to Zanzibar, quality should be monitored throughout the supply chain. Important activities include investigating suspected adverse reactions, assessing product-quality complaints, ensuring appropriate storage and transportation, and implementing recalls when necessary. The applicable official instructions should specify reporting obligations, required forms and record-retention periods.

Post-market monitoring complements the controls applied before a medicine is sold. Marketing authorization and manufacturing-site inspections provide safeguards before market entry, while post-market surveillance and complaint handling help identify problems that emerge during use. Together, these activities support the continued safety and quality of medicines throughout their lifecycle.

Just because there is guidance published does not mean that it is being used well or that everyone knows exactly what they must do in every situation. So when looking at the rules for medicines from India to Zanzibar it is important to tell the difference between having a system and knowing if it is working. This is important when looking at the information about how medicines from India are regulated in Zanzibar.

4. RESULTS AND REGULATORY ANALYSIS

4.1. Marketing authorization and registration

ZFDA issues a comprehensive compendium of guidelines for marketing authorization of medicinal products and other related product, ZFDA its covering renewals, post-approval variations, non-standard procedures and specialized product classification.

The ZFDA’s main role is to ensure that medicinal products entering Zanzibar are of acceptable quality, safe and effective, and meet applicable standards.

National authorization requirement: The published registration instrument establishes the need for a national authorization step. Applicants must submit the official application forms through the ZFDA Regulated Information Management System (RIMS) portal. Public listings alone are insufficient and do not replace the current regulatory instrument.

For foreign made products; The product manufactured outside Zanzibar, (e.g. India made pharmaceutical products). Must be verified the following component; -

- **Product Identity**: Exact brand/generic name, strength, dosage form, and formulation.
- **Entities**: Marketing Authorization Holder (MAH) and Applicant details.
- **Facilities**: Specific manufacturing, packaging, and testing sites.

 Quality & Evidence: Full specifications, stability testing data, container labeling, and Good Manufacturing Practice (GMP) compliance certificates.

Regional EAC assessment: Joint EAC assessment can reduce duplicated work through shared standards and collaborative reviews; however, it is not itself a marketing authorization. Evaluation through the EAC is not equivalent to receiving legal permission from the ZFDA to market a product in Zanzibar. Indian CDSCO approvals or domestic Indian licences should not be assumed to replace the applicable ZFDA national review process.

4.2. Importation

The Zanzibar Food and Drug Agency (ZFDA) publishes guidelines governing the importation and exportation of pharmaceutical products. Product registrations and permit applications are also processed through its digital portal. A lawful importation workflow requires attention to four core elements: confirming the medicine's registration status or obtaining an official exemption; ensuring that the local importer holds valid business and premises licences; obtaining a shipment-specific import permit; and preparing the required commercial and quality documentation. Such documentation may include commercial invoices, packing lists, batch numbers, expiry dates, Certificates of Analysis (CoAs), transport and storage-condition records, and evidence of official authorization.

Applicants should recognize that manufacturer export approvals and Indian Good Manufacturing Practice (GMP) compliance certificates are separate from ZFDA import requirements and do not substitute for local permits. Importers should confirm that all required documents and permits have been obtained to prevent customs delays or rejection at the port. Issuance and shipping arrangements should be aligned before goods are dispatched from the exporting country. Pre-shipment verification is particularly important for temperature-sensitive cold-chain products, controlled substances and unregistered pharmaceuticals imported under special-use exemptions.

4.3. Quality assurance and GMP

The ZFDA's GMP oversight may involve local and overseas pharmaceutical manufacturing facilities supplying products to Zanzibar, with reference to applicable EAC GMP guidance. The ZFDA website describes GMP compliance requirements, manufacturing-site inspections and related regulatory activities. Applicants should provide current, site-specific documentation requested by the ZFDA and verify which procedures apply to their products and facilities.

India revised its pharmaceutical manufacturing requirements in 2023. Pharmaceutical manufacturers are required to comply with the applicable standards governing their manufacturing facilities and operations.

Cross-cutting interpretation

Lifecycle stage	Indian/manufacturer-side evidence	Zanzibar-side control	Practical verification
Registration	Product dossier; manufacturing/testing site; current Indian GMP evidence and product status.	ZFDA marketing authorisation under current compendium; national applicant/holder and applicable pathway.	Current dossier checklist, route, accepted reliance evidence, fees and review clock.
Import	Export release and shipment/batch documentation.	Importer/premises permissions and shipment-specific import controls.	Whether product authorisation is required before shipment and exact permit documents.
Quality	Revised Schedule M GMP and quality system [3].	ZFDA/EAC GMP inspection framework, batch/quality oversight and distribution inspection [7].	Recognition/validity of certificates; site inspection or reliance route; cold-chain records.
Post-market	Manufacturer/MAH safety and quality system; recall cooperation.	ZFDA PV reporting, PMS, inspection and recall mechanisms [1,8,9].	Who reports what, to which portal, within what timeframe, and local contact details.

DISCUSSION

The principal regulatory distinction is between source-country manufacturing compliance and destination-country market control. Revised Schedule M strengthens the evidence base for Indian manufacturing quality, while ZFDA's separate authorisation, import, inspection and surveillance instruments govern the product's Zanzibar lifecycle [1,3,6-9]. This division is consistent with the broader role of national regulators and regional reliance/harmonisation mechanisms in protecting medicine quality and access [4,5,10].

A practical benefit of the framework is that manufacturers and applicants can prepare a coordinated evidence package: a quality dossier and site evidence suited to ZFDA review, a shipment plan synchronized with permits, and post-market arrangements covering safety and defects. EAC joint processes may provide efficiencies where a product and pathway qualify, but the final national requirements and legal status must be verified for Zanzibar.

This review has important limitations. The manuscript is based on targeted web retrieval, not an executed multi-database search; selection was not independently duplicated; and the literature on this exact India-to-Zanzibar pathway appears limited. Public web pages and their downloadable instruments may change. No interviews, ZFDA administrative data, registration timelines, import volumes, quality-testing results or adverse-event statistics were collected. We therefore make no claims about processing performance, compliance rates, market share or comparative product quality.

RECOMMENDATIONS

1. Confirm the current ZFDA product pathway and applicable dossier before submission.
2. Map each manufacturer and manufacturing-site certificate to the exact legal entity and product.
3. Secure all required import permissions before dispatch.
4. Establish Zanzibar-specific pharmacovigilance (PV), complaint-handling, recall and traceability contacts.
5. Maintain a register of regulatory instrument versions because ZFDA guidance is updated.
6. Publish a single, dated pathway map linking registration, GMP inspection, import permits and post-market duties.
7. Clarify the current use of EAC joint assessment and reliance procedures in Zanzibar.
8. Make current fees, target review times and application-status definitions easy to locate.

Future research: Future research should examine application-level timelines, dossier deficiencies, import-permit processing, GMP inspection outcomes and post-market surveillance (PMS) signal-to-action pathways using regulator-approved data.

CONCLUSION

Indian manufacture and Zanzibar market authorisation are complementary but distinct regulatory domains. India's revised Schedule M addresses GMP at the manufacturing source; ZFDA's current requirements cover authorisation, importation, quality oversight and post-market control. EAC harmonisation can support common standards and work-sharing, but applicants should confirm the product-specific Zanzibar pathway and all current obligations with ZFDA. The structured database search and final source verification remain to be completed before journal submission.

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