

Guidance for Market Entry in the Assistive Technology Sector

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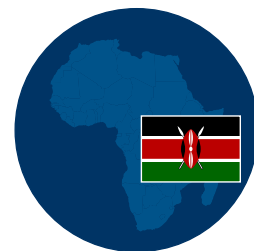


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Annex D. Country description: Kenya



Overview of Kenya's assistive technology market entry

Kenya has a well-defined market entry process, with most relevant information available online. However, certain aspects, such as tax exemptions, remain unclear, and the regulatory landscape is evolving, which means that changes may be imminent. Locally manufactured products are generally favoured in public procurement, while international products often experience longer registration and certification timelines. For international suppliers, the entire market entry process can take anywhere from 6 to 24 months.

Key government stakeholders

- **National Council for Persons with Disabilities (NCPD):** Promotes equal opportunities for persons with disabilities.
- **National Fund for the Disabled of Kenya:** Provides funding and equipment to persons with disabilities.
- **Kenya Bureau of Standards (KEBS):** Is tasked with ensuring product quality, developing standards and aims to be more active in the assistive technology supply chain, particularly in quality checks.
- **Ministry of Health's Rehabilitative Services Section:** Plays a role in the implementation of quality standards and the development of rehabilitative and assistive technology policy.
- **Ministry of Health's Pharmacy and Poisons Board:** Ensures that facilities holding or intending to hold Kenyan marketing authorization comply with national Good Manufacturing Practices (Ministry of Health of the Republic of Kenya, 2023a).
- **Kenya Revenue Authority:** Implements tax exemptions for assistive technology as described in section 35 of the 2003 Persons with Disabilities Act (Republic of Kenya, 2003).

Specifications

- Assistive products list: The Essential Medical Supplies List (Ministry of Health of the Republic of Kenya, 2023b) includes assistive products. However, newer technologies face challenges in gaining official recognition.
- Product certification and regulation: KEBS does not yet have clear specifications for assistive technology but generally aligns with international ISO standards. National specifications are currently under development.

Kenya market entry process

Business entity registration

- Companies intending to supply medical products must register with the Kenya Pharmacy and Poisons Board. The process is strict, and lack of local knowledge can create challenges. Many companies opt to hire local consultants to assist with navigation.
- Kenyan businesses seeking a manufacturing license or overseas facilities intending to hold Kenyan marketing authorization must comply with national Good Manufacturing Practices available on the Pharmacy and Poisons Board website (Ministry of Health of the Republic of Kenya, 2023).

Product certification

- Since Kenya-specific assistive technology standards are still in development, there is an unwritten consensus among stakeholders that products meeting international ISO standards are generally accepted.
- To participate in public tenders, each assistive product must be certified by the Kenya Pharmacy and Poisons Board. This certification process can take up to two years for multiple products.
- International manufacturers must appoint a local authorized representative (for example, a distributor or customs agent) to act as the official liaison with regulators.
- Evaluation process
 - Medical devices, including assistive technology, are classified into four risk categories (A to D), with Class A being the lowest risk. The risk classification depends on manufacturer claims and intended use/purpose.
 - The manufacturer or its local representative must submit a registration application to the Pharmacy and Poisons Board.
 - An application fee is charged upon submission, followed by a review for completeness before formal evaluation begins.
 - Once the application is accepted for evaluation, the evaluation fee is charged and the process proceeds.

Quality assurance

- The Pharmacy and Poisons Board outlines its inspection requirements in its Good Practice Guidelines (Pharmacy and Poisons Board, Ministry of Health of the Republic of Kenya, 2023).
- Multiple pre-inspections may be required, increasing the overall timeline for the import process.
- International manufacturers generally rely on third-party inspections to obtain a Certificate of Conformity, which is required for product shipment.
- Local manufacturers undergo on-site inspections by regulatory authorities to verify compliance with quality standards.
- KPPB conducts inspections of manufacturing sites to assess adherence to Good Manufacturing Practices. These inspections are required for obtaining a manufacturer's license and are periodically repeated based on risk assessments.

Import procedures

- The import permit process is overseen by the Kenya Trade Network Agency, a government agency under the National Treasury. Import permit guidelines are detailed on the Kenya Trade Network Agency website (Kenya Trade Network Agency, 2024).
- Customs clearance is the most challenging aspect of the import process. Backlogs can cause average wait times of one month. Each additional day incurs daily fees, and documentation issues can prolong this further. Policy changes have led to delays of up to six months in extreme cases.
- Hiring a clearing agent is highly recommended to facilitate smoother customs processing.

Duties and taxes

- Tax exemptions primarily apply to donated assistive products or those procured by NGOs. This encourages donations and “free” assistive products.
- Companies seeking tax exemptions must obtain an official exemption letter from the NCPD or the National Society of the Blind. However, these letters are rarely issued to businesses and are instead reserved for individuals with disabilities.
- Moreover, there are zero-rating VAT exemptions, including:
 - Hearing aids (tariff No. 9021.40.00)
 - Spectacle lenses (tariff No. 7017.10.00)
 - Artificial joints and other artificial body parts (tariffs 9021.31.00 and 9021.39.00)

Sales and distribution

- As part of the Rehabilitation Services and Assistive Technology Strategy (2022–2026), the country is preparing for the Kenya Medical Supplies Authority (KEMSA) to become the central public procurement entity for assistive technology by 2026.
- Currently, public procurement is fragmented across various ministries, primarily the Ministry of Education and Ministry of Health.
- Ministries distribute products directly to beneficiaries, mainly through the Kenya Institute of Special Needs Education and the NCPD.
- When tenders are issued, evaluation criteria typically focus on product quality, pricing and previous supplier experience.

Local production in Kenya

- The Kenyan Government is encouraging local manufacturing through Special Manufacturing Zones, such as the Naivasha Industrial Zone.
- These zones offer tax incentives and subsidized utilities to attract manufacturers.
- The Naivasha-Mombasa railway provides cost-effective transportation, further supporting local production efforts.
- However, these initiatives are largely led by the Ministry of Trade and have limited focus on health-related products, including assistive technology.
- Outside of designated zones, high material and utility costs make local production less competitive than imports.

Conclusion

Kenya's assistive technology market-entry process is well-structured but presents significant time and cost challenges for international suppliers. Regulatory reforms are underway and local manufacturing incentives exist, but complexities remain in customs clearance, product certification and tax exemption approvals. Companies seeking market entry should work closely with local partners and clearing agents to navigate these barriers effectively.



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