Guidance for Market Entry in the Assistive Technology Sector

FOCUS ON SELECT AFRICAN COUNTRIES

South Africa

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GLOBAL PARTNERSHIP FOR ASSISTIVE TECHNOLOGY

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Annex F. Country description: South Africa

Overview of South Africa's assistive technology market entry

South Africa has a well-established market entry process, with information generally accessible and broadly agreed upon online. However, there are occasional instances of limited clarity, particularly in the public procurement process. The regulatory environment has been in place for several years, is regularly updated and is often cited as a model by other low- and middle-income countries. It is also important to note that locally manufactured goods are typically favoured in public procurement.

Key government stakeholders

- **South African Health Products Regulatory Authority (SAHPRA)**: Responsible for issuing licenses for manufacturers, distributors, and importers of medical devices, and to certify medical products.
- **South African Bureau of Standards (SABS)**: Tasked with developing standards for assistive technology in South Africa and providing conformity assessment services.
- **National Department of Health**: Drives policy-making and works alongside SABS to develop standards for assistive technology by involving sector professionals.

Specifications

- South African standards, known as South African National Standards (SANS), are closely based on ISO standards. For example, SANS 7176 for wheelchairs is equivalent to the ISO 7176 standard. In most cases, assistive product specifications are developed when the product is part of a public tender.
- SABS has also developed non-product-specific standards. The South African quality management system aligns with ISO 13485, the international standard for medical devices. Organizations must maintain a quality manual that outlines their quality management system, which includes details about the organization, facilities, personnel, quality assurance policies, procedures, work instructions, controls and activities that demonstrate compliance with South African regulatory requirements. For more information on the documents required for the quality manual, refer to the SAHPRA Guideline on Medical Device Quality Manual (South African Health Products Regulatory Authority, 2023).

South Africa market entry process

Business entity registration	• Manufacturers wishing to supply assistive technology in South Africa must be registered in the country or work through registered distributors. • Additionally, some business entities must obtain a license to manufacture, import, export, or distribute medical devices. The need for this license depends on the risk level of the products the business entity supplies. Medical devices are classified into four risk categories (A to D), with Class A being the lowest risk. Assistive products mostly fall under Class A, with a few classified as Class B. Business entities handling only Class A medical devices are currently exempt from obtaining this license. • For Class B medical devices, business entities must submit detailed information to obtain the license, including: - A list of all medical devices imported into South Africa, classified with the Global Medical Device Nomenclature Code; - A Certificate of Free Sale from the country of manufacture or final assembly, verifying that the devices are legally sold or distributed in the open market and approved by regulatory authorities in the country of origin; - Where relevant, a certificate of conformance or analysis. • Licenses are valid for five years or until the guideline is revised, whichever occurs first. To be considered for a license, industry stakeholders must demonstrate that they use a comprehensive Quality Management System which addresses all aspects of quality assurance, including contracts, purchasing, manufacturing, final product handling, storage, servicing, documentation controls, audits, training, complaint handling and export documentation.
Product certification	• Obtaining international product certifications often facilitates compliance with local standards. • To participate in national tenders, assistive technology distributors must have their products certified by SAHPRA. Previously, SABS managed local standards like ISO 1684 and ISO 7176 for wheelchairs, but now SAHPRA also verifies compliance with ISO 13485. Once an organization achieves ISO 13485 certification, it applies to all products manufactured by the organization, with new products simply added to the certification document. A new medical device plan requires registration with SAHPRA within the next 3-4 years to facilitate product tracing. • Suppliers operating solely in the private sector face no restrictions on the types of products they import, although non-compliance with tender specifications disqualifies them from participating in public tenders.
Quality assurance	• Rigorous quality controls are required to participate in national tenders. • Customs checks focus on verifying paperwork and certifications and also on conducting direct product quality inspections.
Import procedures	• SAHPRA has published a process flow for the import of medical products (South African Health Products Regulatory Authority, 2025). • The process usually takes between several days to 3-4 weeks.
Duties and taxes	• Assistive products are subject to tax exemptions. These exemptions depend on the code associated with the product. Products can be exempted from import duties but are still liable to VAT. If the distributor is registered as a VAT vendor, in that case VAT is refundable. • Users of assistive technology will first have to register to be classified as a permanently disabled person before they can claim tax deductions. These are usually not full tax exemptions. • If taxes are being paid, customs will determine the applicable rate. The product will be weighted and analysed, and the tax will be based on the product's cost.

Sales and distribution	• The primary sales channel for importers is public procurement. To participate in public tenders, organizations must register in the Central Supplier Database (CSD), which is administered by the National Treasury and which can take up to six months. The National Treasury handles all national tenders. Once registered, organizations gain access to tenders related to the products. • To register in the CSD, organizations must: • Have assistive products certified (as outlined in the Product Certification section) • Comply with the requirements of public tenders, which can be found on the government website (product specifications, pricing, local content - a score is determined based on the inclusion of local labour and materials in the product – and black economic empowerment level of 1). • Once their products are included in the tender list, suppliers typically make efforts to convince public entities to purchase their products. These products are listed on a public database and competitors may also procure products from the list.

Local production in South Africa

- South Africa's strong manufacturing capabilities, affordable land and competitive labour make it an appealing location for local assistive technology production. Local production in South Africa goes from manufacturing out of raw materials to basic assembly and changing packaging. Several local business entities have successfully launched the production of assistive technology, and some have even become exporters.

- However, the local industry is currently dominated by imports, with barriers such as home-country tax requirements limiting the ability to produce abroad. While there have been some successes, substantial government incentives towards assistive technology manufacturing in South Africa are currently lacking.

Conclusion

South Africa presents a well-regulated but competitive market for assistive technology, with established procedures and a strong emphasis on quality control. While there are tax exemptions and certifications available to facilitate market entry, navigating the regulatory landscape requires a thorough understanding of local standards and product certifications. For businesses looking to enter the market, engaging in public procurement and establishing a presence through local partnerships is essential. With its well-developed infrastructure and manufacturing capabilities, South Africa also holds potential for local production, although further government incentives would benefit the industry's growth.

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