Guidance for Market Entry in the Assistive Technology Sector

FOCUS ON EGYPT

ATscale
GLOBAL PARTNERSHIP FOR ASSISTIVE TECHNOLOGY

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Annex C. Country description: Egypt

Overview of Egypt's assistive technology market entry

The assistive technology market in Egypt is experiencing significant growth, driven by an aging global population, increasing prevalence of disabilities, and rapid technological advancements. However, entering the assistive technology market in Egypt presents significant challenges as stakeholder experiences vary widely. However, products that comply with international standards generally face a smoother process. Typically, market entry typically takes several months and involves multiple interactions with national authorities. Engaging a customs agent is essential, especially for navigating tax exemptions, which remain unclear and are inconsistently applied. On the other hand, the government is taking measures to stimulate local production to decrease dependency on international markets.

Key government stakeholders

- **Egyptian Drug Authority (EDA)**: Oversees medical device registration, quality assurance, and import procedures.
- **Central Administration of Medical Devices**: Serves as the main point of contact for the registration process.
- **Egyptian Authority for Unified Procurement Medical Supply and Management of Medical Technology (UPA)**: Responsible for distributing medical supplies and equipment to public health facilities.
- **Ministry of Trade and Industry**: Promotes economic development through promoting exports and local production.

Specifications

While no specific assistive technology specifications were identified through desk research, general medical device requirements apply:

- Manufacturers must comply with ISO 13485:2016 and ISO 9001, ensuring the implementation of a quality management system that meets both regulatory and customer requirements.
- Distributors require suppliers, including those abroad, to adhere to these standards.

Egypt market entry process

Business entity registration	• The registration process depends on the classification of the entity: - Regular business registration: handled by the Bureau of Commerce. - Medical device entity registration: managed by the EDA and involves a one-time registration. Some businesses choose to operate without this status due to its complexity. - Collaboration with international NGOs: requires special approval from the Ministry of Social Affairs, which also oversees NGO registration.
Product certification	• Certification depends on risk classification. Assistive products are generally considered low-risk and may not require certification. • However, risk classification is not systematic, and extensive documentation, including certification and product testing, is required. • Product certification is typically part of the import authorization process.
Quality assurance	• Quality checks are conducted by multiple entities, including the EDA, customs officials and the Ministry of Trade and Industry, to ensure the safety and compliance of imported products. • Customs officials may perform physical inspections for quality, they often lack expertise specific to assistive products. • Business entities typically hire customs agents to facilitate the clearance process.
Import procedures	• The import process can take a few days to several weeks, depending on documentation accuracy. • Original documents with blue-ink signatures and stamps are required to confirm authenticity. • Detailed import procedures including pre-import registration are provided by the General Organization for Export and Import Control, operating under the Ministry of Trade and Industry. The Egyptian Drug Authority (EDA) outlines specific regulatory requirements and technical guidelines on its official website (Egyptian Drug Authority, 2002). • Import process can last from a couple of days to a couple of weeks. Having the right documentation from the start will speed up the process. It is important to note that original documents with blue ink signatures and stamps are required to confirm authenticity. • Key Steps in the Import Process: 1. Appointment of an Egyptian Registration Holder: Required if the manufacturer lacks a local presence. 2. Contract with importer: Must include product categories, minimum yearly purchases, bonus schemes, free sales certificates, and Global Trade Item Number codes. 3. Contract review: Includes issuance of the S-14 form and proforma invoice. 4. Import permit application via the "MeDevice" portal: Requires submission of the proforma invoice, product specifications, Global Trade Item Number codes, free sale certificate, and declaration of conformity. The EDA issues initial acceptance within 20 days. 5. Addressing EDA comments: If issues arise, the applicant has 60 working days to respond. 6. Final evaluation: The Medical Devices Import Approvals Unit conducts further review and may request additional documentation. 7. Issuance of import license: Once approved, the import registration license is issued, typically taking 5–8 months. The import permit, valid for one year, must be renewed if the contract extends beyond its expiration. 8. Shipping: After securing the import permit, suppliers can proceed with shipping. It is essential that documents such as the commercial invoice, packing list, airway bill or bill of lading and certificate of origin are correctly issued and confirmed.

Duties and taxes	• Business entities may qualify for import duty and VAT exemptions, subject to a defined process.
	• VAT Exemption Process:
	  - VAT Registration: Businesses must register with the Egyptian Tax Authority.
	  - Application for Exemption: Companies submit details, including Harmonized System and supporting evidence.
	  - Compliance: Businesses must maintain accurate records and submit VAT returns regularly.
	• Exemptions from taxes on assistive products are available with donor-issued invoices (e.g., from GIZ – Deutsche Gesellschaft für Internationale Zusammenarbeit, the main development agency of Germany – or USAID – the United States Agency for International Development, the agency of the United States government that has been responsible for administering foreign aid and development assistance), which eliminate customs duties. VAT is initially paid and later reimbursed upon submission of proof to the Ministry of Finance.

Sales and distribution	• Public procurement accounts for 10–20% of the supply. • NGOs play a significant role in procuring assistive products. • Multiple government ministries, including the Ministry of Health, Ministry of Defense and Ministry of Education, manage procurement for their respective sectors.

Local production in Egypt

The UPA has attempted to attract international manufacturers to establish local production. However, the offered terms have not been competitive enough to shift production away from imports, particularly from China, due to cost advantages.

For companies considering local production, the following steps must be taken:

1. Approval must be obtained from the Industrial Development Society.
2. A suitable manufacturing site must be secured.

Despite UPA's efforts, local production remains limited, with imports continuing as the primary supply channel for assistive products in Egypt.

Conclusion

Egypt's assistive technology market is highly regulated, with complex registration, certification and import processes. While aligning with international standards eases entry, challenges remain due to inconsistent tax exemptions and lengthy approvals. Public procurement is limited and NGOs play a key role in distribution. Despite UPA's efforts to stimulate local production, high costs keep imports the primary supply channel. Success in the market requires careful planning, local partnerships and strict regulatory compliance.

For the full report, please refer to "Guidance to Africa Market Entry in the Assistive Technology Sector: Focus on Select African Countries".

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