Guidance for Market Entry in the Assistive Technology Sector

FOCUS ON SELECT AFRICAN COUNTRIES

ATscale
GLOBAL PARTNERSHIP FOR ASSISTIVE TECHNOLOGY

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List of abbreviations

CE	Conformité Européenne, that is, compliance with the relevant European Union legislation for regulated goods sold within the European Economic Area
ISO	International Organization for Standardization
ISPO	International Society for Prosthetics and Orthotics
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit, that is, the main development agency of Germany
GST	Goods and services tax
NGO	Non-governmental organization
UNDESA	United Nations Department for Economic and Social Affairs
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VAT	Value-added tax
WHO	World Health Organization

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Executive Summary

In low- and middle-income countries, particularly across Africa, access to assistive technology remains significantly constrained. A key factor limiting access is the complexity of market entry for industry stakeholders, exacerbated by fragmented regulatory frameworks, inconsistent quality standards and unpredictable taxation policies.

This report provides a structured, step-by-step guidance for manufacturers, importers and distributors – local, regional or global – aiming to enter African assistive technology markets, with a specific focus on Egypt, Kenya, Nigeria and South Africa. This report also provides an overview of key challenges of market entry in the assistive technology sector for policymakers at country, regional or global levels.

The analysis is based on a comprehensive situation assessment combining desk review and key informant interviews with 65 stakeholders active in assistive technology provision across the African continent. The research identified five essential steps for market entry:

1. **Product Certification** – National certification processes vary significantly and can be costly and time-consuming. However, compliance with international standards, such as the Conformité Européenne (CE) or International Organization for Standardization (ISO), often facilitates approval.

2. **Quality Assurance** – Assistive products undergo varying degrees of quality checks at customs, with procedures often inconsistent across different jurisdictions and product categories.

3. **Import Procedures** – While generally straightforward, import processes benefit from collaboration with local clearing agents to mitigate bureaucratic delays.

4. **Duties and Taxes** – While some countries offer tax exemptions for assistive products, these policies are often inconsistently applied. Complete assistive products are more likely to qualify for exemptions than their components and parts.

5. **Sales and Distribution** – Market access is primarily through public procurement and private sector sales. Public procurement processes are frequently fragmented across multiple government entities.

Shakira, a 12-year old from Malawi, attends school, reads, learns and plays with her friends thanks to her hearing aids.
© DeafKidzInternational

The report highlights key systemic challenges, including unclear regulatory responsibilities among government agencies, the high costs of compliance and limited transparency in public procurement. Additionally, while local production of assistive technology is often proposed as a solution to improve accessibility, its viability remains uncertain due to infrastructure limitations and capital constraints.

Two primary recommendations emerge from this research:

- **Simplify and digitize market entry processes** – Governments should create clear, streamlined and transparent regulatory pathways for assistive technology industry stakeholders. Digitalizing registration, certification and procurement processes would enhance efficiency and reduce entry barriers.

- **Strengthen local distributor and service provider capacity** – Manufacturers should invest in knowledge transfer programmes for local distributors and service providers, thereby ensuring they possess the necessary expertise to properly supply, fit, train, repair and maintain assistive products.

By addressing these challenges African countries can benefit from more inclusive and competitive assistive markets, ultimately improving access to assistive technology for millions of individuals in need. Future efforts should also explore harmonized regional policies to facilitate cross-border trade and streamline market entry procedures across multiple countries.

1. Context and objectives

1.1 Background and context

Over 2.5 billion people worldwide need assistive technology, a number projected to exceed 3.5 billion by 2050 (World Health Organization (WHO) and United Nations Children's Fund (UNICEF), 2022). Assistive products, including wheelchairs, prostheses, spectacles and hearing aids, are vital for persons with disabilities, ageing populations, individuals with chronic conditions, and others. Most people will require assistive products at some stage in their lives. Despite this growing need, only 10 percent of people in low- and middle-income countries have access to necessary assistive technology (WHO and UNICEF, 2022).

Lack of access to assistive technology exacerbates social and economic inequalities, including isolation, exclusion from education and employment and poorer health outcomes. Improving access to assistive technology can lead to increased participation in education and the workforce which contributes to economic growth. It also reduces the burden on caregivers and healthcare systems. Data suggests that every dollar invested in assistive technology can result in a return of up to nine dollars considering the cumulative gains that access to assistive technology can have in health, for the community and the economy (ATscale, 2020a).

Barriers to assistive technology access include inadequate public funding, lack of awareness, weak supply chains and an underdeveloped workforce (Tay-Teo et al., 2021; WHO and UNICEF, 2022). These challenges are particularly acute in Africa where rapid population growth and an ageing demographic further increase demand. With Africa's population projected to reach 2.5 billion by 2050 (United Nations Department of Economic and Social Affairs (UNDESA) Population Division, 2022), expanding access to assistive technology is a critical public health and economic priority. Assistive technology services have been described as either fragmented or absent in several African countries (Visagie et al., 2017). Member States of the WHO African Region adopted a regional framework to guide the planning and implementation of priority interventions to promote access to assistive technology (WHO Regional Office for Africa, 2021). Evidence and policy actions have been taken, including but not limited to the assessment of assistive technology needs and national assistive technology systems, the adoption of national assistive product lists and the promotion of cross-country initiatives (Clinton Health Access Initiative, 2020, 2021; Ministry of Health of the Federal Republic of Nigeria, 2022; Kahonde & Mji, 2024; Matter & Eide, 2018; Smith et al., 2024; Visagie et al., 2022).

Market failures contribute to these access gaps (ATscale, 2024; Savage et al., 2021). Robust markets typically feature multiple suppliers, clear regulations and efficient entry and exit processes. However, in many African

countries, assistive technology markets remain underdeveloped due to regulatory complexity, inconsistent demand, information asymmetries and high costs. Market-shaping interventions can include interventions on both the demand and the supply sides, such as improved data access, streamlined regulation and strategic procurement (Savage et al., 2021). For example, trade conditions can be aligned with government commitments towards social inclusion and investors can, through their investment overall strategy and specific decisions, protect and promote the rights of people who need assistive products (International Finance Corporation – World Bank Group, 2024; Ministry for Foreign Affairs of Finland, 2023).

In this document, "market entry" refers to the processes, along with the regulatory, legal and procedural requirements, that industry stakeholders, including manufacturers, importers and distributors, must navigate before selling and distributing assistive products for the benefit of end users. There is no one single assistive technology market but rather several markets for the different assistive products, each with their own industry stakeholders, user groups, and others. Assistive technology markets are traditionally fragmented. In each country, most assistive products have their own market, with their own size and characteristics of the population in need, stakeholders, manufacturers, production processes, specialized workforce, quality standards, among other factors.

1.2 Objectives

The report focuses on barriers that hinder industry stakeholders – local, regional, or global – from entering assistive technology markets. One of these barriers is a knowledge gap regarding market entry processes, which often vary between countries and even within subregions in a country, making it difficult for stakeholders to scale operations. The time and cost of navigating these barriers further discourage access to assistive technology in the African region. Therefore the objective of this report is to provide step-by-step guidance for manufacturers, importers and distributors – whether operating locally, regionally, or globally – who are considering entering assistive technology markets in the African region.

This report also provides policymakers at country, regional or global levels an overview of key challenges at each step of market entry, and offers recommendations towards healthy markets that governments and industry stakeholders can support implementing. By addressing entry barriers, the goal is to promote well-functioning markets that ensure the availability of affordable, high-quality assistive technology across Africa.

2. Methodology

2.1 Scope

A situation assessment of assistive technology markets in the African region with a focus on market entry was completed. The report focuses on the markets for **four assistive products** with a large need: **wheelchairs, prostheses**, **spectacles** and **hearing aids**. Annex A describes the four assistive products in focus. The report focuses on assistive products that meet the WHO assistive product specifications (WHO, 2021). This excludes low-quality products, which are prevalent in low- and middle-income countries. Furthermore, the report proposes findings focusing on **four countries** of the African region: **Egypt**, **Kenya**, **Nigeria** and **South Africa**. The focus on four countries allows for detailed national examples. The four countries were selected for their large populations, active assistive technology markets and relatively stable regulatory environments. However, the four countries are not thought to be representative of the diversity of national contexts across the African region.

2.2 Methods

This research was conducted in 2024 and drew on both secondary and primary data sources, including a desk review and interviews with 65 key informants with experience in assistive technology provision in Africa. Key informants represented various stakeholders, including international organizations, United Nations agencies, industry groups, manufacturers and donors. Interviews were conducted with manufacturers, importers, distributors, and other organizations active in the four countries in focus. A detailed description of the methodology is provided in Annex B.

2.3 Limitations

This research has the following limitations. Firstly, it focuses on four assistive products – wheelchairs, prostheses, spectacles and hearing aids – rather than the full spectrum of assistive products. Digital assistive technology, including software and platforms, was not included in this analysis, although its market dynamics differ significantly from those of physical products.

Secondly, the study examines market entry in four countries, which are not necessarily representative of the entire African region. As a result, findings may not be directly applicable to other national contexts. Each of these four countries has a large population, and the analysis was conducted at the national level. Consequently, smaller markets and regional variations within countries are not fully reflected in this report. The country examples provided should be contextualized before applying them to other settings.

Thirdly, while the study includes interviews with 65 key informants, stakeholder experiences with market entry varied widely. As a result, the research may not capture the full range of market entry experiences. Additionally, most participants represented non-governmental organizations (NGOs) and industry stakeholders. While public sector representatives across the countries were represented, due to the fragmentation of assistive technology-related responsibilities across different governmental ministries and agencies, the full perspective of all ministries and regulatory agencies may not be fully included. However, this underscores the fragmentation of this area in the public sector which we also highlight in the findings.

Finally, the research was conducted between June and November 2024. Both assistive technology markets and broader economic and geopolitical contexts, including global trade conditions, are rapidly evolving. This means that some findings may become outdated as conditions change.

A technician of the National Centre for Orthopedic Devices in Senegal working on locally made orthopaedic shoes. © ATscale

3. Results

Children in a playschool in South Africa using wheelchairs manufactured locally. © Shonaquip Social Enterprise

This section summarizes the results arising from the desk review and key informant interviews in terms of the following factors: 1. The assistive technology ecosystem and its stakeholders; 2. Preconditions for assistive technology market entry; 3. Five steps of assistive technology market entry and related guidance; and 4. Summary descriptions for the four countries in focus.

3.1 The assistive technology ecosystem and its industry stakeholders

A well-functioning assistive technology market requires coordinated efforts from multiple stakeholders evolving within its ecosystem, including the following conditions:

- Government entities responsible for regulation, quality control and public procurement
- Industry stakeholders, including manufacturers, importers and distributors, engaged in product supply and logistics, all of which can have local, regional or global operations

- Local and international NGOs supporting service provision and funding

- Service providers who are essential in the delivery of services surrounding assistive technology provision

- Current users, potential users and their families and representatives who help shape demand-driven solutions.

Understanding the interactions between all stakeholders is crucial for improving market entry efficiency and ensuring that assistive technology reaches those in need.

Assistive technology industry stakeholders, whether individuals or organizations, operate within a complex landscape that can be categorized according to three key dimensions:

- **Type of organization** – Industry stakeholders include organizations driven by different purposes:

  - For-profit organizations
  - Non-profit organizations
  - Social enterprises

- **Geographical scope** – Industry stakeholders may have a smaller or larger geographical footprint, and the scale of their operations might be as follows:

  - **Global**
  - **Regional** (that is, spanning several countries)
  - **Local**

This guidance primarily focuses on global industry stakeholders, as they are more common in markets worldwide. However, local production is also addressed in a separate section.

- **Role in the supply chain** – Assistive technology stakeholders play different roles, each with distinct responsibilities as outlined hereunder:

  - **Manufacturers** design and/or produce assistive products for market availability.
  - **Importers** introduce assistive products manufactured in other countries into new markets.
  - **Distributors** (or wholesalers) facilitate the availability of assistive products by connecting manufacturers and importers with suppliers and users.

Illustration 1: Landscape of assistive technology industry stakeholders

Local stakeholders play a vital role in this ecosystem. These include government entities, industrial stakeholders, NGOs, service providers and civil society organizations, such as organizations of persons with disabilities. In some countries service provider organizations play an active role in assistive technology market development. For example, this is the case in Kenya and Nigeria. In all countries government entities are involved in the assistive technology sector.

3.1.1 Government entities: ministries, departments, and agencies

In the four focus countries in focus, multiple government entities – including ministries, departments and agencies – are involved in the assistive technology sector. Their roles often overlap, leading to unclear divisions of responsibility. For example, in Egypt the Ministry of Health, Ministry of Defense and Ministry of Education play key roles in the public procurement of assistive products. The complex landscape can discourage international industry stakeholders from entering new markets. For example, to ease the import process, many choose to collaborate with local importers or clearing and customs agents when expanding into these markets.

Across all four countries in focus, the Ministry of Health (National Department of Health in South Africa) plays a central role in shaping assistive technology policies. However, the primary government entity responsible for market entry is not always within the Ministry of Health. In Kenya, for instance, the key public entity is the National Council for Persons with Disabilities and falls under the Ministry of Labour and Social Protection. In Nigeria the key public entity is the National Commission for Persons with Disabilities and falls under the Ministry of Humanitarian Affairs, Disaster Management and Social Development.

Another key government entity is the national standards bureau, which establishes and enforces regulatory frameworks with the aim to ensure safety, quality and reliability of assistive products. In Kenya, Nigeria and South Africa these bureaus play an essential role in setting standards and in ensuring compliance within the assistive technology market.

3.1.2 Local production

Local production refers to the domestic manufacturing and/or assembly of assistive product components into functional products. This can be achieved using either industrial or non-industrial production methods. Whether led by local or foreign industry stakeholders, local production is often viewed favourably by national authorities of low- and middle-income countries as a means of improving access to assistive technology and of stimulating the economy.

Producing assistive products locally eliminates the need for international shipping, reduces lead times, simplifies logistics, diversifies supply chains and lowers overall costs. It also encourages development of products directly suited to the local context and needs, and increases potential for a feedback loop with persons in need of such assistive technology within the local community. Sourcing materials locally may also reduce tariffs or taxes, although securing tax exemptions for imported components can be more challenging than for fully assembled assistive products. Additionally, local production minimizes reliance on international shipping, lowering the carbon footprint and enabling the use of sustainable, locally available materials. It also allows for product customization to meet the specific needs of users in diverse local contexts. Collaborative local manufacturing can strengthen communities by leveraging existing expertise and infrastructure rather than requiring the construction of specialized production facilities. There is a healthy supply of skilled engineers and production cadres and workers in low- and middle-income countries, and integrating assistive technology manufacturing into their existing work could help address local demand while fostering specialized workforce development.

This, in turn, could stimulate job creation and economic growth, and also provide opportunities of employment and entrepreneurship for persons with disabilities in the local community. Furthermore, local production can enhance market resilience by mitigating the impact of global supply chain disruptions. Proximity to regulatory bodies also facilitates compliance with local standards and strengthens quality control mechanisms.

Despite these advantages, successful local production of assistive products in Africa remains limited. Barriers include both the significant capital investment required, especially in regions where financing options are scarce, and the challenges of meeting and maintaining consistent quality standards. Locally produced products must compete with established alternatives that benefit from economies of scale, and some assistive products require advanced manufacturing technologies and specialized infrastructure. Some products require advanced components that cannot be manufactured locally, necessitating imports and reducing the potential benefits of domestic production. Infrastructure challenges – such as unreliable electricity supply and inefficient transportation networks – can disrupt manufacturing processes and raise costs. Irregularities in the procurement processes – such as favoritism, bribery or lack of transparency – may lead to contracts being awarded to inefficient or foreign suppliers regardless of quality or cost. This undermines fair competition and discourages local producers from entering or sustaining their activities in the market. Finally, large-scale donations of assistive products, while well-intentioned, can flood markets with free goods. This can reduce demand for locally produced assistive products and, in the long term, discourage investors and innovators from developing sustainable local production systems.

Among the four assistive products in focus, wheelchairs appear most viable for local production due to the high costs associated with international shipping. However, only a few local initiatives, such as Motivation in Kenya and CE Mobility and ShonaquipSE in South Africa, were identified. Some assistive product components that require customization – such as prosthetic sockets, specialized spectacle lenses, and hearing aid earmoulds – are already produced locally in many settings. However, the full-scale local production of prostheses, spectacles, and hearing aids remains challenging due to the need for specialized infrastructure and expertise.

ATscale is currently conducting an analysis of assistive technology production at global, regional and local levels, with findings to be published separately. While local production has significant potential, most assistive products used in low- and middle-income countries continue to be imported. Consequently, the findings of this study contribute to understanding the steps to market entry and options for strengthening access to assistive technology in these markets.

3.2 Preconditions for market entry

Industry stakeholders considering entering an assistive technology market typically develop a research-based market entry strategy. This strategy involves assessing demand, cost structures (pricing, reimbursement and funding), market competition, branding and entry modes (such as direct exporting, joint ventures, licensing, franchising, or establishing a local subsidiary).

Additional considerations include regulatory classifications (such as whether an assistive product is classified as a medical device), warranty and after-sales support requirements, language and communication needs (such as product manuals in local languages) and intellectual property protection.

This research has identified five key preconditions that facilitate market building, thereby enabling industry stakeholders to enter assistive technology markets:

1. **Clearly defined responsibilities across stakeholders** – A complete ecosystem with clearly assigned roles enhances access to information and ensures accountability. However, in the four countries in focus, and in low- and middle-income countries more broadly, public sector involvement in assistive technology remains fragmented. Overlapping roles and a lack of accountability discourage international manufacturers from engaging in such markets.

2. **Significant and predictable funded in-country demand** – A stable and well-funded market allows organizations to anticipate demand, assess market size and establish a sustainable model. However, in many low- and middle-income countries, assistive technology purchases fluctuate due to inconsistent public funding and private spending. Product costs that are high compared to willingness to pay further limit market growth.

3. **Local capacity to properly assess needs and fit assistive products** – A skilled workforce is essential for fitting assistive products to users and providing after-sales support. In most low- and middle-income countries, however, a shortage of trained professionals hinders assistive technology adoption. The research found that most countries have some capacity for fitting spectacles, but there is a shortage of trained professionals with expertise specific to wheelchairs, prostheses and hearing aids.

4. **Clear and transparent market processes** – Registration procedures, import regulations, tax exemptions and purchasing mechanisms must be predictable and accessible. The lack of transparency and consistency in these processes creates uncertainty for industry

stakeholders, who must navigate unclear procedures and inconsistent rule enforcement and therefore take significant risks.

5 **Enforced product certification and regulation** – Available and enforced national standards, minimum quality requirements and regulatory harmonization are essential for market entry. Governments oversee assistive product regulations through national standards bureaus which define product specifications. These specifications ensure quality in public procurement processes and establish eligibility for tax exemptions. However, regulatory frameworks vary widely, and many countries lack a systematic approach to reviewing and updating product lists and specifications.

The presence and enforcement of assistive technology regulations remain inconsistent across low- and middle-income countries. Developing a national assistive product list can help guide policy, reimbursement schemes and workforce training. WHO (2025a) emphasizes the need for structured policy frameworks, yet many countries have not adopted standardized procedures for maintaining national product lists and specifications.

These prerequisites are specific to the assistive technology market and do not encompass broader factors influencing supplier entry, such as infrastructure, security and accessibility of market information. A key consideration for international manufacturers is the need for a local distribution network. In the four countries in focus, international manufacturers rarely establish local offices or subsidiaries, with only a few large manufacturers doing so. Instead, they typically partner with local distributors, who often handle a broad range of medical products beyond assistive technology. Additionally, while market data on assistive product supply and demand is valuable for long-term planning, some stakeholders note that the demand for assistive technology in Africa currently far exceeds supply, and that any available assistive product would likely find a market.

3.3 Five steps for entry in assistive technology markets and step-by-step guidance

Five key steps for entering assistive technology markets were identified through desk research and key informant interviews. These steps provide a structured framework for describing market entry processes and represent the essential procedures that manufacturers, importers and distributors must follow to successfully enter an assistive technology market.

The goal of the market entry process is to establish a sustainable presence that delivers value to all stakeholders involved in the market. A sustainable presence enables an industry stakeholder to continue introducing new products as they become available, adapting to evolving market needs and demand, or responding to changes in purchasing power that make new product introductions viable.

Before progressing through the five steps of the market entry process, an industry stakeholder must be registered in the given country as an authorized entity permitted to conduct activities related to assistive technology. This typically includes showing adherence to global and/or national minimum standards including but not limited to Good Manufacturing Practices (WHO, 2025b). Business entity registration is a country-specific process that requires collaboration with local entities.

The five steps for entering assistive technology markets are as follows:

1. **Product certification** – The process by which an assistive product is certified as conforming to applicable product standards.

2. **Quality assurance** – The practical implementation of controls to ensure that the product meets the quality requirements specified in the product standards.

3. **Import procedures** – The process governing how a product enters a country, including compliance with documentation and customs clearance requirements.

4. **Duties and taxes** – The compulsory levies imposed by governments, primarily to generate revenue for public expenditures. In international trade, these include import duties and taxes on goods entering a country. Some countries grant duty-free or tax-free status to selected products under free trade agreements. In specific cases, assistive technology manufacturers, importers and distributors may be exempt from customs duties and taxes.

5. **Sales and distribution** – The mechanisms through which assistive products reach users in the country, and any after-sales services and support is provided. Several sales channels exist, including public and private procurement. While private procurement methods vary between entities, this guidance focuses primarily on public procurement, which typically follows a structured tendering process. Public tenders specify the type of assistive technology to be procured by the government, along with required quantities and relevant specifications.

The sequence of these steps depicted in this guidance is indicative. In some cases, they may not occur in the order presented or may take place concurrently rather than sequentially. For example, quality assurance might precede product certification or occur during the import process. Additionally, multiple stakeholders may be involved in the market entry process for a given product. For instance, importers and distributors often collaborate with manufacturers to facilitate their entry into local markets. In many instances, the market entry process is initiated in response to a specific public tender.

Illustration 2: Five steps for entry in assistive technology markets

This step-by-step guidance provides insights into market entry according to the five identified steps. Country-specific details for each step are available in the following section.

3.3.1 Product certification

KEY FINDING: PRODUCT CERTIFICATION CAN BE COSTLY AND TIME-CONSUMING. CERTIFICATION IS SIMPLER FOR ASSISTIVE PRODUCTS THAT MEET INTERNATIONAL STANDARDS.

Certification is the process through which an assistive product is verified to meet specific product standards. This process typically involves certification specific to the product. Product certification can often be expensive and time-consuming, with the process taking up to two years in some countries. However, certification is generally simpler for products that comply with international standards, such as CE or ISO. A common challenge for importers is the certification of imported components versus complete products, as components are often not recognized as medical products. Product certification is usually easier for single-use items, such as prosthetic joints, compared to multi-use items, such as other components of prostheses.

3.3.2 Quality assurance

KEY FINDING: QUALITY ASSURANCE FOR ASSISTIVE PRODUCTS PRIMARILY INVOLVES IN-PERSON QUALITY CHECKS AT CUSTOMS. THE RIGOUR AND DURATION OF THESE CHECKS VARY, BUT THEY TEND TO BE STRICTER AND MORE TIME-CONSUMING FOR NEW SUPPLIERS.

Quality assurance ensures that a product meets the specified standards for quality. In practice, quality assurance checks are often conducted in person at customs. Customs agents, who are typically non-specialized and handle a broad range of products, conduct these checks, often without the expertise or resources for systematic inspections. The level of scrutiny varies greatly by country, region and the officials involved. The process can be inconsistent and challenging to predict. Additionally, third-party inspections may be required for international manufacturers. New suppliers should account for the time and cost associated with potential delays in each market.

Even in countries with rigorous checks the entry of substandard products remains a problem. The scope of quality assurance processes, the standards inspectors use and whether those processes are fit for purpose can vary significantly. Inspectors may struggle to reliably assess the quality of different types of assistive products, particularly if they lack specialized training. Furthermore, some stakeholders have reported incidents of fraud, especially when products shipped fail to meet the quality requirements. The presence of such substandard products undermines market confidence and presents risks for users.

3.3.3 Import procedures

KEY FINDING: THE IMPORT PROCESS IS GENERALLY STRAIGHTFORWARD, BUT STAKEHOLDERS RECOMMEND WORKING WITH LOCAL CLEARING AGENTS TO REDUCE DELAYS.

Import procedures focus on the rules that govern the entry of products into a country, such as the documentation needed to clear customs. Typically, the process requires submitting various documents, such as proforma invoices, product specifications and certificates of conformity, in addition to ensuring that the product meets quality assurance standards. External suppliers often collaborate with local clearing agents to streamline and expedite this process, although finding agents can be challenging.

Some countries impose strict currency regulations, which can affect the import of high-cost items, such as wheelchairs, prostheses and hearing aids. In these cases, an additional license may be required, which could delay shipments by several weeks. Import procedures can also vary depending on whether products are transported by air or sea.

3.3.4 Duties and taxes

KEY FINDING: EVEN WITH TAX EXEMPTIONS OR REDUCTIONS IN PLACE, ASSISTIVE PRODUCTS ARE OFTEN SUBJECT TO CUSTOMS DUTIES AND VALUE ADDED TAX (VAT). THE APPLICATION OF CUSTOMS DUTIES LARGELY DEPENDS ON THE CLEARING AGENTS' FAMILIARITY WITH ASSISTIVE PRODUCTS. THE PROCESS FOR OBTAINING TAX EXEMPTIONS OR REDUCTIONS IS HIGHLY CASE-SPECIFIC, AND FINISHED PRODUCTS ARE MORE LIKELY TO BE TAX-EXEMPT THAN COMPONENTS.

Duties and taxes refer to mandatory contributions to government revenue levied on imported goods. Import duties apply to goods entering the country, while VAT and Goods and Services Tax (GST) are consumption taxes imposed on the added value of a product or service. Following WHO recommendations, some countries offer exemptions or reductions in taxes and duties for essential health products, including their components and ingredients in the case of pharmaceuticals (WHO, 2020). These exemptions or reductions can make assistive products more affordable in the long term, provided any savings are passed on to purchasers and users. The rationale for tax exemptions is that enabling individuals to become economically active can boost tax revenues over time, while the fiscal impact on public finances remains marginal.

Tax exemptions or reductions may apply to customs duties, VAT/GST, or both. However, the conditions for obtaining these exemptions are often unclear, and when they are specified, the process can be complex. The research indicates that even when tax exemptions are available, they are rarely applied in practice. Exemptions are generally granted when products are imported for donations or when an NGO secures the exemption. Obtaining the necessary documentation can be time-consuming, taking anywhere from six months to three years, depending on the country and the relationship with local authorities. Even in the absence of a tax exemption, the tax policy is complex, as it varies according to the tax code. Correctly identifying the relevant code is crucial to avoid misunderstandings, especially with less familiar products.

The likelihood of obtaining import duty exemptions also varies across different assistive technologies. Exemptions are generally more readily applied to fully assembled products. Among the four products in focus, imported wheelchairs are the most likely to receive exemptions, as they are widely recognized as assistive products. However, securing import duty exemptions for prostheses is more difficult, as they are typically imported as separate components rather than as complete products. Some components have other uses, making exemptions impossible in many cases.

Hearing aids, being more technically complex, require a certain level of expertise to be identified correctly as assistive products, a level of knowledge not always available at customs. Additionally, hearing aids are often procured in smaller quantities and are less widely recognized than other assistive products. Spectacles, by contrast, are rarely classified as assistive products. An assistive product in high demand, spectacles are often viewed as consumer products rather than assistive devices which means they are less likely to receive import duty exemptions.

Assistive products	Likelihood of duty and tax exemption
Wheelchairs	Possible
Prostheses	Possible for some components
Spectacles	Rarely possible (least likely)
Hearing aids	Possible, but is inconsistently applied

3.3.5 Sales and distribution

KEY FINDING: SALES INVOLVE MULTIPLE CHANNELS FOR IMPORTERS, WITH THE PRIMARY ONES BEING PUBLIC AND PRIVATE PROCUREMENT. PRIVATE PROCUREMENT PROCESSES VARY WIDELY, WHILE PUBLIC TENDERS OFTEN ADDRESS ONLY A SMALL PORTION OF DEMAND AND ARE FRAGMENTED ACROSS MULTIPLE MINISTRIES, MAKING THEM DIFFICULT TO NAVIGATE.

Sales and distribution focus on the various buyers of assistive technology once the products have been imported. There are several channels for importers, with the main ones being public procurement and private procurement. Private procurement, whether through direct distribution with manufacturers or indirect distribution via distributors, varies depending on the entity involved. Non-profit organizations play a significant role in these countries in supplying assistive products at no cost or limited cost. This research specifically examines public tenders, which tend to follow a more structured and standardized process. Public tenders define the type of assistive technology to be procured by the government, along with required specifications and quantities.

Public procurement generally accounts for only a small portion of the supply in low- and middle-income countries, with NGOs handling a larger share. In the four countries in focus, the public procurement process appears fragmented, with various ministries handling procurement according to their specific needs, each with its own procedures. Procurement occurs both at the national level and within subnational jurisdictions, with different requirements and stakeholders involved in each case.

Public tenders for assistive technology are limited, and accessing alternative channels for importers (private procurement) can be particularly challenging for new suppliers. Public procurement mechanisms can also present barriers for new industry players if they are not perceived as transparent and fair. Key informants in this research noted instances where tenders were issued despite contracts already being awarded to predetermined industry stakeholders.

Competing in tenders requires significant resources, which smaller industry players may lack. The need for extensive documentation, regulatory compliance and sample submissions can be overwhelming. Additionally, local registration requirements in some countries may prevent key players from participating in public tenders, forcing them to rely on local distributors, which can lead to higher prices and reduced competitiveness.

Visually impaired student Brenda from St. Bernadette Primary school in Hoima, Uganda, listens to a recorded lesson from an audioplayer
© UNICEF

3.4 Country summaries

The structures and stakeholders involved in the market entry of assistive products vary significantly across the four countries in focus. This section provides a summary of the assistive technology market entry process in Egypt, Kenya, Nigeria and South Africa, with information presented in terms of market entry prerequisites and of the five steps of market entry described above. The examples presented reflect real-world policies and practices, rather than best practices, highlighting both strengths and areas for improvement. Annexes C–F present more detailed descriptions of the market entry processes for each country in focus.

3.4.1 Egypt

PRECONDITIONS

The Ministry of Health, Ministry of Defense and Ministry of Education play key roles in the public procurement of assistive products in Egypt. The country lacks national specifications for assistive technology. Instead it follows ISO standards that focus on manufacturing quality and management systems rather than product-specific requirements. Registering as a medical device business entity in Egypt is a complex process, and separate permissions are needed to work with international NGOs.

Medical device entities must register all assistive products, with the registration process being simpler for products classified as low risk compared to those categorized as medium or high risk. Egypt does not have a dedicated pooled public procurement entity, which complicates access to public tenders and limits industry stakeholders' access to demand information.

The Egyptian Drug Authority oversees the regulation of medical devices and the import process, but activities such as taxation and procurement are managed by multiple ministries, creating a fragmented approach to the supply of assistive products. Interviewed stakeholders reported varying experiences with the market entry process in Egypt.

PRODUCT CERTIFICATION

Assistive products with international certifications, particularly CE, face fewer obstacles when importing into Egypt. However, the process is often lengthy due to extensive documentation requirements and inconsistent procedures.

QUALITY ASSURANCE

Quality checks are conducted by multiple entities. Customs officials responsible for quality assurance often lack expertise in medical products. Industry stakeholders typically employ customs agents to ensure smooth clearance through customs.

IMPORT PROCEDURES

Detailed procedures are provided by the Ministry of Trade and Industry. The import process for medical products into Egypt can take anywhere from a few days to several weeks, with the process being faster if proper documentation is in place. Original documents with blue ink signatures and stamps for authenticity are required. Egypt imposes currency regulations that cap shipments over US$2,000, which require an import license from the Ministry of Finance, potentially delaying shipments by 2 to 3 weeks. These regulations particularly impact the import of higher-value assistive products, such as wheelchairs, prostheses and hearing aids.

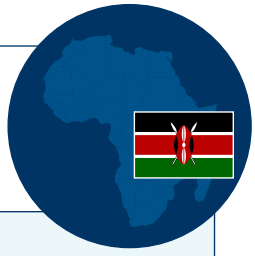
DUTIES AND TAXES

Assistive products are eligible for exemptions from import duties and VAT.

SALES AND DISTRIBUTION

In Egypt, public procurement accounts for less than 20 percent of the assistive technology supply. Most users acquire assistive products through NGOs.

3.4.2 Kenya



PRECONDITIONS

Kenya does not yet have national assistive technology specifications for market entry, but the country generally aligns with international standards like ISO. National specifications are currently under development. Kenya offers Special Economic Zones where industry stakeholders can register, although these zones do not provide preferential conditions compared to other stakeholders. Setting up a business entity in Kenya is costly and challenging for foreign entities, requiring the assistance of a local consultant to navigate the registration process.

Kenya has a fragmented structure with multiple agencies involved in regulating, quality controlling and overseeing public procurement of assistive technology, including the Ministry of Health, the National Council for Persons with Disabilities and the Kenya Bureau of Standards, making the regulatory landscape complex.

PRODUCT CERTIFICATION

Suppliers must certify each product and appoint a local representative to ensure compliance with regulatory standards. Certification can take up to two years.

QUALITY ASSURANCE

International manufacturers undergo third-party quality controls to obtain a certificate of conformity for shipments to Kenya, while in-country manufacturers are inspected directly by Kenyan quality authorities at their production sites.

IMPORT PROCEDURES

The most challenging aspect of the import process is customs clearance. Stakeholders have reported waiting up to six months due to changes in national policies. Hiring a clearing agent is essential for navigating this process.

DUTIES AND TAXES

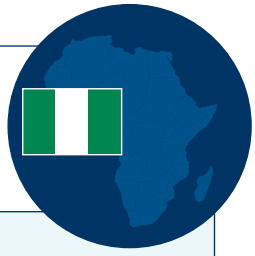
While assistive products can be exempted from import duties and VAT, suppliers report an effective tax rate of approximately 20 percent of the product value, despite the theoretical exemptions.

SALES AND DISTRIBUTION

Public procurement in Kenya is fragmented and only covers a small portion of the demand for assistive technology. Currently, fewer than 10 percent of the population has access to assistive products, with around 60 percent of the supply coming from NGOs.

When tenders are issued, the evaluation criteria typically focus on product quality, pricing and prior experience. Local registration requirements prevent some key players from participating in public tenders or force them to rely on local distributors, which results in less competitive pricing.

3.4.3 Nigeria



PRECONDITIONS

Despite a national priority assistive technology list, Nigeria currently lacks national standards for assistive technology, relying instead on certified professionals to apply good manufacturing practices. Business entities must register for tax compliance through a straightforward process. Nigeria lacks a dedicated pooled public procurement entity which complicates access to public tenders and limits industry stakeholders' access to demand knowledge.

The regulatory environment is characterized by overlapping responsibilities among agencies like the Standards Organization of Nigeria, the National Agency for Food and Drug Administration and Control and several professional boards, which can lead to coordination gaps.

PRODUCT CERTIFICATION

Suppliers meeting international standards face no significant issues. In some cases, certification can be replaced by licensing medical workers employed by assistive technology suppliers.

QUALITY ASSURANCE

Quality checks are primarily conducted at customs. Known products can be easily imported, while new products require samples and details for approval through a straightforward process.

IMPORT PROCEDURES

The import process is informal, and a local partner, typically a distributor, is recommended to manage logistics. Identifying the right partner can be challenging, but with proper documentation, the process is generally straightforward.

DUTIES AND TAXES

Assistive products are not exempt from import duties or VAT.

SALES AND DISTRIBUTION

Public procurement in Nigeria is limited, with estimates suggesting that less than 10 percent of the demand for assistive technology is met through government supply. It is estimated that 20 percent of spectacles supplied come from NGO sectors. Tenders are often long and complex, requiring an in-country presence to collaborate with the government throughout the selection process.

3.4.4 South Africa

PRECONDITIONS

South Africa has national specifications for assistive products, which are based on ISO standards for each product category. Manufacturers must register locally or partner with registered distributors to supply assistive technology in South Africa.

The country has a simplified approach to government involvement, with the National Department of Health working closely with the South African Bureau of Standards and the South African Health Products Regulatory Authority to develop standards and regulate assistive products.

PRODUCT CERTIFICATION

Suppliers prioritize obtaining international product certification to facilitate local approval. The certification process is costly, lengthy and involves audits and consultants.

QUALITY ASSURANCE

Obtaining certification involves rigorous quality controls, which are essential for participating in national tenders. Direct product quality inspections are conducted at customs.

IMPORT PROCEDURES

The import process is generally considered straightforward and efficient. The only potential issue is occasional delays of a few days at customs. Overall, the process usually takes between a few days and three to four weeks.

DUTIES AND TAXES

Assistive products can be exempted from import duties but not from VAT.

SALES AND DISTRIBUTION

Public tenders play a key role in the supply of assistive technology. Suppliers must meet specific conditions, such as product quality, pricing and local presence, to be included in the tender list, which is then used by public entities to procure the required products.

4. Discussion and conclusion

4.1 Recommendations

This research focused on describing the market entry processes for four assistive products: wheelchairs, prostheses, spectacles and hearing aids. The report detailed the key stakeholders involved, the prerequisites and outlined the five main steps identified in the process: product certification; quality assurance; import procedures; duties and taxes; and sales and distribution. It provided step-by-step guidance to support industry stakeholders aiming to enter assistive technology markets in Africa, with country summaries from Egypt, Kenya, Nigeria and South Africa.

To successfully scale up access to assistive technology, a systems-level approach is required. Improving market entry and related processes is one of several critical interventions needed to enhance supply. Likewise, interventions are necessary to stimulate demand. Achieving better access to high-quality, affordable assistive technology in Africa requires coordinated action from all relevant stakeholders, including from both government and industry players.

Governments have the capacity to structure assistive technology systems and regulate markets, while industry stakeholders can contribute by improving product quality, pricing, durability and customization options. The research also identified other important stakeholders, including local businesses, NGOs, suppliers, service providers and organizations representing users including persons with disabilities.

The research highlights two key recommendations to facilitate market entry for new industry stakeholders, aiming to create an enabling environment for stakeholders to enter the market and generate value for all involved. The two recommendations are presented below.

4.1.1 Simplify and digitize market entry for assistive technology

Firstly, governments should simplify and digitize market entry processes for assistive technology. This would enhance the transparency and clarity of market processes while ensuring the enforcement of product certification and regulation. Currently, stakeholders often have differing perceptions of market entry processes within the same country, which can lead to confusion and inefficiencies. Unclear processes deter industry stakeholders from participating, thereby resulting in higher costs, delays and reduced access for those in need.

Additionally, specific regulations can inadvertently drive up costs. For instance, in many low- and middle-income countries, industry stakeholders that are not locally registered are excluded from public tenders, even if they offer high-quality, affordable products with the best cost-benefit profile. One international manufacturer shared that, in order to bid in Rwanda, they must use a local distributor, which adds 20 percent to the price due to intermediary costs. Similarly, UNICEF is often unable to participate in public tenders due to local registration requirements.

Exempting all assistive products, including components and spare parts, from import duties and establishing clear, comprehensive guidance would help stimulate the market. This could be achieved through an analysis of the impact of tax exemptions on revenue collection, alongside the development of criteria for when such exemptions can be applied. Systems should be established to monitor the effects of tax exemptions on access to assistive technology, and regular consultations with ecosystem stakeholders should be held to assess effectiveness. In the longer term, cross-country collaborations through economic communities, such as the Common Market for Eastern and Southern Africa and the East African Community, could facilitate the harmonization of tax policies on assistive technology, promoting regional trade and broader access.

The most common market entry processes could be optimized and clarified by collecting feedback from local stakeholders and potential market entrants to identify key barriers. To enable this, key government entities must understand the benefits of optimizing market entry processes. For example, ensuring that relevant industry stakeholders can participate in tenders, even if not locally registered, or providing a fast-track registration process for those offering competitive bids, would encourage participation. Optimizing these processes may require adjustments to broader procurement policies that are not specifically related to assistive technology.

Enhancing the dissemination and digitization of information on assistive technology market entry processes will further stimulate market entry. Creating a clear, visual guide outlining each step of the market entry process and distributing it widely – on government websites and to both current and potential industry stakeholders – would help spread awareness of market opportunities. All relevant links to further information on specific processes or necessary requirements should be easily accessible. Additionally, organizing online seminars to present the process, address questions and collect feedback from stakeholders – including manufacturers, importers and distributors – would ensure better access to information. The effectiveness of these efforts should be regularly monitored to ensure that market entry processes and their implementation remain accessible, transparent and up to date.

4.1.2 Strengthen the assistive technology knowledge of distributors and service providers

Manufacturers should focus on strengthening the knowledge of distributors and service providers regarding assistive technology. This would address the critical prerequisite of developing local capacity to properly fit assistive products to meet user needs and preferences. Most international manufacturers rely on local distributors to make their assistive products available in local markets, particularly in smaller markets where establishing local branches or subsidiaries is rare.

In many countries, these distributors serve as manufacturer representatives and typically distribute a wide range of medical products beyond assistive technology. However, they often lack in-depth expertise specifically related to the products they distribute. Furthermore, distributors are generally based in urban areas and assistive products are seldom available in rural and remote regions.

Manufacturers could encourage distributors to adopt a regional rather than a national scope of activities to help scale up the market and justify the development of specialized expertise in assistive technology. Identifying regions where distributors could effectively operate – serving neighbouring countries with similar user needs, preferences, and existing distribution networks – would help foster greater market reach.

Manufacturers could also support this by working with local distributors to build their capacity and expanding regional distribution networks. To incentivize such expansion, manufacturers could offer benefits such as preferential pricing, favourable delivery terms and logistical support.

Additionally, manufacturers could encourage distributors to build local capacity in service providers. They could hold distributors accountable for their local capacity-building efforts. Developing tailored training programmes for distributors, such as e-learning modules focused on the specific requirements of assistive technology and localized marketing strategies, would support this capacity-building process. Introducing incentives for distributor teams to participate in these training programmes, such as a certification system, would further enhance the effectiveness of these efforts.

Furthermore, establishing feedback loops to regularly update and refine the training content and offering dedicated technical support to distributors would help address product-related challenges more efficiently. Over time, a "train-the-trainer" model could be employed to expand the reach of the training programme and significantly increase the number of trained distributors and service providers.

This approach, widely used in the hearing aid industry, has been successful in training regional distributors, who then go on to train local service providers. This creates a scalable and sustainable system for capacity-building, benefiting distributors and service providers of assistive technology, and in turn users.

4.2 Future perspectives

This guidance described market entry processes in low- and middle-income countries of Africa and provided related guidance and recommendations. While this guidance considered four countries, future efforts could explore other countries in Africa or other contexts, such as South Asian, South East Asian or Latin American ones.

Market building and shaping strategies hold promises to improve access to assistive technology, and must consider the demand as much as the supply sides of markets. Market building and shaping initiatives for assistive technology in the African context is expected to contribute significantly in addressing the unmet needs in the continent. Moreover, a more detailed analysis of local and regional production and assembly possibilities in this region, as well as trade related barriers and solutions, can strongly complement this research. This is particularly relevant given that, at the time of writing, international trade conditions were being affected by the introduction of new protective tariffs on imports by some countries. Such changes in trade conditions can significantly disrupt the global supply chain for assistive products and their components, thereby reducing both their availability and affordability.

The possibilities of emerging innovations in assistive products and service provision should be considered in the African context. This could include innovations emerging from the continent that suit the local needs, as well as the potential of South-South collaborations, for example with emerging South Asian manufacturers.

Finally, this research also calls for the need of harmonized regional (that is, multi-country) policies and approaches to facilitate development of regional hubs of excellence, cross-border trade and streamline market entry procedures across multiple countries.

Workers in a workshop in Kenya, who are wheelchair users themselves, are assembling wheelchairs. © Walkabout Foundation

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Annex A. The four assistive products in focus

Product	Wheelchairs	Prostheses	Spectacles	Hearing aids
Definition	Chairs on wheels that people, who are unable to walk, use for moving around (ATscale, 2019a).	Artificial body parts, such as arms or legs, that replace missing body parts and their function (ATscale, 2020b).	Two small pieces of special glass or plastic in a frame worn in front of the eyes to improve sight (ATscale, 2020c).	Devices worn inside or next to the ear by people unable to hear well to help improve hearing (ATscale, 2019b).
Need for assistive technology in Africa and low- and middle-income countries in general	In 2019, around 10 million people needed a wheelchair in Africa – only 5% had one (ATscale, 2019a).	In 2017, 5 million people in Africa lived with an amputation. In low- and middle-income countries, only 5–15% of people needing a prosthetic device have access (McDonald et al., 2021).	In 2023, approximately 26.3 million people in Africa have a form of visual impairment. Of these, 20.4 million have low vision, and 5.9 million are estimated to be blind (WHO Regional Office for Africa, 2025a).	In 2023, estimates showed that 40 million people in Africa have hearing loss (WHO Regional Office for Africa, 2025b). Current coverage of people in need of hearing aids in low- and middle-income countries is less than 3% (of 72 million people worldwide).
Types of assistive technology available in low-and middle-income countries	Wheelchairs available in low- and middle-income countries are usually standard models not tailored to specific personal needs. Some low-quality wheelchairs are also provided by local craftspeople.	Low-cost mechanical prosthetics are usually made from one raw material. There is a larger need for lower limb prosthetics than upper limb ones.	Non-customized spectacles, near-vision spectacles serving as ready-made spectacles, and refurbished/ recycled donated spectacles. Ready-to-assemble spectacles are slowly entering the market and would be particularly relevant to cover a section of the population in need in low- and middle-income countries. Alternative pathways should also be required, as these spectacles do not meet universal needs.	Personal amplifiers of unknown quality and unadjustable to the user's hearing loss are common. Hearing aids that are available in low- and middle-income countries are usually behind-the-ear models, which have the widest coverage range for severity levels and that can be customized to suit the hearing loss of its user, and body-worn models that are the least complex with a device worn on the body and earbuds placed in the ear.
Price range in low- and middle-income countries	Manual wheelchairs that are adapted to local conditions would have to be affordable, durable in rough terrains, low maintenance, and with widely available replacement parts. Appropriate everyday wheelchairs are usually priced at US$150–US$350 (ATscale, 2019a). Lower-quality ones are usually priced at US$80–US$150.	Basic mechanical limbs are sold for US$1,000–US$3,000 by leading manufacturers (ATscale, 2020b). Manufacturers from middle-income countries offer lower-priced limbs at US$100–US$500. Several start-ups have been selling LMIC-appropriate products at US$80–US$200.	Spectacles are usually available for US$50–US$200 (ATscale, 2020c). Some NGOs in low- and middle-income countries can offer subsidized spectacles for US$20. Ready-to-assemble spectacles are priced at US$5–US$10.	In high-income countries, hearing aids are priced anywhere between US$600–US$3,000 (ATscale, 2019b). Some NGOs can procure them at lower prices in low- and middle-income countries. The UNICEF Supply Catalogue, through pooled procurement, also offers more competitive pricing.

Annex B. Methodology description

The research was conducted in 2024 using both secondary (desk review) and primary (key informant interviews) sources.

The secondary research drew from past ATscale publications – including product narratives, market intelligence reports and credit facilities for assistive technology – as well as global reports from key stakeholders, such as GDI Hub, Humanity & Inclusion, UNICEF and WHO. Additionally, country-specific documents and datasets, including national assistive product lists, assistive technology strategies and legal and regulatory frameworks, were reviewed. This desk review helped outline a general market entry process and preliminary country-specific pathways, identifying key information gaps and areas requiring validation due to conflicting sources.

The primary research involved individual, semi-structured interviews conducted between June and November 2024. These interviews covered core topics such as market needs and challenges, the market entry process (including regulatory and legal procedures), government policies and public funding. Supplementary topics were tailored to each stakeholder's profile and the insights they provided.

Most key informants were recruited through ATscale's network, ensuring diverse perspectives. Reasonable accommodations, such as sign language interpretation, were provided as needed. A total of 65 stakeholders participated, representing global, regional and local manufacturers, distributors, international organizations, local NGOs, and public entities. Purposeful sampling ensured the inclusion of stakeholders with expertise in one or more of the four countries and assistive products in focus.

As shown in the tables below, many stakeholders had experience across multiple countries and assistive products. In the four focus countries, more stakeholders specialize in prostheses and wheelchairs than spectacles and hearing aids.

Number of key informant interviews per country

Country	Egypt	Kenya	Nigeria	South Africa	Cross-country
Number of key informants	8	13	8	9	27

Number of key informant interviews per assistive product

Assistive product	Wheelchairs	Prostheses	Spectacles	Hearing aids	Cross-product
Number of key informants	5	12	7	2	39

At the time of the interviews, the stakeholders were representing the following organizations: Abuja Association of the Deaf; African Organization for the Development of Centers for Persons with Disabilities; African Union; Alfaset; Assistive Technology Industry Association; Barkley and Oates; Christian Blind Mission; Circleg; Clinton Health Access Initiative; Cure Bionics; Dynalimb Technologies; Future Visions; Global Disability Innovation Hub; H.A.S.S. Group; Hand in Hand; Horus Prosthetics; Humanity & Inclusion; HumanWare; International Committee of the Red Cross; International Society for Prosthetics and Orthotics; International Society of Wheelchair Professionals; Jumping Kids; Kenyan Bureau of Standards; Kenyan Ministry of Health, Rehabilitation Services and Assistive Technology; KTWO Healthcare; Lapaire Glasses; Light for the World; Ministry of Health of South Africa; Modern Solutions; Momentum; National Council for Persons with Disabilities (Kenya); Nigeria Association of the Blind; Noncommunicable Diseases Alliance Kenya; Orthofit Orthopaedics; OrthoMedics; Ottobock; Restoring Vision; United Nations Relief and Works Agency for Palestine Refugees in the Near East; USAID; Verina; Vision Spring; World Health Organization.

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:

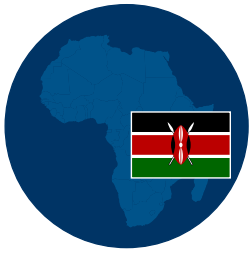
1. Approval must be obtained from the Industrial Development Society.
2. A suitable manufacturing site must be secured.

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.

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.

Annex E. Country description: Nigeria

Overview of Nigeria's assistive technology market entry

In Nigeria the market entry process is lengthy and complex, although stakeholders share a consistent view of it. The regulatory environment is evolving which means regulations may change soon. Most manufacturers and importers rely on local agents, who can be difficult to identify. Assistive technology is generally not exempt from VAT or customs duties, although exemptions may apply to suppliers of high-quality products and NGOs. Policy work related to assistive technology is ongoing, including a recent situation assessment (Clinton Health Access Initiative, 2021).

Key government stakeholders

- **Ministry of Health:** Ministry responsible for policy and development of guidelines; published a national priority assistive products list (Ministry of Health of the Federal Republic of Nigeria, 2022), which is instrumental to the enactment of the 2018 Discrimination Against Persons with Disabilities (Prohibition) Act (Federal Republic of Nigeria, 2019).

- **National Commission for Persons with Disabilities**: Government agency responsible for promoting the rights of persons with disabilities in Nigeria; has published an investment case for assistive technology (National Commission for Persons with Disabilities, 2022).

- **Standards Organization of Nigeria (SON)**: Government agency responsible for conformity assessment of medical devices.

- **National Agency for Food and Drug Administration and Control (NAFDAC)**: Government agency responsible for the regulation of medical devices, including assistive technology.

- **Medical Rehabilitation Therapists Board (MRTB)**: Government agency responsible for licensing rehabilitation of professionals.

Specifications

- In theory, all products imported in Nigeria undergo the Standards Organization of Nigeria Conformity Assessment Programme (SONCAP). It is a pre-shipment verification process to ensure products comply with applicable industrial standards or approved equivalents and technical regulations before shipment. Under SONCAP imports are verified and tested in the exporting country, and a SONCAP Certificate is issued to certify that the products meet the relevant standards and regulations.

- In practice, no specific Nigerian specifications for assistive technology have been developed, although there is an Assistive Product List available online. New specifications are currently being developed and will primarily align with WHO and ISO standards.

Nigeria market entry process

Business entity registration	• All business entities operating in Nigeria must be registered to comply with tax obligations, which also requires the submission of audited financial statements. The registration process is relatively straightforward, requiring basic documentation of the business entity. • For suppliers of assistive technology employing medical workers, it is mandatory for their staff to be licensed by the Medical Rehabilitation Therapists Board.
Product certification	• A common challenge faced by importers involves the classification of imported components versus complete products, as components are often not recognized as medical products. • Product certification can be substituted by the licensure of medical workers employed by assistive technology suppliers (conducted by the MRTB and the Optometrists and Dispensing Opticians Registration Board). Suppliers whose products meet international standards, such as ISO or International Society for Prosthetics and Orthotics (ISPO), should not encounter significant issues, as these standards are considered more rigorous than any standards the Nigerian Government might impose.
Quality assurance	• Any product already known to SON can be imported into Nigeria without much difficulty. For new products, SON requires samples, use case assumptions and cost details before approving import. • At customs, several agencies – including NAFDAC, SON and the Customs Office – inspect shipments. However, beyond customs, minimal government quality checks have been reported.
Import procedures	• The import process includes physical verification at customs and may require documentation from the manufacturer or sender. Having a local partner to manage the import process is recommended. These partners are mostly local distributors, but they can be difficult to identify without proper guidance. Once documentation is in order, the process is generally quick and straightforward. • The import documents required depend on the type or nature of goods. Importers of goods should check which import documents are applicable to their goods. This information is available from SON (SON, 2025). • Distributors must also engage with the Central Bank of Nigeria for foreign exchange, which is necessary for purchasing products in different currencies. Obtaining foreign exchange can be time-consuming and is often done at unfavourable rates, which presents a significant challenge for importers.

Duties and taxes	• According to the document describing the Priority Assistive Product List of Nigeria, the country does not grant tax exemptions for assistive technology (Ministry of Health of the Federal Republic of Nigeria, 2022). However, tax exemptions may sometimes be obtained for high-quality products through the Federal Ministry of Industry, Trade and Investment. Importers can apply for an Import Duty Exemption Certificate through an online platform (Ministry of Finance of the Federal Republic of Nigeria, n.d.). • NAFDAC and the Customs Office also take a percentage of the product price. However, overall taxes on medical components are relatively low compared to other industries, with reported figures around 6% (comprising 5% VAT and 1% customs duty). • NGOs may obtain full tax exemptions, but this requires engagement with the appropriate stakeholders in the Ministry of Health.
Sales and distribution	• Applying to public tenders is a lengthy and rigorous process: - 3–4 months for the tender to be approved by the national assembly and parliament and then to be advertised by the government; - Suppliers have 6 weeks to apply, then the government conducts its selection process; - Once selected, if the supplier is importing, it can take 4–5 weeks for import to be completed. • Participating in public tenders requires an in-country presence to collaborate with the government throughout the selection process. • Public tenders can be found online, although accessing them may require a small fee.

Local production in Nigeria

- Some existing local production of assistive technology is available, but it is informal and unstructured. Some products are made locally, while others are assembled in Nigeria. Much of the local production occurs in workshops, and most of the products do not meet established standards. Some local producers have reported resistance to locally made products from health workers, as well as limited protection against global competitors.

- The National Commission for Persons with Disabilities is working on developing local production by looking at Nigerian standards specific to local production. The plan will begin with local assembly, although no concrete actions have been taken yet.

Conclusion

Nigeria's assistive technology market offers significant opportunities, but navigating its entry process requires understanding a complex regulatory landscape. While the market is developing, challenges exist, including the evolving regulatory environment, the need for partnerships with local distributors, and difficulties with product certification and with tax exemptions. However, with an in-country presence, adherence to relevant standards and proper collaboration with government bodies, businesses can successfully enter the Nigerian markets.

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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