Paving the path for quality assistive products and services in Pakistan

Summary

In Pakistan, there is a notable lack of regulations on the quality of assistive products (APs) and assistive technology (AT) services. The absence of comprehensive quality standards and regulatory mechanisms results in the provision of sub-standard products and services, leading to ineffective products, dissatisfaction among users, product abandonment, and even harm to the health and well-being of users. While regulatory bodies overseeing drugs and medical devices exist, such as the Drug Regulatory Authority of Pakistan (DRAP) and the Pakistan Standards and Quality Control Authority (PSQCA), they do not provide comprehensive quality standards for APs and AT services.

To address these challenges, key stakeholders convened a policy roundtable, generating context-specific solutions and formulating key recommendations.

Assistive technology is the application of organized knowledge and skills related to assistive products, including systems and services.

Assistive products maintain or improve an individual's functioning and independence, thereby promoting their well-being. Examples of assistive products include hearing aids, wheelchairs, communication aids, spectacles, prostheses, pill organizers, and memory aids.

Key Recommendations

- Examine prevailing practices and options that are hindering access to good quality APs and how one can stimulate, support, and encourage local production of APs.
- Clearly define and identify the priority APs that are essential for addressing the diverse needs of the population.
- In the short term, engage all relevant stakeholders to develop and submit standards and specifications for the priority Assistive Products List (APL) to the DRAP for national-level registration.
- In the long term, develop a national-level policy to establish comprehensive quality standards for a wide range of APs and AT services in Pakistan.

The **absence of comprehensive quality standards and regulatory mechanisms** results in the provision of sub-standard products and services.

Introduction

According to the 2019 Global Burden of Disease study, one in five Pakistanis experiencing health conditions could benefit from rehabilitation.[i] Despite this substantial need, there is currently no designated organization or central body responsible for establishing comprehensive quality standards for a diverse array of APs. Aligning with international standards set by organizations such as UNICEF and the World Health Organization (WHO) to ensure the quality of AP services is paramount. This entails measuring the quality of APs against applicable technical standards or guidelines, considering factors such as strength, durability, capacity, safety, and comfort.

Problem Statement

In Pakistan, like many other low- and middle-income countries, the regulatory frameworks for APs are weak. The Drug Regulatory Authority of Pakistan (DRAP) and the Pakistan Standards and Quality Control Authority (PSQCA) are the organizations overseeing the quality of medical products. However, they do not cover all types of APs and are limited to only a few, such as wheelchairs and hearing aids. In Pakistan, there are currently no approved regulatory standards in place for APs.[ii] Additionally, quality control of the development of APs is constrained, primarily because many of these products are imported. Despite the enforcement of import duty relaxation for specific APs, such as wheelchairs, hearing aids, and prostheses,[iii] the regulation of the quality of imported APs remains inadequate.

Global evidence on quality standard regulation mechanisms for assistive products and services

- National regulatory bodies that regulate drugs and medical devices also oversee a wide range of APs. They set a clear definition for APs that are considered to be “medical devices,” qualifying them for regulation.[iv] Examples include the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom and the Food and Drug Administration (FDA) in the United States.
- These regulatory bodies also guide and regulate AP manufacturers. They are responsible for setting specific requirements for product development, testing, and submission for regulatory approval.[v]

Key findings of the Policy Roundtable

- The absence of a national-level policy to establish quality standards for APs represents a significant gap. Without a foundational policy, the development and implementation of comprehensive quality standards will likely face challenges in terms of coordination, consistency, and enforcement.
- The role of existing regulatory bodies is limited. The DRAP is only a registration body, not a regulation body for APs. Similarly, the PSQA is mandated to establish standards but lacks the enforcement power to ensure compliance.
- A priority APL does exist, but there are no set standards for those products, and many are not included in the DRAP list.
- Local production and customization of APs should be encouraged, fostering innovation, economic growth, and improved accessibility for individuals with diverse needs.
- There is a need to understand the utilization of APs from the users' perspective.

Way forward for policymakers

1. The Ministry of National Health Services, Regulation, and Coordination (MoNHSR&C)
    i. Take proactive steps to advocate for the development of comprehensive standards for APs and AT services. This advocacy effort should involve engaging with relevant regulatory bodies to establish clear, enforceable standards.
    ii. Facilitate dialogue and collaboration between ministries and regulatory agencies to address existing confusion or ambiguity regarding their roles.
    iii. Request the PSQCA to propose standards for APs and AT services that align with international rules and regulations.
2. The PSQCA
    i. Form a working group by engaging manufacturers, health care professionals, users, and relevant industry stakeholders to develop standards and specifications for APs.
    ii. Consult with global entities, such as the WHO, the International Organization for Standards (ISO), and the International Society for Prosthetics and Orthotics (ISPO) in the development of national standards for APs.
    iii. Adopt the WHO's Priority APLvi to guide the selection of APs.
    iv. Submit these standards to the DRAP for national-level registration.
3. The DRAP
    i. Register APs recommended by the PSQCA according to national standards into the system for national-level registration.
    ii. Strengthen the capacity of drug inspectors for the regulation of APs by including rehabilitation professionals in the team and training existing staff on the quality standards of APs.
    iii. Facilitate the adoption of the DRAP rules and policies for APs at the provincial level to regulate the supply chain of priority APs.
4. All stakeholders
    i. To foster local production and customization of APs, examine policies that can encourage and support local production. For example, tax exemption for local manufacturers, subsidies on raw material import, etc.
5. Academic institutions
    i. Understanding how individuals utilize APs in real-world settings is essential for optimizing service delivery, identifying challenges, and improving overall effectiveness. In Pakistan, it is not clear how effective APs are, and more effort is needed in this area. Encourage and commission academic institutions to conduct research on users' perspectives.

ReLAB-HS is made possible by the generous support of the American people through the United States Agency for International Development (USAID) and is implemented under cooperative agreement number 7200AA20CA00033. The consortium is managed by prime recipient, Johns Hopkins School of Public Health.

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