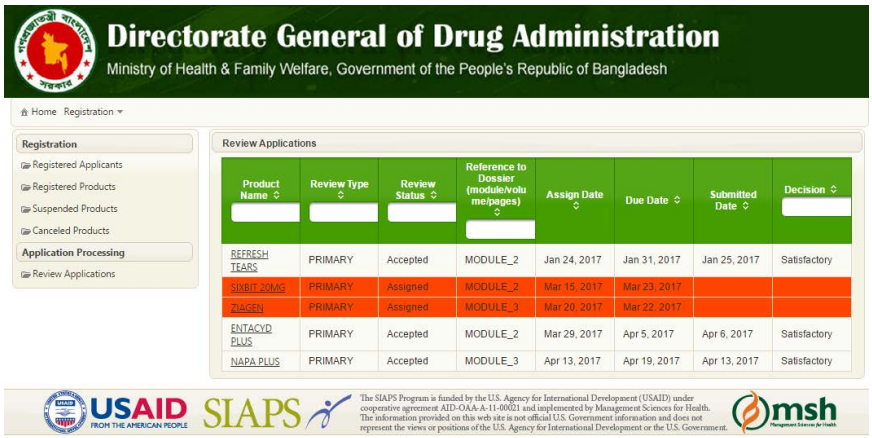
Pharmadex Adapted for Bangladesh's Medicine Registration System

Registering pharmaceutical products in alignment with international standards for medicine registration is critical to improving health and saving lives during the Sustainable Development Goals era. When countries have weak medicine registration systems—backlogs and inefficient tracking of drug registration applications, inefficient drug testing systems, and incomplete data on suppliers and products—money is wasted and millions of people are put at risk of using unsafe and low-quality medicines.

The Directorate General of Drug Administration (DGDA), Bangladesh's national regulatory authority, approves pharmaceuticals for sale in the country along with the specifics of the products and suppliers. Therefore, collecting product-related scientific data, recording that information, and the details of where a product's application is in the registration process are important for DGDA to ensure that the manufactured drugs are safe, effective, and of good quality. Currently, processing and tracking the registration of medicines and suppliers in Bangladesh is a time-consuming and detail-oriented task. Clearly, DGDA needed an efficient procedure for processing pharmaceutical and supplier applications so that timely decisions can be made and supported.

Design of a Bangladesh-Specific Information System

Acknowledging the existing gaps, the DGDA requested that the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program develop an online drug registration system, Pharmadex (https://pharmadexbd.org), to determine data elements for each function and the real-time decision-making process within the DGDA. SIAPS is funded by the US Agency for International Development (USAID) and implemented by Management Sciences for Health (MSH). Responding to that request, SIAPS worked with DGDA through a task force to adapt Pharmadex to a Bangladesh-specific medicine registration system and work flow. The existing database of DGDA's registered drugs, manufacturers, and pharmacies for both local producers and importers was also validated for an effective drug-registration process flow within the online system. To make sure that encrypted data was transferred and that valuable information provided by pharmaceutical companies was safeguarded, SIAPS assisted the DGDA in establishing a data center and installed Pharmadex in it. Simultaneously, SIAPS installed a dedicated file network-attached storage device within DGDA to provide local-area network nodes with file-based shared storage through a standard Ethernet connection to protect the confidentiality and privacy of the submitted dossiers.



Screenshot of Pharmadex

What is PharmaDex?

Pharmadex is an integrated information system that facilitates the submission, review, and evaluation of applications and dossiers. It can capture and track whether the dossier requirements for medicine registration submitted by a pharmaceutical company are based on common technical document (CTD)[1] format.

Key Features of Pharmadex

- Designed as a web-based system—allows for online application and information sharing with the regulated industry and consumers
- Provides a modular structure—helps DGDA integrate and coordinate their work, from product registration, licensing, and pre- and post-marketing inspections to quality control, pharmacovigilance, and administration
- Built-in document tracking and management system—facilitates archiving, documentation, management, and retrieval of dossiers and provides a platform for developing electronic document management systems
- Uses international standard dictionaries—provides standard terminologies and dictionaries with built-in international nonproprietary names, the Anatomical Therapeutic Chemical classification system, and the Medical Dictionary for Regulatory Activities
- Provides one-stop access to a regulatory approval package—enables access to product approval history, approval letter, and approved product information
- Provides administrative capabilities—allows for automatic printing of acknowledgment letters and registration certificates
- Enhances performance monitoring—monitors built-in key performance metrics and generates activity reports for the DGDA

Who Will Use Pharmadex?

DGDA staff and pharmaceutical companies are expected to be the primary users of Pharmadex.

User Manual

A step-wise user manual for a Bangladesh-specific Pharmadex has been developed to serve as a resource guide for pharmaceutical companies and DGDA officers on how to enter information and operate the system.

Minimum System Requirements for Pharmadex

Computer CPU:	Pentium-based processor
Memory:	1GB of RAM
Hard disk space:	1GB of free disk space
Additional drives:	CD-ROM drive (R/W if backup is to be done on CD) External schedulable hard disk backup drive (minimum 1GB)
Operating system and database:	Windows 7 and MySQL
Browser:	Google Chrome, Mozilla Firefox etc.
Printer:	Any Windows-compatible printer (laser printer is preferred to ink jets)
Power backup:	UPS minimum 1200 VA

1 International standards for medicine registration based on a common format proposed by the International Council for Harmonization for Technical Requirements for Pharmaceuticals for Human Use (ICH), known as the Common Technical Document.

For more information, please visit the DGDA web portal at http://www.dgda.gov.bd/