



Highlights: Launching of Pharmadex- an Online Registration System in Bangladesh

DGDA's Vision

The DGDA will strive to ensure quality and safe medicines for all.

DGDA's Mission

- *Safeguard the health of humans and animals by ensuring that medicines and medical devices meet applicable standards of safety, quality, and efficacy*
- *Ensure the safety and security of the supply chain for medicines and medical devices*
- *Ensure accessibility, including availability and affordability, and rational use of essential medicines*
- *Foster a regulatory environment that supports research and innovation, thereby ensuring moving toward global standards for quality production*

News:

On May 17, 2017, the Honorable Minister Mohammad Nasim, Member of Parliament (MP), Ministry of Health and Family Welfare (MOHFW), officially launched Pharmadex in Bangladesh at DGDA conference room, Mohakhali, Dhaka. Pharmadex (<http://pharmadexbd.org/>) is a web-based integrated information system that facilitates the submission, review, and evaluation of medicine registration



Honorable MOHFW Minister Mohammad Nasim, MP attended the launching event as chief guest. Photo credit-A R M Kamal, MSH

applications and dossiers on the basis of international standards and formats. Minister Mohammed Nasim appreciated the initiative taken by the Director General of Directorate General of Drug Administration

(DGDA) to digitalize its regulatory systems and congratulated US Agency for International Development (USAID) and SIAPS for their support in DGDA's systems strengthening activities.

DGDA, with SIAPS technical assistance, adapted Pharmadex to meet the context of Bangladesh to move toward a more efficient and transparent medicine registration system from the current paper-based process. SIAPS facilitated trainings for DGDA officials and selected pharmaceutical industry representatives to build their capacity to use this tool successfully. SIAPS also supported DGDA in adopting Common Technical Document (CTD) guidelines to make sure that the dossiers submitted to DGDA meet international standards.

At the event, the Director General of DGDA, Major General Mohammad Mustafizur Rahman, presented the highlights of DGDA's regulatory activities and said that, although Pharmadex is a new concept for Bangladesh, it can help DGDA ensure that manufactured drugs are safe, effective, and of good quality.

The President of the Bangladesh Association of Pharmaceutical Industries (BAPI), Nazmul Hassan, MP, also recognized that a system like Pharmadex, aligned with CTD, is needed for the country. He stressed that pharmaceutical companies would need more training at the initial stage to submit applications online.

Miranda Beckman, Deputy Director, Office of Population, Health, Nutrition, and Education, USAID, mentioned that USAID will work shoulder to shoulder to assist DGDA strengthen its capacity on critical regulatory systems and ensure that sustainable health systems exist in Bangladesh.

Commending DGDA for taking such a momentous step, SIAPS Bangladesh Country Project Director Zahedul Islam hoped that by using Pharmadex, the DGDA would be able to perform their regulatory functions more efficiently and effectively.

A total of 150 participants attended the launching ceremony, including senior officials from the MOHFW, DGDA, and Directorate General of Health Services, representatives of BAPI, the Bangladesh Chemist and Druggist Samity, pharmaceutical manufacturers, USAID, World Health Organization (WHO), Promoting Quality of Medicines (PQM) Program, and other international and national organizations, academia, and media.

The USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, implemented by Management Sciences for Health (MSH) partnered with the DGDA to improve the efficiency of the country's medicine registration process and other drug regulatory systems

[What is Pharmadex > link to Pharmadex](#)

Way forward to Implement Pharmadex : Key dates

Hands on practice on submission of the applications for pharmaceuticals:
[Held on 05 July 2017](#)

Capacity building and UAT training on review and evaluation for DGDA officials:
[To be held on 6 and 8 July 2017](#)

Pilot submission of applications starts: [Expected time: 15 July 2017](#)

Joint monitoring and feedback: [Continued process](#)