Text for Medicine registration on PharmaDex web page

The Directorate General of Drug Administration (DGDA) under the Ministry of Health and Family Welfare (MOHFW) of Bangladesh is changing and improving its medicines registration system to ensure the safety and efficacy of medicines as well as to strengthen the potential for the exportation of medicines. The DGDA is therefore adopting the International Standard Common Technical Document (CTD) formats and guidelines for the preparation of registration dossiers for pharmaceuticals that are submitted with the application for registration.

The DGDA is also planning to implement PharmaDex, a web-based information system to track registration applications and to enhance its capacity to successfully manage the registration process in a timely manner.

The registration activities are summarized below:

* Medicine application dossiers from Applicants are received and screened for completeness and that application fees have been included.
* Data on the dossiers is entered into the registration data base; an application number is allocated and information communicated to the applicant.
* Dossier is scheduled for evaluation by DGDA officials who are nominated as screener, reviewer, and moderator. A detailed evaluation report is also be generated.
* Acknowledgement letter, Deficiencies, missing information etc. is communicated to the applicant with deadlines to respond to the queries.
* Marketing Authorization Letter will be provided by DGDA after complete evaluation and approval of the dossier.

In order to register a new product, you must be a registered user of the PharmaDex website and login. If required please contact your administrator for help.