NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA)

National Pharmaceutical Regulatory Agency (NPRA)
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HELPDESK SUPPORT

MISSION

To safeguard the nation's health through scientific excellence in the regulatory control of medicinal products and cosmetics.

VISION

To be an internationally renowned regulatory authority for medicinal products and cosmetics.

OBJECTIVE

To ensure that therapeutic substances approved for the local market are safe, effective and of quality and also to ensure that cosmetic products approved are safe and of quality.

HISTORY

The National Pharmaceutical Regulatory Agency (NPRA), was set up in October 1978 under the quality control activity of Pharmacy and Supply Programme. This institution was established to implement quality control on pharmaceutical products. The infrastructure and facilities were designed to meet the requirements for testing and quality control activities.

Beginning 1985, NPRA was given the task of ensuring the quality, efficacy and safety of pharmaceuticals through the registration and licensing scheme. This is achieved through evaluation of scientific data and laboratory tests on all products before they are marketed.

“NPRA also handles courses and provides trainings to drug regulatory personnels from other countries such as Sri Lanka, Bangladesh, Myanmar, Mongolia and Vietnam.

NPRA is internationally recognised by the World Health Organisation (WHO) as a "WHO Collaborating Centre for Regulatory Control of Pharmaceuticals".”

NPRA ROLES & FUNCTIONS

CENTRE OF REGULATORY COORDINATION & STRATEGIC PLANNING

Responsible for the regulatory activities of pharmaceutical, health supplements, traditional products, and cosmetics as well as licensing activities. Engage in policy and communication with industry & stakeholders, management of the QUEST3+ System and conduct training through local training schemes or international cooperation schemes.

CENTRE OF PRODUCT & COSMETIC EVALUATION

Conducts activities related to the evaluation and registration of pharmaceutical products through assessment of the safety, efficacy, and quality aspects of the products, and safety and quality aspects of health supplement and traditional products. Also responsible for cosmetic notification activities.

CENTRE OF COMPLIANCE & QUALITY CONTROL

Carry out analytical, pharmaceutical, microbiological and pharmacological tests on drugs and cosmetics to determine the quality, efficacy and safety of products in the market. Implements the compliance scheme for pharmaceutical manufacturers, importers, and wholesalers. Also regulates clinical trials, Bioequivalence monitoring, and the licensing scheme for Clinical Trials, Good Lab Practice, & Good Clinical Practice. Manages the Product Recall Scheme for pharmaceutical products, the Cosmetics Control Scheme and the Adverse Drug Reaction Monitoring Program.