The NMRA Act and Establishment of the NMRA

Professor Raveendra Laal Jayakody

Emeritus Professor of Pharmacology, Faculty of Medicine, University of Colombo, Sri Lanka

The National Medicines Regulatory Authority Act (NMRA Act) was enacted in March 2015 and the NMRA (the Authority) established in July 2015. The Cosmetics Devices and Drugs Act which was in operation since 1980 was repealed. The NMRA Act regulated all aspects pertaining to medicines, medical devices and borderline products. Regulation of simple cosmetics was removed from the purview of this Act. A 13 member Authority with ex officio and appointed members with expertise from different fields was instituted. The national testing laboratory was incorporated into the Authority. Areas regulated include import, local manufacture, pharmacies, prescribing, pricing and clinical trials. A National Standing Committee with oversight function and an Appeals Committee is included.