

Law Relating to
**DRUGS &
COSMETICS**

VIJAY MALIK

Containing

- Drugs & Cosmetics Act, 1940 ● Drugs & Cosmetics Rules, 1945 ● Drugs (Prices Control) Order, 2013
- List of Drugs approved during January 2006 to March 2016 ● Transplantation of Human Organs and Tissues Rules, 2014 ● Pharmacy Practice Regulations, 2015 ● List of Schedule H1 Drugs
- National Pharmaceuticals Pricing Policy, 2012 ● List of Banned Drugs and Combination of Drugs
- Pharmaceuticals and Patents ● Guidelines on Registration of Import of Cosmetics and Important Circulars issued by CDSCO ● Penal Laws and other Allied Acts, Rules, Notifications etc.

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containing

Drugs and Cosmetics Act, 1940
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along with

Drugs (Prices Control) Order, 2013
National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012)

Pharmacy Act, 1948

Poisons Act, 1919

**Drugs and Magic Remedies (Objectionable
Advertisements) Act, 1954**

and other

Allied Acts and Rules etc.

with

Information on Herbal Formulations, Cosmetics and Extracts, etc.

by

VIJAY MALIK

B.A., LL.B., M.B.A.

*Author of: "Law for Cinemas,
Videos and Computer Programmes", etc.*

with a Chapter on

Pharmaceuticals and Patents

by

DR. ELIZABETH VERKEY



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[Drugs and Cosmetics Rules, 1945 have been amended up to the
(Second Amendment Rules, 2016)]



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PREFACE TO THE TWENTY-FIFTH EDITION 2016

The new Twenty-fifth Edition, provides the fully amended and updated text of the Drugs and Cosmetics Act, 1940 (with amendments by Amending Act 26 of 2008 enforced on August 10, 2009) and the Drugs and Cosmetics Rules, 1945 as amended up to the Second Amendment Rules, 2016, along with case-law notes, allied Acts, Rules, Orders and Notifications. Also recent notifications and Orders have been given to bring the book up to date.

Additionally, the new edition incorporates the following fresh materials: Transplantation of Human Organs and Tissues Rules, 2014, Pharmacy Practice Regulations, 2015, Number of Licensed Blood Banks in India, Pharmacovigilance Programme of India (PvPI), Reporting of Adverse Drug Reactions and Haemovigilance Programme of India (HvPI).

India, as a signatory to WTO and in compliance with its obligation to introduce TRIPS-compliant IPR regime by January 2005, has affected drastic changes in the patent law relating to Drugs and Cosmetics—inter alia, product patents, a uniform 20 years' period for patent protection etc.—through the Patents (Amendment) Act, 2005, which received the assent of the President of India on 4th April, 2005. Accordingly, the Twenty-fifth Edition incorporates an updated chapter by Dr Elizabeth Verkey on '*Pharmaceuticals and Patents*', and gives an insight into the new Patent law and how it regulates pharmaceuticals.

Separate chapters provide an overview of the Drug Control organisation in India, the functions of the Central and State Governments, the set-up at the Centre, Guidelines for Patients/Consumers and the advise issued by CDSCO, the relevant law relating to Consumer Protection, Adverse Drug Reactions, the role and activities of the ICMR and the National Pharmaceutical Pricing Authority, etc.

The Appendices provide several allied and useful statutes.

A CD-Rom is also included which contains the following:

Guidelines for determining quantum of financial compensation to be paid in case of clinical trial related injury or death; Guidelines for I.V. Fluids Distribution, Storage and Administration; Guidelines on Recall and Rapid Alert System for Drugs (Including Biologicals and Vaccines); Pre-screening Checklist for the submission of Application submitted to CDSCO (HQ); Sources of Medicinal Herbs in India; Manufacturers of Herbal Formulations in India; Manufacturers of Herbal Cosmetics and Eucalyptus Oil in India;

Manufacturers of Standardized Herbal Extracts, Phytochemicals and Essential Oils in India; List of Equipment Manufacturers in India; Major Associations in Pharmaceuticals Industry; World Importers of Herbal Products and List of Drugs approved during January 2006 to March 2016, National Blood Policy and Guidelines for Blood Banks

This has been done to include material which we thought was relevant without substantially increasing the bulk of the book.

Concise and coherent notes that are illustrative as well as instructive have been provided under important sections. New case-law notes have been added, especially under the Drugs and Cosmetics Act, 1940. All systems of medicine such as Allopathic, Ayurvedic, Unani and Siddha, have been brought under the ambit of the stringent drug control law and this work will be indispensable to all manufacturers, sellers, blood banks, hospitals and practitioners and students of these various branches of medicine. The book will be useful for the conduct of clinical trials and the measures that ought to be complied with. A very detailed subject index and product index is provided to help in locating very quickly and effortlessly the information sought for.

The help and guidance provided by Dr Nitya Nand, former Director, Central Drug Research Institute, Lucknow and an eminent scientist, is gratefully acknowledged.

Every effort has been made to make the work more useful and maintain its accuracy and authenticity.

Free updates to this edition shall be available at
www.ebcexplorer.com

Suggestions for further improvement of the work are welcome.

April 13, 2016

—VIJAY MALIK

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“A legal classic on the subject providing a thorough analysis on all aspects, with reader friendly approach.”

The present twenty-fifth edition provides the fully amended and updated text of the Drugs and Cosmetics Act, 1940 (as amended by Amending Act 26 of 2008 enforced on August 10, 2009) and the Drugs and Cosmetics Rules, 1945 as amended up to the Second Amendment Rules, 2016, along with case-law notes, allied Acts, Rules, Orders and Notifications. Also recent notifications and Orders have been given to bring the book up to date. This exhaustive work is the most comprehensive and up-to-date manual on the subject.

Fresh new materials covered include:

- Transplantation of Human Organs and Tissues Rules, 2014;
 - Pharmacy Practice Regulations, 2015;
 - Number of Licensed Blood Banks in India;
 - Pharmacovigilance Programme of India (PvPI);
 - Reporting of Adverse Drug Reactions and Haemovigilance Programme of India (HvPI);
 - List of Drugs approved during January 2006 to March 2016.
- **Also includes:**
 - Transplantation of Human Organs and Tissues Act, 1994;
 - Transplantation of Human Organs Rules, 1995;
 - National List of approved Testing Laboratories.

Brief and coherent case-law notes have been provided under important sections. New case-law notes have been added, especially under the Drugs and Cosmetics Act, 1940. The Appendices provide several allied and useful statutes. A very detailed subject index and product index facilitate quick and easy search.

The updated chapter on 'Pharmaceuticals and Patents', by Dr. Elizabeth Verkey gives an insight into the new Patent law and how it regulates pharmaceuticals.

FREE CD-ROM provides numerous guidelines and useful lists featuring regulations regarding Clinical Trials, I.V. Fluids, Recall and Rapid Alert System for Drugs; Sources of Medicinal Herbs in India, National Blood Policy and Guidelines for Blood Banks, etc.

This unique work is highly acclaimed among the medical, pharmaceutical as well as legal fraternity for its practical and vibrant approach.

The pharmaceutical manufacturers and sellers, foreign companies wanting to invest in this sector in India, blood banks, hospitals and medical practitioners, lawyers and law firms all will find the conscientious work indispensable.



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