

The historical milestones of various pharma-events and salient features of different Acts and Rules pertaining to profession are integral component of the text. The students of pharmacy, we are sure, will find contents of the book interesting and educative.

We thank management of PharmaMed Press, especially, Mr. Anil Shah for his efforts in publishing this book.

C.K. Kokate

*Ably assisted and Co-authored by
S.B. Gokhale*

Preface to Second Edition

After several reprints to First Edition, this Second Edition of our book is being brought out covering added features of pharmaceutical ethics, legislation and profession. This revised edition has eleven more chapter included along with updated information on events of today and Annexures. The text of the book is student-centric. It is explained in lucid manner, which is understandable by an average under-graduate student of pharmacy and allied sciences.

We wish to thank Prof. Ganachari, Dr. Pramod and Mr. Vijay (PA to Prof. Kokate) for their assistance.

We also thank the management of Pharma Med Press for publishing the revised edition of the book.

C.K. Kokate

June, 2012

S.B.Gokhale

Contents

<i>Preface</i>	<i>vii</i>
<i>Preface to Second Edition</i>	<i>viii</i>
CHAPTER 1	
General Introduction	1
CHAPTER 2	
History of Drug Legislation and Pharmacy Profession in India	5
CHAPTER 3	
Pharmaceutical Ethics	16
CHAPTER 4	
The Pharmacy Act, 1948	21
CHAPTER 5	
The All India Council for Technical Education Act, 1987	39
CHAPTER 6	
The University Grants Commission (U.G.C.) Act, 1956	43

CHAPTER 7	
The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules, 1955	46
CHAPTER 8	
The Drugs and Cosmetics Act, 1940 and Rules, 1945	51
CHAPTER 9	
Good Clinical Practice (GCP)	114
CHAPTER 10	
The Narcotic Drugs and Psychotropic Substances Act, 1985 and Rules, 1985	123
CHAPTER 11	
Medicinal and Toilet Preparations (Excise Duties) Act, 1955 and Rules, 1956	136
CHAPTER 12	
The Industries (Development and Regulations) Act, 1952	146
CHAPTER 13	
Medical Termination of Pregnancy Act, 1971 & Rules, 2003	149
CHAPTER 14	
Essential Commodities Act, 1955	152
CHAPTER 15	
Insecticides Act, 1968	156

CHAPTER 16

The Consumer Protection Act, 1986 164

CHAPTER 17

Poisons Act, 1919 168

CHAPTER 18

Shops and Establishments Act 171

CHAPTER 19

Prevention of Cruelty to Animals Act, 1960 175

CHAPTER 20

**The Prevention of Food Adulteration Act, 1954
and Rules, 1955** 178

CHAPTER 21

**National Pharmaceutical
Pricing Authority (NPPA).....** 184

CHAPTER 22

National Blood Policy 187

CHAPTER 23

Pharmaceutical Policy-2002 190

CHAPTER 24

**The Drugs (Price Control)
Order (DPCO), 1995** 194

CHAPTER 25

**WTO, GATS and The Indian Patents Act,
1970 with Amendments** 201

CHAPTER 26

Good Laboratory Practice (GLP)..... 209

CHAPTER 27**Adverse Drug Reactions (ADRs) 212****CHAPTER 28****List of Prohibited Drugs in India 215***Annexure 219**References 223**Index 227*