

D.D. Banerjee

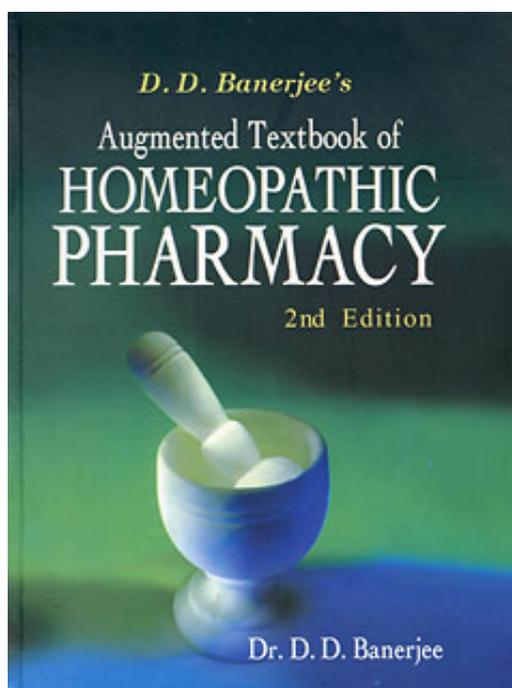
Augmented Textbook of Homoeopathic Pharmacy

Reading excerpt

[Augmented Textbook of Homoeopathic Pharmacy](#)

of [D.D. Banerjee](#)

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Homoeopathic Pharmacy Acts

LEGISLATION

The homoeopathic pharmacy comprises of the following three aspects :

- Manufacture or preparations of drugs and medicines.
- Commerce or /and trading.
- Profession or practice.
 - A pharmacist or a homoeopathic druggist or physician must be familiar with the existing laws and rules relating to the manufacture, sale of homoeopathic drugs —or profession.
 - He should also have the knowledge of the general laws relating to commerce, trade and taxation or by statute or rules promulgated by the Central or State Government.
 - A homoeopathic drug or medicine manufacturer should also have knowledge of the import-export procedures, relating to import of exotic drug materials or medicines.
 - Also should have knowledge of laws and rules of materials, such as alcohol (Dept.

of Excise). All laws and rules may be always revised from time to time. As such, the laws or rules mentioned therein-after is from the existing law book.

THE IMPORT, MANUFACTURE, SALE AND DISTRIBUTION

The homoeopathic drugs and medicines are regulated mainly by:

- i. The Drugs and Cosmetic Acts 1940 (XXIII of 1940) and thereafter amended several times.
- ii. The Drugs and Cosmetic Rules 1945, and thereafter amended several times.
- iii. The Dangerous Drugs Act 1930 (11 of 1930) and Rules, 1957, and amendments thereafter.
- iv. The Drugs and Magic Remedies (Objectionable Advertisement) Act 1954 (XXI of 1954) and Rules 1955.
- v. The Medicinal and Toilet Preparations (Excise Duties) Act 1955 (XVI of 1955).
- vi. The Drugs (Price Control) Order 1970 and 1971, etc.

DEFINITION OF HOMOEOPATHIC MEDICINE

Rule 2 (dd) of the Drugs and Cosmetic Rules defines the homoeopathic medicines as, 'Homoeopathic medicines include any drug which is recorded in homoeopathic provings of therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative homoeopathic literature of India and abroad and which is prepared according to the techniques of homoeopathic pharmacy and covers combinations in ingredients of such homoeopathic medicines but does not include a medicine which is administered by parenteral route.

Provisions relating to sale of homoeopathic medicines are prescribed in part VI-A, in which:

Rule 67-A (1) The State Government shall appoint Licensing Authorities for the purpose of this part for such areas as may be specified.

(The above Licensing Authority is generally the Director of Drugs Control of the respective State Government.)

Rule 67-A (2) Application for the grant or renewals of a licence to sell, stock or exhibit for sale or distribution of homoeopathic medicines shall be made in Form 19-B to the Licensing Authority and shall be accompanied by necessary fees.

Provided that if the applicant applies for renewal of licence after its expiry but within one month of such expiry the fee payable for renewal of such licence shall be rupees five plus an additional fee of rupees five.

But at present (i.e. from 1983) the above licence fees of both for the retail and wholesale dealer have been increased.

The Licensing Authority will issue the requisite licences.

Rule 67-C. Forms of licences to sell drugs

(1) A licence to sell, stock or exhibit for sale or distribute homoeopathic medicines by retail or by wholesale shall be issued in Forms 20-C or 20-D, as the case may be.

67-D. Sale at more than one place—If drugs are sold or stocked for sale at more than one place, separate applications shall be made and a separate licence shall be obtained in respect of each place.

67-E. Duration of licences—An original licence or a renewed licence unless it is sooner suspended or cancelled, shall be valid up to the 31st December of the year following the year in which it is granted or renewed:

Provided that if the application for renewal of the licence in force is made before its expiry or if the application is made and the additional fee paid within one month of its expiry, the licence shall continue to be in force until orders are passed on the application. The licence shall be deemed to have expired, if application for its renewal is not made within one month after its expiry.

64-EE. The certificate of renewal of a sale licence in Forms 20-C and **20-D** shall be issued in Form 20-E.

67-F. Conditions to be satisfied before a licence in Forms 24-C or 20-D is granted—

- A licence in Forms 20-C or Form 20-D to sell, stock or exhibit for sale or distribute homoeopathic medicines shall not be granted to any person unless the authority empowered to grant the licence is satisfied that the premises in respect of which the licence is to be granted are clean. In the case of a licence in Form 20-C the sale premises is in charge of a person who is, in the opinion of the licensing authority, competent to deal in homoeopathic medicines.
- Any person who is aggrieved by the order passed by the Licensing Authority under sub-

rule (I) may, within 30 days from the date of the receipt of such order, appeal to the State Government, after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for representing his case, make such order in relation thereto as it thinks fit.

67-G. Conditions of licence—Licence in Forms 20-C or 20-D shall be subject to the conditions stated therein and to the following further conditions, namely:

- The premises where the homoeopathic medicines are stocked for sale or sold are maintained in a clean condition.
- The sale of homoeopathic medicines shall be conducted under the supervision of a person competent to deal in homoeopathic medicines.
- The licensee shall permit an Inspector to inspect the premises and furnish such information as he may require for ascertaining whether the provisions of the Act and the rules made thereunder have been observed.
- The licensee in Form 20-D shall maintain records of purchase and sale of homoeopathic medicines containing alcohol together with names and addresses of parties to whom sold.
- The licensee in Form 29-C shall maintain records of purchase and sale of homoeopathic medicines containing alcohol. No records of sale in respect of homoeopathic potentised preparation in containers of 30 ml. or lower capacity and in respect of mother tincture made up in quantities up to 60 ml. need be maintained.

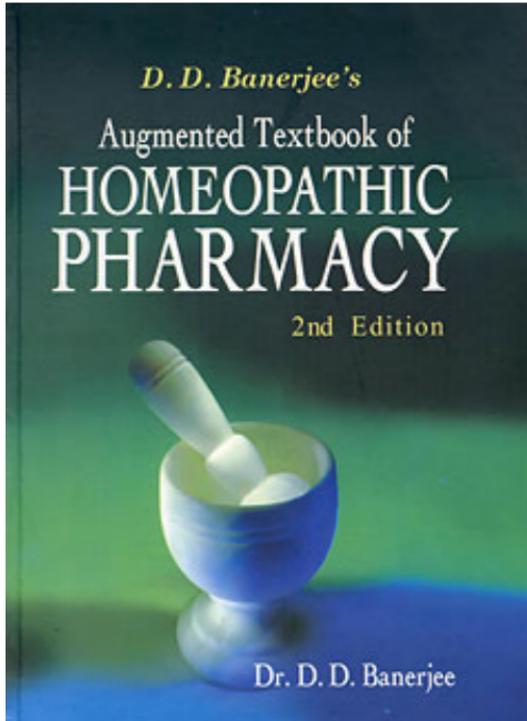
67-H. Cancellation and suspension of licences—

- The Licensing Authority may, after giving the licensee an opportunity to show cause

why such an order should not be passed by an order in writing stating the reasons therefore, cancel a licence issued under this part or suspend it for such period as he thinks fit, if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or rules made thereunder:

Provided that if such failure or contravention is the consequence of an act or omission on the part of an agent or employee, the licence shall not be cancelled or suspended unless the licensing authority is satisfied:

- That the act or omission was instigated or connived at by the owner of the business or, if the owner is a firm or company, by a partner of the firm or a director of the company: or
 - That the owner of the business or an agent or employee of the owner had been guilty of a similar act or omission within twelve months before the date or which the act or omission took place and that the owner had, or reasonably ought to have had, knowledge of that previous act or omission; or
 - If the act or omission was a continuing act/omission, and the owner of the business had or reasonably ought to have had knowledge of that previous act or omission; or
 - That the owner of the business had not used due vigilance to ensure that the conditions of the licence or provisions of the Act or the rules made thereunder were observed.
- A licensee whose licence has been suspended or cancelled, may appeal to the State Government whose decision shall be final.



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