



Packages and commodity rules, 1977 and the drugs and cosmetics act, 1940

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Abstract

Rule 24 specifies the procedure for examination and determination of quality and error in packages at the premises of the manufacturer or packer. Under the rule the director or any authorized person can examine the packages and carry out tests at the premises of the manufacturer or packer. Rule 25 provides for an action to be taken on completion of examination of packages at the premises of manufacturer or packer. If an error is found. Then the director or authorized person shall take punitive action against the manufacturer or the packer as the case may be.

Keywords packages and commodity rules, 1977 and the drugs and cosmetics act, 1940

Introduction

Rule 24 specifies the procedure for examination and determination of quality and error in packages at the premises of the manufacturer or packer. Under the rule the director or any authorised person can examine the packages and carry out tests at the premises of the manufacturer or packer.

Rule 25 provides for an action to be taken on completion of examination of packages at the premises of manufacturer or packer. If an error is found. Then the director or authorised person shall take punitive action against the manufacturer or the packer as the case may be.

The following amendments have been carried out in the provisions of the Rules during 2003-04.

- Exemption was given to packages containing bidis and incense sticks from declaration of month and year of packing on their labels.
- Declaration of MRP on bidi packages has been exempted for a period of 1 year w.e.f. 17.6.03.
- Packs containing seeds permitted to declare months and year as per Seeds Act.
- Exemption given to bottles containing alcoholic and spirituous liquor from the declaration of MRP has been withdrawn.
- Information to be given in dual languages
- 40 kg of white cement packing permitted.

The drugs and cosmetics act, 1940

Drug and Cosmetics form important items of human consumption and application. Hence there are several laws that regulate the production, supply and distribution of these two items. They are as follows:

- The Dangerous Drugs Act. I 930;
 - The Drugs & Cosmetics Act, I 940;
 - The Drugs & Magic Remedies (Objectionable Advertisements) Act. 1954;
 - The Drugs (Control) Act. 1950;
 - The Narcotic Drug & Psychotropic Substances Act, I 985.
- The meaning of "drug" is a substance used as a medicine for

curing of disease. It does not include heroin, lemp LSD. etc.

Nature and Scope

The Drugs and Cosmetics Act. I 940 regulates import. Manufacture distribution and sale of drugs and cosmetics. It is a Central Act and applies to the whole of India. The Act provides separately for the three systems of medicines, viz. the indigenous system (Ayurvedic, Unani), Homeopathic system and the Allopathic system. There is a separate technical Advisory Board for each of these systems. Cosmetic is defined as any article which is used for cleansing, beautifying, promoting attractiveness, or altering the appearance (Sec. 3a). Thus in an interesting decision, several High Courts in the country have held that guttaka or tobacco preparations used for cleansing of the teeth is a cosmetic within the meaning of the Act because it ultimately promotes the attractiveness of a person. This interpretation has been confirmed by the Supreme Court. "The definition of 'drug' is an illustrative one. Thus bleaching powder has been held to be a drug within the meaning of Section 3b."

The Drugs and Cosmetics Act, 1940 was amended in 1964 which includes the following:

- Ayurvedic, unani drugs were brought within the purview of the Drugs and Cosmetics Act, 1940 by this statute.
- It includes "all medicines intended for internal or external use or in the diagnosis, treatment, mitigation or prevention of disease in human being" as processed and manufactured in accordance with the formula described in the ayurvedic and any systems of medicine.(Sec 3b)
- Section 33 makes the same provisions for and definitions of misbranded, adulterated and spurious drugs as related to allopathic drugs. It also regulates the manufacture, storage and sale of these drugs.
- If the Government is satisfied that any of these drugs involve any risk to human beings or animals or that it does not have the therapeutic value claimed, the Government may ban it.

Salient Features

Under Sec 7.a Drugs Consultative Committee has been formed. It advises the Central, State Government as well as the Drug Technical Advisory Board. The Act lays down the standards of quality for drugs (Second Schedule to Act). It also prohibits the import of misbranded, spurious and adulterated drugs. (Secs 9, 9 - A&B) and cosmetics (Sec 9 C 9D). The Central "Government has the power to prohibit import of spurious, misbranded, adulterated, or inferior quality drugs and cosmetics (Sec. 10). It also has the power to prohibit import of drugs and cosmetics in public interest (Sec 10 A). Under this provision several voluntary organizations had urged the Government of India to prohibit the import of certain contraceptives which had proved carcinogenic and unsafe in the West. Chapter IV of the Act regulates the manufacture, sale and distribution of spurious, substandard, adulterated and misbranded drugs and cosmetics."

The Central Government also has the power to prohibit manufacture, sale of any drug or cosmetic in public interest (Sec. 26 a). A complainant can have the facility of analysing the drug or cosmetic on payment, at the central Drug Laboratory. Generally the report of Government analyst is taken as conclusive evidence, though it is open to the complainant to have it privately tested and submit that report also. But then it will become necessary to get it examined by the analyst as otherwise his report is likely to be challenged. In practice, the Drug Controller of India, and the Directorate of Health Services in each state are good forums to 'first approach in case of a complaint of a public nature. The consumer should know:

1. That in respect of patent or proprietary medicines, there must be a list of ingredients of formula displayed in the prescribed manner on the label or container. Vaccines, etc., must comply with World Health Organization standards (set out in the Second Schedule to the Act)
2. That the misbranding of drugs is illegal. This includes branding which makes the product look better or more therapeutic than it is or makes a false claim regarding the drugs (Section 17)
3. That drugs are adulterated if they contain any "filthy, putrid or decomposed" substance or they have been stored or packaged in insanitary conditions or contain toxic substances (Section 17 A)
4. That drugs are spurious if imported under the wrong name or have the wrong label or have been substituted by a different drug (Section 17B)
5. That there are similar provisions relating to cosmetics (Sections 17C & D)
6. That the importing of the above categories of drugs are prohibited and it is an offence to manufacture, sell, exhibit or offer for sale or distribute drugs and cosmetics which are not of standard quality, or fall within categories as mentioned above or which have been imported or manufactured without a licence. This is an offence of strict liability.

The drugs & magic remedies (Objectionable Advertisements) act, 1954

The Drugs & Magic Remedies, (Objectionable Advertisements) Act, 1954 is an interesting law.

Nature and Scope

Its basic object is to control the advertisement on drugs, to prohibit advertisement of remedies for certain diseases for which no cure is normally possible and to prohibit advertisement of remedies which are supposed to be magical cures.

The Drugs and Cosmetics Act regulates the import, manufacture, sale and distribution of drugs and cosmetics. Its main aim is to protect the consumer from sub-standard drugs and cosmetics.

The Act defines advertisement to include notice, circular, label, wrapper, and even an announcement made orally or by any means of producing or transmitting light, sound or smoke (Sec.2).

Drug

Includes medicine (internal or external), any substance or article other than food.

Magic Remedy

Is defined to include talisman, mantra, kavacha or any charm supposed to possess a miraculous power to cure. While deciding whether an advertisement is prohibited or not under this Act, the advertisement must refer to a drug, substance, article offered for diagnosis, cure or treatment etc. of the disease as in Sec. 2.

Salient Features

The Act lists at least 54 diseases for which no cures can be advertised. Among these are leucoderma obesity, sexual impotence, insanity, small pox, sterility, cancer, etc. It extends to the whole of India except Jammu & Kashmir. The Act prohibits any person from taking any part in advertising a drug for cure of menstrual disorders, abortions, prevention of conception, and diseases specified in the second schedule.

Section 3 sets out the diseases and disorders in respect of which advertising is banned.

However, the provisions of the Act are not applicable to sign boards/notices displayed by registered medical practitioners on their premises, any treatise dealing with subjects specified in Sec. 3, any advertisement published by the Government and any advertisement published with the previous sanction of the Government.

A criminal complaint can be filed for violation of this Act, with the Magistrate of first class. In practice, however, it is better and quicker to approach the Drugs Controller of the State (each State has one) and ask that authority to issue notices to the erring party.

Section 3 sets out the diseases and disorders in respect of which advertising is banned:

- a. The procurement of miscarriage in women or prevention of conception in women
- b. The maintenance or improvement of the capacity of human beings for sexual pleasure
- c. The correction of menstrual disorders in women
- d. The diagnosis, cure, mitigation, treatment or prevention of any disease specified in the Schedule (54 disease are listed, for example, appendicitis, deafness, diabetes, cancer, epilepsy, pneumonia, typhoid and leprosy)

Section 4 states that no person shall take part in the

publication of any advertisement relating to a drug if it contains matter which:

- a. Directly or indirectly gives a false impression regarding the true character of the drug or
- b. Makes a false claim for the drug, or
- c. Is otherwise false or misleading in any material particular

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