

## Advertisement Of Drugs – Whether Prohibited Or Regulated Under Drug Laws In India

written by Sanjay Kumar | February 17, 2021



We have seen advertisements of drugs in electronic media. However, there still remains a cloud of doubt in the minds of pharmaceutical companies about the legality of these advertisements. In this article, we will analyze the Drugs & Cosmetics Act 1940, the Drugs & Cosmetics Rules 1945, the Drugs and Magic Remedies (Objectionable Advertisement) Act 1954, the Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955 and judicial precedents. Position under the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 ("DMRA"), and the Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955 ("DMR Rules")

Section 3 of the DMRA prohibits the certain advertisement of drugs for the treatment of specific diseases and disorders. The schedule of the DMRA provides a list of diseases for which any advertisement is prohibited.

This section prohibits any advertisement referring to any drug used for:

- (a) the procurement of miscarriage in women or prevention of conception in women; or
- (b) the maintenance or improvement of the capacity of human beings for sexual pleasure; or
- (c) the correction of menstrual disorder in women; or
- (d) the diagnosis, cure, mitigation, treatment, or prevention of any disease, disorder, or condition specified in the schedule.

Section 4 of the DMRA prohibits misleading advertisement of drugs if they:

- (a) directly or indirectly gives a false impression regarding the true character of the drug, or
- (b) make a false claim for the drug; or
- (c) are otherwise false or misleading in any material particular.

Section 5 of the DMRA prohibits the advertisement of magic remedies for the treatment of certain diseases, claiming directly or indirectly to be efficacious for any of the purposes specified in Section 3.

Judicial Precedents: The Supreme Court in the Hamdard Dawakhana case<sup>[1]</sup> held that the main object and purpose of the DMRA is to prevent people from self-medicating with regard to the various diseases. Self-medication to treat serious diseases mentioned in the DMRA and the DMR Rules has a deleterious effect on the health of the community and is likely to affect the wellbeing of the people.

Having thus found that some medicines have a tendency to induce people to resort to self-medication because of elated advertisement, it was thought necessary in the interest of public health that the puffing of advertisements is put to a complete check and that the manufacturers are compelled to route their products through recognized sources to be properly tested and considered by expert agencies.

The SC further held that the DMRA read as a whole, does not merely prohibit advertisements relating to drugs and medicines connected with diseases expressly mentioned in Section 3 of the Act but also covers all advertisements which are objectionable and unethical and are used to promote self-medication or self-treatment.

As per Section 14 of the DMRA, it permits the following kind of advertisements:

(a) Any signboard or notice displayed by a registered medical practitioner on his premises indicating the treatment for any disease, disorder or condition specified in Section 3.

(b) Any treatise or book dealing with any of the matters specified in Section 3 from a bonafide scientific or social standpoint.

(c) Any advertisement relating to any drug sent confidentially to a registered medical practitioner.

(d) Any advertisement relating to a drug printed or published by the government.

(e) Any advertisement relating to a drug printed or published by any person with the previous sanction of the government.

Advertisement is allowed with respect to certain types or classes of drugs by various notifications by the Ministry of Health and Family welfare.

The central government notified that the provisions of clause (a) of Section 3 in so far as they relate to the prevention of conception in women and those of Section 6 shall not apply to or in relation to any advertisement in respect of contraceptives, provided that the advertisement shall relate only to such contraceptives approved by the government.[2]

The following classes of advertisement are permitted subject to certain conditions [3]:

- Leaflets or literature accompanying packings of drugs
- Advertisement of drugs in medical, pharmaceutical, scientific and technical journals
- Price Lists or Therapeutic indexes published by manufacturers, importers or distributors of drugs duly licensed
- Medical Literature distributed by medical detailers appointed by manufacturers, importers or distributors of drugs, duly licensed
- Advertisement of chemical contraceptives for oral use only if advertisement relates to chemical contraceptives for oral use having the following composition per tablet[4]
- DL-Norgestrel 0.30 mg. Ethinyl Estradiol 0.30 mg. or
- Levo-norgestrel 0.15 mg. Ethinyl Estradiol 0.03 mg. or
- Centchroman 30 mg.

In the matter of *Cipla Ltd Vs State of Tamil Nadu*[5] decided in 2018 by the Madras High Court, Cipla was prosecuted for the advertisement of EK Pill, an emergency contraceptive. The drug contained Levonorgestrel 1.5 mg whereas the notification dated 30.04.1992 of MHFW permitted the advertisement of drugs viz., Levonorgestrel 0.15 mg. The petitioner was granted approval from DCGI

which was later withdrawn. However, the approval of DCGI was in force on the date of offence, so the petitioners were given relief.

In the matter of *Mahesh Ramnath Sonawane Vs The Union of India*<sup>[6]</sup>, a PIL filed by a petitioner sought action against the advertisement of Tablet D' Cold total, Syrup D' Cold and Cough, Gelusil MPS antacid, Glycodin Cough Syrup, Benadryl Cough Formula on various TV channels. It was held that Section 2(b) of the Drugs & Cosmetics Act, 1940 which defines 'drug', is an inclusive definition that has got a very wide sweep. It, therefore, does not restrict itself to any particular type of medicine or drugs. Thus, advertisements cannot be used to promote self-medication or self-treatment of any drug.

We find it necessary to evolve a comprehensive policy. The authorities have to first decide whether all drugs or medicines can be allowed to be advertised on such channels and if such advertisement is to be permitted, what should be the content thereof. The contents cannot be contrary to provisions of the 1954 Act, be it Section 3 or Section 4. If advertisements can be permitted, the fact that such advertisements encourage self-medication or self-treatment will also be required to be kept in mind and adequate safeguards in that respect may be required to be provided. The writ petition was allowed with necessary direction to regulatory authorities.

Position under Drugs & Cosmetics Act 1940, Drugs & Cosmetics Rules 1945

The Central Government amended Rule 74 and 78 of the Drugs & Cosmetic Rules and notified that no advertisement can be made in respect of Schedule H, H1 and X except with the previous sanction of the Central Government.<sup>[7]</sup>

Advertisement of Ayurveda Drugs

The Central Government amended the Drugs & Cosmetics Rule, 1945 and Rule 170 is inserted in Part XIX to prohibit the advertisement of Ayurveda, Siddha and Unani drugs unless a unique identification number is obtained from the licensing authority.<sup>[8]</sup>

Conclusion

Thus, in the light of combined reading of the Drugs & Cosmetics Act, 1940, Drugs & Cosmetics Rules, 1945, Drugs and Magical Remedies (objectionable) Act 1954, all advertisement of drugs are prohibited unless permitted by the central government, licensing authorities or exempted from the application of Drugs & Cosmetics Act, 1940, Drugs & Cosmetics Rules, 1945 and Drugs and Magical Remedies (objectionable advertisement) Act 1954 either by the law itself or by notification.

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<sup>[1]</sup> Hamdard Dawakhana and Others V/s. The Union of India and Others AIR 1960 SC 554: Cri. LJ 735: 1975 Drug Cases P 233

<sup>[2]</sup> Ministry of Health Notification No. S.O. 282, dated January 24, 1961

<sup>[3]</sup> Ministry of Health Notification No. G.S.R. 843, dated May 29, 1967

<sup>[4]</sup> Ministry of Health and Family Welfare (Deptt. of Health), Noti. No. G.S.R. 446(E), dated April 30, 1992

<sup>[5]</sup> CRL.O.P.No.19364 of 2015

<sup>[6]</sup> 2014 SCC OnLine Bom 4008

<sup>[7]</sup> GSR 289 (E) dated 15th April 2015 Ministry of Health & Family Welfare

<sup>[8]</sup> GSR 1230 (E) dated 21st December 2018 Ministry of Health and Family Welfare

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