DIRECT MARKETING AND ADVERTISEMENT OF CERTAIN MEDICAL DEVICES TO PATIENTS IN INDIA – A DILEMMA

Swathi Kamath

ABSTRACT

This article attempts to highlight that while the Medical Device Rules, 2017 have been passed with an intent to provide access to patients with high quality, safe and effective medical devices, there is no law to permit and regulate dissemination of equally high quality and safe information about medical devices to the people who would potentially be using them.

Except the United States of America and New Zealand, no other country in the world allows direct to patient marketing of medical devices. Even these countries do not have separate marketing laws for pharmaceutical products and medical devices.

This article is unique because firstly, it is probably the first time that an attempt has been made to address the status quo of the Indian law on marketing of medical devices i.e. Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 that has existed with minor amendments for more than 65 years. Secondly, no other country in the world has passed a separate legislation that allows marketing of medical devices to the public at large.

This article also provides suggestions on what the new law permitting and regulating marketing/promotion of medical devices should cover to make it an effective one.

I. INTRODUCTION

Under the extant marketing law i.e. The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 (**"**DMRA**"**) that controls advertising and marketing of medical devices in India, direct to patient advertising of certain medical devices for treatment of certain conditions listed in the Schedule of the DMRA Act is not permitted. Violation of the provisions of this Act is a criminal offence that could lead to maximum one year of imprisonment.[1] The legislation was enacted in 1954, when the field of medical science had not developed and witchcraft and black magic was majorly prevalent in India. It promised "magic remedies" in the form of any talisman, amulet or any other object which possessed miraculous powers to cure, diagnose, prevent or mitigate a disease in humans or animals.

* Swathi Kamath, Legal Head & Company Secretary, Entero Healthcare Solution Pvt. Ltd.

[1] S. 7, The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.

The Indian government has finally seen the need to regulate medical devices distinctly and differently from pharmaceuticals and have introduced the Medical Device Rules 2017. These Rules are a breath of fresh air as they include the much-needed prescribed product standards for medical devices, single window clearance, perpetual licenses as opposed to time bound licenses, simpler registration for importers etc. However, the outdated DMRA Act continues to maintain its status quo without any amendments in line with the current economic situation. The Government has ignored this important piece of legislation and has left this extremely critical subject of patient education unattended for many decades.

II. ADVANTAGES OF DISALLOWING DIRECT TO PATIENT ADVERTISING OF MEDICAL DEVICES

The DMRA Act has definitely been beneficial in prohibiting advertisements relating to childbirth, women's diseases, menstrual disorders, infertility and impotency, treatment of cancer, rheumatism etc. in the early days when self-styled babas and witch doctors would deceive gullible patients owing to low literacy and inadequate health education.

In the current context, even though medical science has advanced and literacy rates have increased significantly, this prohibition restricts product specific advertisements which exaggerate the benefits of the product and downplay its risks. This leads to unrealistic expectations in the patient and could lead to distrust in their doctor who may be more informed about the product's performance in the long term. Additionally, pressure created by a patient to opt for a particular device, in response to such ads, may lead to over utilisation of medical devices, which may not be the most suitable option, thus causing doctors discomfort to satisfy inappropriate patient requests for specific treatments or devices. It is also thought that too many advertisements could confuse a patient.

III. DISADVANTAGES OF DISALLOWING DIRECT TO PATIENT ADVERTISING OF MEDICAL DEVICES

In the present context where "data is king", consumers are bombarded with advertisements on televisions, mobile phones and other products of daily use. Interestingly, patients or potential patients do not have access to similarly advertised information on disease/health awareness and the possible treatments available. It would be important for a cardiac patient to know what technologies are available for the condition that s/he is suffering from, especially in this "Right to Information" Age. Patients will be able to make more informed choices after considering their doctor's

advice and the information available to them. There will be joint decision making between the patient and the doctor with respect to the course of treatment to be adopted for the patient. Patients should be provided with evidence-based healthcare information which will help them in actively sharing the decision-making process with the doctor as it ultimately impacts their life. The doctors will also benefit from such advertisements as it will help update their knowledge with respect to newer technologies and their effects.

The primary objective[2] of the DMRA Act was to prevent people from self-medication and self-treatment and for that purpose commending certain drugs and medicines was prohibited. At the time when this law was passed in 1954, there was no scientifically proven cure for most of the diseases listed in the Schedule. However, medical science has significantly advanced over the last 65 years and a cure/remedy is available for most of the said diseases today.

IV. CURRENT LAW ON DIRECT TO PATIENT ADVERTISING IN FOREIGN JURISDICTIONS

Along with the United States of America, New Zealand allows direct to consumer advertising under their Medicines Act 1981. Direct to consumer advertising in these two countries allows (i) *product claim advertisements,* which promote a specific product and include both the product name and specific therapeutic claims and (ii) *reminder advertisements,* which provide the name of the product without containing or suggesting its use. New Zealand's rationales[3] behind permitting such advertisement are:

1. Harnesses private incentives to cover the cost of disseminating knowledge and to close the gap between what research has found and what doctors and patients know.

2. Meets increasing consumer demand for medical information, in a well-controlled and responsible way.

3. Informs consumers about new treatments.

4. Encourages people to seek medical attention for conditions or symptoms that might otherwise go untreated, including asymptomatic diseases.

[2] Hamdard Dawakhana v. Union of India, AIR 1960 SC 554.
[3] Ministry of Health, New Zealand, *Direct-to-Consumer Advertising of Prescription Medicines in New Zealand A discussion paper*, November 2000, available at http://www.moh.govt.nz/notebook/nbbooks.nsf/0/5c66d8aaa038df034c2569cb000c76b2/$FILE/dtcaDiscussionDoc.pdf.

5. Promotes patient compliance, and persistence, with recommended treatment.

6. Promotes better communication between patients and their doctors.

7. Improves the efficiency of public health care spending.

Sections 57 and 58 of The Medicines Act 1981 of New Zealand includes various provisions imposing certain restrictions on such advertisements to ensure socially responsible dissemination of information to the public. Some of the restrictions relate to not publishing any contradictory or conflicting information that is required to be on the product, the ad should not contain false or misleading information or imply that the product advertised is not harmful or habit-forming or suggest that the product is a panacea or is infallible or has been used or recommended by a registered health professional etc.

Countries like Korea, Japan, Australia, Hong Kong, China have adopted a protectionist policy of not allowing direct to patient advertising on the assumption that the public is confused when exposed to so much information and the medical information presented in such advertisements is too complex to be comprehended by laymen.

V. INDIAN SCENARIO

When the DMRA Act was passed in 1954, the objective was to prevent manufacturers from making dubious claims about certain drugs possessing magic cures and inducing patients to self-medicate. However, it is pertinent to note that the legislative intent at that time was only with reference to pharmaceutical products which can be self-administered and medical devices were not covered. Medical devices were read into the DMRA Act after the Supreme Court ruling in 1975.[4] Devices were pushed under the umbrella of "drugs" by way of an amendment to the definition of "drugs" in the Drugs and Cosmetics Act, 1940 in 1982. Hence, the DMRA Act became applicable to certain medical devices only in 1982. Thereafter, medical device manufacturers were obliged to comply with all the marketing related requirements that were applicable to pharmaceutical manufacturers. The Delhi High Court has, in one case, allowed such advertisements of devices based on the underlying principles that (i) the advertisement is only informing the public about the improved methodology and improved equipment availability of the

[4] Zaffar Mohammad @ Z.M. Sarkar v. The State Of West Bengal, 1976 SCR (2) 782.

procedure involved in the surgery; (ii) the public cannot self-medicate in this case and has to undergo surgery.[5]

The Drugs Consultative Committee has met several times to discuss the legislative need to distinguish between medical devices and pharmaceutical products owing to the increasing complexities in regulating both with the same laws and logic. The Medical Device Rules were finally rolled out in 2018 which shall separately regulate manufacture, import, distribution, clinical investigation, quality standards, labelling and the shelf life of medical devices. However, marketing of medical devices has not yet been addressed and regrettably continues to be a dilemma for the medical device industry.

The Draft DMRA Amendment Bill dated 3rd February 2020 has been circulated for comments/objections. The Ministry of Health has decided to briefly consider amending this vintage legislation. It is merely a brief consideration because the only significant amendments are the enhancement of penalty, addition of more diseases/conditions to the Schedule of the DMRA Act and constituting an Ayurvedic, Siddha and Unani Drugs Technical Advisory Board. But even the 2020 Bill, despite the passing of Medical Device Rules 2018, does not draw a distinction between the marketing of pharmaceutical products and implantable medical devices given that implantable medical devices cannot be self-administered. If this distinction is made, further steps to permit and regulate medical device marketing can be incorporated in the amended law.

The Bill is, therefore, still skewed and is missing out on an important opportunity of striking a balance between promoting patient education and ensuring that it is done in a responsible manner. The Bill continues to promote the extreme protectionist stance that was taken in 1954 instead of transforming into a consumer enabling and empowering legislation.

VI. SOLUTION PROPOSED

There is no doubt that a patient deserves to have access to quality and accurate information with respect to products that could potentially change their lives. The DMRA Act needs a complete overhaul in order to bring the legislation up to date with the present-day market reality. The law should be capable of ensuring that balanced and reliable information is disseminated to the public at large, thereby highlighting the risks alongside the benefits of the product, like in the United States of America where direct to patient marketing is permitted though regulated under the Federal Food, Drug and Cosmetic Act of 1938. The advertisements

[5] Amit Singh & Anr. v. The State, Crl. M.C. No. 648/2011, High Court of Delhi.

should not just aim at spreading product specific content, but also create disease/health awareness without creating fear in the minds of public, thereby enhancing the dialogue between the doctor and patient.

The regulator will also play an important role in monitoring/vetting these advertisements and taking strict action against the wrongdoers. It can be made mandatory that a copy of every publication or media should be uploaded on the regulator's website as well. Higher and stronger penalties can be levied on the advertising media and the medical device company.

The legislators may also impose restrictions such as permitting advertising of products only after the product claims have been approved by the relevant regulator, the product has all the relevant licenses and registrations, prohibition on comparability and superiority claims etc.

VII. KEY TAKEAWAYS

1. The name of the enactment needs to be changed. The words "Magic Remedies" in 2020 is regressive and unacceptable. Our laws need to keep pace with science and technology.

2. Given that the Indian medical device market is estimated to grow to US $8.16 billion in 2020 at a Compounded Annual Growth Rate of 16%,[6] and that it is impossible to eliminate direct to patient advertising on the internet, it is beneficial to have an appropriate regulated environment to advertise in contrast to relying on industry self-regulation.

3. Self-administration of most medical devices like stents, implants etc. is not possible, so the risk of advertising of medical devices directly to the patient is much lower compared to pharmaceutical products. Hence, the government should revamp the archaic DMRA Act on a priority basis and ensure that patients' unmet needs of quality healthcare education are being satisfied.

4. All direct to patient/public marketing material should have a brief summary about all associated risks/side effects along with the benefits of the device. Medical device companies and advertising agencies will have to find creative ways to do this given the time and space constraints involved in advertising.

[6] World Health Organisation, *Medical Device Manufacturing in India- A Sunrise*, 2017, available at https://pharmaceuticals.gov.in/sites/default/files/medicaldevicemanufacturinginindia-asunrise-170221053503%20%281%29.pdf.

5. Doctors are the last mile contact for the patients with respect to the patient's condition and available treatments, so doctors should not come under the pressure of their patients and should independently advise what is best for them.

6. Medical device manufacturers/distributors and the advertising media should be made severely liable for publishing any provocative, deceptive or misleading information in the public. The product claims should be limited to what has been approved by the regulatory authority. The current provisions should be amended with higher fines and imprisonment period to create a strong deterrent. This has also been recently discussed in a meeting of the Drugs Consultative Committee.[7]

7. Regulators also need to have a robust system in place to monitor and review marketing and promotional material targeted to patients and penalise the wrongdoers appropriately in order for the revised law to have a powerful deterrent value. This regulatory body could be something similar to Advertising Standards Council of India (**"**ASCI**"**) or the Central Consumer Protection Authority under the Consumer Protection Act, 2019. The Ministry of AYUSH has signed a MOU with ASCI to monitor misleading advertisements being published in print and TV media with respect to Ayurvedic, Unani and Siddha drugs. The option of getting these materials pre-vetted by the regulator can also be made available to the medical device industry at their cost.

[7] *Minutes of 56th Meeting of Drugs Consultative Committee*, Central Drugs Standard Control Organization, available at https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadCommitteeFiles/56thDCCmeeting.pdf, last seen on 29/04/2020.