Advertisement of Medical Devices in India

Thought Leadership • April 4, 2022

Medtech is prospering amid the pandemic. But thorny questions arise over advertising medical equipment and devices in India, where the government is understandably concerned about unethical marketing, to protect the public from being exploited. In an attempt to better understand and disentangle this legal minefield, Senior Associate Ashutosh Upadhyaya examines the various provisions and pitfalls in his article for Asia Business Law Journal. The Code for the Self-Regulation of Advertising Content in India (ASCI code), published by the Advertising Standards Council of India, does not set any standards for advertisements of medical devices. However, provisions under the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 (DMRA), the primary legislation governing advertising medical devices, contain ample reason for more cautionary consideration of legality. Before assessing the limitations of advertisement, it is imperative to first understand how medical devices are legally defined? Section 2 of the DMRA defines drugs, among other things, as a "medicine" for the internal or external use of human beings or animals, yet also "any substance" intended to be used for diagnosis, cure, mitigation, treatment or prevention of disease in human beings or animals. It further defines drugs as "any article", other than food or "any article intended for use as a component" of any medicine, substance or article as referred to in this section. The terms "any article" and "any substance" are broad enough to cover medical devices. In addition, the Ministry of Health and Family Welfare updated its regulations on 11 February 2020, adding various medical devices and apparatus to the definition of drugs under section 3 of the Drugs and Cosmetics Act, 1940. Considering the fact that the DMRA dates back to 1954, a bigger question now emerges as to whether the said definition of drugs includes modern medical devices and equipment. From a case law viewpoint, consider Justice YV Chandrachud's Supreme Court judgment (25 November 1975) in the case of Zaffar Mohammad ZM Sarkar v the State of West Bengal. This clarified the law, holding that a machine is a tangible thing that can be both seen and felt – and, as such, it answers the description of an article within the meaning of section 2 of the DMRA. Essentially, this brackets modern medical equipment and devices under the DMRA's generalised definition of "drugs", which brings us to the core issue of various deliberations, which is section 3 of the DMRA. This section prohibits the advertisement of drugs for treating certain diseases and disorders. It states that no person shall take any part in the publication of any advertisement for "any drug" (remembering this includes medical devices or equipment), which suggests or is calculated to lead to the use of that drug for the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the schedule - or any other disease, disorder or condition specified in the rules under this act. This schedule contains a fairly comprehensive list of 54 diseases, conditions or disorders, from fever, diabetes and cancer to disorders of the brain and optical system. The DMRA prohibits any form of advertisement for the diagnosis, cure, mitigation, treatment or prevention of the above-mentioned diseases, disorders or conditions. Such advertisements may be in contravention to the provisions of both the DMRA and the ASCI code. The objective of the DMRA was further clarified in

the Supreme Court of India judgment of Hamdard Dawakhana (Wakf) v Union of India and Ors (1959). While partially upholding the DMRA's constitutionality, the Supreme Court stated that the purpose of the act is to prevent "objectionable" and "unethical advertisements", to discourage self-medication and self-treatment.

Let caution prevail

This brings us to our conclusion that an advertisement of any drug (including medical devices or equipment) for diagnosis, cure or mitigation of any disease or disorder is likely to be challenged under the provisions of the DMRA. However, whether the said advertisement is unethical or objectionable is a moot point. It would be erroneous not to mention that there are certain safety nets. For instance, informative videos like user manuals or video guides do not fall under the category of advertisements, or in any manner promote diagnosis, cure, mitigation, treatment or prevention of diseases. However, caution should prevail, since such safeguards can only be determined upon reviewing the precise content of an informative video.