LEGAL GAPS, CONSUMER TRAPS

A Critical Look at Health Product Advertising in India

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LEGAL GAPS, CONSUMER TRAPS: A CRITICAL LOOK AT HEALTH PRODUCTS ADVERTISING IN INDIA

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The Centre for Health Equity, Law & Policy is a research, knowledge production and advocacy forum which works on law & policy issues related to health, embedding its work in the right to health as envisaged within India's constitutional framework and her international commitments. It is located at the Indian Law Society, Pune.

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1. INTRODUCTION

1.1 Overview and Structure

Over the years, advertising has become integral to consumer engagement with products, influencing choices, generating recall value and shaping societal behaviours around purchasing. With the advent of social media and telecommunications technologies, advertising has become more pervasive and impactful than ever before. As the market becomes more competitive, companies use advertisements to manage the consumer's expectations of, exposure to and experience with a brand or product, further influencing their buying behaviour and decision-making.[1] And, as social media and e-commerce rapidly gain popularity, consumers have become more vulnerable to deceptive advertisements, with influencers making unsubstantiated, exaggerated or fabricated claims, uninhibited due to a lack of monitoring.[2] This is especially dangerous in cases where consumer health and well-being are directly associated with the advertised product.

While advertising can be broadly categorised into two segments - health and nutrition-related and non-health and non-nutrition-related - evidence suggests that health and nutrition advertisements often mislead consumers and lead to dire consequences.[3] Advertisers exploit consumer vulnerabilities by promising miracle cures or quick-fix solutions, fostering a skewed perception of product benefits and instilling a false sense of urgency. This manipulation of consumer perception negatively affects market dynamics and jeopardises individual health outcomes.

Law and regulation have a considerable role in minimising the harm such advertisements cause. In India, several statutes and regulatory authorities are tasked with monitoring, preventing and reprimanding false and misleading advertisements. This paper aims to assess the legal and policy framework, its implementation, and its effectiveness in protecting consumers in India. It reviews and summarises various laws, regulations, and regulatory authorities that govern the advertising of health products in India, analyses the challenges of implementing the existing legal framework, and explores successful legal models and practices from other jurisdictions.

The paper is organised into four sections. **Section 1** provides an overview of misleading advertising of health products in India, focusing on the background, context, and nuances of the issue. **Section 2** outlines the laws and regulations governing misleading advertising of health products in India, critically evaluating the existing legal framework and addressing implementation challenges and gaps. This section also explores the self-regulation model adopted by the Indian advertising and pharmaceutical industry. **Section 3** examines the

[1] Sunderaraj, R. (2018). Impact of Advertisement on Buying Behaviour of Consumers in Sivakasi. *ICTACT Journal on Management Studies*, 4(3). https://ictactjournals.in/paper/IJMS_Vol4_Iss3_Paper4_800_808.pdf.
[2] Tayyab Mukhtar Qureshi, M., & Gopal, K. (2023). The Impact of Unethical and False Advertising on Social Media Towards Consumer Buying Behaviour: An Examination Among Young Adults in Malaysia. *International Journal of Business and Technology Management*, 5(1). https://doi.org/10.55057/ijbtm.2023.5.1.13.
[3] Hasler, C. M. (2008). Health Claims in the United States: An Aid to the Public or a Source of Confusion? *The Journal of Nutrition, 138(6)*, 1216S1220S. https://doi.org/10.1093/jn/138.6.1216s.

regulatory frameworks of the United States of America and the United Kingdom and discusses the strengths and weaknesses of these health product advertising regimes. Finally, **Section 4** concludes by outlining current challenges in the legal framework, offering recommendations for improving the regulation of health product advertisements in India, and emphasising the lessons that can be learned from global practices.

This paper is a result of thorough desk and literature review of academic papers, community and civil society research, reports, media articles and judicial decisions, all of which provided a foundation of existing knowledge and context on the issue. Legal analysis of relevant Indian statutes was conducted to identify regulatory gaps and challenges. Key informant interviews were conducted to gain expert insights on the previous, ongoing and emerging work by consumer organisations in this regard. Conversations with experts were also helpful in understanding the expectations and promises of the law and what is delivered in reality. The regulatory framework in India is discussed alongside legal frameworks in the US and the UK. Both these countries have a huge concentration of and high spending on advertisements for health products and have acclaimed models of state and self-regulation, respectively. A few examples from other countries are also included as emerging and successful practices. This paper does not delve into health and nutrition claims made by advertisers of non-health products. It also does not examine the judicial application of the laws, or consider consumer perspectives.

1.2 Persistence of False Advertisements in India – Background and Context

The menace of false advertisements is well known and has been a persistent concern despite multiple laws and penal sanctions. Advertising has existed in all contexts where commerce is practiced. The spurt of its growth in India can be attributed to the opening up of the economy in the 1990s, resulting in companies beginning to spend heavily on marketing. During the 1980s, the largest advertiser was Hindustan Lever, with multiple pharmaceutical companies following suit.[4] Earlier advertisements mainly focused on imagery, accompanied by limited claims, while remaining true to the primary purpose of advertising - educating and informing the consumer. However, with the emergence of competitive markets, cable and satellite TV emerged as the dominant mediums, effectively taking over from print media. This shift altered how advertisers reach their target audience and opened up new opportunities for businesses to connect with consumers and increase their brand visibility.

Over the years, the government introduced various legislative and regulatory measures to address deceptive advertising, including amendments to the *Monopolies and Restrictive Trade Practices Act* in 1984 and the establishment of the Advertising Standards Council of India (ASCI) in 1985 to self-regulate the industry. Despite these efforts, false advertising remained rampant, prompting the enactment of the *Consumer Protection Act* in 1986 to

[4] Consumer Unity & Trust Society (CUTS). (2012). *Study on the Status of Law Enforcement for Misleading Advertisements in India and its Impact on Consumers*. https://cuts-cart.org/pdf/Study_on_the_Status_of_Law_Enforcement_for_Misleading_Advertisements_in_India.pdf.

protect consumers from exploitation, adulterated and sub-standard goods and services and to safeguard their interests.[5] Subsequent amendments and revisions to consumer protection laws culminated in the enactment of the *Consumer Protection Act* in 2019 to keep up with the information age, advancement of e-commerce and growing technological advancements. It introduced stricter norms for misleading advertisements.[6]

More often than not, consumers resort to courts to address misleading claims by brands and institutions. Sometimes these cases involve rival companies filing against deceptive advertisements and deprecating the rival's product.[7] However, despite legal action through courts, complaints against false and misleading advertisements have continued to increase. From 2017 to 2020, the Consumer Protection Authority's Grievance Against Misleading Advertisements (GAMA) Portal received more than 12000 complaints.[8] During the COVID-19 pandemic, brands exploited the situation by falsely promoting their products as "boosting immunity," "killing COVID-19 germs," and "curing COVID-19."[9]

In the current context, one primary reason for the widespread nature of this issue is the mass expansion of marketing in the information age. Brands increasingly use digital marketing strategies offering significant revenue potential and broader reach. Consequently, the majority of objectionable advertisements in 2022-23 were disseminated through digital marketing tools, with 87% of influencer-related advertisements found to have violated the guidelines set by the Consumer Protection Authority. [10]

Inbox Overload: Canada's Anti-Spam Legislation

In 2014, Canada introduced its Anti-Spam Legislation (CASL) to protect consumers and businesses from unconsented spam and electronic messages. The Act prohibits companies from sending commercial electronic messages and using false and misleading representations to promote products and services.[11] Under the Act, an electronic message includes emails, text messages, and instant messages through social networks.[12] The central theme of the legislation is consent. Therefore, under CASL, companies need to ask permission before they start marketing messages. Any contravention of the law attracts heavy administrative penalties prescribed by the Act.[13]

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[5] *Consumer Protection Act, 1986*, Statement of Object and Reasons.
[6] Department of Consumer Affairs. (n.d.). *FAQs on Consumer Protection Act 2019*. https://consumeraffairs.nic.in/sites/default/files/file-uploads/latestnews/FAQ.pdf.
[7] *Horlicks Limited v Zydus Wellness Products Limited*, CS (Comm) 464 of 2019.
[8] Over 12000 complaints about misleading advertisements on TV received in 4 years: Government. (2021, February 5). *The Economic Times*. https://economictimes.indiatimes.com/industry/services/advertising/over-12000-complaints-about-misleading-advertisements-on-tv-received-in-4-years-government/articleshow/80710124.cms?from=mdr.
[9] Anand, S. (2021, January 22). Those '99.9% germ killer' ads can put creators in jail. *The Economic Times*. https://economictimes.indiatimes.com/industry/services/advertising/ccpa-issues-advisory-on-misleading-ads-related-to-covid-19/articleshow/80373064.cms.
[10] Advertising Standards Council of India. (2022). *Half Yearly Complaints Report*. https://www.ascionline.in/wp-content/uploads/2022/11/half-yearly-complaints-report-2022-23.pdf.
[11] *Canada Anti-Spam Legislation*, 2014, Sec 6.
[12] *Canada Anti-Spam Legislation*, 2014, Sec 1(2).
[13] *Canada Anti-Spam Legislation*, 2014, Sec 20.

In India, brands use SMS and email services extensively to send commercial and promotional messages to consumers. They have increasingly taken to instant messaging applications like WhatsApp to send promotional messages without users' permission.[14] This leads to much unwanted spam and overwhelming marketing content targeted towards the consumer. An anti-spam law can help rectify brands' misuse of emerging platforms while also balancing the interests of the business, like in Canada.[15] Countries like South Korea have also adopted anti-spam legislation, which has reduced commercial spam.[16]

To read more about CASL, click here.

1.3 Behind the Hype: Analysing Misleading Health Product Advertisements and Their Impact

Rights-based Imperatives

The right to health encompasses the right to enjoy facilities, goods, services, and conditions necessary for the realisation of the highest attainable standard of health.[17] It includes access to health-related education and information,[18] thereby covering access to authentic and transparent information about drugs and food products. The Supreme Court of India, in an ongoing case, has ruled that the right to health includes the entitlement of consumers to receive information about the quality of products offered for sale by manufacturers, service providers, advertisers, and advertising agencies.[19]

The focus of this paper is on various health products, such as allopathic drugs, those from Ayurvedic, Unani, and Siddha (ASU) practices, medical devices, food products, health supplements, and nutraceuticals. While so, it should be noted that other products also make misleading health claims that violate the law. For example, a water purifying system claiming to be "Doctors' 1st Choice RO Purifiers" misleads consumers as there is no acceptable scientific evidence to support this claim and other benefits.[20]

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[14] Satapathy, S. (2024, April 16). *WhatsApp Spams and How Brands in India are Overdoing it!!* Kuttl. https://www.kuttl.in/post/whatsapp-spams-and-how-brands-in-india-are-overdoing-it#:~:text=Many%20WhatsApp%20users%20in%20India%20are%20facing%20a%20worsening%20experience.

[15] Innovation, Science and Economic Development Canada. (2024). *Canada's Anti-spam legislation (CASL) – Performance measurement report 2022–23*. https://ised-isde.canada.ca/site/canada-anti-spam-legislation/en/canadas-anti-spam-legislation-resources/performance-measurement-reports/canadas-anti-spam-legislation-casl-performance-measurement-report-2022-23#5.

[16] Ju, J., Cho, D., Lee, J. K., & Ahn, H. (2021). Can It Clean Up Your Inbox? Evidence from South Korean Anti‐spam Legislation. *Production and Operations Management*. https://doi.org/10.1111/poms.13398.

[17] Committee on Economic, Social and Cultural Rights, "General Comment 14," (Twenty-second session, 2000), U.N. Doc. E/C.12/2000/4 (2000), available at https://www.refworld.org/pdfid/4538838d0.pdf.

[18] The Office of the High Commissioner for Human Rights (OHCHR), "Factsheet No. 31," accessed April 27, 2023, https://www.ohchr.org/sites/default/files/Documents/Publications/Factsheet31.pdf.

[19] *Indian Medical Association v Union of India*, WPC No. 645 of 2022, order dt. 7.05.2024.

[20] Nagarajan, R. (2015, September 3). ASCI upholds complaint against Kent purifier ad, questions "scientific" claims of ad. *The Times of India*. https://timesofindia.indiatimes.com/india/asci-upholds-complaint-against-kent-purifier-ad-questions-scientific-claims-of-ad/articleshow/48793326.cms.

Studies have identified three types of health-related advertisement elements: functional claims, process claims, and health imagery, with the latter having the most significant impact on consumers.[21] Research on the influence of health drink advertisements on consumers revealed that most consumers purchased a product based on the image created by the advertisement without looking at the ingredients list or verifying the claims made.[22] Whether through unsubstantiated claims, false testimonials, or deceptive packaging, advertisements erode the trust between consumers and brands while undermining a consumer's right to make informed choices.[23]

Targeted Audiences

Manufacturers of health products often target specific groups, such as children, the elderly, or women, using misleading and exaggerated claims. While targeted marketing is not inherently wrong, it can mislead consumers when combined with false and unverifiable claims. Studies in other jurisdictions have expressed concern regarding advertisements targeted towards the elderly. Advertisements use personal and narrative strategies to create an authoritative image of traditional medicine and build an emotional connection with the elderly audience to promote sales.[24] The Supreme Court of India made such an observation in the ongoing case of *Indian Medical Association v Union of India*. The court highlighted the impact of misrepresented claims in advertisements issued by Fast Moving Consumer Goods (FMCG) and pharmaceutical companies, which affect the health of children and senior citizens who consume their products based on such advertisements.[25]

As regards children, a 2023 report published by Nutrition Advocacy in Public Interest (NAPi) on the rise of ultra-processed food consumption in India noted that many advertisements promote junk food high in fat, salt, and sugar (HFSS). These advertisements often target children using persuasive and appealing techniques.[26] Younger children may not comprehend the purpose of advertisements, and advertisers depend on their ability to influence their parents to make purchases, ultimately resulting in increased consumption of an unhealthy diet.[27]

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[21] Chrysochou, P., & Grunert, K. G. (2014). Health-related ad information and health motivation effects on product evaluations. *Journal of Business Research, 67(6),* 1209–1217. https://doi.org/10.1016/j.jbusres.2013.05.001.

[22] P.K, Rhia. (2024). A Study on Effects of Advertisement on Consumer Buying Behaviour of Health Drinks. *International Journal of Scientific Research & Engineering Trends, 10(1)*, 2395–2566. https://ijsret.com/wp-content/uploads/2024/01/IJSRET_V10_issue1_114.pdf. See also Sakhlecha, N., Nithya, C., & Keerthi Jain, K. (2021). The Influence of Motivational Advertisement on Consumer Buying Behavior With reference to Health drinks in Tirupattur district. *International Research Journal of Engineering and Technology, 8(8)*. https://www.irjet.net/archives/V8/i8/IRJET-V8I8439.pdf.

[23] Soti, R. (2022). The Impact of Advertising on Consumer Behavior. *World Journal of Advanced Research and Reviews, 14(3)*, 706–711. https://doi.org/10.30574/wjarr.2022.14.3.0577.

[24] Yao, Y. (2023). Multimodal Critical Discourse Analysis of False Healthcare Product Advertising. *Academic Journal of Humanities & Social Sciences*, *6*(23). https://doi.org/10.25236/ajhss.2023.062302

[25] *Indian Medical Association v Union of India*, WPC No. 645 of 2022, order dt. 23.04.2024.

[26] Nutrition Advocacy in Public Interest. (2023). *The Junk Push Report*. https://napiindia.in/docs/The-Junk-Push-Report-LR.pdf.

[27] Mehta, R., & Bharadwaj, A. (2021). Food advertising targeting children in India: Analysis and implications. *Journal of Retailing and Consumer Services*, *59*, 102428. https://doi.org/10.1016/j.jretconser.2020.102428. See also Kapoor, S., & Kapoor, S. (2020). *Misleading Advertisement and its Impact on Children*. Indian Institute of Management Kozhikode. https://forms.iimk.ac.in/research/markconf20/Proceedings/109.pdf.

The Nexus with Disease

The impact of false advertisements for food products has a direct causal link with the increase in the consumption of unhealthy foods and the increase in non-communicable diseases (NCDs).[28] Several organisations in India have urged the government to address the growing burden of NCDs. In response, the central government introduced the National Multisectoral Action Plan for Prevention and Control of Common NCDs (2017-22).[29] However, implementation of this plan remains a significant challenge.[30] A key aspect related to accuracy is that of clear, informative, and honest labelling, in order for consumers to make informed choices aligned with their right to health, by decreasing the consumption of unhealthy food and drinks.

The COVID-19 pandemic played a significant role in bringing consumers closer to proactive healthcare, which caused a massive spike in the number of Indian households consuming dietary supplements and nutraceuticals.[31] A recent survey revealed that seven out of ten consumers confirmed the regular intake of various nutraceuticals, ranging from vitamins to dietary supplements, with 79% of them taking these supplements without consulting a doctor.[32] The need for proactive healthcare, though necessitated by the pandemic, is also boosted by advertisements that have taken advantage of people's heightened anxieties and uncertainties.[33] Numerous products are being marketed to provide protection against the virus or boost the immune system.[34]

Information Asymmetry

Various consumers have expressed concerns about the claims made by health supplements. Some have experienced life-threatening consequences after consuming protein supplements, believing their claims to be accurate and verified.[35] Health supplements and

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[28] Boyland, E., McGale, L., Maden, M., Hounsome, J., Boland, A., Angus, K., & Jones, A. (2022). Association of Food and Nonalcoholic Beverage Marketing With Children and Adolescents' Eating Behaviors and Health. *JAMA Pediatrics*, *176*(7), e221037. https://doi.org/10.1001/jamapediatrics.2022.1037

[29] Ministry of Health and Family Welfare. (2019). *National Multi sectoral Action Plan for Prevention and Control of Non Communicable Diseases*.

[30] Perappadan, B. S. (2023, September 22). Public health advocates demand warning labels, ban on junk food ads. *The Hindu*. https://www.thehindu.com/sci-tech/health/public-health-advocates-demand-warning-labels-ban-on-junk-food-ads/article67334550.ece.

[31] Ernst and Young. (2022, February). EY Report: The confluence of Food, Pharmaceuticals, Ayurveda and Technology paving the way for the rise of India's Consumer Health and Nutrition sector. https://www.ey.com/en_in/news/2022/02/the-confluence-of-food-pharmaceuticals-ayurveda-and-technology-paving-the-way-for-the-rise-of-indias-consumer-health-and-nutrition-sector.

[32] LocalCircles. (2024, February). *7 in 10 consumers confirm taking some type of nutraceuticals*. LocalCircles. https://www.localcircles.com/a/press/page/india-nutraceuticals-consumer-survey.

[33] Indu, R., & Jagathy Raj, V. P. (2012). Developing a Theoretical Framework for a Study on the Impact of Advertising Credibility of Consumer Healthcare Products. *European Journal of Commerce and Management Research, 1(1)*. https://www.academia.edu/71977994/Developing_a_Theoretical_Framework_for_a_Study_on_the_Impact_of_Advertising_Credibility_of_Consumer_Healthcare_Products.

[34] Agarwal, S. (2022, April 4). *The increase in consumption of nutritional supplements (and their efficacy) in the Covid-19 pandemic.* The Indian Express. https://indianexpress.com/article/lifestyle/health/nutritional-supplements-covid-19-pandemic-meaning-herbs-dietary-benefits-health-7816861/

[35] Navya, P.K. (2023, August). *A dose of danger: Spurious supplements harm consumers*. Deccan Herald. https://www.deccanherald.com/india/a-dose-of-danger-spurious-supplements-harm-consumers-2645728.

nutraceutical advertisements require special attention because, unlike medicines, these products are categorised as food and do not undergo strict regulatory compliance. They are readily available in the market, leading the government to consider bringing nutraceuticals under the authority of drug control regulations.[36]

Under Indian law, companies cannot advertise specifically listed drugs directly to consumers without the permission of the central government.[37] These are essentially drugs that require a prescription. However, advertisements for over-the-counter (OTC) and Ayurvedic medicines are allowed. Complicating this picture, there is no published list of legally recognised OTC drugs. In 2023, the National Medical Council notified a list of therapeutic drugs that could be purchased without a prescription under its regulations.[38] However, the regulations do not mention specific drug names and are currently suspended.[39] Due to the lack of classification between prescription-only and OTC drugs, as well as poor enforcement of prescription-only status, people can generally buy any medicine at the pharmacy without a doctor's advice.[40] In addition, pharmaceutical companies have been quick to identify consumer ease of visiting a pharmacy over a hospital and thus spend resources on marketing and improvising products in new formats.[41] For example, advertisements for pain relief roll-ons, balms, and nasal sprays are common and well-circulated in India.[42] However, there is a considerable risk of irrational use and over-consumption of these drugs. In 2018, the government banned 328 drugs, some of which were commonly advertised. This action was based on the Drugs Technical Advisory Board findings, which highlighted the lack of therapeutic justification and the risk to human health,[43] in complete contrast to the information communicated by the advertisers through catchy jingles and imagery.

Pharmaceutical companies are permitted to promote drugs to healthcare practitioners, a practice regulated by the voluntary Uniform Code of Pharmaceutical Marketing Practices

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[36] Govt panel to review if nutraceuticals should be brought under CDSCO. (2024, February 18). *The Economic Times*.https://economictimes.indiatimes.com/industry/cons-products/food/govt-panel-to-review-if-nutraceuticals-should-be-brought-under-cdsco/articleshow/107794633.cms?from=mdr.

[37] *Drugs & Cosmetic Rules, 1945*, Rules 74 and 78. *See also Drugs and Magic Remedies (Objectionable Advertisement) Act 1954*, Section 3.

[38] National Medical Commission lists drugs which can be sold without prescription. (2023, August 12). *The Hindu*. https://www.thehindu.com/sci-tech/health/nmc-lists-therapeutic-categories-of-drugs-which-can-be-sold-sans-prescription/article67188028.ece.

[39] NMC Puts New Medical Practitioner Conduct Rules on Hold. (2023, August). *The Health Master.* https://thehealthmaster.com/2023/08/26/nmc-puts-new-medical-practitioner-conduct-rules-on-hold/

[40] World Health Organisation Special Initiative on NCDs and Innovation Team. (2024). *Commercial Determinants of Noncommunicable Diseases in the WHO European Region* (p. 46). https://www.who.int/europe/publications/i/item/9789289061162.

[41] Shaghaghi, A., Asadi, M., & Allahverdipour, H. (2014). Predictors of Self-Medication Behavior: A Systematic Review. *Iranian Journal of Public Health*, *43*(2), 136–146. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4450680/#ref32.

[42] Volini's new campaign urges people to move on from home remedies for pain relief. (2023, June). *Exchange4Media*.https://www.exchange4media.com/advertising-news/volinis-new-campaign-urges-people-to-move-on-from-home-remedies-for-pain-relief-127931.html.

[43] *What are FDC drugs and why has the govt decided to ban them?* (2018, September 13). Business Today. https://www.businesstoday.in/industry/pharma/story/what-are-fdc-drugs-and-why-has-the-govt-decided-to-ban-them-110595-2018-09-13.

(UCPMP).[44] An observational study of the material circulated for drug promotion revealed that the information provided was biased, incomplete, inauthentic, and unreliable.[45] Several other studies have also expressed concerns about misleading drug promotional literature.[46]

Misleading claims made by advertisers cause significant information asymmetry, which often leads to commercial gains and causes irreparable injury to consumer welfare and rights and to individual health and wellness. To contextualise the challenges to fair, accurate, and transparent advertising in India, it is essential to look at the existing regulatory framework that vertically and horizontally governs advertising for health-related products.

2. THE LEGAL FRAMEWORK IN INDIA

In India, misleading advertisements are governed by various regulations and authorities. Four regulations that define misleading advertisements are the *Consumer Protection Act 2019*, the *Food Safety and Standards Act 2006*, the *Drugs and Magical Remedies (Objectionable Advertisements) Act 1954*, and the *Insurance Regulatory and Development Authority of India (Insurance Advertisements and Disclosure) Regulations, 2021*. Each law uses a different threshold to determine what constitutes a false, misleading, or deceptive advertisement, while they all impose penalties.

The diagram on the following page covers all regulations covered by and relevant to this paper. Other general and industry legislations governing the issue of false and misleading advertising are not covered by the paper. Some of these include the *Bureau of Indian Standards Act 2016*, the *Insurance Regulatory and Development Authority of India (Insurance Advertisements and Disclosure) Regulations 2021*, and the *Trade Marks Act 1999.*

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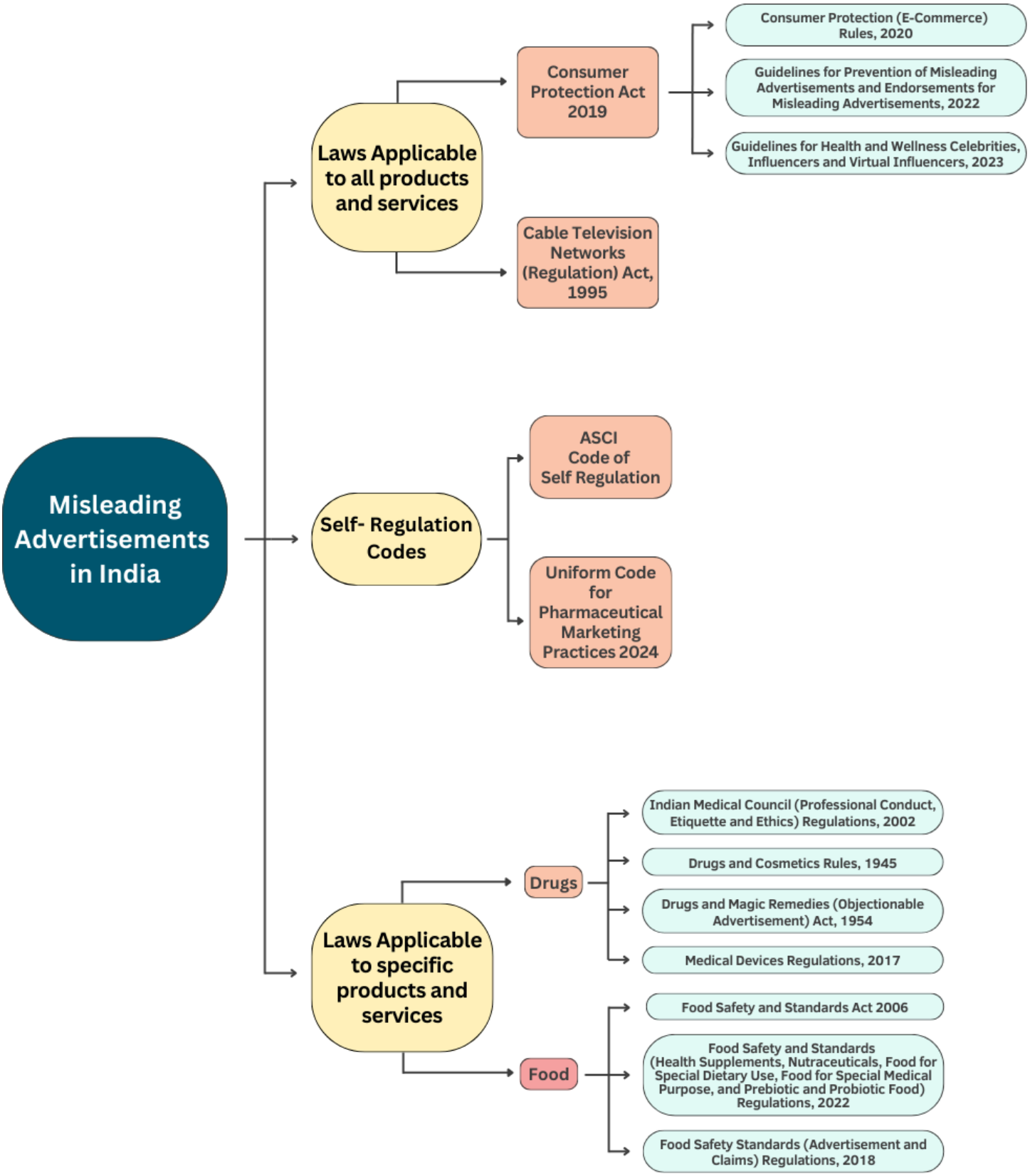
[44] Ministry of Chemical and Fertilisers Department of Pharmaceuticals. (2024). *Uniform Code of Pharmaceutical Marketing Practices*. https://pharmaceuticals.gov.in/sites/default/files/UCPMP.pdf

[45] Randhawa, G. K., Singh, N. R., Rai, J., Kaur, G., & Kashyap, R. (2014). A Critical Analysis of Claims and Their Authenticity in Indian Drug Promotional Advertisements. *Advances in Medicine*, *2015*(1), 469147. https://doi.org/10.1155/2015/469147.

[46] Cardarelli, R., Licciardone, J. C., & Taylor, L. G. (2006). A cross-sectional evidence-based review of pharmaceutical promotional marketing brochures and their underlying studies: is what they tell us important and true?. *BMC family practice*, *7*, 13. https://doi.org/10.1186/1471-2296-7-13. See also Villanueva, P., Peiró, S., Librero, J., & Pereiró, I. (2003). Accuracy of pharmaceutical advertisements in medical journals. *The Lancet*, *361*(9351), 27–32. https://doi.org/10.1016/s0140-6736(03)12118-6.



Regulations and Guidelines on Health Product Advertising in India

2.1 General Regulatory Framework

Among the various regulations that apply, the ones discussed below are relevant to all products and services, making them horizontally applicable to every advertisement.

2.1.1 Consumer Protection Act, 2019

The ***Consumer Protection Act 2019*** is the cornerstone of consumer rights in India. It was amended in 2019 after first being legislated in 1986. This was a welcome change that introduced definitions for misleading advertisements and recognised them as unfair trade practices. The Act defines a misleading advertisement for any product or service and prohibits false deception, guarantee, and deliberate hiding.[47] It establishes the Central Consumer Protection Authority (CCPA) vested with powers to issue directions and penalties against false or misleading advertisements. The CCPA can ask the advertiser to either stop or change an advertisement and may also impose a penalty.[48] This includes imprisonment for up to two years, a fine of up to INR 10,00,000, and penalties for subsequent offences, which may include imprisonment for a term which may extend to five years and with a fine which may extend to INR 50,00,000.[49]

Despite a considerable overhaul in 2019, the Act struggles to keep pace with the rampant use of false advertising. A major hurdle is enforcement. Regulatory bodies like the CCPA often grapple with limited resources, workforce, and infrastructure, hindering their ability to monitor and penalise misleading advertisements effectively.[50] The Act also establishes consumer dispute redressal agencies at various decentralised levels. However, these forums lack investigative powers and suffer from inadequate infrastructure and a shortage of qualified personnel, particularly at the local level. Furthermore, most complaints about false and misleading advertisements filed in consumer courts are submitted by individuals who have been directly impacted and have suffered financial losses. While other violations of the law do occur, they are not taken cognizance of because consumer courts do not have the authority to proactively investigate misleading advertisements and take up such cases of their volition.[51]

Exacerbating this malaise is the sluggish rate at which legal processes and consumer courts function, leading to delayed justice for complainants. Indeed, by the time a misleading advertisement is addressed, the harm might already be done. Moreover, while the CPA provides mechanisms for redressal, many consumers are unaware of how to use these tools

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[47] *Consumer Protection Act, 2019*, Section 2(28).
[48] *Consumer Protection Act, 2019*, Section 21.
[49] *Consumer Protection Act, 2019*, Section 89.
[50] Mehta, A. (2024, May 17). *Research project on False Advertising in the area of Health* (A. Mathur & V. Divan, Interviewers) [Personal communication]. *See also* Saroja, S. (2024, May 7). *Research project on False Advertising in the area of Health* (A. Mathur & V. Divan, Interviewers) [Personal communication]. *See also* Nagarathna, A. (2022). Consumer Protection Act 2019- A review of Criminal Sanctions Protecting Consumers. *International Journal on Consumer Law and Practice*, *8*(1). https://repository.nls.ac.in/cgi/viewcontent.cgi?article=1068&context=ijclp.
[51] Mehta, A. (2024, May 17). *Research project on False Advertising in the area of Health* (A. Mathur & V. Divan, Interviewers) [Personal communication].

effectively, which diminishes the overall impact of the Act. A survey by the Consumer Unity and Trust Society (CUTS) in Rajasthan revealed that 62 per cent of respondents were unaware of the *Consumer Protection Act*, highlighting a significant lack of awareness regarding consumer rights and available legal recourse.[52]

The CCPA has taken proactive steps to curb misleading advertisements, particularly during the COVID-19 pandemic. However, implementing penalties and corrective actions can be inconsistent and slow.[53] Guidelines were introduced to ensure stakeholders know the rules and do not unknowingly violate them. While brands have leveraged celebrity endorsements to enhance their products' appeal and prevent false claims, the CCPA issued **Guidelines for Prevention of Misleading Advertisements and Endorsements in 2022**. These guidelines apply to all advertisements and clearly outline the conditions for various advertisement formats and mediums.[54] They also mandate clear disclaimers in advertisements. Endorsers are required to conduct due diligence before promoting a product and must disclose any material connection with the advertiser. [55]

The CCPA also issued **Guidelines for Health and Wellness Celebrities, Influencers, and Virtual Influencers** in 2023 to prevent misleading claims and endorsements by social media influencers for health and wellness products.[56] Despite these guidelines, between June 2021 and December 2023, the ASCI listed 581 profiles of non-compliant social media influencers and brands, underscoring the widespread misuse of digital platforms to propagate fabricated claims and false urgency about various products.[57] In line with these guidelines, the Supreme Court, in an ongoing case, has also directed endorsers to make informed claims while noting that celebrities and social media influencers will be equally liable for misleading ads if they endorse any deceptive product or service. [58]

During the pandemic, the CCPA also issued advisories to protect consumers. The first, issued in 2021, called for an end to misleading claims related to COVID-19 without scientific evidence, and the second, issued in 2021, emphasised compliance with the ***Consumer Protection (e-commerce) Rules, 2020***. The rules impose a duty on sellers in a marketplace to

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[52] Consumer Unity & Trust Society (CUTS). (2011). *Is Consumer Protection Proving a Myth?* https://cuts-cart.org/is-consumer-protection-proving-a-myth/.
[53] *CCPA issues notices to companies for misleading advertisements*. (2021). Business Standard. https://www.business-standard.com/article/current-affairs/ccpa-issues-notices-to-companies-for-misleading-advertisements-121010100745_1.html.
[54] Department of Consumer Affairs. (2022). *Guidelines for Prevention of Misleading Advertisements and Endorsements for Misleading Advertisements*. https://consumeraffairs.nic.in/sites/default/files/CCPA_Notification.pdf.
[55] Department of Consumer Affairs. (2022). *Guidelines for Prevention of Misleading Advertisements and Endorsements for Misleading Advertisements*, Guideline 13.
[56] Department of Consumer Affairs. (2023). *Additional Influencer Guidelines For Health and Wellness Celebrities, Influencers and Virtual Influencers*. https://consumeraffairs.nic.in/latestnews/additional-influencer-guidelines-health-and-wellness-celebrities-influencers-and-virtual.
[57] Advertising Standards Council of India. (2024, February). *Non-Compliant Social Media Influencers and Brands.* Asci.social. https://asci.social/noncompliant
[58] Anand, A. (2024, May 7). *Patanjali misleading ads: Supreme Court orders removal of online ads, halts sale of suspended products*. Mint. https://www.livemint.com/news/india/patanjali-misleading-ads-sc-orders-takedown-of-online-ads-halt-on-sale-of-suspended-products-11715086571074.html.

ensure that advertisements for marketing goods or services are consistent with the actual characteristics, access, and usage conditions of goods or services.[59]

The *Consumer Protection Act* and the CCPA are deployed to reduce false and misleading advertisements by simplifying means of grievance redressal. However, brands, endorsers, and social media influencers often find ways to avoid obligations under the Act and its supporting guidelines due to a lack of active monitoring. Penalties under the Act are usually only issued after multiple complaints, and a misleading advertisement has often already run its course before it is taken down.

High Stakes: Canada's *Competition Act*

In Canada, the *Competition Act 1985* prohibits any false or misleading representations and deceptive marketing.[60] The Act applies to representations irrespective of their form. The law offers a criminal and civil regime with serious economic ramifications. Under the criminal regime, on a summary conviction, a person can be imprisoned for up to one year and/or a fine of up to C$200,000. If convicted on a formal charge, a person can be imprisoned for up to 14 years and/or a fine at the court's discretion.[61] In the civil system, as amended in 2022, individuals can face fines of up to C$750,000 for the initial offence, while corporations can be fined up to C$10,000,000. For repeat offences, the fines can increase to C$1,000,000 for individuals and C$15,000,000 for corporations.[62] The prospect of criminal liability and hefty fines act as a deterrent for businesses.[63] The Competition Bureau, an independent law enforcement agency, also actively warns off businesses, nudging them towards best practices.[64] The Bureau has also been active in updating the law to curb environmental and greenwashing claims,[65] advertising unhealthy food to

[59] *Consumer Protection (E-Commerce) Rules, 2020*, Rule 6(4)(c).
[60] *Competition Act, 1985*, Section 74.01.
[61] *Competition Act, 1985,* Section 52.
[62] Competition Bureau Canada. (2022, June 24). *Guide to the 2022 amendments to the Competition Act*. Government of Canada. https://competition-bureau.canada.ca/how-we-foster-competition/education-and-outreach/publications/guide-2022-amendments-competition-act#sec02.
[63] Competition World. (2016). A global survey of recent competition and antitrust law developments with practical relevance. In *Norton Rose Fulbright* (p. 20). https://www.nortonrosefulbright.com/-/media/files/nrf/nrfweb/imported/competition-world--q2-2016.pdf?revision=8eaf3be2-0a57-41f0-9f4e-7fd680f65928&revision=5248360944327387904.
[64] Competition Bureau Canada. (2024, January 18). *Online reviews posted by employees: businesses could be liable*. Government of Canada. https://www.canada.ca/en/competition-bureau/news/2024/01/online-reviews-posted-by-employees-businesses-could-be-liable.html.
[65] Competition Bureau Canada. (2024b, June 27). *Environmental claims and greenwashing*. Government of Canada. https://competition-bureau.canada.ca/how-we-foster-competition/education-and-outreach/environmental-claims-and-greenwashing.

children,[66] introducing front-of-package symbols,[67] and updating natural health product labelling guidance.[68]

Penalties under India's *Consumer Protection Act* are lower than those under the Canadian law, and the Act offers alternate remedies. Higher penalties protect consumers by deterring advertisers from engaging in unfair or deceptive practices.[69]

To read more about the Competition Act, click here.

2.1.2 Cable Television Networks (Regulations) Act, 1995

All advertisements aired on TV channels are regulated in accordance with the Advertising Code prescribed under the ***Cable Television Networks (Regulation) Act 1995***.[70] The code requires all advertisements carried out on cable services to conform to the laws of the country. The rules make the ASCI Code (discussed below) compulsory for television and prohibit advertisements that violate the code to be aired on a cable service.[71] (Due to a notable lacuna, since the *Press Council of India Act 1978* does not mandate the ASCI Code, print media advertisements are not subject to its compulsory application.)

In 2017, the Ministry of Information and Broadcasting issued a strict warning to channels, instructing them to advertise only products and drugs that have valid licences. This action was taken in response to exaggerated and improper claims of ASU and homoeopathic products and drugs being promoted.[72] Under the Act, any contravention is punishable by imprisonment of up to two years and/or a fine of up to INR 2000 for the first conviction and by imprisonment of up to five years and/or a fine of up to INR 5000.[73]

The Supreme Court, in an ongoing case, has directed all advertisers and advertising agencies to submit a "Self-Declaration Certificate" for all new advertisements before they are issued, telecast, aired, or published.[74] This certificate should confirm that the advertisement does not contain misleading claims and complies with all relevant regulatory guidelines, including those outlined in the *Cable Television Networks Rules 1994* and the Norms of Journalistic

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[66] *Child Health Protection Act (C-252), 2021.*
[67] Ministry of Health. (2022). *Regulations Amending the Food and Drug Regulations (Nutrition Symbols, Other Labelling Provisions, Vitamin D and Hydrogenated Fats or Oils): SOR/2022-168*. https://canadagazette.gc.ca/rp-pr/p2/2022/2022-07-20/html/sor-dors168-eng.html.
[68] Ministry of Health. (2022b). *Regulations Amending the Natural Health Products Regulations: SOR/2022-146*. https://canadagazette.gc.ca/rp-pr/p2/2022/2022-07-06/html/sor-dors146-eng.html.
[69] Rhodes, A. (2023). A Survey on Drip Pricing and Other False Advertising. *SSRN Electronic Journal*. https://doi.org/10.2139/ssrn.4430453.
[70] *Cable Television Networks (Regulation) Act, 1995*, Section 6.
[71] *Cable Television Networks (Amendment) Rules, 2006*.
[72] Centre warns channels on ads with false claims about drugs. (2017, July 23). *The Times of India*. https://timesofindia.indiatimes.com/india/centre-warns-channels-on-ads-with-false-claims-about-drugs/articleshow/59722393.cms.
[73] *Cable Television Networks (Regulation) Act, 1995*, Section 16.
[74] Ministry of Information & Broadcasting. (2024). *Supreme Court Mandates Self-Declaration by Advertisers/ Advertising Agencies Before Releasing Advertisements*. Press Information Bureau. https://pib.gov.in/PressReleaseIframePage.aspx?PRID=2022649&s=09#:~:text=The%20self%2Ddeclaration%20certificate%20is%20to%20certify%20that%20the%20advertisement.

Conduct of the Press Council of India.[75] There are several concerns about the enforceability of these directives and the resistant industry response to them, including that they introduce an additional layer of regulatory compliance to an already complex system.[76] A key issue in the persistence of false advertising is the inadequate implementation of existing laws, lack of monitoring resources, and lack of harmonisation within various governing laws, making the operability of this new ex-ante obligation uncertain.

2.2 Industry-Specific Laws and Regulations

Apart from the laws described above, special legislations govern the advertising of health products covered by this paper. They are vertically applicable depending on whether the product or service is classified as a drug or food.

2.2.1 Drugs

Advertisements of all products classified as 'drugs' are governed by the ***Drugs and Magic Remedies (Objectionable Advertisement) Act 1954*** (DMRA). The law defines drugs to include medicines and any other substance meant for diagnosing, curing, treating, or preventing disease, as well as any product other than food.[77] This definition has been given a wide sweep so as to not restrict any particular type of drugs - for example, balms - from the application of the law.[78] While prohibiting the advertisement of certain drugs for the treatment of specific diseases and disorders, the Act also prohibits the advertisement of drugs with misleading information.[79] Any violation results in imprisonment for up to 6 months and/or a fine for the first offence and imprisonment for up to one year and/or a fine for subsequent offences.[80] The primary objective of the DMRA is to prevent self-medication by regulating objectionable and unethical advertisements promoting self-treatment.[81] The ***Drugs and Magic Remedies (Objectionable Advertisement) Rules 1955*** supplement the DMRA by allowing the state drug regulatory authorities (SDRA) to scrutinise misleading drug advertisements.[82]

Legal action has been sought under the DMRA against advertisements for drugs such as Tablet D' Cold Total and Syrup D' Cold circulated on various TV channels.[83] Affected consumers have also taken the matter to the courts due to the State machinery's inaction.[84]

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[75] Press Council of India. (2022). *Norms of Journalistic Conduct*. https://presscouncil.nic.in/WriteReadData/Pdf/Norms2022.pdf.
[76] Agarwal, A. (2024, June 26). *Centre likely to ease rules on self-declaration for ads after industry meeting*. Hindustan Times. https://www.hindustantimes.com/india-news/centre-likely-to-ease-rules-on-self-declaration-for-ads-after-industry-meeting-101719381351973.html.
[77] *Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954,* Sec 2(b).
[78] *Mahesh Ramnath Sonawane v Union of India* 2014 SCC OnLine Bom 4008.
[79] *Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954,* Sec 5.
[80] *Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954,* Sec 7.
[81] *Hamdard Dawakhana v Union of India* AIR 1965 SC 1167.
[82] *Drugs and Magic Remedies (Objectionable Advertisement) Rules, 1955*, Rule 3.
[83] *Mahesh Ramnath Sonawane v Union of India* 2014 SCC OnLine Bom 4008. *See also* Cipla Ltd v State of Tamil Nadu Crl.O.P.No.21919 of 2008.
[84] *G. Jayaprakash v State of Kerala* WP(C). No. 5740 of 2017.

A study on the enforcement of the DMRA in Andhra Pradesh revealed a high prevalence of misleading claims for fevers, diabetes, and asthma and found that the implementation of the Act was weak.[85] Industry bodies globally have made arguments in favour of a self-regulation code for the marketing and advertising of pharmaceutical products, emphasising the sufficiency of such codes.[86] In order to enable greater transparency the Ministry of Health and Family Welfare issued the Uniform Code for Pharmaceutical Marketing Practices, requiring them to submit a 'self-declaration' that pharmaceutical companies are following the code.[87] This move is in line with the demands of pharmaceutical companies for a common code.[88] However, voluntary codes have been found to be ineffective due to the clear conflict of interest in their operation and implementation. A clear example of pharma influence in India is the industry mobilisation that took place to stall the shift of nutraceuticals falling under the ambit of drug authorities.[89]

Enforcement of the DMRA varies across states due to factors that are similar to those of the *Consumer Protection Act 2019*. These include enforcement capacity, priorities, resources, and political will. For example, Maharashtra stands out as a top implementer of the DMRA, with strong enforcement mechanisms, well-trained staff, and a proactive approach to tackling false advertising, resulting in higher compliance rates.[90] On the other hand, states like Uttar Pradesh show better enforcement than other states but still face challenges due to resource constraints and competing priorities.[91] States with weaker enforcement, such as Bihar, struggle to prioritise consumer protection measures due to limited resources, inadequate infrastructure, and a lack of political will. Urban-rural divides may exacerbate

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[85] Ayyanar, R., Boyanagari, M., & Shankar, M. (2017). Enforcement of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, in the State of Andhra Pradesh: situational analysis and lessons learnt. *Journal of Pharmaceutical Health Services Research*, *9*(1), 47–52. https://doi.org/10.1111/jphs.12207.

[86] Saroja, S. (2024, May 7). *Research project on False Advertising in the area of Health* (A. Mathur & V. Divan, Interviewers) [Personal communication]. *See also* Zetterqvist, A. V., Merlo, J., & Mulinari, S. (2015). Complaints, Complainants, and Rulings Regarding Drug Promotion in the United Kingdom and Sweden 2004–2012: A Quantitative and Qualitative Study of Pharmaceutical Industry Self-Regulation. *PLoS Medicine*, *12*(2). https://doi.org/10.1371/journal.pmed.1001785. *See also* World Health Organisation Special Initiative on NCDs and Innovation Team. (2024). *Commercial Determinants of Noncommunicable Diseases in the WHO European Region* (p. 46). https://www.who.int/europe/publications/i/item/9789289061162.

[87] Ministry of Chemical and Fertilisers Department of Pharmaceuticals. (2024). *Uniform Code of Pharmaceutical Marketing Practices*. https://pharmaceuticals.gov.in/sites/default/files/UCPMP.pdf.

[88] Kumar, A. (2022, November 8). *"Freebies" to doctors: Pharma industry lobby seeks new code to regulate marketing interaction*. Moneycontrol. https://www.moneycontrol.com/news/trends/current-affairs-trends/freebies-to-doctors-pharma-industry-lobby-seeks-new-code-to-regulate-marketing-interaction-9468671.html.

[89] Kumar, A. (2024, July 17). *Pharma groups criticise plan to shift nutraceuticals under drug authority*. Business Standard. https://www.business-standard.com/health/pharma-groups-criticise-plan-to-shift-nutraceuticals-under-drug-authority-124071700367_1.html.

[90] Saxena, D. (2024, May 13). *Research project on False Advertising in the area of Health* (A. Mathur & V. Divan, Interviewers) [Personal communication]. Received written responses to a questionnaire. *See also* Nautiyal, S. (2022, March 2). *Maharashtra FDA detects new cases of violation of DMR Act, 1954 in the past three months*. Financialexpress. https://www.financialexpress.com/business/healthcare-maharashtra-fda-detects-new-cases-of-violation-of-dmr-act-1954-in-the-past-three-months-2448998/.

[91] Saxena, D. (2024, May 13). *Research project on False Advertising in the area of Health* (A. Mathur & V. Divan, Interviewers) [Personal communication]. Received written responses to a questionnaire. *See also* Chandra, S. (2013, April 19). Advertisements for magical remedies under scanner. *The Times of India*. https://timesofindia.indiatimes.com/city/varanasi/advertisements-for-magical-remedies-under-scanner/articleshow/19639357.cms.

enforcement challenges, with rural areas receiving less attention and resources.[92] The DMRA faced significant criticism, prompting the government to introduce an amendment in 2020. The proposed amendment broadens the definition of advertisement to include electronic and other media, introduces harsher penalties, and expands the list of diseases for which advertisements promoting cures are prohibited. However, no update about the status of the draft is available, with momentum apparently at a standstill.[93]

The ***Drugs and Cosmetics Act 1940*** considers a drug to be misbranded if its label, design, or statement makes a false claim.[94] The Act stipulates a penalty of up to two years' imprisonment for violations of this provision.[95] The ***Drugs and Cosmetics Rules 1945***, prohibit advertisement for specific schedules of drugs and false or misleading claims.[96] A rule that banned advertisements for AYUSH products without the licensing authorities approval was removed as the government believed that existing regulations were sufficient to address the issue.[97] However, the Supreme Court recently stated that the letter withdrawing the application of the rule was only an administrative instruction and did not override Rule 170 under the *Drugs and Cosmetics Rules*.[98]

The burgeoning demand and growth of ASU products in the last decade has also impacted the advertising world, with brands making fabricated and hyperbolic claims. Despite complaints and formal court proceedings, brands dealing in AYUSH products often claim cures for diabetes, asthma, COVID-19, and other diseases, in stark violation of the DMRA.[99] There have been cases where consumers fell seriously ill after using Ayurvedic medicines with exaggerated claims. In multiple cases, consumers have complained of jaundice, high blood pressure, pain, and swelling in joints.[100] In Canada, people have been hospitalized for lead poisoning, causing them severe abdominal pain.[101] A US-based study has also found that consumption of herbal or dietary supplements puts one at a higher risk of acute liver

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[92] Saxena, D. (2024, May 13). *Research project on False Advertising in the area of Health* (A. Mathur & V. Divan, Interviewers) [Personal communication]. Received written responses to a questionnaire.
[93] Ministry of Health and Family Welfare. (2020). *Draft of the Drugs and Magic Remedies (Objectionable Advertisements) (Amendment) Bill, 2020*. https://main.mohfw.gov.in/sites/default/files/Draft%20of%20the%20Drugs%20and%20Magic%20Remedies.pdf
[94] *Drugs and Cosmetics Act, 1940*, Sec 17(c).
[95] *Drugs and Cosmetics Act, 1940,* Sec 27(d).
[96] *Drugs and Cosmetics Rules, 1945*, Rule 74, 78 and 148B.
[97] Ministry of AYUSH. (2024). *Misleading advertisements by AYUSH product manufacturers*. https://sansad.in/getFile/annex/263/AU329.pdf?source=pqars#:~:text=Drugs%20and%20Magic%20Remedies%20(Objectionable,media%20and%20Government%20has%20taken
[98] Rajagopal, K. (2024, May 7). Advertisers to submit self-declarations before promoting products in media, SC orders. *The Hindu*. https://www.thehindu.com/news/national/advertisers-to-submit-self-declarations-before-promoting-products-in-media-sc-orders/article68150472.ece.
[99] Misleading ads for traditional medicine under Centre's scanner. (2017, January). *The Hindu*. https://www.thehindu.com/business/Industry/Misleading-ads-for-traditional-medicine-under-Centre%E2%80%99s-scanner/article17074731.ece
[100] Paudyal, B., Thapa, A., Sigdel, K. R., Adhikari, S., & Basnyat, B. (2019). Adverse events with ayurvedic medicines- possible adulteration and some inherent toxicities. *Wellcome Open Research*, *4*. https://doi.org/10.12688/wellcomeopenres.15096.3.
[101] Gitelman, J., An, H., Spilchuk, V., & Kim, J. (2023). Lead toxicity from Ayurvedic medicines. *CMAJ*, *195*(30), E1010–E1012. https://doi.org/10.1503/cmaj.230592.

damage.[102] In such a context, there is a need to regulate the sector urgently. A lack of clarity in regulations concerning ASU products exists, and many consumers are unaware of the issues involved. ASU manufacturers often market their products as drugs while legally categorising them as food to avoid strict testing requirements. Unlike drugs, ASU products are available at local stores without the need for any sales licenses. Consumers are left uninformed about the contents of such products and, ultimately, the potential side effects they may cause.[103]

Even though the Ministry of AYUSH has established Pharmacovigilance Centres to undertake surveillance and reporting of objectionable or misleading advertisements of AYUSH products,[104] between March 2021 and February 2022, 10035 instances of misleading advertisements were reported and sent to the respective state licensing authorities.[105] However, at the time of writing no information is available on the resolution of these cases. Accentuating the lack of transparency, it is unclear whether penal action has been taken or if any entities are under investigation.

Finally, it is important to note that medical devices are considered drugs under the *Drugs and Cosmetics Act 1940*.[106] Regarding advertising and promoting medical devices in the country, neither the ***Medical Device Rules 2017*****,** nor the *Drugs and Cosmetics Rules 1945*, contain specific provisions. For a few investigative devices, the Central Drugs Standard Control Organisation (CDSCO) does grant marketing authorisations. However, there is no specific guidance for manufacturers to advertise or market medical devices.[107]

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[102] Kesar, V., Channen, L., Masood, U., Grewal, P., Ahmad, J., Roth, N. C., & Odin, J. A. (2021). Liver Transplantation for Acute Liver Injury in Asians Is More Likely Due to Herbal and Dietary Supplements. *Liver Transplantation*, *28*(2), 188–199. https://doi.org/10.1002/lt.26260.

[103] Chandra, S. (2024, March 1). *Patanjali controversy and the lure of a magic cure: Safety standards dangerously fail consumers*. The Indian Express. https://indianexpress.com/article/opinion/columns/patanjali-controversy-sc-bans-patanjali-products-patanjali-ayurveda-consumer-protection-act-9189099/.

[104] Ministry of AYUSH. (2021, December). *Advertisement of Herbal Medicine as Magic Remedies*. Press Information Bureau. https://pib.gov.in/PressReleasePage.aspx?PRID=1782667.

[105] Ministry of AYUSH. (2023). *Monitoring of Misleading Advertisements*. https://sansad.in/getFile/loksabhaquestions/annex/1714/AU2289.pdf?source=pqals

[106] Ministry of Chemicals and Fertilizers. (2020). *Medical Devices notified as Drugs*. Press Information Bureau. https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1609670#:~:text=The%20NPPA%20vide%20Notification%20dated,3.

[107] *Medical Device Rules, 2017*.

Global Standards: Medical Device Ad Regulations in the EU and US

In the European Union, medical device advertising is tightly regulated to prevent misleading claims. This is further supplemented by local country regulations. The *European Union Medical Device Regulation 2017* requires that advertisements be truthful, not exaggerate benefits, and be supported by clinical evidence.[108] Manufacturers must ensure compliance with these and country standards; in case of non-compliance, each country prescribes penalties.[109] Online advertising is broadly allowed in the EU, with country-specific restrictions applicable. For example, in Italy, promotional websites and all advertisements need approval from the Ministry of Health. Further, once an advertisement is approved, secondary approval is required before it is posted online.[110]

The Food and Drug Administration regulates medical device advertising in the United States. Advertisements must be truthful, not misleading, and provide a balanced view of benefits and risks.[111] High-risk devices often need pre-market approval, and the FDA actively monitors and takes action against non-compliant advertisements.[112]

Without clear guidance on medical device marketing, India could benefit from studying global regulations. The strict rules in the EU require clinical evidence to support advertising claims, ensuring consumer safety and trust. US labelling requirements, which involve providing a balanced view of benefits and risks in advertisements, can help consumers make informed decisions and enhance the credibility of medical device marketing.

To read more about EU advertising regulations, click here, and for US medical device advertising, click here.

Other than the CDSCO and SDRAs, the Medical Council of India also regulates advertising of pharmaceutical products and services, particularly by healthcare practitioners (HCPs). The ***Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002*** prohibit HCPs from advertising and limit their interactions with pharmaceutical companies.[113] However, HCPs are permitted to make a formal announcement in the press and to advertise only for a few specific reasons provided under the regulations. They are also mandated to adhere to all applicable laws. For example, the regulations strictly prohibit doctors from advertising in any medium, including making promises of 'guaranteed treatment'.[114] Non-compliance with the DMRA, other statutes and the code of ethics may result in the medical council initiating disciplinary action based on a complaint for misconduct, which could lead to removal from the registry of medical practitioners.[115] But,

[108] *European Union Medical Device Regulation, 2017*, Article 7.
[109] *European Union Medical Device Regulation, 2017*, Article 113.
[110] *Legislative Decree No 137/2022*, Article 26. *See also Legislative Decree No 138/2022*, Article 22.
[111] *Federal Food, Drug, and Cosmetic Act, 1938,* Section 801.6.
[112] *Federal Food, Drug, and Cosmetic Act, 1938*, Section 807.87.
[113] Medical Council of India. (2002). *Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002*.
[114] Ibid., Regulations 6.1 and 1.9.
[115] Ibid., Regulations 8.5 and 8.3.

HCPs are bombarded with promotional material and samples by pharmaceutical companies, which often leads to higher prescribing frequency.[116] Pharmaceutical companies also market their products through medical education events.[117] In India, all such activities by pharmaceutical companies are governed by the industry's self-regulation code, which does little to protect and prevent malpractice. Recent events in the United States should portend ominously: exposure to unrelenting and unbridled promotion resulted in a medically induced opioid crisis.[118]

The Indian Medical Council's ethics regulations do not specifically cover healthcare institutions, which have also ventured into intensive marketing practices through social media. In a 2023 draft of Regulations relating to the Professional Conduct of Registered Medical Practitioners, which was later withdrawn, the National Medical Commission (NMC) discussed the issue of advertisement by corporate hospitals, putting it at par with the mandate for HCPs.[119] Since the NMC is only allowed to regulate doctors and not corporate entities, pursuing a favourable directive through the judicial process will be crucial in this regard.[120]

2.2.2 Food and Nutrition Products

The ***Food Safety and Standards Act 2006*** (FSS Act) provides an expansive definition of the term 'advertisement' by encompassing labels, wrappers, and other documents.[121] Though the Act does not define a misleading advertisement, it prohibits brands from making false, misleading, or deceptive claims.[122] The penalty for misleading advertising under the FSS Act

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[116] Srivastava, R., & Mishra, V. P. (2022). Exploring The Impact Of Pharmaceutical Marketing On Prescribing Behaviour Of Doctors In India: A Critical Review. *Journal of Positive School Psychology*, *6*(5), 3452–3470. https://journalppw.com/index.php/jpsp/article/view/6708/4391. *See also* Akhoon, N., Sharma, S., Moe, H., Nair, D., & Shashidhar, V. (2020). A study of perceptions and exposure of drug promotional literature among clinicians in a teaching hospital. *Perspectives in Clinical Research*, *0*(0), 0. https://doi.org/10.4103/picr.picr_36_19. *See also* Spurling, G. K., Mansfield, P. R., Montgomery, B. D., Lexchin, J., Doust, J., Othman, N., & Vitry, A. I. (2010). Information from Pharmaceutical Companies and the Quality, Quantity, and Cost of Physicians' Prescribing: A Systematic Review. *PLoS Medicine*, *7*(10), e1000352. https://doi.org/10.1371/journal.pmed.1000352.

[117] Biswas, I., & Singh, R. K. (2022). Analyzing Digital Strategies In Pharmaceutical And Healthcare Sectors. *Journal of Survey in Fisheries Sciences*, *8*(3), 287–295. https://doi.org/10.53555/sfs.v8i3.2074. *See also* Kumar Gupta, S., Nayak, R. P., & Sivaranjani, R. (2016). A study on the interactions of doctors with medical representatives of pharmaceutical companies in a Tertiary Care Teaching Hospital of South India. *Journal of Pharmacy and Bioallied Sciences*, *8*(1), 47. https://doi.org/10.4103/0975-7406.171695.

[118] Centre for Disease Control and Prevention. (2024, April 23). *Understanding the Opioid Overdose Epidemic*. Overdose Prevention. https://www.cdc.gov/overdose-prevention/about/understanding-the-opioid-overdose-epidemic.html?CDC_AAref_Val=https://www.cdc.gov/opioids/basics/epidemic.html.

[119] Medical Council of India. (2023). *National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations.* https://www.nmc.org.in/rules-regulations/national-medical-commission-registered-medical-practitioner-professional-conduct-regulations-2023-reg/.

[120] Dutta, S. S. (2024, April 1). *Advertisement norms for doctors, corporate hospitals can't be different, says NMC panel*. ThePrint. https://theprint.in/health/advertisement-norms-for-doctors-corporate-hospitals-cant-be-different-says-nmc-panel/2019838/.

[121] *Food Safety and Standards Act, 2006*, Section 3(b).

[122] *Food Safety and Standards Act, 2006*, Section 3(zf) and Section 24.

may extend to a fine of INR 10,00,000.[123] The Food Safety and Standards Authority of India (FSSAI) has regulated food and nutrition products, particularly in flagging misleading advertisements. In 2023, its Advertisement Monitoring Committee identified 170 cases of food and beverage advertisers making exaggerated and unscientific claims.[124] However, FSSAI cannot issue a directive to run corrective advertisements to neutralise the impact of misleading ones, leaving the consumer vulnerable to misinformation. Under the ***Food Safety and Standards (Advertisements & Claims) Regulations, 2018***, deceptive claims or advertisements are strictly prohibited and considered punishable offences under the FSS Act. The regulations clearly define health, nutrition, conditional and prohibited claims while outlining the permissible scope of advertising.[125]

The FSSAI and the relevant regulations have proved insufficient to protect consumers, especially children, from foods with a high concentration of fat, sugar, and salt (HFSS). Key shortcomings include the limited ability to protect children-targeted advertisements and the lack of criteria to define HFSS foods.[126] Public health and consumer organisations have consistently emphasised the need for a strong regulatory framework to safeguard vulnerable populations from marketing HFSS foods, with clearly defined evidence-based criteria for classifying such foods.[127] Of all the mandatory and optional guidelines available, only the Guidelines for Prevention of Misleading Advertisements and Endorsements for Misleading Advertisements, 2022, attempt to restrict HFSS food advertising to children.[128] Most recently, a public interest litigation has been filed before the Supreme Court to mandate Front-of-Package Labelling (FOPL) with clear warning labels for foods high in salt, sugar and fat levels.[129]

In 2017, the Ministry of Health and Family Welfare proposed a Multi-Sectoral Action Plan for the Prevention and Control of Common Non-Communicable Diseases, which identifies the need for cooperation among various stakeholders and ministries while pushing for more strict regulation of marketing and advertising of unhealthy foods.[130] While this makes the

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[123] *Food Safety and Standards Act, 2006*, Section 53.
[124] Sumeda, S. G. &. (2023, May 7). Explained | Misleading food ads and regulations to curtail them. *The Hindu*. https://www.thehindu.com/news/national/explained-misleading-food-ads-and-regulations-to-curtail-them/article66815388.ece#:~:text=As%20per%20the%20regulator%2C%20the.
[125] Food Safety and Standards Authority of India. (2018). *Food Safety and Standards (Advertising and Claims) Regulations*. https://fssai.gov.in/upload/uploadfiles/files/Compendium_Advertising_Claims_Regulations_04_03_2021.pdf.
[126] Gupta, A. (2024, May). *Research project on False Advertising in the area of Health* (A. Mathur & V. Divan, Interviewers) [Personal communication]. *See also* Bassi, S., Bahl, D., Gopal, S., Sethi, V., Backholer, K., Gavaravarapu, S. M., Babu, G. R., Suparna Ghosh-Jerath, Bhatia, N., Aneja, K., Kataria, I., Mishra, P., Arjan de Wagt, & Arora, M. (2023). Are advertising policies affirmative in restricting the marketing of foods high in fat, salt and sugar (HFSS) in India?: Evidence from SWOT Analysis. *The Lancet Regional Health - Europe*, *21*, 100315–100315. https://doi.org/10.1016/j.lansea.2023.100315.
[127] Gupta, A. (2024, May). *Research project on False Advertising in the area of Health* (A. Mathur & V. Divan, Interviewers) [Personal communication].
[128] Department of Consumer Affairs. (2022). *Guidelines for Prevention of Misleading Advertisements and Endorsements for Misleading Advertisements*. https://consumeraffairs.nic.in/sites/default/files/CCPA_Notification.pdf.
[129] Abhimanyu Hazarika. (2024, August 9). *PIL in Supreme Court seeks warning labels on packaged food to show fat, sugar, salt levels*. Bar and Bench - Indian Legal News. https://www.barandbench.com/news/pil-supreme-court-labels-packaged-food-fat-sugar-salt.
[130] Ministry of Health and Family Welfare. (2019). *National Multi sectoral Action Plan for Prevention and Control of Non-Communicable Diseases*.

plan promising, the lack of implementation, infrastructure, and a general will to act are significant stumbling blocks, highlighting the challenges that need to be addressed for effective regulation.

Advocacy for front-of-package labelling has been a longstanding effort. In September 2022, the FSSAI issued draft amendments to the ***Food Safety and Standards (Labelling and Display) Regulations 2020***. The amendments proposed developing a health star rating system to rate food products on a scale of ½ to 5 stars.[131] This proposal was strongly opposed by civil society groups and the National Human Rights Commission due to the lack of participation from consumer rights groups and other factors such as opting for assignment of stars through AI algorithms and higher stars for positive ingredients.[132]

Additionally, FSSAI has also relaxed the required thresholds for fat, sugar, and salt to eight times above international standards.[133] This has allowed the sale of unhealthy packaged products without any content restrictions, presenting them as 'healthy' to consumers. Even though FSSAI has faced heavy criticism for this decision, it continues to disregard international standards. In a recent case where the quality of Indian spices was questioned, the FSSAI relaxed restrictions on the use of pesticides in food products rather than tightening them.[134]

Lastly, there is an increasing demand for nutraceutical products and health supplements in the Indian market. Related advertisements are often targeted at specific consumer groups but do not always provide a complete and clear picture of the product, with the potential risks outweighing the benefits. This situation, coupled with easy access and a declining vigour for scientific proof and frustration towards vague communications, underscores the need to maintain product standards and prevent deceptive marketing.[135] In response, the FSSAI issued the ***Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purposes, and Prebiotic and Probiotic Foods)***

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[131] Food Safety and Standards Authority of India. (2022). *Draft FSS (Labelling & Display) Amendment Regulations, 2022*. EPlatform for Comments. https://comments.fssai.gov.in/Bestviewwl.aspx?NOTIFICATION_ID=4123.

[132] Gupta, A. (2024, May). *Research project on False Advertising in the area of Health* (A. Mathur & V. Divan, Interviewers) [Personal communication]. *See also* Iyer, A. (2022, August 19). *Front of package labeling: Why is the "health-star rating" bad for food safety in India?* Down to Earth. https://www.downtoearth.org.in/health/front-of-package-labeling-why-is-the-health-star-rating-bad-for-food-safety-in-india--84422. *See also NHRC issues notice to FSSAI on packaged food labelling*. (2023, November 25). BusinessLine. https://www.thehindubusinessline.com/news/nhrc-issues-notice-to-fssai-on-packaged-food-labelling/article67573357.ece. For more information on the proposed labelling system and FOPL: Nutrition Advocacy in Public Interest. (2022). *HSR vs.Warning Labels Health Star Rating(HSR)*. https://napiindia.in/docs/HSR-vs.-Warning-Labels-Key-Points.pdf and Nutrition Advocacy in Public Interest. (2022b). Warning Labels for Unhealthy Foods. In *https://www.napiindia.in/docs/Policy-brief-FOPL-Feb-22.pdf*.

[133] Khurana, A., & Dhingra, S. (2021, September 18). *Food fudge: The story behind why India still does not have front-of-pack labelling*. Down to Earth. https://www.downtoearth.org.in/news/food/food-fudge-the-story-behind-why-india-still-does-not-have-front-of-pack-labelling-79078.

[134] Mukherjee, V. (2024, May 4). *FSSAI relaxed pesticide norms in April, allowing 10x more residue in spices*. Business Standard. https://www.business-standard.com/india-news/fssai-relaxed-pesticide-norms-in-april-allowing-10x-more-residue-in-spices-124050400269_1.html.

[135] Cornish, L. S., & Moraes, C. (2015). The Impact of Consumer Confusion on Nutrition Literacy and Subsequent Dietary Behavior. *Psychology & Marketing*, *32*(5), 558-574. https://doi.org/10.1002/mar.20800.

Regulations, 2022. These regulations state that advertisements should not claim that a health supplement or nutraceutical product has the property of preventing, treating, or curing a human disease.[136] However, brands often circumvent these and claim various health and immunity benefits, which has often adversely affected consumer health, as documented both in India and abroad.[137] The differentiation between food/ health supplements and drugs can be ambiguous, especially when the nutritional content and vitamins are emphasised explicitly for commercial purposes, leading to a subjective classification. There is also an absence of statutory guidance in this regard - classification is decided on a case-to-case basis, ultimately misleading consumers and highlighting the complexity and ambiguity of the situation.

Nutritional Guardians: Chilean *Food Act*

The Chilean *Food Act*, which came into effect in 2016, is a distinctive law that mandates warning labels on the front of food packaging, limits marketing targeted at children and prohibits the sale of foods and beverages with added sugars, sodium, or saturated fats above specified nutrient or calorie levels in schools. [138] Furthermore, the Act bans the use of optional nutrition and health claims, such as "sugar-free," on high-fat, sugar, and salt (HFSS) foods due to their potential to mislead consumers.[139] These claims are strictly prohibited for food supplements, sports foods, and infant formulas, regardless of their nutritional composition.[140] The *Food Act* is a step forward in battling the high rate of NCDs in Chile.[141]

[136] Food Safety and Standards Authority of India. (2022). *Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purposes, and Prebiotic and Probiotic Foods) Regulations*. https://www.fssai.gov.in/upload/advisories/2022/03/6243ef28079ceDirection_Nutra_30_03_2022.pdf.
[137] Ministry of Health and Family Welfare. (2003). *A Comprehensive Examination of Drug Regulatory Issues, including the problem of spurious drugs*. https://pharmaceuticals.gov.in/sites/default/files/MashelkarCommitteeReport.pdf. Section 7.1. *See also* Deloitte. (2023, September). *Paradox Of Nutraceuticals: Pumping Supplements Unchecked Not A Wise Choice*. Deloitte India. https://www2.deloitte.com/in/en/pages/life-sciences-and-healthcare/articles/paradox-of-nutraceuticals.html. *See also* Geller, A. I., Shehab, N., Weidle, N. J., Lovegrove, M. C., Wolpert, B. J., Timbo, B. B., Mozersky, R. P., & Budnitz, D. S. (2015). Emergency Department Visits for Adverse Events Related to Dietary Supplements. *New England Journal of Medicine*, *373*(16), 1531–1540. https://doi.org/10.1056/nejmsa1504267.
[138] Decree 13 Amending Supreme Decree No. 977/1996 on Food Health Regulations, Chile, 2015.
[139] Ibid., Article 1.
[140] Ministry of Health. (2017). Resolution No 860 - Approves Technical Norm No 191 on nutritional guidelines to declare the healthy properties of foods. https://www.fao.org/faolex/results/details/en/c/LEX-%20FAOC208108/.
[141] Campbell, M. (2022a). Chile: Front-of-Package Warning Labels and Food Marketing. Journal of Law, Medicine & Ethics, 50(2), 298–303. https://doi.org/10.1017/jme.2022.55.

The law has successfully reduced advertisements targeted at children, leading to a decline in unhealthy food purchases.[142] Additionally, it has also led to brands reformulating their products to reduce the amounts of sugar and sodium.[143] Other countries have also followed suit and introduced restrictions on broadcast media, regulating children's exposure to such advertisements. These include South Korea, Taiwan, and the UK. In India, NCDs account for 64 per cent of deaths, impacting a significant portion of the population.[144] FOPL and restrictions on the marketing of HFSS food are crucial legal interventions that are long overdue in India.[145]

To read more about the Chilean Food Act, click here.

2.3 Self-Regulation Codes

Having examined statutory frameworks on false advertising of health products, it is apposite to look at the self-regulation codes operating in India. Over the years, the advertising industry has been subject to regulation through both self-regulation and State oversight. Self-regulation occurs when the industry governs itself to ensure that all advertisements adhere to a set of established rules and are truthful and accurate.[146] This model is introduced to balance industry and consumer interests. In India, there are two functional codes for advertising and the pharmaceutical industry.[147]

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[142] Taillie, L. S., Bercholz, M., Popkin, B., Reyes, M., Colchero, M. A., & Corvalán, C. (2021). Changes in food purchases after the Chilean policies on food labelling, marketing, and sales in schools: a before and after study. The Lancet Planetary Health, 5(8), e526–e533. https://doi.org/10.1016/s2542-5196(21)00172-8. See also Dillman, F. R., Fernanda Mediano Stoltze, Reyes, M., Lindsey Smith Taillie, Corvalán, C., & Correa, T. (2023). Restricting child-directed ads is effective, but adding a time-based ban is better: evaluating a multi-phase regulation to protect children from unhealthy food marketing on television. International Journal of Behavioral Nutrition and Physical Activity, 20(1). https://doi.org/10.1186/s12966-023-01454-w.

[143] Reyes, M., Smith Taillie, L., Popkin, B., Kanter, R., Vandevijvere, S., & Corvalán, C. (2020). Changes in the amount of nutrient of packaged foods and beverages after the initial implementation of the Chilean Law of Food Labelling and Advertising: A nonexperimental prospective study. PLOS Medicine, 17(7), e1003220. https://doi.org/10.1371/journal.pmed.1003220.

[144] World Health Organization. (2023, November). NCD voices inform India's programme for NCD prevention and control | Knowledge Action Portal on NCDs. Knowledge Action Portal on NCDs. https://knowledge-action-portal.com/en/news_and_events/country-stories/8299.

[145] For more on need of FOPL and broadcast restrictions in India: Bassi, S., Bahl, D., Gopal, S., Sethi, V., Backholer, K., Gavaravarapu, S. M., Babu, G. R., Suparna Ghosh-Jerath, Bhatia, N., Aneja, K., Kataria, I., Mishra, P., Arjan de Wagt, & Arora, M. (2023). Are advertising policies affirmative in restricting the marketing of foods high in fat, salt and sugar (HFSS) in India?: Evidence from SWOT Analysis. The Lancet Regional Health - Europe, 21, 100315–100315. https://www.thelancet.com/journals/lansea/article/PIIS2772-3682(23)00175-0/fulltext.

[146] International Chambers of Commerce. (2020). *The Benefits of Advertising Self-Regulation in Ensuring Responsible and Compliant Advertising*. https://iccwbo.org/wp-content/uploads/sites/3/2020/06/2020-icc-srtoolkit-benefits-of-sr.pdf.

[147] Dickinson‐Delaporte, S., Mortimer, K., Kerr, G., Waller, D. S., & Kendrick, A. (2020). Power and responsibility: Advertising self‐regulation and consumer protection in a digital world. *Journal of Consumer Affairs*, *54*(2). https://doi.org/10.1111/joca.12295.

2.3.1 Advertising Standards Council of India Code

The Advertising Standards Council of India (ASCI) is a non-statutory self-regulation body that enforces the ASCI Self-Regulation Code. While this code has been widely recognised across government institutes in India, it is not legally binding. It applies to all advertisements intended for consumers in India, regardless of the place of origin. A stated aim of the ASCI is to not hamper a product's sale while controlling the content of its advertisement.[148] Since its inception and as of April 2024, the ASCI has identified and resolved 5945 complaints.[149] The effect of the ASCI's monitoring and increased vigilance in the last few years have prompted calls for lending it and the code statutory power to ensure compliance and uphold ethical standards in advertising.[150] The basic tenets of the code include a mandate for truthful and honest representation and claims, non-offensive content, prohibition on the use of advertising to promote harmful and hazardous products and services and ensuring fairness in competition.[151] Subsequently, the ASCI has also issued self-regulation guidelines for specific sectors, including to govern food and beverages, and celebrities in advertising.

Despite establishing important advertising principles, collaborating with various ministries, and addressing suo moto complaints, the ASCI remains a private self-regulatory body with limited power to enforce its guidelines and principles. A survey conducted by the Federation of Indian Chambers of Commerce and Industry to study the effectiveness of self-regulation in India revealed that 56% of respondents, who were professionals from the advertising and marketing sectors in India, believed that the existing self-regulatory framework was inadequate and ineffective.[152]

The ASCI Code is oriented more towards the industry than consumers. There are several flaws in its functioning that defeat ASCI's commitment to consumer protection. In some cases, when false advertisements are reported, the ASCI has asked the complainant to provide data to raise objections against claims made in the advertisements, a task that is difficult for consumers or welfare organisations to undertake. The ASCI gives parties the option to appeal through an independent review process (IRP) for a fee of INR 1,47,500.[153] Though meant to deter advertisers from taking each claim to IRP, in effect it stops consumer and civil society organisations from appealing since usually only brands can afford this fee.[154]

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[148] Advertising Standards Council of India. (2024). *The Code for Self-Regulation of Advertising Content in India*. ASCI. https://www.ascionline.in/wp-content/uploads/2024/04/Code-Book_Codes_Webready.pdf
[149] Advertising Standards Council of India. (n.d.). *Complaint Outcomes.* ASCI. Retrieved April 30, 2024, from https://www.ascionline.in/complaint-outcomes/
[150] Kumar Gupta, M. (2017). "ASCI & Its Self- Regulation Code for Advertisers". *RJPSSs, 43*(1), 270–276. https://anubooks.com/uploads/session_pdf/1667995147RJPSSs-Vol-43-No-1-2017-36%20Dr%20Manish%20Kumar%20Gupta.pdf
[151] Advertising Standards Council of India. (2024). *The Code for Self-Regulation of Advertising Content in India*. ASCI. https://www.ascionline.in/wp-content/uploads/2024/04/Code-Book_Codes_Webready.pdf
[152] Federation of Indian Chambers of Commerce & Industry. (2024). *Advertising Standards in India: An Introduction* . https://ficci.in/public/storage/SEDocument/20240/Survey_on_Advertising_Standards.pdf.
[153] Advertising Standards Council of India. (2022, August). *Complaints Procedure*. https://www.ascionline.in/wp-content/uploads/2022/11/asci_complaints_procedures.pdf.
[154] Mehta, A. (2024, May 17). *Research project on False Advertising in the area of Health* (A. Mathur & V. Divan, Interviewers) [Personal communication].

Under the current framework at ASCI, any complaints made are referred to its Consumer Complaints Council (CCC). This council can offer recommendations and suggestions to advertisers, but it is purely voluntary for the advertiser to act upon them. The decision from the CCC takes 4-5 weeks to be conveyed, by which time the advertisement in question may have already run its course. Additionally, the CCC does not have the authority to mandate corrective advertising to rectify consumer perceptions. This complaints redressal process often lacks transparency as complainants are not given reasons for rejection of a complaint and an option to review or appeal the CCC's decision.[155] The ASCI also limits complaints to advertisements not older than 3 months, letting old advertisements still in circulation remain unchallenged.[156]

ASCI's membership includes advertising agencies, media, advertisers, and several other professional bodies.[157] However, not all advertisers are members of ASCI, making it optional to follow its mandate. Lastly, at its core, the ASCI Code consists of general principles but does not provide specific details on what constitutes a false or misleading claim or the evidence an advertiser should present if called upon to do so. The code also does not outline ASCI's process for addressing grievances through the CCC. This information is essential for a self-regulation code to be effective and to maintain some control over advertisers. For instance, the UK self-advertising code specifies the types of claims that an advertiser can make and the necessary evidence and statutory approval required, as discussed later.

2.3.2 Uniform Code for Pharmaceutical Marketing Practices

While advertisements related to drugs and pharmaceutical products are heavily regulated, there is a gap in policy related to the promotion and marketing of drugs and medical devices by companies to healthcare practitioners (HCPs). To provide guidance in this area, the central government issued the updated **Uniform Code of Pharmaceutical Marketing Practices in 2024** (UCPMP).[158] The code provides guidance on marketing of pharmaceutical and medical device products in India. It covers the conduct of medical representatives, the provision of brand reminders and free samples, continuing medical education, and relationships with HCPs, among other crucial areas. It prohibits creating promotional material that disguises the real nature of the marketed drug, such as in mailings or journal advertisements.[159]

Though the self-regulation model is widely and internationally used for pharmaceutical advertising, a key issue is the voluntary nature of the codes and the conflict of interest inherent to their effective functioning. The lack of deterrent sanctions and the codes' non-statutory status skew in favour of advertisers. The same issues persist in the UCPMP, which lacks enforcement mechanisms and also does little to comprehensively cover the types of marketing tactics covered by pharmaceutical companies in India. For instance,

[155] Ibid.
[156] Ibid.
[157] Advertising Standards Council of India. (n.d.). *Current Members of Advertising Standards Council Of India*. ASCI. Retrieved July 18, 2024, from https://www.ascionline.in/current-member/.
[158] Ministry of Chemicals and Fertilizers Department of Pharmaceuticals. (2024). *Uniform Code for Pharmaceutical Marketing Practices*. https://pharmaceuticals.gov.in/sites/default/files/UCPMP%202024%20for%20website_0.pdf
[159] Ibid., Rule 3.

various hospitals, clinics and companies have started advertising screening and laboratory tests regardless of age and risk factors.[160] The UCPMP does not address this, thus creating a regulatory gap.

3. GLOBAL ADVERTISING MODELS

Health product advertising is heavily regulated across jurisdictions. Similar to the Indian model, various countries regulate drugs, medical devices, food and nutrition products with a mix of self and State regulation.[161] The advertising regimes of the United States and the United Kingdom have been selected for discussion due to their distinctive regulatory frameworks and historical evolution. The US exemplifies a State-focused regulatory model, primarily governed by federal and state laws, with agencies like the Federal Trade Commission playing a crucial role.[162] In contrast, the UK showcases a robust co-regulation approach, where the Advertising Standards Authority enforces one of the more comprehensive self-regulation codes.[163] Both countries have seen their advertising regulations evolve since the 19th century, adapting to emerging modes and issues such as digital advertising and influencer marketing.[164] Despite critiques, these models provide valuable insights into the effectiveness and challenges of different regulatory approaches, offering lessons for global advertising practices.

3.1 United Kingdom

General Overview

In the UK, false advertising for health products is regulated through a combination of statutory laws and self-regulation codes. Key legislation includes the *Consumer Protection from Unfair Trading Regulations 2008*, which is based on the principle that advertising claims must be substantiated, accurate, and not misleading. In addition, the Advertising Standards Authority (ASA) is a self-regulating body that enforces the UK Code of Non-broadcast Advertising and Direct & Promotional Marketing (CAP Code)[165] and the UK

[160] Economic Times Brand Equity. (2022, August). *Orange Health promotes its "Lab test in 60 minutes" in new ad - ET BrandEquity*. ETBrandEquity.com. https://brandequity.economictimes.indiatimes.com/news/advertising/orange-health-promotes-its-lab-test-in-60-minutes-in-new-ad/93320749.

[161] To read more about advertising laws in various jurisdictions: Chambers and Partners. (2023, October). *Advertising & Marketing 2023*. https://practiceguides.chambers.com/practice-guides/advertising-marketing-2023 and International Comparative Legal Guides. (2023, July). *Pharmaceutical Advertising Laws and Regulations 2023-2024*. https://iclg.com/practice-areas/pharmaceutical-advertising-laws-and-regulations.

[162] Petty, R. D. (2015). The historic development of modern US advertising regulation. *Journal of Historical Research in Marketing*, *7*(4), 524–548. https://doi.org/10.1108/jhrm-02-2015-0005.

[163] Hawkins, R. A. (2017). The origins of marketing practice in Britain: from the ancient to the early twentieth century. *Journal of Historical Research in Marketing*, *9*(4), 467–487. https://doi.org/10.1108/jhrm-06-2017-0024.

[164] Miracle, G. E., & Nevett, T. (1988). A Comparative History of Advertising Self‐regulation in the UK and the USA. *European Journal of Marketing*, *22*(4), 7–23. https://doi.org/10.1108/eum0000000005278.

[165] Advertising Standards Authority. (2014). *UK Code of Non-broadcast Advertising and Direct & Promotional Marketing*. https://www.asa.org.uk/codes-and-rulings/advertising-codes/non-broadcast-code.html.

Code of Broadcast Advertising (BCAP Code).[166] ASA derives its legal basis and authority from the *Control of Misleading Advertisements Regulations 1988* (CMAR), which allows it to refer advertisers who continuously make false claims and fail to cooperate with self-regulation for legal action with the Office of Fair Trading (OFT).[167] Other regulations that govern this area are the *Human Medicines Regulations 2012*[168] and the *Food Safety Act 1990.*[169]

The UK has a deeply entrenched system of self-regulation that predates the introduction of legal regulation in the country. Thus, regulations are not used to determine whether advertisements are misleading but to provide legal support for self-regulation, thereby increasing its effectiveness.[170] For instance, under the CMAR, a complainant is required and encouraged to exhaust all appropriate means of remedy, such as approaching the self-regulatory body, before making a complaint with the OFT.[171] This means that legal action is only pursued if the remedies under the self-regulation codes fail. Unlike the Indian framework where there is an evident lack of coordination in the operation and formulation of the *Consumer Protection Act* and the ASCI Code, this system provides coordination and statutory support for self-regulation.

Laws Applicable to Food

The *Food Safety Act 1990* (FSA) prohibits the dissemination of false or deceptive descriptions of food products.[172] As per the regulation related to nutrition and health claims made on foods, only those claims authorised on the Great Britain Nutrition and Health Claims Register (GB NHC Register) are permitted to be advertised.[173] The regulation provides detailed guidance on the kind of claims allowed and prohibited. For instance, nutrition and health claims are required to be based on scientific evidence and may only be used in commercial communications if they have been authorised following scientific assessment of substantiating evidence.[174] These strictures ensure a high level of consumer protection, with a comprehensive definition of "claim" and the prohibition of any non-compliant claims.[175] The regulation also extends enforcement and compliance responsibilities to the ASA, bolstering the system of co-regulation, where statutory and voluntary requirements work in conjunction.[176] In contrast with the UK FSA, the FSSAI 2018 guidelines in India list out types

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[166] Advertising Standards Authority. (2010). *UK Code of Broadcast Advertising*. https://www.asa.org.uk/codes-and-rulings/advertising-codes/broadcast-code.html.
[167] *Control of Misleading Advertisements Regulations, 1988*, Regulation 2(2).
[168] *Human Medicines Regulations, 2012*.
[169] *Food Safety Act, 1990*.
[170] *Director General of Fair Trading v Tobyward Ltd* (1989) 2 ALL ER 266.
[171] *Control of Misleading Advertisements Regulations, 1988*, Regulation 4.
[172] *Food Safety Act, 1990*, Section 15.
[173] Department of Health & Social Care. (2021). *Nutrition and health claims: guidance to compliance with Regulation (EC) 1924/2006*. Regulation 1.6 https://www.gov.uk/government/publications/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-1924-2006-on-nutrition-and-health-claims-made-on-foods/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-19242006#nutrition-law.
[174] Ibid.
[175] Vaqué, L. G. (2014). Authorized Health Claims Pursuant to Regulation (EC) No 1924/2006: The Difficulty of Producer-Consumer Communication. *European Food and Feed Law Review*, *9*(1), 2–10. https://effl.lexxion.eu/article/EFFL/2014/1/264.
[176] Department of Health & Social Care. (2021). *Nutrition and health claims: guidance to compliance with Regulation (EC) 1924/2006*. Regulation 9.1 https://www.gov.uk/government/publications/nutrition-and-health-claims-guidance-to-compliance-with-regulati

of claims but fail to provide an authorisation process or detailed guidance on how claims can be made. There is also no reference to self-regulation measures.

Research has revealed that advertising restrictions for HFSS products on children's TV channels were inadequate[177] to protect them from exposure to excessive unhealthy food advertisements that influence their eating behaviour.[178] As a result, TV and on-demand programme services are not allowed to broadcast advertisements and sponsorships for less healthy food and drink products between 5:30 am and 9:00 pm. Additionally, paid-for advertisements targeting UK users for these products are prohibited from being placed online at any time.[179] These restrictions are overseen by the Office of Communications, a statutory body, with the ASA serving as the frontline regulator.[180] Though these restrictions offer an effective and enforceable strategy to tackle obesity in the UK, there has been delay in enforcement until 2025, which is likely to slow down the momentum of reform.[181] On the other hand, despite civil society efforts, India is characterised by the absence of robust legal protection to guard against HFSS and targeted advertising directed at children.

Dietary supplements are defined under the *Food Supplements (England) Regulations 2003* (FSR), which set out specific labelling requirements such as a list of ingredients and nutritional information.[182] These supplements are considered 'food' and related advertisements can only make general health claims if accompanied by an appropriate specific health claim, which is authorised by the GB NHC Register.[183] For instance, an advertisement suggesting a scientific increase in muscle mass was found to be in breach because the claims were not based on authorised claims that appeared in the Register.[184] Claims that state or imply a food prevents, treats, or cures human disease are

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on-ec-1924-2006-on-nutrition-and-health-claims-made-on-foods/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-19242006#nutrition-law.

[177] Ng, D., Froguel, A., & Clark, M. (2020). *Analysis of revenue for ITV1, Channel 4, Channel 5 and Sky One derived from HFSS TV advertising spots in September 2019*. Cancer Research UK. https://www.cancerresearchuk.org/sites/default/files/cruk_report_on_sept19_nielsen_tv_ad_analysis_-_final22july20.pdf.

[178] Cairns, G., Angus, K., Hastings, G., & Caraher, M. (2013). Systematic reviews of the evidence on the nature, extent and effects of food marketing to children. A retrospective summary. *Appetite*, *62*(0195-6663), 209–215. https://doi.org/10.1016/j.appet.2012.04.017.

[179] Department of Health & Social Care, & Department for Digital, Culture, Media & Sport. (2021). *Introducing further advertising restrictions on TV and online for products high in fat, salt and sugar: government response*. https://www.gov.uk/government/consultations/further-advertising-restrictions-for-products-high-in-fat-salt-and-sugar/outcome/introducing-further-advertising-restrictions-on-tv-and-online-for-products-high-in-fat-salt-and-sugar-government-response#executive-summary.

[180] Office of Communications. (2023). *Regulation of advertising for less healthy food and drink*. https://www.ofcom.org.uk/siteassets/resources/documents/consultations/category-1-10-weeks/254183-regulation-of-advertising-of-less-healthy-food-and-drink/associated-documents/regulation-of-advertising-for-less-healthy-food-and-drink.pdf.

[181] Clark, M. (2022, December 15). *Junk food marketing restrictions: so near and yet so far - CRUK*. Cancer Research UK - Cancer News. https://news.cancerresearchuk.org/2022/12/15/junk-food-marketing-restrictions-so-near-and-yet-not-quite/.

[182] Department of Health. (2011). *Summary information on legislation relating to the sale of food supplements*. https://assets.publishing.service.gov.uk/media/5a7b8297e5274a7318b8f20d/Supplements_Summary__Jan_2012__DH_FINAL.doc.pdf.

[183] Advertising Standards Authority. (2014). *UK Code of Non-broadcast Advertising and Direct & Promotional Marketing*. Section 15 https://www.asa.org.uk/codes-and-rulings/advertising-codes/non-broadcast-code.html.

[184] Advertising Standards Authority. (2013). *ASA Adjudication on LA Muscle Ltd*. https://www.asa.org.uk/rulings/LA-Muscle-Ltd-A13-242376.html.

prohibited. Medicinal claims can only be made for a product licensed by the Medicine and Healthcare Products Regulatory Authority (MHRA).[185] While not strictly defined by the law, nutraceuticals are regulated under general food law and must comply with health claims regulations. In India, unlike the regulations for dietary supplements and nutraceuticals in the UK, authorization is not required for health claims. This leaves the market open to unsubstantiated and unverified claims by advertisers.

Laws Applicable to Pharmaceutical Products

The *Human Medicines Regulations 2012* impose several restrictions. They prohibit the marketing of medical products that are not licensed by the MHRA, and advertising of prescription drugs.[186] Also, OTC drugs can be advertised but must include clear labelling requirements, such as the product's active ingredients, instructions for use, and warnings about side effects.[187] Further, Ayurvedic products, which are classified under herbal medicines, must comply with the Traditional Herbal Registration Scheme to ensure safety, quality, and efficacy.[188]

The MHRA's Blue Guide on advertising and promoting medicines in the UK is a comprehensive catalogue for advertisers.[189] Along with referring to the CAP Code, the MHRA also encourages advertisers to consult with trade associations or self-regulatory bodies to check their advertisements. For example, for OTC medicines, the Proprietary Association of Great Britain reviews all of their members' advertising against their codes of practice.[190] There is a vast difference in India, in that there is a lack in guidance of drug advertising as compared to the UK. The MHRA Blue Guide is a comprehensive and detailed set of guidelines of dos and don'ts, while the DMRA in India is a colonial-era legislation that is brief and inadequate to keep pace with the times. Additionally, the pharmaceutical self-regulation code in India, UCPMP, falls short in comparison to the CAP Code in the UK. The UCPMP only covers advertisements to healthcare professionals and omits direct-to-consumer advertisements of OTC drugs.

The MHRA enforces regulations but delegates a large portion of its responsibility to the Association of the British Pharmaceutical Industry (ABPI), a prominent national industry trade group. To prevent unauthorised marketing of prescription-only medicines, the ABPI has developed a Code of Practice for companies, along with various guidance documents and support mechanisms.[191] The ABPI's self-regulatory authority, the Prescription Medicines Code of Practice Authority (PMCPA) administers these.[192] The MHRA also works closely and engages with other industry and self-regulatory authorities through joint statements, group

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[185] *Human Medicines Regulations, 2012*, Section 15.2.
[186] Ibid., Section 284.
[187] Ibid., Section 291.
[188] Ibid., Section 302.
[189] Medicines and Healthcare products Regulatory Agency. (2014). *Blue Guide: advertising and promoting medicines*. https://www.gov.uk/government/publications/blue-guide-advertising-and-promoting-medicines.
[190] Proprietary Association of Great Britain. (2019). *Advertising Consumer Code for Medicines*. PAGB. https://www.pagb.co.uk/otc-medicines/advertising-consumer-code-for-medicines/.
[191] Prescription Medicines Code of Practice Authority. (2021). *The ABPI Code of Practice for the Pharmaceutical Industry*. https://www.pmcpa.org.uk/media/3406/2021-abpi-code-of-practice.pdf.
[192] Prescription Medicines Code of Practice Authority. (2024). *Consultation on the proposed changes to the 2021 ABPI Code and the Constitution and Procedure*. https://www.pmcpa.org.uk.

meetings and memorandums.[193] This classification, between the marketing of prescription-only and OTC drugs, is absent from the Indian framework and the UCPMP self-regulation code.

Despite the regulatory framework, the MHRA is heavily inclined to give corporations the benefit of the doubt, leading to a heavy reliance on self-regulation as a self-contained form of governance. The MHRA only investigates a small number of allegations of illegal promotion, with the majority of complaints being handled by the PMCPA.[194] Monitoring marketing practices, including adherence to approved labels, is mainly entrusted to self-regulatory bodies organised by pharmaceutical industry trade associations. Research has shown this has led to frequent violations of self-regulation codes and the law. Lengthy complaint processing times allow companies to continue questionable practices while investigations are ongoing.[195] There have been calls for government regulators to increase their role and impose heavy penalties on repeat offenders to ensure compliance and maintain public trust in the regulatory system, using the US model as an example.[196]

Observations

The UK's framework is heavily reliant on self-regulatory bodies. A major criticism, then, is also the potential for conflicts of interest. Despite the ASA's and PMCPA's efforts to improve governance and transparency, structural power imbalances persist. That the CAP Code is written and partially presided over by industry representatives raises concerns of transparency and procedural intergrity. In tilting towards industry, this can compromise the ASA's ability to act independently and in the public interest.[197] While aiming to work in both the industry's and the public's interest, the ASA's self-regulatory system may favour the industry due to its governance structure, funding model, and limited public engagement. Similarly, companies found in breach of the ABPI Code must pay "administrative charges" to contribute to the costs of processing complaints. These payments are not explicitly fines, effectively signaling that deterrence is not deployed against companies who indulge in wrongful marketing.[198]

On the other hand, the UK's legal framework for advertising health products is well-regulated and comprehensive, albeit complex, with multiple independent players at

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[193] Medicines and Healthcare products Regulatory Agency. (2014). *Blue Guide: advertising and promoting medicines*. https://www.gov.uk/government/publications/blue-guide-advertising-and-promoting-medicines.

[194] Zetterqvist, A. V., Merlo, J., & Mulinari, S. (2015). Complaints, Complainants, and Rulings Regarding Drug Promotion in the United Kingdom and Sweden 2004–2012: A Quantitative and Qualitative Study of Pharmaceutical Industry Self-Regulation. *PLOS Medicine*, *12*(2), e1001785. https://doi.org/10.1371/journal.pmed.1001785.

[195] Mulinari, S., Pashley, D., & Ozieranski, P. Patterns of company misconduct, recidivism, and complaint resolution delays: A temporal analysis of UK pharmaceutical industry self-regulation within the European context. *Regulation & Governance*. https://doi.org/10.1111/rego.12609.

[196] University of Bath. (2024, June). *UK Drug Companies Repeatedly Violate their Marketing Code, warns research*. Www.bath.ac.uk. https://www.bath.ac.uk/announcements/new-research-uk-drug-companies-repeatedly-violate-their-marketing-code-warns-research/.

[197] Auxtova, K., Brennan, M., & Dunne, S. (2020). To Be or Not to Be Governed Like That? Harmful and/or Offensive Advertising Complaints in the United Kingdom's (Self-) Regulatory Context. *Journal of Business Ethics*, *172*. https://doi.org/10.1007/s10551-020-04480-x.

[198] Prescription Medicines Code of Practice Authority. (2021). *The ABPI Code of Practice for the Pharmaceutical Industry*. https://www.pmcpa.org.uk/media/3406/2021-abpi-code-of-practice.pdf.

different levels. A key success is the robust guidance available on the types of claims and the authorisation process. The framework is mature in establishing a functional relationship between statutory and voluntary authorities to better monitor and evaluate false and misleading advertisements. A huge plus is that compliance with the appropriate Advertising Code enforced by ASA is mandatory, which gives teeth to the organisation to take necessary actions. Self-regulation is widely supported by professional bodies, regulators, and industry. However, it has been suggested that the government should consider implementing a more rigorous and punitive approach to addressing corporate misconduct that extends beyond self-regulation.[199]

UK Laws and Regulations at a Glance

Product Category	Type of Claim Allowed	Requirement	Proof of Claim	Prior Approval
Food Products	Nutritional and health claims	Comply with Food Information Regulations 2014 and Regulation (EC) No 1924/2006	Must be substantiated by generally accepted scientific evidence	No, but must comply with the regulations
Dietary Supplements	Nutritional and health claims	Comply with Food Supplements (England) Regulations 2003	Must provide evidence that claims are scientifically valid, typically involving published studies and/or clinical trials	No, but must comply with statutory regulations
Nutraceuticals	Nutritional and health claims	Regulated under general food law and must meet health claims regulations	Must be substantiated by scientific evidence, the same as dietary supplements	No, but claims must comply with relevant regulations
Over-the-counter (OTC) Drugs	Safety, efficacy, and usage claims	Medicines and Healthcare products Regulatory Agency (MHRA) approval required	Requires robust clinical trial data proving safety and efficacy	Yes, MHRA approval before advertising
Prescription Drugs	Safety, efficacy, and usage claims (restricted to healthcare professionals)	MHRA approval required	Extensive clinical trials and peer-reviewed studies prove safety and efficacy	Yes, advertising to the public is not allowed; professional materials must be MHRA-approved

[199] Davis, C., & Abraham, J. (2013). Is there a cure for corporate crime in the drug industry? *BMJ*, *346*. https://doi.org/10.1136/bmj.f755.

Ayurvedic Products	Traditional use and efficacy claims	Must comply with the Traditional Herbal Registration Scheme (THRS)	Must demonstrate quality, safety, and efficacy, supported by traditional use and some scientific evidence	THRS registration is required before marketing
Medical Devices	Safety, efficacy, and performance claims	Conformity assessment and UK Conformity Assessed (UKCA) marking required by the MHRA.	Must provide clinical data demonstrating safety and performance, supported by scientific evidence	Yes, MHRA approval is required before advertising.

3.2 United States of America

General Overview

The United States has long-standing federal laws that regulate false and deceptive advertising. The Federal Trade Commission (FTC) and the US Food and Drug Administration (FDA) are the primary authorities responsible for overseeing the advertising of health products. A Memorandum of Understanding divides responsibilities between the two authorities. The FDA is responsible for claims found in labelling, such as on packaging, product inserts, and other promotional materials available at the point of sale, and the FTC is responsible for claims in all forms of advertising.[200] Along with other federal Acts, all states also have consumer protection laws that apply to advertisements and products sold in that state.[201]

False advertising falls under the category of 'unfair business practices,' and each advertisement is evaluated based on its overall impression. Authorities focus largely on the type of claims made by the advertisement. The FTC, under its broad statutory mandate, can request the advertiser to provide evidence of the claim made. If the evidence is not sufficient, the FTC can take legal action to prevent further misleading advertising.[202] While the FTC applies to all advertising, the FDA regulations distinguish between claims based on the type of claim (health claim, structure/function claim, or drug claim) and the type of product (food, supplement, or drug).[203]

Enforcement is primarily through the FTC and FDA and state authorities, which use monetary penalties, cease-and-desist orders and court reviews to ensure compliance with laws. Between 2003 and 2016, numerous pharmaceutical companies received significant financial penalties from US federal and state authorities for participating in illegal activities,

[200] The Federal Trade Commission, & The Food and Drug Administration. (1971). *MOU 225-71-8003*. https://www.fda.gov/about-fda/domestic-mous/mou-225-71-8003.
[201] The Lanham Act 1946 is the federal legislation regulating trademarks in the US. The Act prescribes liability for false advertising as a civil actionable claim under section 43(a). For more information: Tushnet, R. (2011). Running the Gamut from A to B: Federal Trademark and False Advertising Law. *University of Pennsylvania Law Review*, *159*(5). https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1823396.
[202] Federal Trade Commission. (2021). *A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority*. https://www.ftc.gov/about-ftc/mission/enforcement-authority.
[203] *Federal Food, Drug, and Cosmetic Act, 1938*.

such as engaging in deceptive marketing practices and off-label marketing.[204] Over the last decade, the FTC has filed 120 cases challenging health claims made for supplements.[205] According to some studies, this penalty-based and state-enforced system while not eradicating the problem, is more successful at detecting and penalising wrongdoing than self-regulation systems.[206]

Laws applicable to Food

The FDA oversees the labelling of food products, including dietary and health supplements, to ensure that labels are truthful and not misleading. The agency mandates that labels include accurate nutrition information, ingredient lists, and any necessary health warnings.[207] It also approves health claims on labels that suggest a relationship between a food or dietary supplement and a disease or health-related condition. These claims must be backed by significant scientific agreement among qualified experts.[208] For example, a product claiming to lower the risk of heart disease must have substantial scientific evidence supporting that claim. However, under the *Dietary Supplement Health and Education Act* of 1994, which defines dietary supplements, the FDA does not have the authority to approve dietary supplements for safety and effectiveness or their labelling before they are sold. Despite this, the FDA monitors and inspects the dietary supplement marketplace and imposes marketing and labelling requirements.[209] Similar to the UK's regulations, health claims in the US also require authorization, which is not the case under Indian law.

Additionally, under the *Nutrition Labelling and Education Act* (NLEA) of 1990, food products are considered misbranded unless their label bears nutrition information specified by the Act.[210] After the NLEA was implemented, the FTC also issued a policy statement on food advertising that automatically makes claims acceptable for advertising if they conform to FDA regulations. Therefore, claims inadmissible for labelling are not admissible in advertising as well.[211] This link between advertising and labelling is valuable for monitoring and scrutinizing product claims. However, in India neither the DMRA nor the *Drugs and Cosmetics Rules* make this connection.

The FTC regulates advertising and marketing practices. Its mandate is to ensure that all advertising claims, including those made for food products and dietary supplements, are truthful, not misleading, and substantiated by competent and reliable scientific evidence.[212]

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[204] Arnold, D. G., Stewart, O. J., & Beck, T. (2020). Financial Penalties Imposed on Large Pharmaceutical Firms for Illegal Activities. *JAMA*, *324*(19), 1995. https://doi.org/10.1001/jama.2020.18740.
[205] Federal Trade Commission. (n.d.). *Health Claims*. https://www.ftc.gov/news-events/topics/truth-advertising/health-claims.
[206] Vilhelmsson, A., Davis, C., & Mulinari, S. (2016). Pharmaceutical Industry Off-label Promotion and Self-regulation: A Document Analysis of Off-label Promotion Rulings by the United Kingdom Prescription Medicines Code of Practice Authority 2003–2012. *PLOS Medicine*, *13*(1), e1001945. https://doi.org/10.1371/journal.pmed.1001945.
[207] *Federal Food, Drug, and Cosmetic Act, 1938*, Section 403A.
[208] *Federal Food, Drug, and Cosmetic Act, 1938*, Section 403(r).
[209] FDA Office of Dietary Supplement Programs. (n.d.). *Dietary Supplements*. US Food & Drug Administration. https://www.fda.gov/food/dietary-supplements.
[210] *Nutrition Labeling and Education Act, 1990*.
[211] Economic Research Service. (n.d.). *Regulation of Advertising and Labeling: Conditions of Private Information Supply*. https://www.ers.usda.gov/webdocs/publications/41905/51665_ah715c.pdf?v=0.
[212] *Federal Trade Commission Act,1914*, Sections 5 and 12.

For instance, if a company advertises a supplement as boosting immunity, the FTC requires that the claim be supported by solid scientific proof.[213]

However, there are criticisms regarding the effectiveness of these regulations. For instance, during a study conducted from 2007 to 2016, it was discovered that despite FDA warnings, several dietary supplements marketed for sexual enhancement, weight loss, etc., contained undisclosed and unapproved pharmaceutical ingredients. This indicates shortcomings in the enforcement and existing framework for non-pre-approval of dietary supplements.[214] The FTC has also been criticised for its ineffectiveness in regulating advertising targeted towards children. Its efforts at introducing such regulation received strong criticism from food-making industries, which sought self-regulation through the Children's Advertising Review Unit (CARU).[215] In addition, the current regulations do not cover the online sales context sufficiently, where consumers often cannot inspect products directly and must rely on the information presented by retailers. In these circumstances, regulatory action by federal agencies is necessary to mandate clear and conspicuous disclosure of required labelling information in the online marketplace.[216] Lastly, the FDA's current system relies heavily on Warning Letters and is undermined by inadequate resources and a lack of clear enforcement mechanisms, providing insufficient consumer protection from misleading labels, and fostering an environment where voluntary compliance is the primary 'enforcement' mechanism.[217]

Laws applicable to pharmaceutical products

All marketing and advertising of pharmaceutical products is also primarily overseen by the FDA and the FTC.[218] The FDA is responsible for the approval and regulation of both prescription and non-prescription (OTC) drugs, ensuring that they are safe and effective for their intended uses.[219] It mandates that drug labels include comprehensive information such as indications, dosage instructions, potential side effects, and contraindications. Prescription drug labels must also include a detailed package insert with additional medical information.[220] The FDA also reviews and approves all claims related to a drug's safety and

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[213] Federal Trade Commission. (2022, December). *Health Products Compliance Guidance*. https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Guidance-508.pdf.

[214] Tucker, J., Fischer, T., Upjohn, L., Mazzera, D., & Kumar, M. (2018). Unapproved Pharmaceutical Ingredients Included in Dietary Supplements Associated With US Food and Drug Administration Warnings. *JAMA Network Open*, *1*(6), e183337. https://doi.org/10.1001/jamanetworkopen.2018.3337.

[215] Mello, M. M. (2010). Federal Trade Commission Regulation of Food Advertising to Children: Possibilities for a Reinvigorated Role. *Journal of Health Politics, Policy and Law*, *35*(2), 227–276. https://doi.org/10.1215/03616878-2009-051.

[216] Pomeranz, J. L., Cash, S. B., Springer, M., Del Giudice, I. M., & Mozaffarian, D. (2022). Opportunities to address the failure of online food retailers to ensure access to required food labelling information in the USA. *Public Health Nutrition*, *25*(5), 1–9. https://doi.org/10.1017/s1368980021004638.

[217] Pomeranz, J. L. (2013). A Comprehensive Strategy to Overhaul FDA Authority for Misleading Food Labels. *American Journal of Law & Medicine*, *39*(4), 617–647. https://doi.org/10.1177/009885881303900403.

[218] US Food and Drug Administration. (2015). *Prescription Drug Advertising | Questions and Answers*. https://www.fda.gov/drugs/prescription-drug-advertising/prescription-drug-advertising-questions-and-answers.

[219] Food and Drug Administration, & Department of Health and Human Services. (2024). *Code of Federal Regulations*. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-201. 21 CFR 201 Labeling Sections 10, 100, & 200.

[220] Ibid., Subpart B and Subpart C.

efficacy before the product can be marketed. However, it does not review the advertisement.[221]

The US is one of only two countries that allows direct-to-consumer (DTC) prescription drug advertisements.[222] DTC advertising of prescription drugs has been widely criticised for leading to over-prescription and the use of expensive medications that may not be necessary, driven by consumer demand rather than medical need.[223] Furthermore, DTC advertisements may not always provide a balanced view of risks and benefits, potentially misleading consumers.[224] Reviews indicate DTC advertising has often failed to satisfy its purpose of aiding consumers with accurate and balanced information.[225] One analysis of consumer-targeted prescription and non-prescription drug advertising on television revealed a huge number of advertisements to be potentially misleading and false.[226]

Drug labelling standards in the US are rigorous and primarily governed by the FDA. These requirements ensure that drug labels provide specific information for safe and effective use by healthcare providers and patients.[227] Key information that must be included on drug labels includes the drug's name, dosage form, strength, recommended dosage, administration methods, indications and usage, contraindications, warnings, precautions, adverse reactions, and detailed pharmacological properties.[228] Additionally, prescription drug labels must include a "black box warning" for drugs with serious or life-threatening risks.[229] These comprehensive labelling requirements aim to provide all necessary information for the safe administration and consumption of the drug, minimising the potential for misuse and adverse effects. This is in stark contrast to the very basic labelling standards enforced in India under the *Drugs and Cosmetics Rules*.

Lastly, the FTC regulates the advertising of non-prescription drugs, ensuring that all promotional claims are truthful, not misleading, and substantiated by scientific evidence.[230] The FDA's authority is limited to overseeing pharmaceutical companies and manufacturers,

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[221] US Food and Drug Administration. (2020). *Drug Advertising: A Glossary of Terms*. https://www.fda.gov/drugs/prescription-drug-advertising/drug-advertising-glossary-terms#substantial_evidence.
[222] Food and Drug Administration, & Department of Health and Human Services. *Code of Federal Regulations*. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-202. 21 CFR 202 Prescription Drug Advertising Section 202.1.
[223] Shrank, W., Avorn, J., Rolon, C., & Shekelle, P. (2007). Medication Safety: Effect of Content and Format of Prescription Drug Labels on Readability, Understanding, and Medication Use: A Systematic Review. *Annals of Pharmacotherapy*, *41*(5), 783–801. https://doi.org/10.1345/aph.1h582.
[224] Stange, K. C. (2007). Time to Ban Direct-to-Consumer Prescription Drug Marketing. *The Annals of Family Medicine*, *5*(2), 101–104. https://doi.org/10.1370/afm.693.
[225] Parekh, N., & Shrank, W. H. (2018). Dangers and Opportunities of Direct-to-Consumer Advertising. *Journal of General Internal Medicine*, *33*(5), 586–587. https://doi.org/10.1007/s11606-018-4342-9.
[226] Faerber, A. E., & Kreling, D. H. (2013). Content Analysis of False and Misleading Claims in Television Advertising for Prescription and Nonprescription Drugs. *Journal of General Internal Medicine*, *29*(1), 110–118. https://doi.org/10.1007/s11606-013-2604-0.
[227] Food and Drug Administration, & Department of Health and Human Services. (2024). *Code of Federal Regulations*. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-201. 21 CFR 201.56 Labeling.
[228] US Food and Drug Administration. (2023). *How Do I Use Prescription Drug Labeling*. https://www.fda.gov/about-fda/oncology-center-excellence/how-do-i-use-prescription-drug-labeling.
[229] Murphy, S., & Roberts, R. (2006). "Black box" 101: How the Food and Drug Administration evaluates, communicates, and manages drug benefit/risk. *Journal of Allergy and Clinical Immunology*, *117*(1), 34–39. https://doi.org/10.1016/j.jaci.2005.10.03.
[230] Federal Trade Commission. (2024). *Truth In Advertising*. Federal Trade Commission. https://www.ftc.gov/news-events/topics/truth-advertising.

which means that marketing activities from healthcare establishments such as clinics, hospitals, and health systems often fall outside the FDA's jurisdiction. As a result, these activities are subject to the general advertising rules and regulations enforced by the FTC.[231]

Self-Regulation

The National Advertising Division (NAD) is a self-regulatory body within the advertising industry, operating under the umbrella of the Better Business Bureau's National Programs. Its primary role is to ensure truthfulness and accuracy in national advertising, providing a platform for resolving disputes over advertising claims without resorting to litigation or government intervention.[232] The NAD initiates reviews based on complaints from competitors, consumers, or its own monitoring activities. When it finds that an advertisement is misleading or unsubstantiated, it recommends that the advertiser modify or discontinue the claim. If the advertiser refuses to comply, the NAD can refer the case to the FTC or other regulatory bodies for enforcement action.[233]

The Pharmaceutical Research and Manufacturers of America (PhRMA) plays a significant role in the self-regulation and marketing of drugs in the US. PhRMA is an industry trade group representing leading biopharmaceutical research companies.[234] It has established a Code on Interactions with Healthcare Professionals, which sets ethical standards for marketing practices and interactions with healthcare providers. This code aims to ensure that drug marketing is conducted in a manner that prioritises patient welfare and the integrity of the healthcare decision-making process.[235] PhRMA's self-regulation efforts include guidelines that prohibit certain marketing practices, such as lavish gifts and entertainment for healthcare professionals while promoting transparency in clinical trials and financial relationships between industry and healthcare providers.[236] These guidelines are designed to mitigate potential conflicts of interest and ensure that promotional activities are grounded in accurate, evidence-based information. PhRMA has also issued DTC advertising principles[237] for its members.

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[231] J. Moore, T., & Alexander, G. C. (2023, January 26). A dangerous loophole for drug ads needs to be closed. *STAT*. https://www.statnews.com/2023/01/26/drug-ads-dangerous-drug-advertising-loophole/#:~:text=False%20and%20misleading%20ads%20about.

[232] Better Business Bureau. (n.d.). *National Advertising Review Board*. BBBPrograms. https://bbbprograms.org/programs/all-programs/national-advertising-review-board.

[233] American Bar Association. (2015). *Self-Regulation of Advertising in the Unites States: An Assessment of the National Advertising Division*. https://s3.amazonaws.com/cdn.kelleydrye.com/content/uploads/attachments/Self-Regulation-of-Advertising-in-the-United-States-An-Assessment-of-the-National-Advertising-Divis.pdf.

[234] Pharmaceutical Research and Manufacturers of America. (n.d.). *Our Mission*. PhRMA. https://phrma.org/About.

[235] Pharmaceutical Research and Manufacturers of America. (2002). *PhRMA Code on Interactions with Healthcare Professionals*. https://meded.ucsf.edu/sites/meded.ucsf.edu/files/inline-files/PhRMACode.pdf.

[236] Pharmaceutical Research and Manufacturers of America. (2016). *Responsible Sharing of Information About Medicines*. https://phrma.org/resource-center/Topics/Safety-Medicines/phrma-principles-on-responsible-sharing-of-truthful-and-non-misleading-information-about-medicines-with-health-care-professionals-and-payers.

[237] Pharmaceutical Research and Manufacturers of America. (2018). *Direct to Consumer Advertisements Principles*. https://phrma.org/resource-center/Topics/Cost-and-Value/Direct-to-Consumer-Advertising-Principles.

Research reveals that self-regulation in the US has not been as strict or impartial in regulating DTC advertising as external regulation by government agencies like the FTC and FDA.[238] Additionally, while the PhRMA code prohibits typical gifts such as pens and mugs, it does allow gifts valued at $100 or less that are meant for educating patients or healthcare professionals. The code also permits providing meals and free samples.[239] Moreover, the effectiveness of PhRMA's self-regulation is often questioned because compliance is voluntary, and violations do not always result in significant penalties. This has led to calls for stronger oversight and more rigorous enforcement mechanisms to ensure that marketing practices genuinely protect consumer interests and maintain the integrity of healthcare delivery.[240]

PhRMA also has a huge influence on various governmental actions and inactions as well as inter-country trade and investment agreements.[241] Similarly, there are concerns that NAD's guidelines lack enforceability and may be influenced by the industry's financial interests.[242] For instance, despite ethical guidelines, there have been instances where aggressive marketing practices have led to the promotion of drugs for off-label use or the downplaying of potential risks, contributing to public health issues like the opioid crisis.[243]

Observations

While the FDA and FTC aim to protect consumers, their jurisdictions are distinct yet complementary. The collaboration between the FDA and FTC ensures substantial oversight - from the information provided on the product packaging to the claims made in advertisements. An example of this distinction can be seen in the regulation of health supplements: the FDA reviews and approves the health claims on a supplement's label,

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[238] Applequist, J., & Ball, J. G. (2018). An Updated Analysis of Direct-to-Consumer Television Advertisements for Prescription Drugs. *Annals of Family Medicine*, *16*(3), 211–216. https://doi.org/10.1370/afm.2220. *See also* Frosch, D. L., Grande, D., Tarn, D. M., & Kravitz, R. L. (2010). A Decade of Controversy: Balancing Policy With Evidence in the Regulation of Prescription Drug Advertising. *American Journal of Public Health*, *100*(1), 24–32. https://doi.org/10.2105/ajph.2008.153767.

[239] Pharmaceutical Research and Manufacturers of America. (2019). *Code of Pharmaceutical Marketing Practices*. https://www.ifpma.org/wp-content/uploads/2022/12/PhAMA-Code-21st-Edition-1.pdf.

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while the FTC scrutinises advertisements for the same supplement to ensure that they are not deceptive. By working together, the FDA and FTC provide a robust framework to protect consumers from false or misleading claims about food products and dietary supplements, ensuring that all claims are accurate and scientifically substantiated.

The self-regulation system for advertising in the US, under the control of the NAD and PhRMA, has shown both effectiveness and limitations. These bodies provide a framework for ethical advertising practices, encouraging companies to adhere to established standards. For example, the FTC and NAD's collaboration in monitoring and reviewing health product advertising has led to increased scrutiny and compliance.[244] The NAD also offers a platform for resolving disputes without resorting to litigation, which can be both time-efficient and cost-effective. However, the self-regulation system has notable weaknesses - laxity and bias being two - which are also evident in the functioning of NAD and PhRMA.

US Laws and Regulations at a Glance

Product Category	Type of Claim Allowed	Approval Process	Threshold of Evidence	Prior Approval Required
Food Products	Nutritional and health claims	Comply with FDA regulations (e.g., NLEA)	Must be substantiated by scientific evidence	No, but must notify the FDA and comply with regulations. Only health claims require FDA authorisation
Dietary Supplements	Nutritional and health claims	Comply with the Dietary Supplement Health and Education Act (DSHEA)	Must provide evidence that claims are scientifically valid, typically involving published studies and/or clinical trials	No, but must notify the FDA and comply with regulations. Only health claims require FDA authorisation
Nutraceuticals	Nutritional and health claims	Regulated under general food law and DSHEA	Must be substantiated by scientific evidence, the same as dietary supplements	No, but must notify the FDA and comply with regulations. Only health claims require FDA authorisation
HFSS Foods	Nutritional and health claims (with restrictions on targeting children)	Comply with general food advertising regulations (FTC)	Requires evidence to support health claims, usually scientific studies	No, but must notify the FDA and comply with regulations. Only health claims require FDA authorisation
Over-the-counter (OTC) Drugs	Safety, efficacy, and usage claims	FDA approval required	Requires robust clinical trial data proving safety and efficacy	Yes, FDA approval before advertising

[244] Mengist, D., Foster, K., & Pippins, R. (2023). FTC and NAD Remind Industry of Their Authority Over All Health Product Advertising (Including Rx). In *Food and Drug Law Institute*. https://www.fdli.org/2023/02/ftc-and-nad-remind-industry-of-their-authority-over-all-health-product-advertising-including-rx/.

Prescription Drugs	Safety, efficacy, and usage claims	FDA approval required	Extensive clinical trials and peer-reviewed studies prove safety and efficacy	Yes, FDA approval before advertising
Ayurvedic Products	Traditional use and efficacy claims	Must comply with DSHEA and FTC regulations	Must demonstrate quality, safety, and efficacy, supported by traditional use and some scientific evidence	No, but it must comply with the regulations
Medical Devices	Safety, efficacy, and performance claims	FDA approval and 510(k) clearance or PMA required	Must provide clinical data demonstrating safety and performance, supported by scientific evidence	Yes, FDA approval is required before advertising.

4. CONCLUSION AND RECOMMENDATIONS

The Indian system designed to protect consumers from misleading advertising is often opaque and ineffective, posing a dire **threat to public health and the right to health** enshrined in the Indian Constitution. With the proliferation of products based on unsubstantiated health claims, the urgency for a robust legal and policy framework cannot be overstated. Vulnerable consumers, often with limited information, are bombarded with deceptive advertisements that exploit their health concerns, leading to potentially dangerous health choices and financial losses. This rampant misinformation not only undermines consumer protection but also jeopardizes the fundamental right of individuals to make informed health decisions, threatening their overall well-being and trust in health-related communications. The need for immediate and comprehensive regulatory reform is critical to address these challenges and protect the health and rights of the population.

Industry arguments against overregulation through advertising laws foists the burden on consumers to be responsible for their choices. In a market saturated with deceptive advertisements, consumers often lack the knowledge and resources to differentiate between truth and falsehood. This underscores the necessity for a more **proactive regulatory approach that does not overly depend on consumer vigilance**. Presently, regulations for misleading advertisements in India are fragmented. Multiple regulators have overlapping mandates, each defining 'advertisements' and 'misleading advertisements' in their own context. This lack of a unified approach hinders comprehensive oversight of advertising. It is crucial to harmonise the existing framework, prioritising enforceability and cooperation among regulators.

Current regulations must also be promptly updated to keep up with the rapid evolution of digital and social media advertising. The extant regulatory framework struggles to keep pace with the dynamic nature of digital platforms, where advertisements can spread rapidly and

target specific groups with personalised messages. Therefore, new policies must **minimise the loopholes related to digital and social media advertising** to robustly protect consumers.

To tackle the issue of inadequate enforcement, policies should include **systematic and routine monitoring, evaluation and review processes to hold enforcing authorities accountable**. Strengthening implementation and monitoring mechanisms is crucial to ensure that regulations are well-crafted and effectively enforced.

To balance industry and consumer representation, the **public's participation in policymaking** needs to be increased. Consumer groups and public health organisations provide valuable insights that can assist in creating more effective regulations that align with consumer needs and expectations. By enhancing public engagement and fostering a participatory approach, far more effective consumer protection measures can be implemented.

Self-regulatory authorities like the ASCI play a crucial role in preventing misleading advertising. However, they are often given responsibilities without the corresponding authority or checks. While the ASCI oversees advertising standards, it lacks the necessary enforcement powers to ensure compliance. This significantly undermines its effectiveness and underscores the urgent need for a more **empowered ASCI with adequate resources and authority** to carry out its mandate. Such a commitment also requires a system to conduct **social audits and implement checks and balances to ensure accountability and transparency in the advertising industry**. Strengthening the existing infrastructure of the ASCI can help expand its coverage over digital and social media and establish regional units for better coverage across the nation.

With the issue of false advertising gaining more awareness, various government offices have issued advisories. An essential advisory by the Ministry of Information and Broadcasting mandates self-declaration for all advertisements, and shifts the regime from ex-post to ex-ante obligations. While this new approach may help prevent misleading advertisements from being aired, it has some ambiguities. A one-size-fits-all approach is unsuitable and cannot be applied to all advertisements and claims. Especially **for health product claims, it is important to have clear definitions, specific claims, and the scientific evidence** required to support each claim. Having clear definitions of the types of claims allowed for health products - structure-function claims, reminder claims etc. - can help in better enforcement of the law. In that vein, the *Food Safety and Standards (Advertisements & Claims) Regulations, 2018*, which define health, nutrition and non-nutrition claims, and require scientific evidence, should be strictly enforced. These definitions should be tailored for advertisements making health and nutrition claims to ensure that all claims are credible and reliable. Here too, there is a need to ensure consistent and clear definitions of words like ‘advertisement’ and ‘misleading advertisements’ across these different sectors and mediums. Such clarity in what amounts to a misleading advertisement can significantly augment enforcement.

Learning from international models can provide valuable insights for strengthening India's regulatory framework. The United States, for example, mandates advertisement design guidelines for pharmaceuticals, requiring supporting material for health claims to be

mentioned in the advertisement. In contrast to consumer courts in India, the FTC protects consumers by filing class action suits on their behalf and ensuring compensation for affected consumers. It might be beneficial to establish a specific commission to address unfair trade practices, similar to the system in Canada, which effectively handles misleading advertisements as part of unfair trade practices under its *Competition Act*.

Similarly, the United Kingdom's approach underscores the importance of a co-regulatory system. The UK model leverages the existing capabilities of various industry bodies, prioritising self-regulation as the primary approach while implementing thorough checks. A clear differentiation between self-regulatory codes for print and media and statutory pre-marketing approvals for drug advertisements ensures that regulatory frameworks remain adaptable and responsive to industry advancements.

International standards, such as the WHO Ethical Criteria for Medical Drug Promotion[245] and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) code,[246] can enhance the regulatory framework. These standards provide a reference point for ethical advertising practices and can help bring India's regulations in line with global best practices. Aligning with these standards supports Sustainable Development Goals, particularly Goal 3, which focuses on ensuring healthy lives and promoting well-being for all at all ages. By adopting these international standards, India can not only meet international obligations, but also improve public health outcomes, increase consumer access and awareness to health-related information, limit deaths related to NCDs, and foster a more responsible and ethical advertising environment.

In conclusion, effective regulation of health product advertising in India calls for a comprehensive approach that tackles existing challenges and draws on global best practices. By establishing clear, uniform definitions across all sectors and mediums, strengthening enforcement and monitoring mechanisms, and fostering active public participation, India can significantly enhance consumer protection and ensure the dissemination of accurate health information. Such reforms are not just regulatory necessities but moral imperatives to safeguard the health and well-being of the population. Implementing these changes will empower consumers, curb the spread of misleading health claims, and promote a more informed and healthier public. This proactive stance will not only protect the individual's right to health but also foster greater trust in health information, ultimately contributing to a more resilient and healthy society.

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[246] International Federation of Pharmaceutical Manufacturers & Associations. (2023). *IFPMA Code of Practice*. https://www.ifpma.org/wp-content/uploads/2018/09/2023_IFPMA-Code-Interactive.pdf.

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