

HEALTH AND WELLNESS CLAIMS: REGULATORY EVOLUTION, PUBLIC PERCEPTIONS, AND SCIENTIFIC CHALLENGES

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Abstract:

Post-2020, assertions of nutritional advantages and preventive benefits of supplements proliferated amid pandemic-driven immunity demands, prompting diverse oversight mechanisms worldwide. Europe's rigorous pre-approval processes yielded few authorisations due to evidentiary hurdles; America's flexible notifications contrasted sharply. Emerging economies integrated incentives via insurance rewards and ad curbs, while Gulf harmonisation stressed label accuracy sans curative promises. Shoppers mix up ingredient lists with health results, liking easy words and personal perks, so they pay more. Hard to prove claims work the same for everyone; some places skip tough tests. Validation barriers loom large: rigorous trials falter on reproducibility; local gaps foster unchecked promotions. Future needs apps, gene tests, and the same rules everywhere to build trust as wellness grows big.

Keywords: EFSA Substantiation, Health Claims, Public Perceptions, Wellness Claims, Wellness Regulation

Introduction:

Wellness has deep historical roots extending across ancient civilisations from the East, including India, to the West (Global Wellness Institute 2023). The principles of wellness have traditionally embraced prevention and a holistic approach to health. In the 19th century, various intellectual, religious, and medical movements emerged alongside mainstream medicine in Europe and the United States. These movements emphasised natural methods, self-healing, and preventive care, laying a foundational framework for contemporary wellness concepts. Since the 1960s and 1970s, wellness and holistic health practices gained increased prominence, largely influenced by the contributions of U.S. physicians and thought leaders like Halbert Dunn, Jack Travis, Don Ardell, and Bill Hettler. Their ideas and writings helped popularise and expand these approaches, affecting the development of practices focused on healthy living, self-help, fitness, nutrition, diet, and spirituality. This evolution has led to the widespread acceptance and growth of the wellness movement in the 21st century, encompassing various disciplines centred around maintaining and enhancing health in a comprehensive and preventative manner.

Health and wellness claims often highlight benefits such as enhanced energy, better mental clarity, stress reduction, or improved physical performance. Consumers are increasingly drawn to wellness products as part of a holistic lifestyle that values preventive care and natural approaches to health maintenance. The appeal lies in promoting balance between body, mind, and spirit, encouraging individuals to take active roles in their health. Wellness claims play a major role in shaping consumer choices by focusing on positive lifestyle outcomes that align with personal goals of vitality and longevity. Products that connect scientifically plausible claims with authentic user experiences tend to build greater trust and engagement in the wellness market. Health and wellness claims encompass statements about food products, supplements, and services that assert nutritional benefits, reduced disease risk, or improvements in general well-being. These claims surged in popularity from 2020 to 2023 amid heightened consumer focus on immunity and preventive health following the COVID-19 pandemic. Regulatory frameworks like the EU's Nutrition and Health Claims Regulation (NHCR) evolved to balance innovation with consumer protection, emphasising scientific substantiation.

Regulatory Landscape (2020-2023)

Post-Brexit in 2021, the UK established the Nutrition and Health Claims Committee (UKNHCC) to assess claims independently from the EU system, focusing on Article 13(5) claims backed by new evidence. EFSA evaluations from this period showed varied outcomes, with positive opinions rare due to stringent totality-of-evidence requirements. Globally, wellness economies grew to \$5.6 trillion by 2022, driven by public health spending increases from 3.9% to 5.8% of health expenditures.

- Article 13 claims targeted general functions like blood pressure maintenance.
- Risk reduction claims under Article 14 faced high rejection rates for insufficient population-level reproducibility.
- US FDA guidelines emphasised "structure/function" claims without pre-approval, contrasting EU pre-market authorisation.

From 2020 to 2023, India's regulatory framework governing health and wellness claims centred on preventing deceptive advertising and incorporating wellness benefits into insurance products. This was mainly overseen by the Food Safety and Standards Authority of India (FSSAI), the Advertising Standards Council of India (ASCI), and the Insurance Regulatory and Development Authority of India (IRDAI). On September 4, 2020, IRDAI introduced guidelines encouraging life and health insurers to include wellness and preventive benefits. Policyholders who engaged in activities such as regular health screenings, yoga, or gym workouts could receive incentives like reward points, discounts on premiums, or increased sum insured (Taxmann, 2020; Compfie, 2020). These features were optional add-ons, and insurers had to provide annual statements showing the rewards accumulated. In August 2023, (Department of Consumer Affairs, 2023) issued further regulations concerning endorsements of health and wellness products by celebrities, influencers, and virtual personas. To enhance transparency and prevent misleading endorsements, these representatives were required to clearly display the credentials of certified medical or fitness professionals backing their claims. These guidelines were crafted following consultations with relevant ministries and FSSAI. ASCI and FSSAI actively enforced rules aimed at curbing exaggerated or false assertions in advertisements related to food products and supplements, in line with international standards. While there was no single central authority dedicated exclusively to wellness claims, these measures helped reduce the incidence of misrepresentation, particularly in wellness-linked insurance offerings (The Economic Times, 2020)

GCC countries, such as the UAE and Saudi Arabia, regulate health and wellness claims for food supplements through federal legislation, municipal agencies, and Gulf Standardisation Organisation (GSO) standards. The focus was on safety, scientific validation, and banning claims of disease cures. In the UAE, supplements were regulated by the Ministry of Health and Prevention (MOHAP) and Dubai Municipality (DM) under Federal Law No. 10 of 2015 and Ministerial Decree No. 239 of 2012. Importers and marketers had to register products via DM's Montaji portal, with MOHAP approval required for medicinal claims. Labels were mandated to include Arabic and English text, detailed ingredient lists, and scientifically supported claims for vitamins and minerals surpassing 30% of the Recommended Daily Allowance (RDA). The GSO's standard 2333:2022 harmonised nutrition and health claims across GCC states, prohibiting such claims on infant foods unless fully compliant and restricting unsupported assertions. Saudi Arabia followed these

standards closely, with the Council of Health Insurance overseeing claims compliance (Standards store, 2022). Regulations distinguished between health claims (e.g., promoting well-being or nutrient benefits) and structure/function claims, both requiring scientific evidence. Claims suggesting disease prevention or cure were explicitly forbidden. Although no significant new regulations were introduced between 2020 and 2023, enforcement on product labelling and imports became more stringent.

Public Perceptions and Typologies

Public views and classifications of health and wellness claims illustrate the complex relationship between consumer comprehension and marketing messages. Many consumers struggle to distinguish between nutrition claims (which relate to nutrient content) and health claims (which pertain to reducing disease risk or providing physiological benefits), often resulting in confusion or doubt. Recognition of certain nutrients, like sodium or vitamin D, tends to build consumer confidence, especially when related to familiar health benefits such as blood pressure management or immune system support (Stuthridge et.al.,2022; Benson et.al.2018).

The clarity of the claim's language greatly affects how consumers interpret it. Claims that are simple and direct are usually more effective and memorable compared to those that use conditional or technical terms, which can confuse or deter consumers. The specificity of the claim's intended audience-whether focused on individual advantages or general public health - also impacts engagement, with claims that feel personally relevant more likely to stimulate buying interest (Nanae et.al., 2022; van et.al. 2007).

Moreover, consumer trust is heavily influenced by the credibility of the claim's source, including endorsements from respected health experts or certifications from recognised regulatory authorities. Social and cultural contexts, such as current health trends and community values, further determine how claims are received and prioritised. The COVID-19 pandemic heightened awareness around health, driving consumers to pay extra for products marketed as offering concrete wellness benefits. Preferences have shifted toward items that not only demonstrate proven health effects but also satisfy sensory qualities like flavour and texture, signalling a more integrated approach to wellness.

Consumers often blur nutrition and health claims, prioritising familiarity, simplicity, and personal relevance over regulatory categories - attitudes toward claims mediated willingness to pay premiums during COVID-19, with health-focused claims boosting purchase intent. Wellness product preferences leaned toward quality, value, and taste amid shifting consumption patterns (Hodgkins,2019; Lara et.al. 2023).

Key dimensions from consumer sorts:

- Nutrient familiarity (e.g., sodium for blood pressure).
- Claim complexity (simple vs. conditional phrasing).
- Target relevance (personal vs. population groups).

Scientific Substantiation Challenges

The European Food Safety Authority (EFSA) is an independent EU agency, to provide scientific advice and risk assessments on food and feed safety, nutrition, animal health, welfare, plant protection, and related areas. Claims require repeatable effects in target populations under specified conditions, per EFSA principles. Physical activity claims linked to mental health gained traction, with research showing mood and sleep improvements (Mahindru et.al.,2023; Hodgkins et.al., 2019). Fitness app adoption highlighted intention predictors like perceived ease, but evidence gaps persisted for proprietary data claims.

Claim Type	Approval Rate (EFSA 2006-2023)	Key Challenge
Article 13	Low (e.g., 10-20%)	Totality of evidence
Article 14	<5%	Population reproducibility
Nutrition	High misplacement by consumers	Simplicity perception

(Source: Author compilation)

Claims require repeatable, statistically significant effects in the general population or target groups under specified conditions, per EFSA's totality-of-evidence approach updated in 2020-2023 evaluations. Physical activity claims linked to mental health gained traction post-2020, with 2023 meta-analyses confirming reductions in depression symptoms and improved sleep quality through moderate aerobic exercise (Ashwell et.al.2023; Mahindru et.al.,2023). Dose-response relationships, where 150 minutes weekly activity yields measurable cognitive benefits, though long-term adherence remains challenging (Mahindru et.al.,2023).

Fitness app adoption key predictors like perceived ease of use and behavioural intention via TAM models, yet proprietary algorithms often lack transparent substantiation for wellness outcomes. COVID-19 accelerated digital health claims, but EFSA rejected several in 2021-2022 for insufficient RCTs demonstrating immunity boosts from supplements.

India lacks a centralised authority like EFSA for mandatory pre-market scientific substantiation of health and wellness claims on food and supplements, relying instead on post-market enforcement by the Food Safety and Standards Authority of India (FSSAI) under the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, etc.) Regulations, 2016. Claims must be truthful, not misleading, and supported by "appropriate scientific evidence," but no specific guidelines define rigor - human RCTs, bioavailability data, or dose-response studies - leading to widespread unsubstantiated assertions like "boosts immunity" or "cures diabetes (Ministry of Corporate Affairs, 2023).

Discussion:

Health and wellness claims, which assert nutritional benefits or disease risk reduction, surged from 2020 onwards, alongside increased consumer focus on immunity post-COVID-19. Regulatory frameworks across regions balanced scientific substantiation with consumer protection, notably the EU's stringent EFSA evaluations and the UK's independent committee post-Brexit. In India, governance is intertwined with advertising and insurance bodies to curb deceptive claims and encourage wellness benefits in insurance products, while the Gulf Cooperation Council harmonised standards for supplement claims, focusing on safety and evidence. Public perceptions expose consumer confusion between nutrition and health claims, influenced by familiarity, claim simplicity, and relevance, with trust affected by credible endorsements and social trends. COVID-19 intensified demand for proven, appealing wellness products. Scientific substantiation remains challenging globally, with EFSA requiring repeatable evidence and stringent trial data; physical activity claims and digital health app evidence show promise but highlight gaps. India faces enforcement challenges due to a lack of centralised pre-market scrutiny, resulting in many unsupported claims. Overall, the evolving wellness claims landscape demands transparent, scientifically backed, and culturally sensitive communication to protect and inform consumers effectively.

Future Directions

Stricter post-2023 regulations may prioritise digital claims and AI-driven evidence reviews. Enhanced consumer education could align perceptions with science. Research gaps remain in long-term wellness outcomes. Innovations and Challenges may be AI predictive analytics for fraud detection and dose-response modelling, Consumer education via apps linking claims to personal health data, and Gender-affirming and mental wellness claims needing inclusive trials.

Conclusion:

The wellness industry's fast growth shows we need claims backed by solid science to protect buyers and encourage new ideas. Different countries' rules, from Europe's strict checks to developing markets' oversight, create conflicts between easy sales and safety, worsened by people misunderstanding claims and weak proof. Mixing old whole-body health ideas with today's needs means creating shared rules focused on strong studies (RCTs), clear labels, and online checks. Moving to smart data predictions, gene-based custom plans, and worldwide agreement will cut dangers, build faith, and drive lasting business success. Leaders, companies, and scientists should team up for fair tests, local tweaks, and live tracking so claims prove real benefits, helping people make smart health picks as trends change.

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