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Why We Must Clarify the Difference Between Drugs and Nutraceuticals

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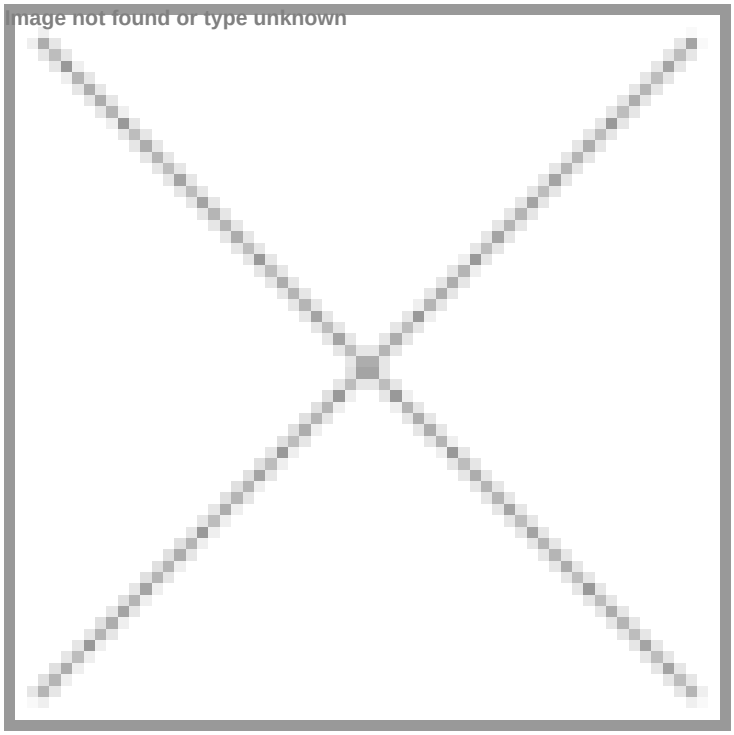
Consumers deserve to understand the difference between products that have undergone extensive testing and those that have not



In India's evolving health marketplace, consumers today have unprecedented access to a wide range of products from over-the-counter (OTC) medications to dietary supplements and herbal remedies. But this growing access comes with a growing misconception: that all health products available at pharmacies or online have been subjected to the same level of clinical testing and regulatory scrutiny.

Self-medication, the act of individuals treating their own health conditions without professional consultation, is common in India, especially among lower- and middle-income groups, with prevalence rates ranging from 8.3% to 92%. Rising healthcare costs, long wait times, and easily available online information have only accelerated this trend. At the same time, the rise of wellness-focused products such as supplements, herbal extracts and fortified foods, has blurred the line between what qualifies as a drug and what does not.

Nutraceuticals, dietary supplements or fortified foods promoted for health benefits, often mimic the appearance of drugs, from packaging to placement in pharmacies, making them indistinguishable from medicines. . Without clear communication, it's easy to assume that all health-related products undergo similar clinical testing before reaching consumers. In reality, that is far from the case.

Regulatory Differences: OTC Drugs vs Nutraceuticals

OTC drugs, such as paracetamol or ibuprofen, are regulated by the Central Drugs Standard Control Organisation (CDSCO) under the Drugs and Cosmetics Act, 1940. These products undergo a multi-phase clinical trial process spanning 3-5 years or even longer. These trials evaluate safety, efficacy, dosage, pharmacokinetics, and potential drug interactions with oversight from institutional ethics committees (IECs) to ensure informed consent and monitor adverse events.

Nutraceuticals, by contrast, fall under the purview of the Food Safety and Standards Authority of India (FSSAI). These include dietary supplements, functional foods, and herbal preparations. While some studies may be conducted to support general wellness claims, there is no legal requirement for large-scale clinical trials before launch. Most do not undergo long-term safety monitoring or pharmacological evaluation.

This regulatory divergence is critical but often unknown to the end user.

One of the reasons for this perception is a lack of awareness about what clinical trials actually involve. For pharmaceuticals, clinical trials are structured, multi-phase studies that include hundreds to thousands of participants. They assess how a product behaves in the body, what potential adverse effects it might have, and how it compares to existing treatment options.

By comparison, when nutraceuticals are studied, the trials are typically small-scale often with fewer than 200 participants and focused more on general well-being than treatment outcomes. These studies are typically shorter in duration, and often lack the level of regulatory or ethical oversight required for pharmaceuticals.

Real-World Risks

Although FSSAI and the Advertising Standards Council of India (ASCI) provide guidance on health claims, enforcement can be inconsistent. The rise of digital platforms and influencer-led promotions makes it easier than ever for ambiguous messages to reach large audiences.

As a result, consumers may believe that all products are backed by rigorous evidence, when in fact the standards vary widely.

The consequences of this misconception are significant. Misguided reliance on untested supplements can lead to health risks, such as liver toxicity, kidney damage, heart complications, or adverse interactions with medications. In addition, lower-income groups, often unable to afford doctor visits or diagnostics, are particularly vulnerable, relying heavily on affordable but unverified products.

The rise of e-commerce exacerbates these risks. Online platforms, with their vast reach and minimal oversight, amplify misleading claims through unverified sellers or influencer endorsements. User reviews often present anecdotal success stories as scientific proof, further confusing shoppers.

Solutions for a safer tomorrow

As India’s health ecosystem expands, so too does the need for clearer public communication. Consumers deserve to understand the difference between products that have undergone extensive testing and those that have not. Greater transparency around clinical evidence, regulatory standards, and marketing claims can help individuals make more informed choices and strengthen public trust in the system as a whole.

Bridging the knowledge gap between pharmaceuticals and nutraceuticals is not about limiting access or innovation. It’s about ensuring that safety, science, and informed decision-making go hand in hand.

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