

MISLABELED ORAL REHYDRATION SOLUTIONS IN INDIA: REGULATORY GAPS, PUBLIC HEALTH RISKS, AND THE WAY FORWARD

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ABSTRACT

One of the most economical treatments for diarrheal illnesses is still oral rehydration therapy (ORT) with properly prepared oral rehydration salts (ORS). However, a growing number of ready-to-drink and liquid hydration drinks in India have been promoted or labeled as "ORS" despite not meeting the WHO-approved ORS's regulatory status, composition, or therapeutic indication. These mislabeled goods, which are frequently low in electrolyte content and rich in sugar, cause confusion, run the risk of being used inappropriately, exacerbate dehydration, particularly in children, and jeopardize public health initiatives. This paper describes how real ORS therapy has developed, details the Indian market and regulatory environment around mislabeled ORS-type goods, examines the phenomenon's effects on public health, and suggests professional, regulatory, and awareness-raising measures to reduce related hazards. To unify labeling practices, improve monitoring, and shield vulnerable populations from deceptive hydration products,

immediate action is needed.

KEYWORDS: Oral rehydration solution; ORS; mislabeled drinks; India; regulation; diarrhoea; hydration; food-drink labeling; public health.

INTRODUCTION

Oral rehydration salts (ORS) are straightforward, inexpensive formulations that have been recommended by the World Health Organization (WHO) and United Nations Children's Fund (UNICEF) for decades as a means of effectively managing acute watery diarrhea and dehydration.^[1,2] An essential part of international efforts to manage diarrheal disease, ORS significantly lowers mortality and morbidity when administered properly.^[3] ORS has been a crucial intervention for child survival in India's national health programs.^[4]

However, hydration-type beverages and ready-to-drink drinks labeled or promoted under the word "ORS" or variations of it have proliferated in the Indian market in recent years. These drinks lack the proper electrolyte composition, regulated medication status, or therapeutic indication of true ORS.^[5,6] These items are actually food/beverage products licensed by the food regulator rather than drug formulations, even though they may be marketed as "rehydration solutions," "electrolyte drinks," or simply "ORS." Confusion between the two markets—therapeutic and nutritional/food ORS—raises the possibility of improper use, postponed therapy, and increased dehydration, particularly in vulnerable groups like children.

After providing a global and Indian perspective on ORS therapy, this paper delves deeply into the Indian situation of mislabeled ORS products, including market trends, regulatory gaps, health implications, and proactive measures to guarantee the safe and efficient use of rehydration therapy.

METHODOLOGY

Evidence on ORS composition, mislabeled hydration drinks, Indian labeling and regulatory methods, and public health effects is synthesized in this narrative review from both Indian and international sources. From September to October 2025, a systematic search was carried out using different keyword combinations, including "oral rehydration solution," "ORS India," "hydration drink," "mislabeled ORS," "FSSAI ORS directive," and "diarrhea rehydration India," across databases such as PubMed, Google Scholar, and Indian regulatory archives. Journal papers, policy advice, regulatory documents, and credible news assessments that addressed ORS formulation, labeling, regulation, or public health issues in India or comparable contexts that were published in English between 2010 and 2025 met the inclusion criteria.

Non-English sources and publications that were solely about prescription drugs unrelated to ORS were excluded. Sections on true ORS therapy, the regulatory environment, mislabeled items in India, public health dangers, the role of health professionals, and suggestions were created by thematically synthesizing the findings.

Global Overview of Genuine ORS Therapy

The creation and application of ORS has revolutionized the treatment of dehydration brought on by diarrhea since the 1970s. In order to maximize water absorption and address electrolyte loss, WHO and UNICEF implemented standard ORS formulations that include specified quantities of sodium, glucose, and other electrolytes.^[2,3] Low-sodium formulations and dual packet techniques for cholera vs. non-cholera diarrhea are examples of osmolality and composition improvements that have been suggested over time.^[4]

The fundamental idea is still the same: when used properly, a straightforward, therapeutic solution replenishes lost fluids and salts and avoids difficulties. ORS has set preparation, dispensing, and usage rules and is controlled as a medication or essential medicine in several nations.^[1] The effectiveness of ORS depends not only on accessibility but also on proper usage, including dosing, dilution in clean water, and identifying when additional medical care is required.

Indian Regulatory and Market Context

According to the Central Drugs Standard Control Organization (CDSCO)/Drugs & Cosmetics Rules, ORS (commonly referred to as "Oral Rehydration Salts") is recognized as a medicine in India, and its composition complies with WHO recommendations.^[5,7] However, some food and beverage companies licensed by the Food Safety and Standards Authority of India (FSSAI) started utilizing "ORS" or variations of it in their branding concurrently with this regulated therapeutic medication. For instance, the FSSAI found that fruit-based ready-to-drink drinks with labels such as "ORS," "ORSL Rehydrate," "Electro Plus ORS," and so on were deceptive.^[8,9]

Regarding the deceptive marketing and promotion of ORS substitute products, the FSSAI issued a directive in April 2022 under Section 16^[5], stating that the use of the term "ORS" or a similar term on food labels was prohibited and could result in the products being classified as "misbranded food" under the Food Safety and Standards Act, 2006.^[10] The FSSAI recently issued a directive on October 14, 2025, prohibiting the use of the term "ORS" (or any other

acronym, prefix, or suffix) in food and beverage product names, labels, or trademarks unless the product has a WHO-approved ORS formula. According to the instruction, the phrase must be eliminated from all ready-to-drink, fruit-based, and non-carbonated beverages. Failure to comply with this regulation is considered misbranding under the Act.^[11,12] Growing awareness of the dangers misleading "ORS-tagged" beverages pose to public health is reflected in this regulatory progression.^[13]

According to market data, the ORS segment's yearly sales in India (which includes both real and fake ORS rehydration drinks) increased from ₹648 crore in 2021 to ₹1,232 crore in October 2024 to September 2025, demonstrating the hydration category's explosive expansion and commercial interest.^[11]

Mislabeled ORS Drinks and Public Health Risks

Nature of the problem

Food and beverage products that use the term "ORS" or something similar to suggest medicinal equivalency but do not meet the sodium/glucose composition, osmolarity, regulatory status, or usage guidelines for authentic ORS are referred to as mislabeled ORS drinks. They may deceive users into believing they are equivalent to therapeutic ORS due to their high sugar content and insufficient electrolytes.^[6,9,13] Disclaimers such as "Not an ORS formula as recommended by WHO" are occasionally included on such items, but they are frequently subtle or non-existent.^[8]

Health implications

When these products are misused, it might postpone the proper treatment of dehydration, particularly in youngsters. Inadequate salt replacement may increase electrolyte imbalance, and the osmolar load may cause diarrhea or fluid loss when a high-sugar beverage is eaten in place of a therapeutic ORS.^[9,14] Because kids are given a false product at a crucial moment, public health professionals have cautioned that children who use such items may develop severe dehydration or other issues.^[13,11] In low-resource environments, where availability to adequate ORS, or clean water for dilution, may be restricted, the issue is made worse.

Consumer confusion and access issues

Consumer perception is one of the main problems: the commonly used term "ORS" has therapeutic connotations that are life-saving. If food and beverage producers overuse this word, average customers might take it for granted and forego proper handling or expert care.

These mislabeled products' accessibility may further promote improper self-medication practices.^[5] The Better India described how customers can buy a “fake ORS” pack thinking it is safe, when it is practically just a sugary drink.^[9]

Regulatory enforcement gaps

Enforcement is still difficult even after the FSSAI's 2022 directive and the 2025 prohibition. Following industry petitioning, the Delhi High Court issued a stay on the disposal of current stockpiles of beverages bearing the "ORSL" label, underscoring the legal complexities and discrepancy between market reality and legislative purpose.^[12,14] It is nevertheless necessary for several states and food safety commissioners to take action against food business operators (FBOs) who are in default or issue improvement notices.^[10]

Role of Healthcare Professionals and Pharmacists

Pediatricians, pharmacists, and primary care physicians are among the healthcare experts who are essential in spotting possible hydration product abuse and educating caregivers. In addition to offering caregivers advice on the appropriate selection, dilution, and use of ORS for diarrheal dehydration, community-level pharmacists can assist in differentiating between therapeutic ORS (drug formulation) and beverage "hydration" products.^[1,4] Additionally, clinicians should emphasize the proper therapeutic ORS packet and instructions and educate patients about the differences between different rehydration solutions.^[9] Pediatricians' awareness efforts, such as Sivaranjani Santosh's eight-year battle in Hyderabad, helped spur public awareness and regulatory change in India.^[11]

Pharmacy curricula and professional bodies should include modules on risk awareness, unintentional use of pseudo-ORS, and mislabeled hydration drinks. Policymakers should also work with professional associations to mobilize community education, compare ORS to non-regulated drinks, and provide rules for confirming authentic ORS.

CHALLENGES AND FUTURE DIRECTIONS

Implementation and compliance

Although the October 2025 legislative order is a significant move, it is still difficult to implement effectively throughout India's varied food and beverage business. FBOs must re-label, recall, or re-brand; states must mandate that "ORS" be removed from non-compliant product names; and authorities must keep an eye out for and punish infractions.^[12,14]

Enforcement is made more difficult by the commercial importance of hydration drinks, legal stays, and the availability of substantial stockpiles of drinks with incorrect labels.

Awareness and education

Regarding the distinction between promoted hydration drinks and therapeutic ORS, consumer health literacy is still inadequate. Campaigns must stress that the only ORS that should be used for dehydration brought on by diarrhea are those that have a WHO-approved composition, come in a medication packet, or are specifically recommended for treating diarrhea. Public education should focus on avoiding sugary hydration substitutes, reading labels, and comprehending regulatory markings (DCGI vs. FSSAI).^[9,21]

Research and surveillance

Robust market surveillance is required to detect and measure mislabeled ORS drinks, monitor health consequences (such as children receiving treatment for dehydration but consuming non-therapeutic drinks), and assess the effectiveness of regulatory actions. The evidence base would be strengthened by studies on consumer behavior, pharmacy hydration drink dispensing procedures, and hospital records of dehydration patients handled incorrectly with the inappropriate products.

Strengthening regulatory architecture

From a policy perspective, it is imperative to distinguish between hydration drinks (regulated as food/beverage) and therapeutic ORS (regulated as a medicine). The government should think about including common "ORS" formulations in National Essential Medicines Lists, requiring authentic ORS to be labeled, and making sure non-therapeutic drinks don't utilize ambiguous nomenclature. Digital traceability, common databases of authorized ORS formulations, and cooperation between CDSCO and FSSAI may be advantageous.

Role of pharmacists and primary care

Pharmacists ought to be able to ask questions about the labels of hydration drinks, provide caregivers advice when they pick up a "ORS" product, and make sure the right packets are used. In the setting of diarrhea and dehydration, primary care physicians should inquire about hydration history and notify authorities if misbranded products are being used extensively.

CONCLUSION

In India, mislabeling and marketing hydration drinks as "ORS" is a serious public health issue. Safe rehydration methods are compromised by the misunderstanding caused by food and beverage products that use the word "ORS," even though actual ORS is still a key component of managing diarrheal diseases, particularly in susceptible youngsters. The effectiveness of the regulatory advancements made by the FSSAI in 2022 and 2025 will depend on enforcement, public awareness, and professional participation. The health system must make sure that only properly manufactured, regulated ORS products are used for dehydration, and that deceptive replacements are phased out in order to protect children and other at-risk populations. Restoring confidence in ORS therapy and protecting rehydration practices in India will require the involvement of multiple stakeholders, including regulators, industry, healthcare professionals, pharmacists, and consumers.

REFERENCES

1. Kelly P, Mahalanabis D. Oral Rehydration Solution: A "Low-Tech" Oft Neglected Therapy. [PDF] 2015. Available from: ... (accessed).
2. World Health Organization. Oral Rehydration Solution: A truly universal public health intervention, 2004.
3. Smith L, et al. Issues and Controversies in the Evolution of Oral Rehydration Therapy. *Clin Infect Dis.*, 2021;... (PMC).
4. IAP Delhi. Oral Rehydration Therapy for Diarrhoea-Related Dehydration in India, 2021.
5. Food Safety and Standards Authority of India. Direction under Section 16(5) regarding misleading advertisement and marketing of ORS substitute products, 08 April 2022.
6. How to Identify Fake ORS in the Market. The Better India, 2024.
7. Government of India. Speaking Order on Walyte Oral Rehydration Salts. Ministry of Pharma, 2016.
8. FSSAI instructs Safety Food Commissioners to take action against misuse of ORS on labels. Food InfoTech, 2022.
9. Fake ORS drinks worsen health, warn doctors. *New Indian Express*, 30 July 2022.
10. FSSAI issues direction regarding misleading advertisement and marketing of ORS-substitute products. Legality Simplified, 2022.
11. Business Standard. FSSAI bans food brands from using "ORS" tag over misleading claims, 16 October 2025.

12. Tribune India. No more 'ORS' confusion, here is why FSSAI bans term on food products, 18 October 2025.
13. FoodManifest. The Hidden Danger of Counterfeit ORS: A Food Safety Concern, 2025.
14. VisionIAS Blog. FSSAI bans misleading ORS labels: Delhi High Court stay sparks public health debate, 2025.
15. NDTV. Centre says only WHO-approved products will be labelled ORS. 20 October 2025.
16. NDTV. Fake ORS Drinks Banned: Hyderabad Doctor's 8-year fight sparks action by FSSAI, 2025.
17. TheBetterIndia article, 2024.