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# BRIEF INSIGHTS ON LABELLING REGULATIONS PERTAINING TO FOOD AND ASU DRUGS

Dr. Himanshu Shekhar Tiwari

(President – Technical) KRM Ayurveda Limited; Dr. Poonam Dang (NABH Co-Ordinator/DMS) KRM Ayurveda Limited

**Abstract**

Label is the "identity card" of a product, which bridges the gap between the manufacturer's promise and the consumer's safety. In the context of the Indian market, the "need" for an Ayurveda product label is both a legal mandate and a commercial necessity. Whether registered as a Drug (Ministry of AYUSH) or as Food (FSSAI), a label monitors critically; legal & regulatory compliance, consumer Safety & medical transparency and misleading claims. A drug is deemed "misbranded" under Section 33-E of the Drug and cosmetic Act and Rule 1945 if it is not labeled in the prescribed manner or bears false/misleading claims, it is a punishable offense. Taking into consideration the abovesaid a review article was framed giving swift insights on the labelling requirements of ASU Drugs and food Drug labels.

***Keywords**: ASU Drugs, label regulation, FSSAI.*

**Introduction**

Over 50% of medication use errors in terms of dosing, intervals, route of administration, etc., are associated with poor prescription drug labeling.[1] Hence, labels are the primary bridges between the manufacturer and the patient, serving as the "final point of safety" to ensure safe medication usage. Labels clearly identify the drug name, strength, and dosage form, provide clear instructions on its administration, highlighting warning signs, contraindications, drug interactions etc. Failing to provide accurate labels can result in compromised patient safety, implementation of fines and even suspension of manufacturing licenses. Hence accurate labels are necessary so as to win trust of healthcare providers and empowers patients to understand their treatment, fostering trust in the healthcare system and improving adherence to medication regimens.

**Material and methods**

An in-depth review was done from published and printed literature, Manual on drugs and cosmetic, The Food Safety and Standards act 2006, Ayurvedic Pharmacopoeias and Formulary, Various government rules and notifications were referred i.e. Legal Metrology Act 2009, Drug & Magic Remedies (Objectionable Advertisement) Rule 1955 etc.

**Observation and Results**

The labeling of Ayurvedic, Siddha, and Unani (ASU) drugs in India is primarily regulated under Rule 161 of the Drugs and Cosmetics Rules, 1945. FSSAI regulates these ingredients when they are marketed as "Ayurveda Aahara" (food).

In India, food labeling is primarily governed by the Food Safety and Standards (Labelling and Display) Regulations, 2020, issued by the Food Safety and Standards Authority of India (FSSAI).These regulations mandate specific information to ensure consumer safety and transparency. Hence, when substances traditionally used as "drugs" (herbs, botanicals, or vitamins) are sold as Food, they fall under the FSSAI (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022. Because these look like medicines but are regulated as food, the label must strictly differentiate them to prevent consumer confusion.

**Mandatory Label Requirements for drugs that fall under the category of Food:** [2]

1. Mandatory categorization of titles: The front of the pack must clearly state the specific category in bold, capital letters, "HEALTH SUPPLEMENT", "NUTRACEUTICAL","AYURVEDA AAHARA" (featuring the Ayurveda Aahara Logo).
2. Statutory disclaimers: These specific warnings are non-negotiable for "drug-like" food products. "NOT FOR MEDICINAL USE" must be prominent and clearly visible. "Not to exceed the recommended daily usage": To prevent toxicity from over-consumption of vitamins/herbs. “Product is required to be stored out of reach of children": Standard safety warning. “Not to be used as a substitute for a varied diet", it ensures consumers don't rely solely on the supplement for nutrition.
3. Usage and dosage Instructions: The label must define recommended usage, the exact serving size (e.g., "1 capsule daily after a meal"), target Group (e.g., "For Adults Only" or "Pregnant women should consult a doctor before use")
4. Nutritional & active Ingredient declaration: label must reflect name of food ,list of Ingredients listed in descending order of their weight or volume at the time of manufacture, nutritional information declared per 100g or 100ml of the product, including energy (kcal), protein, carbohydrates (including total and added sugars), total fat (saturated and trans fats), etc. For vitamins and minerals RDA percentages, should be mentioned on the labels along with RDA percentage recommended by ICMR. The source of the ingredient (e.g.vitamin C from *Amla* Extract") must be listed in the ingredients. Veg/Non-veg symbols must be written. Vegetarian symbol consists of a green color filled circle inside a square with a green outline whereas Non-Vegetarian: A brown color filled triangle inside a square with a brown outline. Every label must display the 14-digit FSSAI license number and the official logo in a color contrasting with the background. Major allergens (e.g., cereals containing gluten, milk, eggs, nuts, soy, and fish) must be clearly declared, often as "Contains: [Allergen Name]". Date of Manufacturing and Expiry date should be mentioned.
5. Prohibited Claims: Under the FSSAI (Advertising and Claims) Regulations, these products cannot claim to prevent, treat, or cure a specific disease (e.g., "Cures Arthritis").

**Mandatory Label Declarations for ASU Drugs** [3]

As per Rule 161, the innermost container of an ASU drug must display the following in indelible ink.

1. Name of the drug: Must be the same as mentioned in the authoritative books listed in the First Schedule of the Act.
2. System of medicine: The label must clearly state "Ayurvedic Medicine," "Siddha Medicine," or "Unani Medicine".
3. Full list of ingredients: Must include the botanical names of plant-based components, along with the specific plant parts (root, flower etc.) and form (powder, extract etc.) in which they are used, and their quantity. If the list of ingredients is large and cannot be accommodated on label, the same may be printed separately and enclosed with the packing and reference to be made to this effect on the label.
4. Manufacturing details: Includes the manufacturing license number (prefixed with "M.L."), batch/lot Number and date of Manufacture.
5. Net Quantity: expressed in metric units (grams, milliliters, etc.).
6. Manufacturer Information: The name and address of the manufacturing premises.
7. Expiry Date: Mandatory display of the shelf-life or expiry date as per Rule 161B.
8. Names of preservatives must be mentioned on label.

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9. Critical Safety Warnings: Specific warnings are required based on the nature of the drugs., If the drug contains Schedule E(1) ingredients (e.g., aconite, mercury) it must carry the caution: "Caution: to be taken under medical supervision" in English and hindi. External Use: Products intended only for external application must be clearly labeled "FOR EXTERNAL USE ONLY".
10. Free Samples: Must be overprinted with "Physician's sample. Not to be sold".
11. For export, labelling requirements are to be fulfilled as per the country in which medicine has to be exported and "For export" should be clearly mentioned on the label.

**Discussion**

Food labels are governed by Food Safety and Standards Regulations, 2020. Whereas, Ayurveda drugs fall under the purview of the Drugs and Cosmetics Act, 1940 and labels on Ayurvedic drug containers need to comply with the requirements specified in this Act (Part XVII, 161).[4] If a product is registered under FSSAI as Ayurveda Aahara, it follows different labeling rules, it must display the Ayurveda Aahara Logo on the front-of-pack, must carry the statutory warning: "ONLY FOR DIETARY USE". It Cannot claim to "treat" or "cure" diseases; it can only mention intended health benefits supported by Ayurvedic texts. In the context of the Indian market, whether the drug is registered as a Drug (Ministry of AYUSH) or as Food (FSSAI), a label serves both as a legal mandate and a commercial necessity It provides the traceability of manufacturing license number and batch Number, which are essential for drug controllers to track the product's origin. It displays the date of expiry (Rule 161B) depicting Shelf-Life to ensure the botanical ingredients are potent and safe for consumption. It ensures consumer safety & medical transparency enlisting potent herbs or minerals that require careful usage informing users with specific allergies. It also mentions Schedule E1drugs further mentioning the "Caution: To be taken under medical supervision. It provides Usage Instructions mentioning the adjuvant, which further aids in enhancing the drug efficacy. It keeps a check on Misleading Claims, defines the boundary between a "Health Supplement" and a "Medicine."

**Conclusion**

Labels are not just stickers; they are legally mandates containing essential scientific and safety data required to prevent medical disasters. These are non-negotiable requirement for regulatory survival, and a high-tech tool for securing the global supply chain. Without precise, standardized labeling, the risk to patient life and corporate viability is absolute.

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