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Pharmaceutical Science

DECLARATIONS ON LABELS OF COSMETICS

KEY WORDS: Cosmetic Rules, Legal Metrology, Drug and Cosmetic Act

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ABSTRACT

The label content on package of product is the identity and source of information about the product. Labels play a vital role in ensuring consumer safety and product transparency. In addition to name of the product and its manufacturer, a cosmetic label provide essential information, expiration dates, ingredients, usage instructions and warnings. Information like quantity and retail price ensure consumer protection and transparency. Keeping the essential content on the label is regulatory compliance. Labels also serve as promotional tool in marketing and sales. In addition to other regulation, the label of cosmetic product is required to comply with the Cosmetics Rules, 2020 and the Legal Metrology (Packaged Commodities) Rules 2011.

INTRODUCTION

Grooming habits and personal presentation continue to evolve with advancements. Now-a-days cosmetics are not only about beauty but also play a crucial role in maintaining hygiene and boosting confidence. However, grooming, self-expression, and personal presentation should not come at the cost of health risks. The products must be safe for application on the human body, and if they are toxic, a clear warnings and precautions must be provided. So while selecting a product, it's essential to choose safe, high-quality products to avoid health risks. From the view of consumers, product packages and labels are the source of information about product nature, use and direction for use, storage and so on. In order to safeguard the consumers and at large the society, the governments have made laws related to labelling of commodities. The Legal Metrology Act, 2009 and the rules made their under such as the Legal Metrology (Packaged Commodity), 2011 deals with the labelling of pre-packaged commodity. A pre-packaged commodity refers to a commodity which without the purchaser being present is placed in a package of whatever nature, whether sealed or not, so that the product contained therein has a pre-determined quantity. Label means any written, marked, stamped, printed or graphic matter affixed to, or appearing upon any pre-packaged commodity. Cosmetics differ from general commodities, and as such, most countries have specific laws to regulate their labelling, manufacturing, sale, import, and other aspects. In India, cosmetics are primarily regulated under the Drugs and Cosmetics Act, 1940, and the Cosmetics Rules, 2020. Cosmetic means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic. The label of cosmetics are required to comply with the requirement, if any specified for cosmetics in the relevant Indian standards laid down by the "Bureau of Indian Standards (BIS)"

MATERIAL AND METHOD

Drugs and Cosmetics Act 1940, Cosmetics Rules 2020, Legal Metrology Act 2009, Legal Metrology (Packaged Commodities) Rules 2011, Bureau of Indian Standards, research paper, manuals and guidance documents, Govt. notifications, and other information were collected and reviewed. Market samples of some manufacturers were also procured and studied.

Labelling Of Cosmetics

The sale or distribution of cosmetic is prohibited unless it is labelled in prescribed manner. The labels of cosmetics are

required to have sufficient information needed for safe and effective use by consumers as enlisted in Table -1. Some of the contents are mandatory to declare and some are voluntary. Certain information are required to be displayed on both inner and outer label, while some content are required on inner and some on outer label of a package. However in case of a package having single label, all the content are required to be kept in such label. The content which are required from rules are mandatory contents. Certain mandatory contents can also be omitted when the products are packaged in very small size as given in Table-1 remarks column. While writing the contents, it is to be noted that no cosmetic may purport or claim to purport or convey any idea which is false or misleading to the intended user. It is also prohibited to alter inscription on containers, labels or wrappers of cosmetic.

Table-1: A checklist of contents for label of cosmetic product

S. No.	Required Content	Content detail	Remarks
1.	Name of the product	Name of the product	
2.	Manufacturer detail	Name, address and licence number of manufacturer.	Name of manufacturer, principle place of manufacture along with PIN code in case of package is very small i.e. 30 g or less in case of solid or semi-solid and 60 ml or less in case of liquid formulation having not enough to give all the required content.
3.	Shelf Life	Dates of expiry and manufacture, PAO and storage conditions	
4.	Ingredients	Ingredient list, vegetarian and non-vegetarian symbols, vegan, paraben free, sulfate free, external application.	Ingredient list not required in case of pack size 30 g or less in case of solid or semi-solid and 60 ml or less in case of liquid formulation.
5.	Safety	Warning,	

	Warning	caution, method of application, hazardous ingredients name and quantity,	
6.	Net quantity	Net weight or volume	Not required in case of package of perfume, toilet water or the like, the net content of which does not exceed 60 ml or any package of solid or semi-solid cosmetic the net content of which does not exceed 30 grams.
7.	Batch number	Batch number	Not required in case of package size 10 g or less in case of solid or semi-solid and 25 ml or less in case of liquid formulation
8.	Prices	MRP and USP including of all taxes	
9.	Consumer care detail.	Name, address, telephone number, e-mail	
10.	Unique Product Identifier	Barcode, GTIN or QR Code	
11.	Others	tested dermatologically, cruelty-free, recyclable packaging	

Name: The name of the product serves as its identity must indeed be present on both the inner and outer labels of a cosmetic product. The requirement, ensure that the product can be clearly identified regardless of whether the consumer is looking at the inner packaging or the outer packaging. The name of product should not be misleading or deceptive in any way. A cosmetic is considered as spurious, if it bears upon its label or container the name of another cosmetic.

Manufacturer Detail: Manufacture for sale or for distribution of cosmetic is permitted under and in accordance with the conditions of a licence issued for such purpose. The manufacturing permission is granted with unique licence number. The name of the manufacturer and complete address of the premises of the manufacturer where the cosmetic has been manufactured is required to be declared on both inner and outer labels. Complete address means the postal address at which the manufacturing premises is situated and is registered or the name of the street, number assigned to the premises of the manufacturer and the name of the city and State where the business is carried on by the manufacturer and the Postal Index Number [PIN] Code. The manufacturer's name helps consumers know the origin of the product. This fosters trust in the brand and its quality. If the product has not been manufactured in a factory owned by the manufacturer, the name and address of the actual manufacturer or the name of the country where it has actually been manufactured as "Made in (name of country)" should be there on the label. A cosmetic is considered as spurious, if the label or container bears the name of an individual or a company purporting to be the manufacturer of the cosmetic which individual or company is fictitious or does not exist. The cosmetic is also considered as spurious, if it purports to be the product of a

manufacturer of whom it is not truly a product.

The manufacturing licence number issued to the manufacturer must be declared either on the inner or outer labels of the cosmetic product. The manufacturing licence number should be preceded by the notations: "M" or "M. L. No." or "Mfg. Lic. No." In the case of imported products, if manufacturing licence is not mandatory in country of origin, then such cosmetics may be allowed without mentioning manufacturing licence number, subject to fulfillment of other import regulations

Shelf Life: The expiry date is essential for cosmetic products to ensure they are used within the time frame during which they remain stable and safe. It is a critical part of cosmetic labelling for consumer protection and is required to be kept on both inner and outer label. The expiry and manufacturing dates also allow consumers to make better purchasing decisions, especially if they are buying in bulk or planning long-term use. Cosmetic label employs varied formats to indicate the product's dates and shelf life such as "use before" or "date of expiry (month and year)" or "use by" or "expiry date" or "expiry XX months from manufactured" or "date of manufacturing" or "expiry date". These formats aim to provide flexibility while conveying the necessary information about the product's lifespan.

Period after opening (PAO) symbol typically looks like an open jar icon with a number inside, followed by the letter "M" (for months), indicating how long the product is safe to use after opening. The PAO symbol is commonly used internationally, especially in regions like the European Union, to indicate the shelf life of a cosmetic product after it has been opened. In India, the PAO symbol is not a mandatory requirement for cosmetic labels. Similarly manufacturers voluntarily include storage instructions as part of good practice, particularly if the product contains ingredients that are sensitive to temperature or moisture. This is done to help ensure the product remains effective and safe for consumers.

Ingredients: Ingredients list on labels empower consumers to make informed choices and helps in identify products. The word "INGREDIENTS" must precede the list of ingredients on the label as a clear heading to inform consumers. Ingredients present in concentrations greater than 1% must indeed be listed in descending order of their volume or weight at the time of addition to the product and then ingredients present in concentrations less than or equal to 1% can be listed in any order. The ingredients on outer label ensures that consumers can easily read and understand the ingredients before making a purchase. To provide maximum transparency, displaying the ingredient list on both the inner and outer labels is a best practice.

Depending upon ingredients, manufacturers make voluntary claims like paraben free indicating the product does not contain parabens. Paraben is a class of preservatives. Sulfate free indicates the absence of sulfates, which are commonly used surfactants. Veg and non-veg symbol represented by green or red/brown logo respectively may be placed on the packages of soap, shampoo, toothpastes and other cosmetics and toiletries for its non-vegetarian or vegetarian origin on voluntary basis. Vegan declares that the product contains no animal-derived ingredients or by-products.

Cosmetics are substances intended for application to external body parts. It is advisable to include the statement "For external use only" on the labels of cosmetic products to ensure consumer safety and prevent misuse. While the exact phrase "For external use only" is not explicitly mandated for all cosmetic products, the rules require that any necessary warnings, usage instructions, or cautionary details be clearly stated on the product's label.

Warning, Caution & Direction for Use: Bureau of Indian

Standards (BIS) IS 4707 deals with the classification of raw materials and adjuncts used in cosmetics in India. The standard is divided into different parts to regulate specific categories of ingredients. The Fourth Revision of IS 4707 (Part-1) specifically addresses the list of colorants and pigments permitted for use in cosmetic products with their safety limits, and usage conditions. IS 4707 (Part-2) outlines the classification of raw materials and adjuncts used in cosmetics and includes various annexures listing raw materials under different categories. Annexure A includes a comprehensive list of raw materials and chemicals prohibited for use in cosmetics and Annexure B is lists of ingredients which cosmetic products must not contain, except under certain restrictions and conditions. Annexure C is the lists of preservatives allowed in cosmetic products, but with specific restrictions and Annexure D is the lists of UV filters that are allowed in cosmetic products, subject to restrictions.

Cosmetics are considered everyday consumer products to enhance personal appearance and hygiene. However, if a cosmetic contains ingredients that may be poisonous or hazardous, it is mandatory to provide specific information and special directions on the product label. In case of cosmetics where a hazard exists it is required to declare (a) adequate directions for safe use, (b) any warning, caution or special direction required to be observed by the consumer, (c) a statement indicating the names and quantities of ingredients that are hazardous or poisonous. These information are required on inner label. This ensures critical safety information remains accessible to the user throughout the product's lifecycle as consumers often discard outer packaging after purchase. Some special provisions and cautions for hair dyes and fluoride containing toothpaste are required which are listed in Table-2.

Table 2. Special provisions and cautions for hair dyes and toothpaste containing fluoride

1.	Hair dyes containing dyes, colours and pigments.	Hair dyes containing Paraphenylenediamine or other dyes, colours and pigments shall be labelled with the following legend in English and local languages and these shall appear on both the inner and the outer labels: "Caution. This product contains ingredients which may cause skin irritation in certain cases and so a preliminary test according to the accompanying directions should first be made. This product should not be used for dyeing the eyelashes or eyebrows; as such a use may cause blindness." Each package shall also contain instructions in English and local languages on the following lines for carrying out the test: "This preparation may cause serious inflammation of the skin in some cases and so a preliminary test should always be carried out to determine whether or not special sensitivity exists. To make the test, cleanse a small area of skin behind the ear or upon the inner surface of the forearm, using either soap and water or alcohol. Apply a small quantity of the hair dye as prepared for use to the area and allow it to dry. After twenty-four hours, wash the area gently with soap and water. If no irritation or inflammation is apparent, it may be assumed that no hypersensitivity to the dye exists. The test should, however, be carried out before each and every application. This preparation should on no account be used for dyeing eyebrows or eyelashes as severe inflammation of the eye or even
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		blindness may result."
2.	Toothpaste containing fluoride	(I) Fluoride content in toothpaste shall not be more than 1000 ppm and the content of fluoride in terms of ppm shall be mentioned on the tube and carton. (ii) Date of expiry should be mentioned on tube and carton.

Quantity: The net quantity on package tells consumers exactly how much product they are purchasing. The outer label is often the first point of contact for the consumer at the time of purchase this is why the outer label of the cosmetics is required to carry a declaration of the net contents. Declaration of net quantity prevents consumers from being deceived by oversized containers with little product inside. The content is expressed in terms of weight for solids, fluid measure for liquids and fluid measure or weight for semisolid cosmetics. If the product inside the package is divided into individual units or portions, then the label should indicate net quantity by weight or volume and also the exact count of individual units or subdivisions within the package.

Batch No.: Batch number is the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection. Batch Number is a mark of identification by which the product can be traced in manufacture and identified in distribution. The batch number should be preceded by the letter "B" or the word "Batch No." or "B. No." or "Batch" or "Lot No." or "Lot". The declaration of batch number can be made on inner or outer label.

In the case of soaps, instead of the batch number, the month and year of manufacture of soap shall be given on the label.

Price: Retail sale price is the maximum price at which the commodity in packaged form may be sold to the consumers inclusive of all taxes. The retail sale price of the package shall clearly indicate that it maximum retail price (MRP) inclusive of all taxes in Indian currency. This prevents hidden charges and ensures that the consumer pays only the amount displayed. Retailers, however, may sell the product at a price lower than the MRP, but they cannot exceed it. In addition to MRP, a new requirement is USP required on outer label. Unit sale price (USP) means the sale price (inclusive of all taxes) per specified unit of weight, measure or number. It is a critical piece of information that helps consumers compare prices of similar products sold in different quantities and packaging.

Consumer Care: Every package shall bear the name, address, telephone number, e-mail address of the person who can be or the office which can be contacted, in case of consumer complaints. This make it easy for consumer to report issues with the product.

Barcode, GTIN or QR Code

A barcode is a graphical representation of data that can be read by machines (scanners). It consists of black lines (bars) and spaces of varying widths. Cosmetic products are typically labeled with 1D barcodes for retail, inventory management, and logistics. A QR code (Quick Response Code) is a two-dimensional barcode that can store a significantly larger amount of data than a 1D barcode. It is made up of black squares and dots arranged on a square grid. The GTIN (Global Trade Item Number) is a unique identifier for products and services, which can be represented in different formats (UPC, EAN, ISBN, etc.). It is used globally to ensure that products are universally recognized. Though these are not statutory requirement, their inclusion is common in the industry. Each of these plays a crucial role in product identification, tracking, and consumer interaction, with QR codes being the most advanced and adaptable to modern needs.

Other Contents

Dermatologically tested suggests the product has been tested for safety under dermatological control. This does not guarantee allergen-free but indicates some level of safety testing. Cruelty free indicates that the product was not tested on animals. SPF Value indicates the Sun Protection Factor used particularly on sunscreen products. Recyclable packaging refers to materials used in packaging that can be processed and reused to make new products, rather than ending up in landfills. This type of packaging is designed with the environment in mind, aiming to reduce waste and conserve resources.

DISCUSSION

Label is a regulatory requirement for displaying the necessary information of the products to the purchaser but it is equally important for manufacturer and marketers. Package and labels are identity of product and brand, and also serves as promotion in sales and marketing. Labelling of commodities are regulated through the Legal Metrology Act and the Legal Metrology (Packaged Commodity) Rules. The desire to appear neat, clean, pleasing and grooming appearance has increase cosmetic uses. Indeed cosmetics differs from medicine and food products and at same time differ from general commodities as it is ultimately applied to human body. The cosmetic harmful effect to health if any must be prevented. In India, the import, manufacture and sale of cosmetics are principally regulated through the Drugs and Cosmetics Act 1940, and the Cosmetic Rules 2020. In context of cosmetic labelling, the Cosmetic Rules 2020 require the information such as name of product, name and address of manufacturer, country of origin (in case of imported product) manufacturing licence number, manufacturing and expiry dates, batch number, net quantity, ingredients, caution and direction of use along with name and quantity of hazardous or poisonous ingredients. Sometime cosmetics are packed in small container, under such circumstances some contents are not mandatory. Even in case of usual packages, some information are compulsory on outer or inner labels. The requirement of the Legal Metrology (Packaged Commodity) are name of the commodity, name and address of manufacturer, country of origin if imported, net quantity, MRP (inclusive of all taxes) unit sale price, month and year of manufacture, best before or use by date, month and year, and consumer care details. The rule also specify that every declarations required to be made on principal display panel (PDP) of the package. The size of numerals and letter depends upon the area of PDP as well as way of displaying such contents.

It is mandatory to write the content specified in the rules but rules doesn't prohibits from writing additional content. Content like recyclable packaging, period after opening, cruelty free etc. donot violate the compliance. While making any additional declaration, it is to be noted that no cosmetic may purport or claim to purport or any idea which is false or misleading to the intended uses. The cosmetics meant for export are required to meet the specific requirement of law of country to which the cosmetic is to be exported in addition to name of cosmetic, name and address of manufacturer or code number as approved by State Licencing Authority, licence number, batch number, and expiry period.

CONCLUSION

Package and labels are the primary product identity of product. Labels are regulatory requirement as well as a promotion tool. The contents of cosmetic label include- product name, manufacturer detail, dates of manufacturer and expiry, ingredient list, information about hazardous ingredient such as name, its quantity, warning, caution and direction for use, batch number, net quantity, maximum retail price inclusive of all taxes, unit sale price, consumer care detail, storage condition, information about external use and so on. The contents of label should be true and not exaggerated.

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