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DECLARATIONS FOR LABEL OF AYURVEDA, SIDDHA AND UNANI MEDICINES

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ABSTRACT

Label and package are the primary identity of the pre-packaged product and source of information that the customers may want to know about it. The laws and regulations related to labelling of commodities are governed under the Legal Metrology Act and Rules, whereas Drugs and Cosmetics Act & Rules are applicable for labelling of medicines including Ayurveda, Siddha and Unani medicines. The declarations of label include name of drug, net quantity, manufacturer's name and address, manufacturing licence number, batch number, date of manufacture, date of expiry, list of ingredients and other particulars such as applicable. Preservatives and colouring agents shall be mentioned on the label of ASU medicines. The label of ASU products having artificial sweeteners should carry a statutory warning stating the name and quantity of the artificial sweetener used. The labelling must comply with the provisions of Drugs and Magic Remedies (Objectionable Advertisements) Act & Rules.

Keywords: Drug & Cosmetic Acts and Rules, Labelling of ASU drugs.

INTRODUCTION

Label is a printed packing material, including package inserts that provide information on the article. The label and package is the primary product identity containing information that the customers may want to know about it. Government has introduced laws and regulations related to labelling in order to safeguard the interests of the consumer and the society at large. The labelling requirements for packaged commodities in India are governed under the Legal Metrology Act 2009 and the Legal Metrology (Packaged Commodities) Rules 2011. The labelling of drugs and cosmetics is governed by the Drugs and Cosmetics Act (D&C Act) 1940 and Drugs and Cosmetics Rules (D&C Rules) 1945. According to Rule 95 applicable for drugs other than Homoeopathic medicines, no person shall sell or distribute any drug unless it is labelled in accordance with the applied Rules in prescribed manner. Rule 96 deals with manner of labelling and Rule 97 gives full detail about labelling of medicines. Rule 102 is for non-sterile surgical ligature and suture. It is known that drugs for export have to meet the specific requirements of the law of the country to which the drug is to be exported; this provision has been provided under Rule 94 which deals with exemption of certain drugs from certain provisions of labelling. Rule 106A deals with labelling of Homoeopathic medicines. Rule 104A prohibition against altering inscriptions on containers, labels or wrappers of drug. Rule 109 describes further particulars for Schedule F or Schedule F (1) and Schedule C drugs were as Rule

109A describes labelling of medical devices. Like Rule 94, Rule 109B deals with exemption of certain labelling requirements for medical devices for export from India. Rule 146 to 148 is related with labelling of cosmetics. As per Rule 146, no person shall sell or distribute any cosmetic unless the cosmetic, if of Indian origin is labelled in accordance with the rules. Rule 148 describes manner of labelling of cosmetics. But as per Rule 147 labels of cosmetics not manufactured for consumption or sale in India shall be adopted to meet the specific requirements of the consignee. Rule 148A prohibits against altering inscriptions on containers, labels or wrappers of cosmetics. Rule 148B prohibition against false or misleading claims of cosmetics. Rule 149 is related with labelling of hair dyes containing dyes, colours and pigments. Rule 32 and 32A prevent the import of drug if it is no labelled in conformity with the Rules. Rule 161, 161A, 161B 169 are related with labelling of Ayurvedic, Siddha and Unani (ASU) medicines. Under D&C Act there are many situations when a drug is deemed to be as misbranded and spurious drug. A drug is considered misbranded, if it is not labelled in the prescribed manner or its label bears any statement, design or device which is false or misleading in any particular. Similarly a drug is called spurious drugs if the label bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist. In the present study an attempt has been made to understand the labelling of Ayurveda Siddha and Unani (ASU) medicines.

MATERIAL AND METHOD

Drugs and Cosmetics Act 1940, Drugs and Cosmetics Rules 1945, Legal Metrology Act 2009 and the Legal Metrology (Packaged Commodities) Rules 2011, Drug & Magic Remedies (Objectionable Advertisement) Act 1954, Drug & Magic Remedies (Objectionable Advertisement) Rule 1955, Pharmacopoeias and Formulary of Indian System of Medicine, research paper, manuals, Govt. notifications, available official interactions and other information were collected and reviewed. Market samples of some manufacturers were also procured and studied.

LABELLING OF AYURVEDIC, SIDDHA AND UNANI DRUGS

Today Ayurvedic, Siddha and Unani (ASU) medicines are usually manufactured on commercial scale, packed, labeled and then come to consumer through distributor, retail pharmacy or mail order pharmacy. A commodity which is placed in its package without the purchaser being present is defined as pre-package commodity from this view the labeling of ASU products are governed by Legal Metrology Act, 2009 and the Legal Metrology (Packaged Commodities) Rules, 2011. But the main regulations for their labelling are the rules related to labelling, packing and limit of alcohol in Ayurvedic (including siddha) or Unani drugs present in Part XVII of Drugs and Cosmetics Rules 1945. Either printed or written in indelible ink, the label of innermost container of ASU drug (or other covering in which the container is packed) should have declaration of name of drug, net quantity, name and address of manufacturer, manufacturing licence number, batch number, date of manufacture, date of expiry, true list of ingredients and other specific particulars as required under the Drug and Cosmetic Rules as well as Legal Metrology (Packaged Commodities) Rules. These declarations are not required for transparent cover or of any wrapper case or other covering used solely for the purpose of packing, transport or delivery.

Principal Display Panel

For label declarations affixing individual stickers is not permissible. Principal display panel mean the total surface area in relation to the package where all the information and declarations as required under the Rules are to be grouped together and given preferably in one place. In the case of a package having a capacity of 10 cubic centimeters or less, the principal display panel may be a card or tape affixed firmly to the package and shall bear the required information. The height of letters in the declaration shall not be less than 1 mm height and when blown, formed, molded, embossed or perforated, the height of letters shall not be less than 2 mm. The height of any numeral in the declaration required under these rules, on the principal display panel shall not be less than as shown in Table-

1 and the width of the letter or numeral shall not be less than one third of its height, except in the case of numeral `1' and letters (i), (I) and (l).

Table 1

Serial Number	Area of Principal display panel in square centimetres (A)	Minimum height of numerals and letters in millimetres	Minimum height of numerals and letters when blown, formed or molded on surface of container in millimeters
	(1)	(2)	(3)
1	$A \leq 50$	1.0	1.5
2	$50 < A \leq 100$	2.0	3.0
3	$100 < A \leq 500$	2.5	4.0
4	$500 < A \leq 2500$	4.0	6.0
5	$2500 < A$	6.0	6.0]

Names of Product: In the case of packages with more than one product, the name and number or quantity of each product shall be mentioned on the package. For ASU drugs the name shall be the same as mentioned in the authoritative books included in the First Schedule of D&C Act. The Label of ASU drugs additionally require mentioning the name of traditional system to which it belongs. For this purpose the label has the word “Ayurvedic medicine” or “Siddha medicine” or “Unani medicine” as the case may be**.**

Net-quantity: A correct statement of the net content in terms of weight, measure or number as the case may be. The weight and volume shall be expressed in metric system. The weight of the wrappers and materials other than the commodity itself shall be excluded from the total weight. Where there is chance that the quantity that is received by the customer may differ due to the any environmental or other factors then it must be ensured that the quantity even if there is loss shall not be less than the net quantity as mentioned on the package. The units of weight or measure or number for pre-packed products shall be specified in accordance with the units specified (Table. 2).

Table 2: Unit of weight and measure for net quantity

Quantity	Application / Uses	Unit for expressing the net quantity -	
		When expressing a quantity less than,-	When expressing a quantity of equal to or more than-
Weight	Commodity is solid, semi-solid, viscous or a mixture of solid and liquid.	- one kilogram, the unit of weight shall be the gram.	- one kilogram, the unit of weight shall be the kilogram and any fraction of a kilogram shall be expressed in terms of decimal of sub-multiples of kilogram or in terms of grams.
Length	Commodity is sold by linear measure.	- one metre, the unit of length shall be the centimetre.	- one metre, the unit of length shall be the metre and any fraction of a metre shall be expressed in terms of decimal of sub-multiples of the metre or in terms of centimetre.
Area	Commodity is sold by area measure.	-one square metre, the unit of area shall be the square decimetre.	-square metre, the unit of the area shall be the square metre and any fraction of a square metre shall be expressed in terms of decimal of sub-multiple of the square metre.

Volume	Commodity is liquid or is sold by cubic measure.	- one litre, the unit of volume shall be the millilitre.	- one litre, the unit of volume shall be the litre and any fraction of a litre shall be expressed in terms of decimal of sub-multiple of the litre.
		- one cubic decimetre, the unit of volume shall be the cubic centimetre.	
		- one cubic metre, the unit of volume shall be one cubic centimetre.	-cubic metre, the unit of volume shall be the cubic metre and any fraction of a cubic metre shall be expressed in terms of decimal sub-multiple of the cubic metre.
Number	For items sold by number the symbol should be N or U.		

Name and address of manufacturer: Every package shall bear the name, address, telephone number, e-mail address, if available, of the person who can be or the office which can be, contacted, in case of consumer complaints. Complete address mean postal address at which the factory is situated or company or firm is registered, in any other case it is name of the street, number assigned to the premises of the manufacturer, the name of the city and State with Postal Index Number [PIN] Code. Name and complete address of the manufacturer and the manufacturing unit if these are located at different places. If the manufacturer is not the packer or bottler, the name and complete address of the packing or bottling unit as the case may be. Any other declaration as may be relevant to them matter must be placed on the packaging.

Manufacturing Licence Number, Batch Number, Date of Manufacture and Date of Expiry

Every ASU drug shall bear on its label the number of the licence under which the drug is manufactured. The figure representing the manufacturing licence number being preceded by the words "Manufacturing Licence Number" or "Mfg. Lic. No." or "M.L.".

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. Actually Batch Number is a mark of identification by which the product can be traced in manufacture and identified in distribution. For ASU products, figure representing the batch number being preceded by the words "Batch No." or "Batch" or "Lot Number" or "Lot No." or "Lot" or any distinguishing prefix.

ASU drugs shall bear on their labels the date of manufacture and the date of expiry. For ASU drug, the date of manufacture shall be the date of completion of the final products, or the date of bottling or packing for issue. The date of expiry of ASU medicines shall be conspicuously displayed on their label of container or package, and after the said date of expiry, these medicines shall not be in circulation. The 'date of manufacture' and 'date of expiry' shall be displayed in the 'numerical month and year, the month shall be printed as two digits and the year as four digits with a slash (/) in between.

List of Ingredients

The label of the container or package of ASU drug shall conspicuously display the true list of all the ingredients used in the manufacture of the preparation together with their quantity. Additionally for preparation of textual reference, a reference to the method of preparation thereof as detailed in the standard text and Adikarana, as are prescribed in the authoritative books specified in the First Schedule. The Ayurvedic Formulary of India (AFI) and National Formulary of Unani Medicine (NFUM) enlist single drugs which are the ingredients of compound formulation, under three class *viz.* drugs of plants origin, drugs of animal origin and drugs of mineral origin. For drugs of plants origin the rule clearly describes to write particulars such as

botanical names, plant part which is the ingredient of the formulation and finally the form in which the plant ingredient used in the formulation. The botanical names of plant based ingredients are given in AFI and NFUM as well as in The Ayurvedic Pharmacopoeia of India (API), Siddha Pharmacopoeia of India (SPI) and Unani Pharmacopoeia of India (UPI). The abbreviations given in API and AFI are usually used to write the plant part and their form in formulation. If the list of ingredients contained in the medicine is large and cannot be accommodated on the label, the same may be printed separately and enclosed with packing and reference be made to this effect on the label.

Additives, preservatives, antioxidants, flavouring agents, chelating agents etc. permitted in the Indian Pharmacopoeia, Prevention of Food Adulteration Act, 1954 and Bureau of Indian Standard Act, 1986 are permitted for use in ASU drugs with the conditions given in Rule 169. Manufacturers shall be responsible to ensure rationality, safety and quantity used of various excipients in the formulation. Additives shall be mentioned clearly with quantities used, in the application for licenses and the record for the same shall be maintained by the manufacturers. Preservatives and colouring agents shall be mentioned on the label of ASU medicines. Artificial sweeteners may be used only in proprietary ASU products and the label of such products should carry a statutory warning stating the name and quantity of the artificial sweetener used.

Specific Particulars

Schedule E(1) is the list of poisonous substances under the ASU systems of medicine. If any of these substances are the ingredient of ASU medicine and that medicine is for internal use for the treatment of human ailments then its label shall be labelled conspicuously with the words “Caution: To be taken under medical supervision‘ both in English and Hindi language.

The label of the container or package of ASU drug for external application shall conspicuously display he words “FOR EXTERNAL USE ONLY”.

Every drug intended for distribution to the medical profession, as a free sample shall further bear on the label of the container the words “Physicians sample. Not to be sold” which shall be over-printed.

The retail sale price of the package

The retail sale price means the maximum price at which the commodity in packaged form may be sold to the consumer and the price shall be printed on the package in the manner as 'Maximum or Max. retail price Rs/ ₹ `.....inclusive of all taxes or in the form MRP Rs/` ₹ .....incl., of all taxes

Prohibited Advertisement

The Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 & Rules 1955 prohibits advertisement of drugs in a manner suggesting that such drugs may be used for the procurement of miscarriage in women or prevention of conception in women, the maintenance or improvement of the capacity of human beings for sexual pleasure, the correction of menstrual disorder in women and curing or preventing any illness specified in the Schedule to Act. Drugs purporting to prevent or cure diseases and ailments mentioned in Schedule J of the D&C Rules such as blindness, baldness, asthma, cancer, obesity and sexual impotence cannot be advertised. This is not applicable with reference to ASU drugs.

DISCUSSION

Pre-packaged commodity means a commodity which without the purchaser being present is placed in a package. Product labelling is a part of the packaging of a product. Labelling of product is regulatory requirement and proper labelling can reinforce brand preference, improve compliance, and facilitate safe and effective uses. One of the functions of labelling is to promote sales and sometimes a consumer gets encouraged to buy a product simply due to attractive label. Drug and Cosmetic Rules 1945 neither instruct nor prohibit about to write dosages and indications on labels. If these are written they should be correct and should not violet any other provisions particularly the Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 & Rules 1955. The ingredients of ASU medicines are classified as plant origin drugs, animal origin drugs and mineral origin drugs and there is no concept of vegetarian or non-vegetarian medicines unlike food products therefore ASU medicines don’t require to bear a green colour filled circle inside

a square with green outline or a brown colour filled circle inside a square with brown outline. Similarly ASU drugs do not requires energy information per serving or dose. Finally referring to the labelling information, manufacturer/packer must take care of the information put out through labels. The information provided on labels should not only ensure the safety and efficacy but should also be clear and accurate.

CONCLUSION

In order to safeguard the consumers, there are laws and regulations related to labelling requirement, manner of labelling and the content of label. The label declarations of packaged commodities include name and address of manufacturer/packer/importer, common and generic names of the commodities, net-quantity, month & year of manufacture/packing/import, sale price of item/packet as MRP Rs. , expiry date, contact no. of the manufacturer/ packer or email address if available of the person who can be or the officer which can be contacted in case of consumer complaints. Affixing individual stickers is not permissible for making declaration.

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