ORIGINAL ARTICLE

A survey of the labeling information provided for Ayurvedic drugs marketed in India

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ABSTRACT

Background: Ayurvedic 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). The present survey was conducted to evaluate whether Ayurvedic drug labels were in compliance with the Drugs and Cosmetics Act, 1940 with respect to their contents. **Materials and Methods:** Ayurvedic drugs container labels at three Ayurvedic pharmacies were selected based on the convenience sampling method. Their contents were checked against a set of quality criteria given in the Act. The results are expressed as percentages. **Results:** Basic manufacturing details were present on all the 190 labels reviewed (101 classical and 89 proprietary formulations). References from authoritative books as specified in the 1st Schedule of the Act were mentioned on 90% of labels of the 101 classical formulations reviewed. Fifty-five percent (n = 56) labels of classical drugs and 79 (88%) labels of proprietary drugs provided an ingredient list. Although 20 (20%) of classical formulations and 13 (15%) of proprietary formulations labels mentioned the Cautions/Warnings, only one language (either English or Hindi) was used. **Conclusion:** Ayurvedic drug container labels were not compliant with most of the requirements specified in the Act.

Key words: Ayurvedic drug container labels, classical formulations, proprietary formulations, Drug and Cosmetic Act 1945

INTRODUCTION

The last century has witnessed many changes in the manufacturing of Ayurvedic drugs. In ancient times, Ayurvedic physicians themselves would prepare medicines for their patients. Today, only a handful of practitioners follow this practice. On the other hand, the manufacture and marketing of Ayurvedic drugs has formalized into a thriving industry, governed by the rules and regulations of the Drugs and Cosmetic Rules, 1945 of the Drugs and Cosmetics Act, 1940.[1]

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Ayurvedic drugs, marketed today, are mainly of two types, classical and proprietary formulations. Classical Ayurvedic formulations are those prepared/manufactured as described in the Ayurvedic *Samhita* (e.g., *draksharishta*, *chandrakala vati,* etc.) while Patent and Proprietary formulations are those formulated using plant extracts (e.g., Liv-52®, Manoll®).[2] Apart from this formal sector, there are many Ayurvedic formulations available through traditional healers and direct purchase over the internet. Interestingly, unbiased information regarding these formulations is not easily available to patients and hence details provided on the labels of the drug containers remain the major source of information to patients.

As Ayurvedic drugs fall under the purview of the Drugs and Cosmetics Act, 1940, the labels provided on the containers (stickers on the containers) of these drugs should comply with the requirements specified in this Act (part 50, 161). As per the Act, the labels should display the following information conspicuously, *viz.* net weight of the formulation, name and address of the manufacturer, license number, batch number, manufacturing date, references from standard authorative texts in case of classical formulations, Ingredient list, drug quantity in metric units, caution warning, maximum content of self-generated alcohol and maximum size of packing in case of *Asavas*.[1]

Against this background, the present survey was conducted to assess the extent to which the labeling information provided on the containers of Ayurvedic drugs marketed in India was in compliance with the Drugs and Cosmetics Act, 1940.

Materials and Methods

Ayurvedic drug containers sold at three drug pharmacies in Mumbai were chosen based on convenience sampling depending on the availability at the Pharmacies, with the only selection criteria being that the formulations should be marketed for sale in India only. The labels were checked against the following points mentioned in the Drugs and Cosmetics Act 1940.

- Name and address of the manufacturer.
- License number (the number of license under which drug is manufactured; it has to be in figures preceded by words like, Manufacturing License Number/ Mfg. Lic. No/M.L).
- Batch number (figure representing batch number preceded by words like lot. number, Batch no.).
- Manufacturing date.
- Net weight of the formulation (in terms of weight, measures or number as the case may be. This weight and volume should be expressed in metric system).
- References from standard authorative texts to be considered in case of classical formulations.
- Ingredient list.
- Drug quantity in metric units.
- Caution Warning (formulations containing drugs specified in Schedule E, which consist of drugs that have to be used with caution. The Caution Warning should be written in both Hindi and English).
- Maximum content of self-generated alcohol and maximum size of packing of alcohol in case of *Asavas*.

The results have been expressed in the form of percentages.

Results

A total of 190 Ayurvedic drug container labels (101 classical and 89 proprietary formulations) were studied. All these labels displayed the four basic criteria, i.e., name and address of the manufacturer, license number, batch no., and the manufacturing date.

With regard to the remaining criteria, it was observed that the net weight of the formulation was mentioned in 99% of the labels belonging to both classical (n = 100/101) and proprietary formulations (n = 88/89).

Approximately 90% (n = 91/101) of the labels of classical formulations provided references for the preparation of the same. Nearly 9% (n = 8/89) labels belonging to proprietary formulations provided references for individual ingredients.

About 55% (n = 56/101) of the labels of classical formulations and 88% (n = 78/89) of labels of proprietary formulations provided an ingredient list. Ninety nine percent labels of the classical (n = 100/101) and proprietary formulations, respectively (n = 88/89) specified the drug quantity in metric units.

Out of 101 classical formulations studied, 30% (n = 30) contained drugs belonging to Schedule E, although the Caution/ Warning was mentioned in only 20 of the 101 examined. In case of labels belonging to Proprietary formulations, 30% (n = 26/89) contained drugs belonging to Schedule E. However, only 15% (n = 13/89) had the Caution/Warning mentioned. Additionally, the Warning was mentioned only in one language (when Hindi and English both are required).[1] None of the labels, either belonging to Classical and Proprietary formulations, provided any information regarding precautions to be taken when consuming the medications.

Out of the 21 *asava* drugs studied, 62% (n = 13/21) specified the maximum content of alcohol but did not specify the maximum size of the packing. It was also surprising to note that about 19% and 33% labels of the classical formulations (n = 19/101) and proprietary formulations (n = 29/89) respectively had the expiry date mentioned on them although this is not mandatory as per the law for drugs marketed in India.

The salient observations are summarized in Table 1.

Table 1: Percent Ayurvedic drug container labels that fulfilled the requirements as per the D and C Act

Criteria	% Formulations which fulfilled the criteria	
	Classical (n = 101)	Proprietary (n = 89)
Listing of references from Ayurvedic texts	91(90.10%)	8 (8.99%)
Presence of an ingredient List	56 (55.45%)	78 (87.64%)
Drug quantity mentioned in metric units	100 (99.01%)	88 (98.88%)
Expiry date	19 (18.81%)	29 (32.58%)
Net weight of the formulation	100 (99.01%)	88 (98.88%)
Caution warning (should be in both Hindi and English)	20 (19.80%) although it was only in one language	13 (14.61%) although it was only in one language

Discussion

The present survey was conducted to assess whether the labels on Ayurvedic drug containers were in compliance with the Drugs and Cosmetics Act, 1940 with respect to their contents.

We observed that majority of the labels did not fulfill all the requirements that were mandatory as per the Act and there was not a single label, which fulfilled all 10 requirements as specified by the Drugs and Cosmetics Act, 1940. The results of the survey showed that nearly 45% of the classical formulations and 12% of proprietary formulations did not provide an Ingredient list.

As per the Act, a reference to the Ayurvedic texts is essential in case of classical formulations to rationalize the preparation of the same. However, this is not required for proprietary formulations. However, we observed that 9% of the proprietary formulations provided textual references for the individual ingredients, which is suggestive of the attempts made by manufacturers to rationalize the use of a particular ingredient in the formulation.

Regarding the issue of Expiry date, the Drugs and Cosmetics Act, 1940 states that the expiry date is mandatory only in case of Ayurvedic drugs that are exported outside the country,[1] thus implying that it is not compulsory for the expiry date to be printed in case of products marketed in India. Unfortunately, this can be interpreted that Ayurvedic products can be used for years without any issues. However, *Sharangadhar Samhita* has clearly specified that all Ayurvedic drugs should have an expiry date.[3] According to this *Samhita* every Ayurvedic formulation has a specific *saviryataavadhi* (shelf life), which means that the active ingredients in the formulation are active only up to a given period of time and further use of such formulations can result into no or poor efficacy, e.g., a *churna* has a *saviryatavadhi* of only four months. If used after this period, the formulation may be ineffective. Hence, through this study we strongly propose that printing of the Expiry date be made compulsory even on those Ayurvedic drugs marketed in India.

The absence of caution warning on the labels is a serious matter as drug container labels remain a source for important information regarding the medications, *viz.*, indications, ingredients, dosage, storage conditions and precautions to consumers and patients, and lack of availability of this information can result in irrational use of these drugs by patients.

None of the labels specified potential drug–drug or drug–food interactions and adverse effects since providing these details for Ayurvedic drugs is not mandatory by the Drugs and Cosmetics Act, 1940. However, considering the wide spread belief that Ayurvedic medicines are "natural" and, therefore, safe can thus lead to life threatening situations in case of misuse or interactions with other medications. Hence, we suggest that the manufacturers should also provide some information about the safety of the formulations (including dosage schedule and drug storage conditions) on the drug labels.

The Drugs and Cosmetics Act, 1940 does not insist on the processing details in case of *Bhasmas,* with the result that none of the labels had any of these details. One can find several methods for preparation of one *bhasma* in Ayurvedic texts.[4] Hence, it is necessary to specify which method has been used to manufacture a particular formulation. As there have been serious concerns regarding the presence of heavy metals and their related toxicity in *Bhasmas* in the recent past,[5,6] a mention of elemental ion content of the heavy metals on the drug container labels will prove advantageous to tackle this problem.

The main limitation of the study is that we could analyze the labels of only 190 of about 630 classical formulations described in the Ayurvedic formulary[4] and over 1000 Patent and Proprietary formulations available in the market.[7]

The present survey highlights that stricter enforcement of law on the marketing of Ayurvedic formulation is necessary.

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