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Article in *International Journal of Research in Ayurveda and Pharmacy* · August 2013

DOI: 10.7897/2277-4343.04434

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DEVELOPMENT OF CONSUMER GUIDELINES FOR APPROPRIATE USE OF AYURVEDIC MEDICINES: NEED OF HOUR

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Received on: 22/05/13 Revised on: 23/06/13 Accepted on: 17/07/13

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DOI: 10.7897/2277-4343.04434

Published by Moksha Publishing House. Website www.mokshaph.com

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ABSTRACT

Severe crisis is being felt by all stakeholders of Ayurveda about appropriate use of Ayurvedic medicines by common consumers. This is more relevant for new clients of Ayurvedic medicines who are very much vulnerable to different advertisements and purchase of Ayurvedic medicines without any thorough knowledge about Ayurvedic medicines. Considering this alarming situation, World Health Organisation country office India sanctioned a project to develop "Consumer guidelines for appropriate use of Ayurvedic medicines". This project was completed successfully in December 2011 and technical report was submitted to WHO in July, 2012. In March, 2013 Dept of AYUSH, Government of India has shown interest to publish technical report of the project for larger benefit of common consumer of Ayurveda. On the basis of greater experiences of Ayurvedic physicians and patients seeking treatment through Ayurveda we prepared guidelines especially about intake of Ayurvedic medicines for consumers. We had addressed criteria from purchase of medicines to parameters during administration with technical advice for storage of medicines. Need of introduction of consumer medicine information (CMI) in packing of Ayurvedic medicines, encouragement for physician advice and awareness about pharmacovigilance programme for Ayurvedic medicines are other suggestive measure for appropriate use of Ayurvedic medicines by common mass of globe.

Keywords: Consumer guideline, appropriate use, consumer medicine information, self medication.

INTRODUCTION

Ayurveda, the most ancient wisdom is alive in Indian social and cultural traditions since dawn of civilisation with aim to serve humanity. Ayurvedic principles amalgamate individual and community life style, prevention and promotion of health and code of conduct to all diseased to back in holistic fold of life with high spiritual end. Therapy of Ayurveda is also dependent on medicines of three sources namely botanical, zoological and mineral/metals. Ayurvedic pharmaceutics is very much accomplished in its preparatory treasures for transitional and ultimate conversion of these raw materials of different origin in to form of quality, safe and effective Ayurvedic medicines. Ayurvedic medicines are very nearer to objectives of global grace on virtue of its intrinsic properties of therapeutics. World Health Organisation realised that here is a need of development of consumer guideline for the appropriate use of Ayurvedic medicines for it's more better consumption and have high value of therapeutic efficacy. Thus a project was sanctioned to first and corresponding author of this paper to prepare a draft guideline for appropriate use of Ayurvedic medicines by commoners, not only for Indians but also for global citizen who so ever is willing to take Ayurvedic medicines under supervision of an Ayurvedic physician.¹ In compliance of provisions of project we did survey with the help of specific questionnaire (available on line too) among physicians and patient of Ayurveda.² After a broader collection of data we drafted guidelines for common consumer of

Ayurvedic medicines. This draft was validated by expert group and finally submitted to World Health Organisation country office in India for further necessary persuasion.³ Recently, Department of AYUSH, Government of India has shown its willingness to publish these guidelines for its proper propagation.⁴

Necessity of Consumer Guidelines

Consumers of Ayurvedic medicines need education on these medicines and treatment procedures as these plays an important role in health care. Consumers are broadly aware of the benefits of relying on the Ayurvedic treatment regimen and medication. But when asked about the range of products that are easily accessible and are in comparatively higher demand, few people can give any response other than referring to a handful of products like Chyawanprash, Triphala, Ashwagandha, Shilajit and the like. Except for a few well known names, any person is hardly aware that the range of products runs into an inventory of anything from 200 to 20000 products produced by over 8000 manufacturers. Likewise, very few users know the difference between branded products and classical products. They also do not know that certain manufacturers have indeed conducted studies on toxicology that they have undertaken animal studies to determine safety and efficacy and that their products are comparatively of a higher standard. The present cross-section of consumers is not in the habit of looking at the label or asking product information.⁵ Claims to treat "cancer, diabetes and cardiac ailments" are made

routinely on the labels of Ayurvedic products sold in the market. Since obtaining a license for manufacturing Ayurvedic products is a relatively simple process with little or no requirement for clinical validation of safety and efficacy, there is nothing to distinguish products which are made following a sound manufacturing process, that abide by the Ayurvedic pharmacopoeias and formularies and those that ignore mandatory requirements and simply make claims. Here it is noteworthy that amendments in Rule 158 made in 2010 are a welcome step taken by dept of AYUSH in right direction to ensure availability of quality Ayurvedic medicines.⁶ In such a situation the public either ignores the Ayurvedic products altogether or whenever they opt for them, they rely on big names, family tradition, advertising and word-of-mouth. Therefore, need of consumer guideline arise for public education which may provide information to individuals and communities that enables them to use medicines in an appropriate, safe and judicious way. Inappropriate use of medicines has serious health and economic consequences for both individuals and the community. Moreover, the focus on non-allopathic systems of medicine in India can be attributed to various reasons including a need to revive a rich tradition, the dependency of 80% of the country's population on these drugs, their easy availability, increasing worldwide use of these medicines, the lack of focused concerted scientific research and the abuse of these systems by quacks. Elsewhere, the increasing use of herbal products worldwide and the growth of the herbal product industry have led to increasing concern regarding their safety. The challenges in these non-allopathic systems relate to the patient, physician, regulatory authorities, the abuse/misuse of these medicines, quality and purity issues.⁷

Causes of Inappropriate Use of Ayurvedic Medicine

Worldwide various surveys (read for conventional medicines) reported that more than 50% of all medicines are prescribed, dispensed, or sold inappropriately, while 50% of patients fail to take them correctly. Moreover, about one-third of the world's population lacks access to essential medicines.⁸ However, for Ayurvedic medicines, no such data is available. But, we hope that this statement may be true for Ayurvedic medicines too. Few common causes of irrational use of Ayurvedic medicine are

- The use of too many medicines per patient (polypharmacy).
- Failure to prescribe in accordance with classical clinical guidelines.
- Inappropriate self-medication, often of 'prescription only' medicines.
- Lack of access to standard Ayurvedic medicines all over the country and across the globe.
- Inappropriate doses may result in lack of efficacy generally and serious side effects in some cases.
- Inappropriate use and over-use of medicines result in wastage of resources- often out-of-pocket payments by patients.

Finally, irrational over-use of medicines can stimulate inappropriate patient demand and lead to reduced access

and attendance rates due to medicine stock-outs and loss of patient confidence in the health system.

Remedy to Check Inappropriate Use of Ayurvedic Medicines

Although, the prescriber's role in promoting appropriate use of medicines is important; But the patient, community and cultural context cannot be ignored. The knowledge, attitudes and education of the consumer in relation to disease aetiology and treatment are critical determinants in health care. The rationale use of Ayurvedic medicines and the success of treatment is lying on knowledge of consumer about appropriate use of medicine. Lacking a trusting relationship, patients may hesitate to ask physicians to clarify either their basic health conditions or the treatment proposed. This hesitancy can be linked to fears of appearing foolish, to differences in social status and language or to lack of encouragement by physicians. Patients who have developed a trusting relationship with their physicians whether at a clinic or a drug shop, may be more likely to listen, to ask questions and to follow advice.⁹ WHO estimates that the average amount of time that a dispenser spends with a patient is less than one minute and that only about half of patients receive instructions on how to take the medicines they receive. Physicians/health care providers sometimes attribute lack of interaction with patients to the pressures of work and a lack of adequate staff. Looking all these practical problem, WHO took this initiative to make learn a consumer up to a minimum level of know how facts about use of Ayurvedic medicines appropriately. WHO think that as Ayurveda medicine is in process of popular acceptance globally so it will be most appropriate to set guidelines for global citizen who are not much aware about Ayurvedic medicines.

Ayurvedic Dosage Forms and Its Intake Methodology

Ayurvedic formulations are presented in a variety of dosage forms as per the need of consumer especially according to status of disease and otherwise as per his/her own age, physical and mental evaluation. Taking all evidences from Ayurvedic classics, classical Ayurvedic medicines and patent proprietary Ayurvedic medicines, defined under section 3 (a) and (h) respectively of Drugs and Cosmetics Act, 1940 are re-established. Subsequently different dosage forms of Ayurvedic medicines are notified in Ayurvedic Formulary of India, an official publication of department of AYUSH, Ministry of Health and Family Welfare, Government of India. Ayurvedic dosage forms which are for internal administration can be broadly classified into

- Primary dosage form: Swarasa, Kalka, Kwatha, Hima, Phanta
- Secondary dosage form: Churna, Vati, Arka, Guggulu, Panaka, Avaleha, Satva, Laksharasa, Lavana, Masi, Ksirapaka, Sneha, Asava-Arishta etc.

In the technical report of project we have submitted a short introduction of Ayurvedic herbal dosage forms, method of preparation, dose, shelf life, adjuvant, therapeutic indications and guidelines for consumer about how to use medicines along with its storage and other

relevant information for intake of a particular dosage forms. Due to limitation of space, we are not quoting that much detail in this paper. Few examples of consumer guidelines are being quoted here for reference in Table 1.

Summary Guidelines for Consumers of Ayurvedic Medicine

On the basis of recommendations made in consultative committee meeting of project we propose under mentioned general guidelines for consumers of Ayurvedic medicines.¹⁰

Common guiding principle

- Consumers of Ayurvedic medicines are advised to consult only those physicians of Ayurveda who are legally allowed to practice Ayurveda as per the law of respective country.
- Consumers should check the authenticity of the claim of the product before using the medicines and should not be carried away only by the advertisements on the name of Ayurveda.
- Consumers should purchase an Ayurvedic medicine as per the prescription of Ayurvedic physicians.
- Ayurvedic medicines manufactured by GMP (Good Manufacturing Practices) certified companies as well as 'standard' and 'premium' brands of Ayurvedic medicines approved by the agencies like Quality Council of India should be preferred by consumers.
- Consumers are encouraged to see and verify manufacturing date, expiry period and comparative cost economy of same medicine of different manufacturers.
- For Ayurvedic classical medicines, in case of any doubt, the consumer is advised to verify the credentials of manufacturer, retailer/dispenser or physician.
- For patent and proprietary Ayurvedic medicines, consumers are suggested to purchase these medicines only from reputed manufacturers of Ayurvedic medicines.
- Consumers are encouraged to ask physicians about the ingredients and particular therapeutic effect on his/her ailment of the prescribed Ayurvedic medicine.
- Consumers are suggested to keep Ayurvedic medicine at safe place with hygienic conditions.

Guidelines about administration of Ayurvedic medicine

- The consumer is encouraged to enquire the following points from the physician related to the consumption of the medicine:
 - a) Time of consumption
 - b) Before/during or after the intake of food
 - c) Duration of the treatment
 - d) Possible Drug-Drug interaction/Drug-Herb interaction
- If an Ayurvedic medicine is advised by physicians that the patient should consume a particular Ayurvedic medicine in the morning hours, it means that the patients should consume that Ayurvedic medicine before breakfast.

- For evening hours, it means that the patient should consume that Ayurvedic medicine in the vicinity of sun set.
- For morning and evening hours, it means that the patient should consume that Ayurvedic medicine with an interval of 12 hours.
- When a patient is taking Ayurvedic medicines and conventional medicines together, in such a situation, it is advised that a consumer should consult the physicians of both streams about the consumption of these medicines.
- Consumers are suggested that at the time of intake of different dosages forms of Ayurvedic medicine, a proper time interval as per advice of health care provider should be followed concerning the sequence of administration of these medicines.
- Consumers are encouraged to emphasize for examination of their Prakriti (Psycho-somatic constitution of human body) by Ayurvedic physicians and should get treatment for their illness in accordance of their Prakriti. Treatment given to patients in accordance of their Prakriti is more effective.
- Consumers are encouraged to use all Ayurvedic dosage forms such as Kwatha (decoction), churna (Powder), vati (Pills), avaleha (confectionary), sneha kalpa (medicated ghrita/oil), sandhan kalpa (fermented medicaments) as per need for their condition.
- Consumers are advised to look for a particular note on the package regarding the presence of substances notified under Schedule-E. In such a situation, the consumers have to be extra vigilant.

Futuristic Approaches for Better Consumer Services

Apart from above, hereby we propose some other measure which may be beneficial for better service to consumer of Ayurvedic medicines. These are as follows;

Induction of packing leaflet with sale of Ayurvedic Medicines

The best possible method to inform consumer about the Ayurvedic medicine is availability of information leaflet elucidating certain compulsory facts about medicines. These details may be depicting ingredients, indications, contraindications, dose, mode of administration, expiry period of those particular Ayurvedic medicines with each and every packing of Ayurvedic medicines. In other words consumer medicine information (CMI) should be designed to inform consumers about administration of medicines whether prescription or OTC products of Ayurveda.

CMI leaflets of Ayurvedic medicines may be produced by the pharmaceutical company that makes the particular Ayurvedic medicine and this should be available from different sources too.

The CMI leaflet may be¹¹:

- Enclosed within the medicine package
- Supplied by the pharmacist as a leaflet or computer print out
- Provided by the physicians
- Available from the pharmaceutical manufacturer, or

The information in CMI leaflets must be:

- Accurate and up-to-date
- Easy for consumers to use
- Consistent with the technical product information
- Clear headings (to help users find information quickly and easily)
- Simple instructions in an understandable language (regional language)
- Straightforward explanations of what consumers need to do.

The CMI leaflet is a reference document that consumers can take home and read away from the pressure of the consultation or the busy pharmacy. Consumer should keep CMI leaflet in a safe place where he/she will be able to find it in hours of need to refer to it later. As arming yourself with relevant, reliable information is a good way to really understand your treatment.

Check on Self-medication

Some people do not consult a doctor before taking medicines. Instead they opt for Self-medication, taking it upon them to decide which medicines they think they need. The forces that drive one to use medication include: real or perceived ill- health, ignorance and addiction or dependence on certain medications. Self medication may also become compelling under certain situations including:

- Poor access to desirable health care because of high costs, long distance and discriminatory policies;
- Poor regulation and/or implementation of regulations on prescription drugs and pharmacy practices (with profit motives overriding the professional requirements);
- Overzealous advertisements of medications, that make claims of efficacy and scope of use but conceal adverse effects;
- Poorly informed public on matters of health and self-care;

- Poverty which puts consultations out of reach for people who cannot afford to pay for professional health care services.

A major share of Ayurvedic medicines are sold without prescription means by methods of self medication. It invites a serious discussion by all concern. These practices lead to inappropriate use of Ayurvedic medicines.^{12,13}

Astuteness of Ayurvedic Medicines

Till the times Ayurvedic medicines were prepared by Acharya of Ayurveda in their direct supervision, these were undoubtedly very much astute. But same quality is not today in Ayurvedic medicines. Reason behind this may be commercial interest which lead to corruption and compromises in preparations of medicines. At present, Ayurvedic medicines are being exposed to several kind of adulteration and many other ill practices during manufacturing by certain companies. There is an urgent need for rectification of all these malpractices by rule of laws and Government of India is taking care of it through several amendments in drugs and cosmetics act, 1940. GMP notification and permissible limit of heavy metal are some of these steps to ensure quality and safe Ayurvedic medicines.¹⁴

Assistance through Pharmacovigilance in Appropriate use of Ayurvedic Medicines

The specific goals of Pharmacovigilance programme for Ayurvedic medicine are to improve patient care and safety in relation to use of Ayurvedic medicines and other interventions. This is also to contribute the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost-effective) use. Consumers of Ayurvedic Medicines are back bone of this programme as the information provided by them only help in successful monitoring of appropriate use of Ayurvedic medicines.¹⁵

Table 1: Depicting Consumer guidelines for intake of different dosage forms

Dosages form	Guidelines	Remarks
Swarasa Kalpana (Self expressed juice)	<ul style="list-style-type: none"> • Take indicated healthy part of plant, • Use juicer, mixer or simple mortar pestle for instant preparation of Swarasa. 	<ul style="list-style-type: none"> • Free from any infestation, infection, contamination, rotten or dried part of plant. • Preferably consumed within an hour.
Kvatha kalpana (Aqueous extract/decoction)	<ul style="list-style-type: none"> • Healthy part of plant should be taken. • Decoction should be prepared in open steel/earthen vessel. c) Packet of raw material or Kvatha churna should be kept in dried and safe place with hygienic condition. 	<ul style="list-style-type: none"> • Consumer should prepare fresh decoction at the time of administration. • Decoction prepared in evening should not be kept overnight for next day consumption.
Churna Kalpana (Powder)	<ul style="list-style-type: none"> • Take air-tight moisture-free packed churna. • Churna should be kept in mouth with precaution so that it cannot irritate palate leading to stimulation of cough or anything undesired. 	<ul style="list-style-type: none"> • Once packed churna is open for medication it should be closed properly. • After opening the package, it is advisable to consume it before 2 months.
Avaleha kalpana	<ul style="list-style-type: none"> • Once packed avaleha is opened for medication it should be tightly closed after every use. Once opened, the Avaleha should be preferably consumed within one month. 	<ul style="list-style-type: none"> • Avaleha should be store properly to check any undesirable growth of microbes as these dosage forms are highly vulnerable
Sneha Kalpana (Medicated ghrita/oil preparation)	<ul style="list-style-type: none"> • Once packed Taila/Ghrita is open for medication it should be tightly closed and stored properly. • For topical/oral /anal/vaginal application proper care and precaution is must. 	<ul style="list-style-type: none"> • It is advisable that any Taila/Ghrita when it is being used for massage it should be lukewarm.

Call for Renaissance of Ayurveda

Several measures to serve ailing humanity with perfection are under active consideration of many stakeholders of Ayurveda. It includes integration of health care, a systematic validation of Ayurveda and many more concrete steps to reform status of Ayurveda which may be a need for renaissance of Ayurveda in India as well as global.¹⁶

CONCLUSION

Promote Appropriate Use of Ayurvedic Medicines

Proper education to consumer group will encourage appropriate use of Ayurvedic medicines for its best therapeutic efficacy. World Health Organisation is continuously encouraging medical practices of Ayurveda in international arena. Therefore to make Ayurveda more acceptable proper consumer guidelines are need of hour¹⁷. In classics of Ayurveda, required information for appropriate use of Ayurvedic medicines are available abundantly¹⁸. But, this should be disseminated in language of lay man for adaptation by common public. For this, Governments and all stakeholder of Ayurveda have to play a very vital role for proper health care services through Ayurvedic medicines.

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Cite this article as:

Chaudhary Anand, Singh Neetu, Katoch D C. Development of consumer guidelines for appropriate use of Ayurvedic medicines: Need of hour. Int. J. Res. Ayurveda Pharm. 2013;4(4):618-622 <http://dx.doi.org/10.7897/2277-4343.04434>

Source of support: Nil, Conflict of interest: None Declared