

In the name of herbal medicine

B. Khakurel¹

R.R. Prasad²

D.D. Bhattarai³

A. Sheak⁴

Abstract

In the quest for safe and cost effective medicines, as much as 65-80% of the world's population have resorted to herbal remedies of one system or another, often led by a wrong notion that things originating from ancient practices cannot have detrimental effect on health. There are evidences of use of potentially toxic or ineffective plant substances in the form of crude powder or extracts contained in already marketed products. Herbal medicines even contaminated with ingredients of modern medicines, pests, microbes and heavy metals are marketed for which drug regulatory authorities often are not fully equipped to deal with. There is an increasing amount of cross-practice. Indiscriminate prescribing and illegal sale-distribution of drugs by health professionals belonging to different traditional systems including traditional healers and quacks, which is on the rise.

In Nepal, there is no specific legislation to regulate the safety, efficacy, quality, sale-distribution, promotion and utilisation of herbal medicines belonging to traditional systems but quite a good amount of exercise has been done to formulate policies and guidelines on herbal medicines, especially in the line of integrating them with PHC services of the national health care system. There is an acute shortage of professional manpower on herbal medicines. There is also a great deficiency of evaluated information on their practical use. There is a need to look at the toxicity and efficacy of herbal remedies in the light of their past history, usefulness and extent of admixture with allopathic therapeutic agents and animal products.

In this article, an attempt has been made to characterise the situation with a view to facilitate identification of issues and approaches towards rationalisation of the sector.

Keywords: Medicinal plants; herbal medicine; Ayurveda; traditional medicine; regulation/legislation & policies, Nepal; work of WHO in areas of herbal medicine.

Introduction

The indigenous or traditional systems of medicines have continued to use plant materials of hundreds of kinds (about 550) all over the world right from the earliest days of mankind. Ayurveda, the forerunner of ancient therapeutic system, has been using hundreds of herbs having remedial values since ancient times and there is still deeply held sentiment attached to it, particularly among the native people. The System has its base on popular beliefs or norms - it does not cause any harm and has stood the test of time, and the practices have mostly passed by from generation to generation for hundreds of years despite the onslaught of modernisation and modern medicines. In fact the practices of herbal medicines in different systems of traditional medicines have contributed to the advent of medical science to the present stage. Quite a large number of ingredients of current modern drugs actually came from the plant kingdom. Some 25% of the prescribed drugs still contain active principles originating from higher plants and nearly two-thirds of the population in developing countries virtually depend on herbal remedy-based therapies.^{1,2} The use of herbal medicine has been increasing even in developed countries in recent years. They are used for conditions like cancer, high blood pressure and allergies as well as for general well being.³ Even though traditional system of medicine has been recognised and is being incorporated in the health care programmes in many developing countries, the extent of trust in them is found to vary significantly from country to country, depending on the local availability of medicinal plants and the level of development of the herb-based clinical practices. The per capita use of herbal remedies in countries like Malaysia and the Republic of Korea far exceeds the consumption of modern medicines. Whatever maybe the trend of utilisation of herbal medicines, consumers' concern everywhere almost similar – safety, efficacy, costs, advertisement and promotion, regulation, and use. Together, there is a problem of concurrent self-medication of different therapeutic agents with total disregard to adverse effects, interaction and optimal use of limited resources available for health care.²

The historic 1978 Alma-Ata declaration suggesting integration of traditional medicine into national health care system⁴ and the subsequent activities implemented under WHO's programme of work have stimulated national governments towards developing policies and regulations on traditional medicines. All these have led to examining the possibility of using these medicines in PHC, encouraging wider use of locally-produced herbal remedies on the one hand, and incorporating practitioners into the national health care system on the other. As a result, in some countries, recognition has been given to traditional medicine as an integral part of the national health system or as an alternative approach run parallelly to modern system.

But the production of traditional remedies, often a cocktail of dozens of herbal ingredients in modern dosage forms, on a commercial scale, has not only posed challenges for the health profession with regard to their safety, efficacy and quality, but has also caused much confusion among consumers (for whom such remedies are almost always directly promoted for scores of trivial indications and many of whom in fact want to use them on their own discretion and choice without being informed about them). Even though manufacturers of herbal remedies advertise their product very effectively, they hardly emphasize product's limitation in terms of safety & efficacy, and also on their rational use by the consumers. Since, the claims assigned to the majority of herbal remedies have not been scientifically substantiated with respect to their safety, efficacy and quality, it is in fact increasingly bothering the regulatory communities these days when nothing significant is coming to rescue them from clinical evaluation and scientific research.

Globally, the current issue is to ensure use of herbal medicines in a regulated and sustainable manner so that herbal medicines could become an integral part of the national health care system. WHO monographs on selected medicinal plants have provided basis for such concern. This has also facilitated the design of national policies and legal frames towards assessment of quality (identification, analysis, formulation rationale, stability), safety (experimental and toxicological data) and efficacy (evidence to support conventional use and claims), rational use (labelling and product information for consumers) and availability for regular supply. Formulation of a list of essential herbal medicines and adoption of adequate measures in registration and licensing systems, and compliance with supply criteria encompassing collection, cultivation, local production, processing, imports and preservation aspects without creating a legal barrier for eco-friendly use of herbal medicines are some of the measures recommended by the WHO.⁵

Currently the WHO SEARO countries have been placing emphasis, inter alia, on standardisation, quality control and utilisation of herbal medicines. The three collaborating centres for research and training in traditional medicines located in Jamnagar and Varanasi in India and in Pyongyang in DPR Korea have been instrumental in facilitating regional activities of priority.⁶ Some of the activities carried out in the Region with the support of WHO are production of traditional medicines complying GMP; quality specifications

and standards for herbal medicines; training of practitioners from PHC view points; developing tools for quality control; standardisation of raw materials; cultivation, and development of herbaria.⁷

In Nepal, traditional systems of medicine have been ingrained in the cultural and social fabric like in any other countries of the Region. Quite a significant proportion of population are still attended by traditional healers and Ayurvedic practitioners despite extension of modern health care up to the village level. As a matter of policy, HMG

is committed to providing inexpensive medicines through different levels of governmental institutions like Ayurvedic, Homeopathic and Unani Clinics throughout the country.

There is a need to utilise available resources both herbs as well as the practitioners in view of limited access of majority of population to modern medicine and the economic advantage in using herbal products.⁸ At the same time, there is growing concern regarding uncertainty of safety, efficacy and quality of herbal products particularly those differing in formulation from the traditional 'Grantha' or 'Shastriya' method on the one hand and injudicious exploitation of herbal plants endangering their rightful existence on the other. Equally relevant from rational use view point is the problem of prescribing and dispensing of herbal medicines by practitioners of modern medicines who actually are devoid of formal

education on herbal remedies. The trend is likely to exist because the manufacturers of modern medicines including foreign-based multinationals are coming into the business of herbal products, of which the target for promotion are the practitioners of modern medicines or the direct consumers rather than the traditional physicians.

Herbal Remedies in Nepal: policies and practices

Considering the importance of high level policy decision and sustained commitment of the government for incorporating traditional medicine into the official health care system, HMG has so far brought

out general measures into existence for action by the concerned agencies. **The National Health Policy 1991, Nepal,**

in the case of Ayurveda, directs that this System will be developed and integrated gradually. Organisational structures for different levels will be developed separately. Encouragement will be provided, as far as possible, to other traditional health systems like Unani, Homeopathy, and Naturopathy. A separate department exists for Ayurvedic Medicine under the Ministry of Health.⁹

Likewise the **Eighth National Plan (1992-1997)** maintains emphasis on the phased development and strengthening of the Ayurvedic System. For the development of this sector, emphasis will be given on the strengthening of the existing institutions, drug production, manpower development and research. The target and programme specified for the development of Ayurveda and other traditional systems highlight that these approaches are recognised in the national health system.¹⁰

The **National Drug Policy, 1995** aims to define, promote and regulate the quality and standards of Ayurvedic, Homeopathic, and other traditional medicines by adopting a scientific approach. In order to achieve this it intends to develop necessary manpower to carry out research, development and standardisation. Production of traditional medicines as per the recognised literature will be facilitated by involving suitably qualified personnel and adopting modern technologies where possible & feasible. Formulations other than those included in the standard traditional "Granthas" and materia medica will be subjected to evaluation for their safety, efficacy and quality.¹¹

Acknowledging the abundance of medicinal herbs in the hills, mountains and plains and a wide practice of cultural and indigenous systems of health care and also realising the constraints faced by the Ayurvedic system of medicine in the absence of a clear national policy, and recognizing official status of this system in the health care existing since time immemorial, HMG has brought out the **National Ayurvedic Health Policy 1996**. The policy emphasizes on a need for upliftment of manufacturing of Ayurvedic medicines. The Policy, inter-alia, aims to make Singh Durbar Baidyakhana as an autonomous and commercially viable unit capable of managing production and supply of standard quality Ayurvedic medicines and thus contributing to the national economy through export or import substitution.¹²

As for the cultivation, production and trading of medicinal herbs, the Ayurvedic Policy encourages standard trade practice on herbs by developing herbal farms in the hills, mountains and plains, and strengthening production, protection, and promotion of the herbs at the community level. All institutions related to herbs will be coordinated to follow a standard practice in domestic trade and export. Ayurvedic dispensaries, both at government and private sectors, will be encouraged to produce quality products by following GMP. Necessary coordination will be established with the Department of Drug Administration and other related institutions for this purpose. An Ayurvedic medicine committee and a laboratory will be developed for testing the quality as well as for carrying out other technical work. A Nepal Ayurvedic Pharmacopoeia will be compiled and published.¹²

The Department of Ayurveda has already drawn a list of about 279 Ayurvedic medicines mostly comprising herbal ingredients under about 40 therapeutic categories for approval by the government.

The **National Industrial Policy 1987** has recognised medicinal herbs processing and herb-based pharmaceutical industries as an industry contributing to basic needs. National priority status and protection in the form of exemption of import duties, excise, sale-tax and other taxes are accorded to

them. Entrepreneurs will also be granted exemption of income tax for a period of 6 years starting from the date of operation.¹³

In the **Second Long-Term Health Plan 1998**, emphasis has been given promoting production of medicinal plants, and manufacturing (formulation and production) of pharmaceutical products from them following good practices intended for such purposes. The plan suggests preparation and use of products formulated from locally available medicinal herbs for the management of common ailments at the peripheral Ayurvedic dispensaries. Such units are also identified as responsible body for promoting cultivation of locally available medicinal plants. The district level institutions will additionally take responsibility for developing herbal gardens (cultivation, collection and preservation) and manufacturing traditional medicaments from such plant materials. At the regional level, the Ayurvedic institutions will have responsibilities to run rural pharmacy services, herbarium and development of herbal gardens.¹⁴

Legal and regulatory frame

Even though all herbal medicines are to be subjected to regulatory requirements, there are hardly any legislative criteria explicit to them. The predominant basis is the firmly grounded beliefs that the time-honoured medicines must be safe and body-friendly.

The Drug Act, 1978 recognises different systems of medicine in use in the country but does not specify system-specific requirements. However, while classifying drugs into groups and sub-groups for the purpose of prescribing and dispensing, the Regulation on Standard of Drugs lists only the modern drugs, thus differentiating prescribing and dispensing of traditional drugs from modern ones.

The legal framework governing regulation of herbal products is the same as for modern drugs. Section 32 of the

Drug Act 1978¹⁵ requires that the manufacturer disclose on the label the system (Allopathic Ayurvedic, Homeopathic or Unani, etc.) it belongs to. The label requirements are the same for all systems of medicine and are given in Schedule 5 and 6 of Regulation on Standard of Drug. The details of regulatory authority, scope and responsibilities, registration and licensing, inspection, quality control, etc. are general for all systems of medicine. Unlike modern medicine, laboratory tests for quantitative analysis of active ingredients responsible for a quantified amount of clinical response cannot be tested in the case of most of the herbal remedies. The licensing authorities, prescribers and consumers all have to contend with the display of a long list

of botanical names mentioned on the label except for regulatory measures

to ensure GMP at the time of manufacturing of the products and to control

physical parameters of ingredients being incorporated in the processing of a batch. Exercising the power delegated by the

Act, HMG has put a ban on combination products containing active ingredients of two or more systems of medicine (for example Ayurvedic, Allopathic, Homeopathic or Unani).

Trading on or cultivating or processing

of raw materials have not been brought under regulatory control so far. It is

not precisely known how many units

are in operation but there is one public sector plant named "Herbs Production, and Processing Company Limited" (HPPCL) to look after this area from national perspectives.

System-specific expert opinion as registration/licensing requirement

Regarding registration or licensing of medicines imported from India, the information and legal documents provided from the regulatory bodies and the expert opinion of the Department of Ayurveda (DA), MoH, HMG, Nepal are the main criteria besides examination of physical quality, label claims, presentation, etc. The number of plant materials that goes in herbal products is so large that hardly any practitioner of traditional medicines can keep or verify information on each component except relying on

manufacturers' claim. However, DDA, being a regulatory body, seeks views of DA in matter of authenticity of formula, origin of product, rationale, usefulness vis-a-vis safety and efficacy. The DA, through its internal committee, assesses the product and concerned documents and records its decision mainly based on the expert opinion provided and the review of parameters that it asks applicants to submit. The details asked for resemble closely with that of DDA requirements - formula description/reference, manufacture/testing procedures and specification, information related to manufacturers, regulatory documents including GMP, therapeutic information and references, quality/stability evidences, samples/labels/promotion materials, prices, presentation, letter of warranty, products, etc.

In the case of application for manufacturing, besides consensus of the DA, the industry is to comply with:

- the Drug Act 1978 and Regulations and Codes.
- commitment to obtain manufacturing license within 2 years after obtaining recommendation for establishment of the industry.
- provision related to layout/design, installation, technical staff, pricing, production condition, formulation details, label information, analytical methodology, GMP, etc.

Problems in the use of herbal remedies

Assessment of safety and efficacy including monitoring adverse effects of herbal product is more complex than for pharmaceuticals. Misidentification and inadequate or even mislabelling have posed a great problem with regard to their quality. A case of atropine poisoning occurred in a country like America due to supplier's mistake in putting deadly nightshade in place of comfrey (*Symphytum* species). There are numerous errors related to misidentification or inappropriate formulation or contamination of herbal remedies. To highlight these concerns the following examples can be cited: a) use of *Aristolochia fangchi* (containing the nephrotoxic aristolochic acid) in place of *Stephania tetrandra* and resulting 80 cases of terminal renal failure in women taking a Belgian Slimming treatment. b) an Australian patient who suffered heart attack as a result of his failure to follow herbalist's instruction to prepare aconite extract, and c) a herbalist who added steroid in his herbal cream or mefenamic acid and diazepam as adulterant in antiarthritic pills implicated for causing nephritis & renal failure, or d) reporting in the UK of poisoning cases following use of Asian traditional medicines containing 6-60% w/w lead.³ Toxic potential of plant material may not be fully appreciated by the consumers even in cases in which toxicity has been demonstrated. Such perception among consumers, health workers and even regulatory bodies is partly attributed to our failure to report and monitor adverse effects associated with herbal medicines. Herbal remedy related toxicities are mostly attributed to the use of a variety of mixture; contamination from pesticide residue, microorganisms, aflatoxins, radioactive substances and heavy metals; persistent use of certain plant that could be toxic in the long-run: variability in chemical constituent even in the same species: problem of nomenclature: adulteration, etc. The persons who are in high risk of toxicity due to herbal remedies are obviously the chronic users, those consuming large amounts, the elderly, the sick, the malnourished, and those on chronic medication of all sorts.

A lot of herbal products are neither truly traditional nor assessed scientifically as per guidelines for evaluation of new products (produced as newer combination in modern dosage forms, dose schedule, etc. using modern technology). These maybe misrepresented under Ayurvedic system and hence require criteria for assessment of safety, quality and efficacy against the label claims (e.g., vitaliser, energetic, aphrodisiac, liver or brain tonic, etc. to name a few). It has also been detected that such products are often adulterated with steroids, antiasthmatics, sex hormones, antibiotics and other potent and toxic chemicals. Such fancy products should be tested from public safety view point.

The use of herbs can be guided by a list of plants which are safe. Other measures could be through regulation of labelling requirement for the level of toxicity in the form of warning and consumer awareness information.¹⁶ For example, the Therapeutic Goods Administration (TGA), Australia has asked manufacturers of royal jelly products to label the product with warning indicating a potential of the product to cause a severe allergic reaction in people who suffer from asthma or allergies.³

Quality control measures

The quality of herbal medicines is determined by a number of factors like parts of plant used, stage of ripeness and the timing of collection, storage conditions and the ecological belts that they come from. This means batch-to-batch assessment

for reproducibility of plant ingredients even from known sources. The variation in ginsenoside from 1.9% to 9% w/w in 50 brands of ginseng sold in 11 countries highlight a need for such assessment.³ This could be a reason behind low degree of use of herbal excipients and ingredients in modern medicines. Equally difficult is the job of testing mixtures in the semi-finished or finished pharmaceutical products. However, comparison with established thin layer chromatographic spots is one example of some of the attempts being practised currently to ensure batch consistency to some extent. As for physical parameters, colour, taste, clarity, particle size and nature give clue to the presence or absence of certain constituents. The Royal Drug Research Laboratory has recently started, on a regular basis, to check some of the physical parameters like label, packing, colour, taste of contents, volume, specific gravity, pH, suspended foreign materials, and alcohol content in finished products. The alcohol content has been found to vary from product to product and even in similar formulations made by different manufacturers. The maximum reported so far is about 70% in one of the fermented products. DDA has arbitrarily fixed the maximum limit to 10% which resembles with the specifications of other countries also. The DDA, just as a thumb rule, is also following an internal convention to regulate newer herbal products whose formulation are not specified in Pharmacopoeia or other recognised "Granthas".

a. *The criteria used for finished products*

- product containing powder plant parts should contain not less than 65 mg/dose.
- product containing dilute extract should contain not less than 25 mg/dose.
- product containing concentrated extract should contain not less than 10 mg/dose.

As far the upper limit, it is always guided by efficacy and acute toxicity data.

b. *Standards of Ayurvedic crude drugs*

Quality evaluation of finished products in traditional medicine including herbal ones is not an easy job due to lack of clear ideas about the active constituents and also due to lack of methodology. Partly in line with the GMP concept it is wise to control at least the input in the first place. It was in this line that some amount of work was done by the Royal Drugs Research Laboratory in establishing standards for crude herbs. The work culminated into a set of four volumes of monograph on one hundred crude drugs used mostly in Ayurvedic medicines. The monograph includes definition, description with macroscopical and microscopical details (photograph and illustration), analytical standards (total ash, acid-insoluble ash), pictorial illustration of wild distribution in Nepal and the bibliographical references (pharmacological and chemical). The monograph also includes annexes on methodology used in developing it, list of 102 medicinal plants used in Ayurvedic products, 25 selected products containing on an average 8 ingredients (range 3-26). The monograph is recommended for use in identification and assay of the crude ingredients wherever possible.¹⁸

Domestic production

The first Ayurvedic hospital was established in 1916 AD. Ayurvedic manpower training was started with the establishment of Ayurvedic college in 1917 AD. Since 1972, T.U. Institute of Medicine (IOM) has started producing middle level manpower. IOM produced a few batches of graduates in integrated curriculum; it stopped in 1990. About 40 graduates of the integrated system are recruited in PHCC.

The only public sector national manufacturing unit for Ayurvedic medicines, popularly known by the

name "Singha Durbar Vaidhyakhana", started producing medicines from 1950 for the general public. Presently, it has been producing some 100 different traditional pharmacopoeial and patented generic Ayurvedic products worth Nepalese Rupees 7.5 million of which 75% goes for public sector distribution. Some 178 Ayurvedic health care institutions located in different parts of the country receive Ayurvedic medicines manufactured by this unit. The medicines are mostly distributed at very good price with a mark-up of only 6% on the actual cost of production. The demand for medicines from this production unit keeps ever-increasing due to its wide popularity but due to the constraint of production facility and lack of adequate integration of modern production technology, it has been facing a challenge to meet the demand. Currently, it is not possible to assess the quality of the finished preparations in the existing production facility except for the physical parameters like consistency, appearance, etc. For its 110 products, it uses about 250 kinds of raw materials - about 65% from Nepal and the rest obtained from neighbouring country India.

Although some structural changes have been introduced recently, the only public sector production unit is still awaiting reformatory measures such as:

- provision for adequate physical facilities (land and building), qualified manpower, and modern equipment;
- extension of production facility in other parts of the country or near the sources of raw materials;
- establishing marketing network;
- strengthening institutional frame-work;
- mobilisation of resources;
- implementation of research and quality assurance plan;
- development of proper documentation and validation system;
- preservation and sustainable exploitation of wildy grown herbs and extension of cultivation, etc.

It is difficult to find statistics on herbal medicine on account of its being true household-based and unlicensed remedy. There are about 30 licensed domestic units producing about 400 herb-based medicines (Ayurvedic) in the form of liquids, powders, tablets, capsules, oils, pastes, pills, extracts, etc. About 100 importers import over 2,000 traditional products containing herbal components.¹⁹ There are about 40 commonly used Unani medicines from 2 companies from Nepal and 10 from India, which are also principally based on herbal constituents. There is only one very poorly equipped Unani Clinic in the public sector providing services to about 2,000 people annually.

Conservation and sustainable use

It is estimated that of 7,000 plant species that are available in varied geographical and climatic conditions of Nepal, some 700 with medicinal value are in wide use. About 3,300 tons of medicinal plants are collected annually providing the government with Rs. 6.7 million in revenue. Improper collection and stretching in of human settlement has been a continuing threat to the existence of many of these species. Some of the mostly used ones and highly valued ones like valeriana, solanum, rauwolfia, belladonna, ergot, pyrethrum and some volatile oil bearing species are in cultivation in place of cash crops. HPPCL and forest conservation authority have developed manual for collection of forest products but due to lack of proper training, it does not seem to be effective in actual practice. Except

for finished products none of the activities related to herbal medicines are regulated by the Drug Act. Collection, processing and export of some of the endangered herbs like *Cordycep cinensis* and *Orchis incarnata* or their processed products are already prohibited under the Forest Act 1992. A number of crude plant drugs still get exported in a throw away price for lack of systematic and scientific approach in collection and marketing of crude herbs. Export of some of the other herbs like *Nordostachys glandulifera*, *Rauwolfia serpentina*, *Cinnamomum cecidodafdonga*, *Valerina wallichii*, *Parmelia nepalensis*, *Podophyllum emodii*, *Stone exduate* (Silajit), *Taxus wallichiana*, *Abis spectabilis*, *Rhubarb*, *Caspicum*, etc. is also prohibited. However, their processed products can be exported with the permission of the government. Certain amount of confusion in regulation relating to export of extract and processed products of prohibited plant species seems to have adversely affected the trade of processed products of lichen resinoid, valerina and cinnamomum.

Conclusion

Since herbal medicines play an important role in the health care of a large proportion of population, both in health and diseased conditions, more so in view of bridging the gap between the availability and unmet demand for modern medicines, concerted efforts should be made to modernise and promote this sector. Through laboratory assessment and mobilising committee of experts in herbal remedies, it is important to establish their safety and efficacy properly. Developing policies and practices governing sustainable use of wild inventory, protection of endangered species, and development of database of traditional remedies and their practitioners (indigenous knowledge and experiences), and the establishment of health gardens will have to be promoted. Time has come to work in line with the WHO slogan, "Save herbs, save life" and facilitate the craze for "back to nature" scientifically and rationally.¹⁷ It is also equally urgent to frame suitable legislative measure more focused on herbal products with a view to better regulate on the one hand and the promotion or protection on the other. Attempt to rationalise practices on the part of manufacturers, practitioners (both traditional and herbal), traders, suppliers, regulatory body and consumers in their respective areas is required.

As a non-regulatory approach to ensure regular supply, some of the locally available medicinal plants (preferably those identified under essential list and having commercial values) can be cultivated in family and community gardens ensuring adequate and continuous supplies and at the same time enabling protection of endangered species from the threat of extinction. Equally important in this effort is the job of imparting basic knowledge and skills about herbs and herbal remedies to PHC workers so that cultivation, identification, and collection of medicinal plants as well as their preparation and use in therapeutics could be effectively promoted within the communities in which they work. While imparting information to communities, care should be taken to refer herbs by their binomial Latin names (genus & species) so as to avoid misidentification and resulting erroneous association of their safety and efficacy.

References

1. Tiwari NN and Joshi MP. Medicinal plants of Nepal: I. *Journal of the Nepal Medical Association* 1990; **28**: 181-190.
2. Sarkar PK. Herbal/Ayurvedic/Indigenous Drugs. *Drug Disease Doctor*; **2** (1): 4-13. Drug Action Forum, Calcutta, 1987.
3. Drew, AK and Myers SP. Safety issues in herbal medicine: implication for the health professions. *Medical Journal of Australian Medical Association* 1997; **166**: 538-541.
4. Balasubramaniam K. Herbal Remedies: Consumer Protection Concerns. *HAI News* 1997; No. 97: 1-2, 11-12.
5. Regulatory Situation of Herbal Medicines - A Worldwide Review (WHO/TRM98.1), 1998: 1-14, WHO, Geneva.
6. Highlights of the Work of WHO in the South-East Asia Region, 1996: 34, WHO/SEARO, Delhi.
7. The Work of WHO in SEAR: Biennial (1995-1997) Report of the RD, 1997: 75-46, WHO/SEARO, Delhi.
8. Bannerman H, Burton J and Wen-Chieh C, eds. Traditional Medicine and Health Care. 1993: 314-316, WHO, Geneva.
9. National Health Policy, 1991, Ministry of Health, Nepal.
10. Health Section of Eighth National Plan (2049-2054), 1993, Ministry of Health, Nepal.
11. Drug Policy 1995. Ministry of Health, HMG/Nepal.
12. Ayurvedic Health Policy, 1996. Department of Ayurveda, Ministry of Health, Nepal.
13. Industrial Policy and Industrial Enterprises Act, 1987, Ministry of Industry, Nepal.
14. Second Long-Term Health Plan, 1998, Ministry of Health, Nepal.
15. Drug Act 1978 and the Regulations thereunder.
16. Huxtable RJ. The Harmful Potential of Herbal and Other Plant Products. International Symposium on Drug Safety 1989: 18-19. Health and Welfare, Canada.
17. Editorial. News Letter of the Asian Network on Medicinal and Aromatic Plants. 1997, No. 23, Thailand.
18. Adhikary SR *et al*. Technical Reports: Standards of Ayurvedic Drugs (DP/ID/SER.A/1075) 1988; **1**: 4-5. Prepared for the Government of Nepal by UNIDO.
19. Regulatory Facts and Figures. *Drug Bulletin of Nepal* 1995; **6** (1): 8. Dept. of Drug Administration, Ministry of Health, Nepal.