# Market entry requirements for herbal medicinal products in Sri Lanka: A case study

C.C. Jayalath[1], M.P. Hettiarachchi[1]* and K.D.N. Kodikara[2]
[1]Dept. of Crop Science, Faculty of Agriculture, University of Ruhuna, Mapalana, Kamburupitiya, Sri Lanka
[2]Agriculture Division, Export Development Board, Colombo 2, Sri Lanka

## Abstract

*The herbal medicinal product sector has been identified as one of the key areas of promoting exports in Sri Lanka. Developed countries have changed dietary habits into herbal products, resulting from increased health awareness. The demand for herbal products exceeds the supply in the major international markets in Europe, Japan and USA. Thus, developing countries have a comparative advantage to export herbal produce for the international market. Both synthetic and natural ayurvedic/herbal medicinal products used in pharmaceutical industry in Sri Lanka are categorized under the same coding system, called Harmonized Commodity Description and Coding System. Thus, market information related to volume exported, price and quantity consumed are not available on trade of herbal produce even in the customs. Information on major herbal products and consumption in Europe, USA, India, Japan, Australia and New Zealand were collected. Low product quality, high cost of production, short supply, insufficient raw materials and their seasonal harvest, lack of market information and lack of research and development, government incentive schemes, recognition as an industry and training and awareness programs were identified as constraints. It is suggested to develop a national plan to promote the industry, cultivation of medicinal plants, allocation of funds to educate suppliers and for extension services to upgrade the industry. This study indicated that herbal medicinal product consumption in Europe has increased in this decade. Import promotion programs in Europe will create higher demand for Sri Lankan produce.*

**Keywords**: Coding system; Harmonized Commodity Description; Herbal medicinal products; Import promotion program

## Introduction

During the past decade, herbal product consumption has increased in developed countries. Many segments of the population have changed into herbal products resulting from increased health awareness, harmful side effects and product withdrawal of chemical products creating more market opportunities both locally and internationally. Present turn over of the herbal and ayurvedic industry in Sri Lanka is approximately 2.5 billion per year. The production and marketing of herbal products have been expanding rapidly in many major markets in the world such as Germany, China, Japan, the USA, France, Italy, UK and Spain.

The main objective of the study was to support herbal producing and exporting, medium and small business entrepreneurs in Sri Lanka, in their efforts to diversify export through sustainable production. As the specific aims of observing market entry requirements for herbal medicinal products; categorization of herbal produce companies according to selected parameters; select the best five companies and study their export volumes and value distribution; identify issues and constraints related to the herbal medicinal industry, strategy option for the development of the herbal produce industry in Sri Lanka; recognize the activities and services of Import Promotion Organizations in Europe were studied.

## Methodology

Relevant literature, publications and studies were reviewed in order to collect information in herbal produce in the world and in Sri Lanka and consulted officials in relevant government organizations. Secondary data on herbal products were obtained from EDB (1994-2003). Thirteen herbal produce companies were visited and information collected by direct personal interviews with the company staff and by filling a structured questionnaire. Existing procedure of exporting products, number of products exporting, quality control certifications, marketing channels, exporting countries, production capacity and local market distribution channels were considered as parameters. Constraints of this herbal produce sector were identified via discussion with managers of the companies.

## Results and Discussion

### Market entry requirements for herbal products

India regulated the import, manufacture, distribution and sale of drugs and cosmetics. Requirements for safety and efficiency varied according to the classification (**1**: already in use for more than 5 years; **2**: in use for less than 5 years; **3**: new medicines) and market availability of the product. Japan herbal products with stated medicinal benefits come under the category of medicinal and pharmaceutical products. For the importation and custom clearance of such products, importer must show proof of having granted an import permit in accordance with the pharmaceutical affair's law, pursuant to Article 70 (1) of the Customs Law.

Germany, Norway and Switzerland herbal products are fully considered as medicines and therefore it needs a product licence. According to the EU Council Directive 75/ 319 EEC essential pre-conditions are needed for the registration of medicines regarding proof of quality, safety and efficacy (Council Directive, 1975).

### Market situation in herbal product companies

There were three major procedures of exporting herbal products; supplementary product, cosmetic or skin care product and medicinal product. Results showed that herbal products are exported only as supplementary products and as cosmetic or skin care products (Table 1). No herbal product was exported as Medicinal product in the selected companies.

**Table 1. Existing procedure for exporting herbal products**

| Existing procedure of exporting the products | No. of companies |
|---|---|
| Supplementary products | 12 |
| Cosmetic or skin care products | 7 |
| Medicinal products | 0 |

Regarding the marketing places for herbal medicinal products in local market, tourist hotels (Table 2) were the best marketing places, as (31 %) herbal medicinal products that were introduced to the tourist hotels a few years ago have become quite popular, and today almost every hotel in the country has set up herbal centers. The supermarkets (25 %) which are a more affluent market segment located in city areas such as Colombo, Kandy etc. and pharmacies (25 %) were the next best marketing outlets in the local market. Ayurvedic hospitals (19 %) also acted as local marketing outlets.

**Table 2. Local marketing outlets**

| Local market | No. of companies | % contribution |
|---|---|---|
| Supermarkets | 8 | 25 |
| Pharmacies | 8 | 25 |
| Tourist hotesls | 10 | 31 |
| Ayurvedic hospitals | 6 | 19 |

**Present situation of the herbal products industry in Sri Lanka**

It is important to get a recommendation letter from the Department of Ayurveda to manufacture herbal medicinal product in Sri Lanka. Eleven companies have obtained the Industrial Technical Institute (ITI) certifications issued on product basis. Only two companies have obtained ISO and 5S certificates but no company was fully adopting Good Manufacturing Practices (GMP) Standards (Fig. 1). Lack of raw material led to high production cost (31 %) followed by 25 % for Electricity, 24 % for labour and 11 % for other costs (Fig. 2).

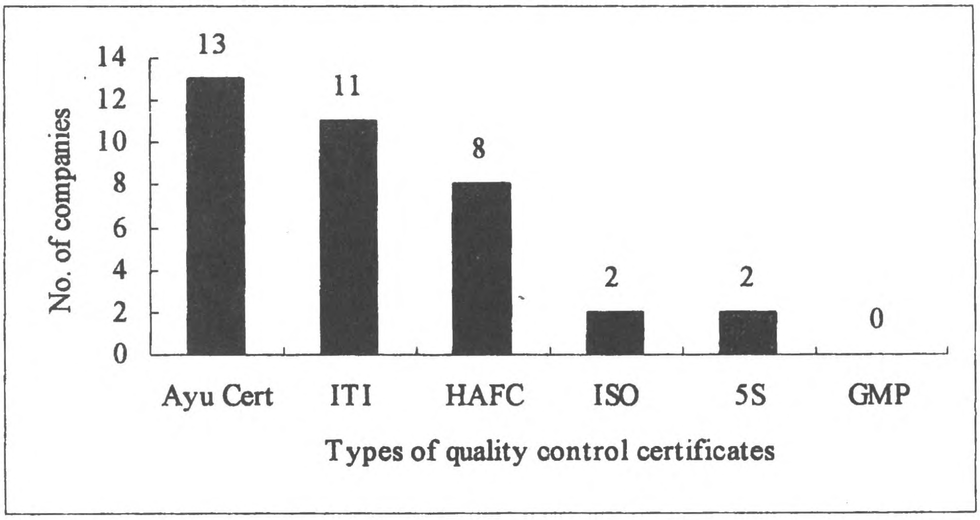


**Fig. 1: Existing quality control certificates up to 2004**

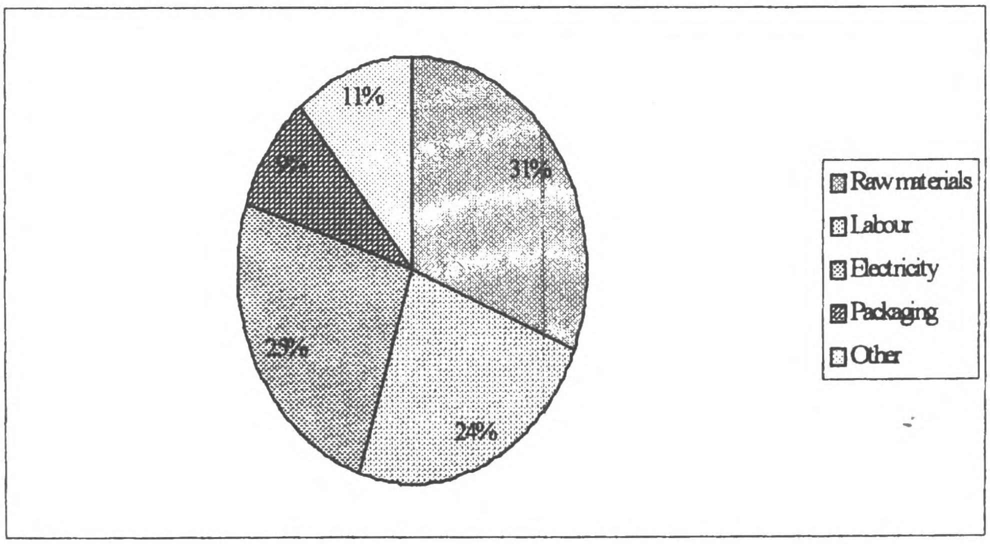


**Fig. 2: Production-cost distribution**

Manufacturers were not eligible to receive financial aid from funding schemes such as traditional crop funding and special low interest loans because Government does not provide much incentives for small and medium scale companies. Most of the companies were not interested in investing time and energy to manage their own lands. Only two selected companies managed their own lands (Fig. 3).

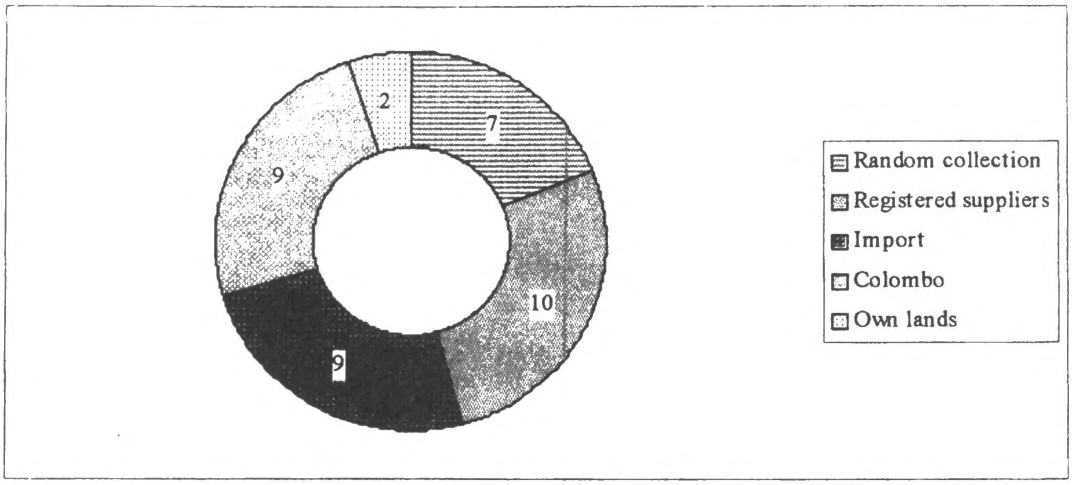


**Fig. 3: Supply source of raw materials**

**Constraints**

In this sector, there were only few companies exporting herbal products to developed countries since 1994. Although the herbal product sector has exponentially increased throughout the world, supply of herbal produce from Sri Lanka was still very limited. Lack of market information, poor research and development, lack of awareness on modern technology and safety, efficacy and quality, short supply of raw materials and lack of association were the major constraints.

**Suggestions**

It is suggested to implement a separate HS coding system to distinguish their herbal products and supplementary products and responsible institutions should maintain a database. Exporters have a responsibility to do their business in a transparent manner. Staff who dealt with export co-ordination should be trained for efficient usage of internet and email.

Data analysis for medicinal plants and products should be done via linkage of institutes; research, extension, universities and herbal producers. Research grant facilities are needed for specific company requirements for new product development, value addition and for postharvest handling. It is necessary to develop national standards for safety, efficacy and quality. New formulation must be added to existing ayurvedic pharmacopoeia and this can be a joint effort with the Department of ayurveda and the private sector.

**Conclusions**

Market entry requirements for herbal medicinal products varied with the country. Strict market regulation was observed in EU countries. Non availability of proven records for clinical, microbiological trials and quality tests limited the marketability of herbal products as herbal medicinal products to obtain the GMP certification. Tourist hotels were the best marketing places in Sri Lanka, followed by supermarkets and pharmacies. Large quantity of herbal products was exported to developed countries. Most of the Sri Lankan herbal produce companies run under capacity. Raw material accounted for the highest cost of production. Sri Lankan companies have tended to produce value added products in recent years. Import promotion organizations have special programmes and services to increase export from developing countries.

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