QUALITY ASSURANCE OF CULTIVATED AND GATHERED MEDICINAL PLANTS*

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Keywords: production, wild-crafting, utilization, Good Agricultural Practices, Good Wild-crafting Practices, quality, safety, efficacy,

Abstract

In the production and utilization of Medicinal and aromatic plants quality assurance has always been a focal issue. Despite this, the last decades have seen a new upsurge in the need to improve the traceability and safety of natural products. The increasing reliability in the production/collection practices of these species is also meant to contribute to the increasing acceptance of these commodities. To date, the major scientific bodies/organizations involved are engaged in the elaboration of guidelines and regulations that should contribute to the availability of validated scientific data on quality, safety and efficacy. Appropriate policies and legal frameworks to guide the protection, trade, and applications of medicinal and aromatic plant materials are also being elaborated (GAP, GCP, GMP, etc.). Due to the versatility, and the occasionally national character of quality assurance related activity there seems to be an increased need for the international harmonization of efforts.

INTRODUCTION

According to an WHO estimate 80 % of the world's population relies chiefly on traditional medicine, a major part of which involves the use of plant extracts or their active ingredients (Akerele, 1992).

There is no doubt that for many, plant medicines are a necessity, as costly pharmaceutical drugs are unaffordable in large areas of the world, while for others – especially in the developed countries - the desire to seek natural alternatives with few side effects is preferable to using conventional drugs.

As indicated by a compilation of experts (Table 1.), especially the countries of the East and Far-East – due to their long standing traditions - use a relatively large number of species with medicinal values, whereas the relatively high share of 11.8 % by the USA could be regarded as the result of the upsurge of interest of the last decades (Schippmann et al., 2002).

* Máthé, Á. and Máthé, I. 2008. QUALITY ASSURANCE OF CULTIVATED AND GATHERED MEDICINAL PLANTS. Acta Hort. (ISHS) 765:67-76 http://www.actahort.org/books/765/765_8.htm

As seen from Table 1, the average number of medicinally used species is around 1 700, which represents 12.5 % of the known 52 885 medicinal species. As a comparison, a study for Hungary states that out of the some 2200 species of the Hungarian flora, the number of Hungarian plants ever used in therapy and popular therapy is estimated at 345, with 52 of them being officinal (Máthé, I., et al., 1987).

TRADITIONAL USES OF MAPs IN TRADITIONAL SOCIETEIES

Without giving a complete survey, the examples on the relevant practices in China, India and Indonesia should illustrate the role of MAPs in societies with long a standing history of traditional medicine.

China

China has possibly the greatest amounts of documentation concerning herbal plants of almost any country in the world. The knowledge about Chinese medicine had accumulated over thousands of years, and had been confirmed through both empirical experience and scientific evaluation.

Chinese medicine has continued to develop with the establishment of traditional medicine colleges and institutions. The medical education is integrated in China with every medical school containing a department of traditional medicine and vice versa.

India

Traditional medicine is used by over 70% of the population. For centuries, ayurveda, siddha, and unani-tibb systems of medicine have coexisted with yoga, naturopathy, and homeopathy. All these systems are well integrated into the national health care system. There are state hospitals and dispensaries for both traditional medicine and homeopathy.

Indonesia

Traditional medicine provides an important resource of for self-care within the health services and through traditional medicine practitioners. Forty percent of the population uses traditional medicine, 70% in rural areas. Over 350 monographs for herbal medicines have been produced in Indonesia and Standards for good manufacturing practice for all such products have been applied since 1991.

TRADITIONAL USES OF MAPs IN THE MODERN SOCIETIES

In the western hemisphere the last decades have seen a new upsurge to improve the traceability and safety of natural products. According to data by Herbalert (2003). This has contributed to significant increases in the consum of these commodities.

The United Kingdom

The herbal medicines market stands at £ 240 million per year, with an estimated 15 million people choosing herbal remedies for everyday ailments, whereas figures for the global market top $ 60 billion per year and rising

Germany

There has been an increasing interest in the use of plant derived medicines also in Germany. Table 2 indicates that as compared to twenty years ago, the increase in the phytomedicinal treatment of cold related illnesses has augmented by some 60 %. Similar tendencies can be observed also in the case of other conditions. The fact that in 66 % of the cases phytomedicines have been used in the conditions of common cold speaks for itself expressing the confidence of the German population.

Besides confidence it is the availability of plant derived medicines to a broader public that can also significantly influence the consumption of these products. According to Craker and Gardner (2006) the utilization of herbal products in the U.S. changed greatly with the passage of the Dietary Supplement Health and Education Act (DSHEA) in 1994 (U.S. Congress 1994). This law established medicinal botanicals as dietary supplements, possibly due to the simple fact that many products used as herbal medicines, such as garlic (*Allium sativum*) and ginger (*Zingiber officinale*), are also common food ingredients and could be purchased as foods, but not as medicines. Trade figures shown in Figure 1 clearly indicate the impact of this important law on the consumption of dietary supplements.

Similar tendencies can be observed also in the countries of the European Union. Figures from the self-medication pharmaceutical market (all medicinal products bought spontaneously by consumers without a medical prescription at public price level, including Value Added Tax (VAT)) seem to verify a similar tendency (Table 3)

SOURCES OF THE RAW MATERIAL

In view of the ever increasing demand on medicinal plant raw materials, one might ask the question, where does this raw material come from and/or is it available in the quantities demanded by the relevant industries.

There is no doubt that the majority of the medicinal and aromatic plants used by the herbal drug industry comes from wild collection (Handa, 2005), with over nine tenths of MAPs used traditionally gathered in Third World countries. According to certain reports ca. 90% of India’s medicinal plant supply to international market is from wild stocks and only 20 of 400 plant species used medicinally are not from wild stocks,

A similar tendency can be observed in China, where of the 5 000 medicinal plants identified and 1 000 to 2 000 commonly used, only 20% are harvested from cultivation. (These countries are the biggest users and exporters of medicinal plants worldwide.)

Wild crafted medicinal plants are under siege also in the United States with the ultimate result of losing over 2 400 acres of native habitat every day, and as many as 29% of the most important plants first used by the indigenous dwellers of North America are threatened with extinction,

Some frightening examples on the indiscriminate harvesting of species in the US make mention of more than 60 million Goldenseal (*Hydrastis canadensis*) roots being harvested or wild- crafted annually, thus driving the species closer to extinction. In the Appalachian mountain range the following native species are presently considered "at risk: American ginseng (*Panax quinquefolium*), Black Cohosh (*Cimicifuga racemosa*), Blue Cohosh (*Caulophyllum thalictroides*), Slippery Elm (*Ulmus fulva*) and Echinacea (*Echinacea angustifolia*).

Over-exploitation has several undesirable features since it is frequently indiscriminate and destructive. Due to the frequently used inappropriate harvesting techniques, the susceptibility of many of these species to over-collection and the ever increasing demands, it could be predicted that this process could/will ultimately lead to the imminent extinction of many species.

Despite of all the menacing signs, there seems to be a consensus that the wild-crafting of medicinal and aromatic plants will remain the main source of raw materials for the industry (Leaman and Salvador, 2005). Consequently stakeholders of the production and utilization of medicinal and aromatic plants should find new ways and means to limit incurring damages and losses.

POSSIBLE SOLUTIONS

Sustainable use of plant resources

The use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations. (WHO Guidelines on GACP, 2003)

Cultivation vs. Gathering

Presently, hardly 10% of raw materials come from a cultivated source, although this could offer the buyers both a more consistent quality and a lower risk of adulteration than do their wild counterparts.

In view of the main quality determining biological factors of medicinal plant production (e.g. Genotype (genetic variability), Ontogenetic variability (stage of development), Morphogenetic variability (organs), Environmental impacts, Harvest and Post-harvest conditions, Contaminations (Adulteration, Pesticides, Herbicides, Heavy-metals, Radioactive isotopes, Microorganisms) (Máthé, 1999), the relevant advantages of cultivation over wild harvest can be summarized as follows:

The cultivation

- provides reliable botanical identity,
- guarantees the steady supply of raw material,
- allows controlled post-harvest handling,
- allows the observation of product standards according to regulations and consumer preferences,
- allows a relatively easy crop certification procedure (organic),
- may offer opportunities for the economic domestication of the medicinal plant species,

- renders possible the agreement between wholesalers and pharmaceutical companies on volumes and prices over time with the grower.

As witnessed by the above list, the main advantages of cultivation over wild-crafting lie - in many instances – in a more reliable quality, i.e.: more efficient methods of quality control.

QUALITY ASSURANCE SYSTEMS

Due to the nature of their utilization, in the production of medicinal and aromatic plants of either cultivated or wild-crafted origin, quality has always been a focal issue. The demand to comply with well defined quality standards in medicinal and aromatic plants urges the elaboration of specific production strategies. Good Agricultural Practices (GAP) are meant to provide defined and reproducible production conditions for medicinal and aromatic plant producers. The introduction of comprehensive, production protocols (Way-Bills) could be expected to contribute to the production of quality phytomedicines.

The Pioneers, i.e. the main stations towards a comprehensive Quality Assurance System in the area GAP have been (Iguera, 2005):

GAP (Good Agricultural Practices)

- 1983 First initiatives for the elaboration of GAP – Angers, France
- 1988 Conference on Medicinal Plants – Novi Sad, Serbia
- 1989 International Society for Horticultural Sciences (ISHS) – Budapest, Hungary
- 1989 Máthé, Á.: "Biological aspects of GAP – Guidelines. Cultivation" Newsletter of Medicinal and Aromatic Plants, Budakalász
- 1991 Pank, Franz, Herbs: "Richtlinien für den integrierter Anbau von Arznei- und Gewürzpflanzen" – Drogenreport
- 1992 World Congress on Medicinal and Aromatic Plants for Human Welfare (WOCMAP) – Maastricht, Holland
- 1995 Permanent Commission for Breeding and Cultivation of the Society for Medicinal Plant Research (GA) – Halle, Belgium
- 1998 5th August, first draft of EUROPAM (EHGA) GAP (Good Agricultural Practices),
- 1999 EMEA Draft Comment on the EUROPAM GAP of August 5, 1998,
- 2000 First EUROPAM (EHGA) version of GWP (Good Wild Crafting Practices)
- 2002 EMEA published "Points to Consider on Good Agricultural and Collection (GACP) Practices for Starting Materials of herbal origin" – EMEA/HMPWP/31/99/Rev. 3
- 2003 WHO releases the final version of "Guidelines on Good Agricultural and Collection (GACP) Practices for Medicinal Plants"

  EMEA published "Public Statement of Good Agricultural and Collection Practices for Starting Materials of Herbal Origin" – EMEA/HMPC/246816/2005

Good Wild Crafting Practices

Good Wild Crafting Practices of Medicinal and Aromatic (Culinary) plants are intended to apply to the harvesting and primary processing of all such plants collected, traded and used. They also apply to all methods of production including organic production. (EUROPAM, 2006). Their significance seems to be relevant since according to the World Health Organization (WHO), more than 21.000 species of species in the world are used for these productions and only about 100 species are regularly cultivated, whereas the remaining species are harvested in their natural habitat.

Some obvious advantages of wild crafting over cultivation are imply that

a) certain species have a long life cycle which means that they require a long period to reach the stage of harvest (e.g.: trees and bushes Horse-Chestnut, Birch, Linden tree, Hawthorn, Elder, Bearberry, etc.)
b) the species is difficult to propagate which means that it is not feasible to domesticate/introduce the species into cultivation (e.g. *Baptista tinctoria*)
c) the species is difficult or impossible to cultivate (Mistletoe, Mosses, etc.)
d) The quantity required of the plant is too small to justify the economic costs of cultivation.

To date, wild crafting production is mainly developed in the regions with a low technological and economical development, particularly in Asia, Africa, Middle and South America and East European Countries.

There have been numerous attempts to elaborate such guidelines in the various parts of the world. The following examples are aimed at highlighting both the tendencies and the stakeholders of this activity:

Guidelines (rather than standards) have been published by the World Health Organization in its WHO Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants (WHO, 2003) and, together with WWF and IUCN, Guidelines on the Conservation of Medicinal Plants (WHO et al., 2003), which was revised along with TRAFFIC. The European Herb Growers Association (EUROPAM) has published Guidelines for Good Wild Crafting Practice (GWP) for Medicinal and Aromatic Plants (EUROPAM, 2003), but this is mainly concerned with product quality (e.g. collecting the right species, correct drying and packaging) and contains virtually nothing about sustainability. There is also an EU Regulation on organic standards (no. 2092/91), which contains hardly anything on wild harvesting (Hamilton, 2005).

In its summary, the perhaps most comprehensive WHO Guidelines on GACP states that WHO has developed the Guidelines on good agricultural and collection practices (GACP) for medicinal plants in order to provide general technical guidance on obtaining medicinal plant materials of good quality for the sustainable production of herbal products classified as medicines. These guidelines are also related to WHO's work on the protection of medicinal plants, aiming promotion of sustainable use and cultivation of medicinal plants.

GACP especially in view of its implications towards sustainability is rather complex. Because of the complexity of the issue, Pierce and Laird (2003) have suggested that it could be useful to simplify systems of certification and labeling for wild medicinal plants by developing

comprehensive standards that combine the three basic categories of interest – product quality, social justice and ecological sustainability.

Total Quality Management vs. Quality Assurance

The policy to obtain high and sufficient quality is encompassed in the term "Total Quality Management" (TQM), which lays down the definition, transmission and guiding/monitoring of the quality specifics of the particular company. (Harnischfeger, 2005).

Quality assurance is defined as the fulfillment of all the requirements, - legal and experience based -, connected with all aspects of manufacturing of high quality herbal medicinal products.

Quality assurance can be defined as a network, encompassing the control and documentation mechanisms insuring the multitude of regulations pertaining to and used in practice of the pharmaceutical industry it is adhered to (Harnischfeger, 2005).

INDEPENDENT THIRD PARTY AUDITS

Based on the above it seems obvious that the independent control of compliance with the pre-defined and accepted standards, the independent Certification of Quality, should be set as the task of independent third party auditors, Audits should be conducted by persons associated with neither the suppliers nor the customers. Auditors should have experience with the commodity and processing being audited.

It is expected, that ultimately, the quality of the commodity (a), the retail- and Large-scale buyers (b, c), the market (d), and the producers (e) could/should equally benefit from the independent auditing.

Which standard(s) to apply ?

Medicinal and aromatic plants (MAP) are offered in a wide variety of products on the market. An estimated 40,000 to 50,000 plant species are used in both traditional and modern medicine throughout the world.

The great majority of MAP species is provided by collection from the wild. This trend is likely to continue over the long term due to numerous factors, including the high costs of domestication and cultivation and the fact that cultivation is not necessarily the most beneficial production system for some MAP species. Wild collection offers valuable income for rural households, especially in developing countries, Moreover, it could provide incentives for the conservation and the sustainable use of important habitats, Ultimately, it can strengthen local economies.

There is a general consensus that guide-lines to the sustainable wild MAP collection are urgently needed to provide specific guidance for industry, collectors, and other stakeholders on sustainable sourcing practices (Plant Specialist Group (MPSG). Stakeholders involved will receive an easy to handle list of criteria, indicators, and verifiers that will enable them to proof

the sustainability of wild collected plant material (ISSC-MAP - International Standard for Sustainable Wild Collection of Medicinal and Aromatic Plants, 2005)

ISSC-MAP covers social and economic factors, but clearly focuses on ecological aspects addressing two important aspects that are often left aside: the need for resource assessments and the question of annual sustained yields.

In addition, as a result of the increased activity of both international and national institutions/authorities, to date, quite a good many standards are available to regulate the production process of medicinal and aromatic plant materials (e.g.: EUROPAM (European Association of the Producers of Medicinal and Aromatic Plants), EMEA (European Agency for the Evaluation of Medicinal Products), WHO (World Health Organization), EUROGAP, etc. All these and in addition, the similar guidelines issued by some of the important medicinal and aromatic plant producing countries (Korea, Japan, China, USA, etc.) seem to create some sort of confusion, uncertainty.

In view of the globalized character of medicinal and aromatic plant trade and utilization, it should be in the interest of all stakeholders to harmonize the individual approaches and to agree upon (elaborate) internationally acceptable minimum standards.

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Table 1. Medicinally used plants world-wide

Country	Plant species	Medicinal plant species	%
China	26 092	4 941	18.9
India	15 000	3 000	20.0
Indonesia	22 500	1 000	4.4
Malaysia	15 500	1 200	7.7
Nepal	6 973	700	10.0
Pakistan	4 950	300	6.1
Philippines	8 931	850	9.5
Sri Lanka	3 314	550	16.6
Thailand	11 625	1 800	15.5
USA	21 641	2 564	11.8
Viet Nam	10 500	1 800	17.1
Average	13 366	1 700	12.5
World	422 000	52 885	

Sources: Duke and Ayensu (1985); Govaerts (2001); Groombridge and Jenkins (1994, 2002); Jain and DeFillipps (1991); Moerman (1996); Padua et al. (1999)

Table 2. Conditions for which German Consumers Use Phytomedicines

Condition	**1970 Poll**	**1997 Poll**
Common cold	41%	66%
Flu	31 %	38 %
Digestive or Intestinal Complaints	24 %	25 %
Headache	13 %	25 %
Insomnia	13 %	25 %
Stomach Ulcer	21 %	24 %
Nervousness	12 %	21 %
Circulatory disorders	15 %	17 %
Bronchitis	12 %	15 %
Skin diseases	8 %	12 %
Fatigue & exhaustion	8 %	12 %

Statistics are derived from consumer polls conducted by the Institute for Demoscopy in Allensbach, Germany. Source: IfD, 1997; Schilcher, 1998

Table 3. Self medication pharmaceutical market for conditions of cough and cold

	€ millions		
	2003	**2004**	**2005**
Austria			
Belgium	76.71	77.36	83.49
Croatia	136.28	130.55	131.94
Czech Republic	19.77	39258,00	30.14
Denmark	19633,00	20363,00	74.20
Finland	39385,00	9.43	8.75
France	39381,00	22.70	23.90
Germany	377.30	349.70	365.70
Greece	944.00	1008.00	1114.00
Hungary	53.20	51.90	49.35
Ireland	11.90	11.70	14.70
Italy	36.20	39.40	43.50
Netherlands	507.00	604.00	629.00
Norway	101.10	99.60	103.50
Poland	17.30	14.42	20.56
Portugal	221.85	217.50	284.20
Romania	47.80	47.90	20729,00
Russian Federation	19.50	22.64	24.78
Slovak Republic	344.00	416.00	532.00
Slovenia	17.30	20.40	26.50
Spain	39324,00	39314,00	9.79
Sweden	285.00	282.00	295.00
Switzerland	20.38	22.36	21.30
United Kingdom	153.80	141.50	151.90
EU-25	542.60	526.20	538.90
Europe	3476.42	3584.00	3873.82

Source: AESGP and AESGP National Associations 2006©

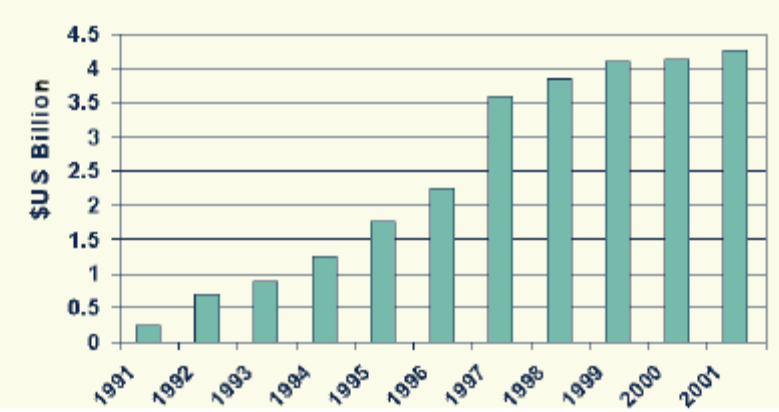

Fig. 1 Sales of dietary supplements. Sales of over $6 billion in U.S. are predicted by 2009 (Market Looks, 2004 – after Craker and Gardner, 2006).