

# QUALITY CONTROL OF BRAZILIAN PHYTOREMEDIES: THE LARGE BIOME DIVERSITY AND THE HIGH DEMAND REQUIRE URGENT AND EFFECTIVE STANDARDIZATION OF PLANT DERIVED PRODUCTS

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Plants and phytomedicines sold in Brazil either informally or over-the-counter lack adequate evaluation of the therapeutic activity. Formerly restricted to mild diseases in small communities, the market of these remedies grew wide to regions where the original cultural use was absent and critical evaluation was poor. Recently, the MERCOSUL trade agreement brought to Southern Latin America the urgent need for standardization of plant derived health products. Although many species are common to southern countries, botanical inconsistency is a major limitation for their quality control. The plant biome diversity in Brazil, for instance, vary from tropical humid to tropical dry areas, flooded hot lands, temperate to cold environment, highly populated to scarcely inhabited wooded regions. Since the changing ecosystem and the regional endophytic microbiota might unequally influence the genome expression, the plant chemical composition, its pharmacological activity and folk use might differ. Interspecies variation and defensives use may also change the uniformity of the end-products. Therefore, taxonomic identification of the raw material is insufficient for general qualification of the pharmaceutical source requiring chemical standardization complemented by efficacy and safety evaluation before scaling up. In Brazil, as in many countries, innovative medicines from natural resources and phytomedicines are searched for use in primary health care. Some government sponsored projects privileged the search for anti-parasitic therapy as for malaria, leishmaniasis and Chagas disease as well. In any case standardization and evaluation of plant material are imperative but the scientific protocols usually vary. Which one is the best to be normalized and followed up? This presentation illustrates an academic collaborative project (BIOTROP Millenium Project-CNPq) done to validate standardization processes: species of the same genus reported in folk medicine to be used for the same illnesses but grown on the vast biome of the Rain Forest, or grown on the temperate Atlantic Forest were chemically and pharmacologically compared. *Cecropia scyadophylla* Mart (Cs) was compared to *C. glazioui* Sneth (Cg); *Geissospermum argenteum* Ducke (Ga) compared to *G. laeve* (Vell.) Baillon (Gl). All of them were collected, dried, powdered and extracted according to the folk use: *Cecropia* 2% with water (AE) and *Geissospermum* 10% with 50% ethanol (EE). Taxonomic identification and DNA extraction were provided for future molecular comparison with species from other regions. AE was partitioned in n-butanol and EE in chloroform at different pH. The *Cecropia* active sub-fractions were further purified by HPLC (C18, water/acetonitrile, 210nm) collecting peaks with AUC > 1% for chemical identification and pharmacological mechanistic studies. The *Geissospermum* sub-fractions were purified in silica column. All the semi-purified extracts were tested for *in vivo* activities (up to 1g/kg *p.o.*) on vital functions (cardiovascular, CNS and behavior, respiratory), complemented by gastrointestinal and anti-inflammatory/analgesic/sensorial screening. The HPLC fingerprint for Cs and Cg showed similar compounds: flavanols, flavonoids and procyanidins mainly. *Cecropia* extracts were hypotensive, inhibited acid secretion and gastric ulcers, depressed CNS. Ga and Gl were rich in alkaloids but inactive by the oral route. The 3 main alkaloids from Gl were geissospermine, geissoschizoline and flavopereirine. The eight alkaloids from Ga were structurally and pharmacologically different from those of Ga. The *in vitro* activity of the *Geissospermum* alkaloids was on neuromuscular transmission and on the excitation-contraction coupling of rat skeletal muscles. The anti-malarial activity reported in folk medicine for all the studied plants was not confirmed to any extract either *in vitro* or *in vivo* models using *Plasmodium chabaudi*.  
Supported by CNPq, FAPEAM

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# HERBAL MEDICINE PROJECTS IN LATIN AMERICA AND PERU

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## **Introduction**

The use of natural resources involving traditional knowledge is regulated by item j) article 8 of Convention on Biological Diversity CBD (1992). At the Andean Region level, it is mentioned at Decision 391 and Decision 486 of Andean Community of Nations (CAN) about a Common Regimen on Industrial Property. Latin American countries have laws that establish the Protection Regime of Collective Knowledge of Indigenous Populations Linked to Biological Diversity (2002).

World Health Organization (WHO) and its Member States cooperate to promote the use of traditional medicine for health care. According to WHO, from 192 surveyed countries only 53 have some form of regulation for traditional medicine and among these only 18% include it in their national pharmacopeia (2002). Likewise, we have to point out the importance of safety and quality as well as productive chain sustainability, social and environmental impact. Latin America has several related initiatives.

## **Latin America**

The Andres Bello Convention as international organization, emerged from Andean countries initiative formed by 12 countries, performed an important work of data compilation regarding herbal medicines from Ibero-America with the support from Ibero-American Development Programme for Science and Technology (CYTED). They specify the identity and composition of a numerous herbal medicines. Later, Biotrade National Programs (with UNCTAD support) at Bolivia, Colombia, Ecuador and Peru promoted a recollection and/or production activities, processing and trade of products or services from native biodiversity. BioTrade enforces criteria of environmental, social and economical sustainability and performs a follow up of agriculture recollection activities. UNCTAD/Biotrade, within the Biotrade Facilitation Programme, selected the first sector to be supported as the Natural Ingredients for Cosmetics and Pharmaceuticals (NICP).

At Central America region, TRAMIL was a project of applied research related to traditional medicine of Haiti, Dominican Republic and other islands, this project was born from common effort from Enda –Caribe and they have been continued along the time. The University of Panama with support from Organization of American States (OAS) developed a project to eliminate the poverty and improve the health conditions using technology for new crops and development of herbal medicines. The Regional Support Program to the Development Network of Herbal Medicines (PLAMSUR) financed 19 projects of herbal medicines development at Argentina, Brazil, Paraguay and Uruguay.

Lately, NOREXPORT Project (Bolivia, Colombia, Ecuador and Peru) supports standardization process at sector, national and regional level. They use Codex Alimentarius and involve all links of productive chain such as seed quality, geographical origin, agriculture knowledge, phytosanitary certificate, etc.

Also, Costa Rica with its project INBIO-BID developed herbal medicines: Quassia Amara, Justicia pectoralis, which allowed protection of Bouganvillea forest using private/university partnership.

Bolivia has selected 300 varieties derived from the Callahuayas pharmacopeia. Ecuador started projects with crops at different climate levels from 4,200 m above sea level, with 48 communities and 80% women.

On the other hand, Argentina Society of Phytomedicine Project “Cultivating Health” raised a proposal to get support from Government for Ambay leaves, Congorosa leaves and Calendula flower (pot marigold).

Chile includes in the National Standards of Medicines 103 herbs recognized as benefit for health from the Ministry of Health and developed, Mosqueta Rose, Oregano, Quillay (soap bank tree), Vanilla and Parsley.

## **Peru:**

The native groups of Peru possess important knowledge with respect to uses and properties of species, registering about 4 400 plants with known uses, placing Peru as the number one country in the world with such level of traditional knowledge. Among them, Peruvian Government is supporting the following: Camu camu, Sacha Inchi, Maca, Purple Corn, Yacon, Tara, Uña de gato (cat claws) (Perubiodiverse Project)

## **Conclusion:**

The chain production development has favored that the term “capacity development” will be understood as an advantage for knowledge transfer.

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Resident at the Pharmacist Department at the Hospital of the University

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UNIVERSITY OF NAVARRA SPAIN Navarra - SPAIN

Graduate Course: Pharmacokinetics and Biopharmacy

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NATIONAL UNIVERSITY OF SAN MARCOS Lima - PERU

Second Specialty: Clinical Pharmacist

- Faculty of Pharmacy and Biochemistry. Graduate School
- Title: Clinical Pharmacist, Thesis: Development of a Computer System for a Unit Dose Regimen.

THE UNIVERSITY OF TOKYO Tokyo - JAPAN

Research Student Certificate

- Graduate School, Division of Pharmaceutical Sciences as Research Student. From April 1st 1990 to March 30th 1992

THE UNIVERSITY OF TOKYO Tokyo - JAPAN

Researcher

- The University of Tokyo Hospital, Computer Medical Center, Department of Pharmacy, from April 1st 1990 to March 30th 1992

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- Ministry of Health and Welfare, National Institute of Health Sciences (formerly National Institute of Hygienic Sciences). Division of Pharmacognosy and Phytochemistry. From April 1st 1992 to March 30th 1996.

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# **NATIONAL POLICY AND REGULATORY SITUATION OF HERBAL MEDICINE IN CUBA.**

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## **SUMMARY**

Cuba is one of the countries inside the WHO Members States of the Region of America that has a national policy on Traditional Medicine integrated to the health national system. There are a National Program for the development and generalization of traditional medicine that include a national policy on herbal medicine. This Program promote the development of technical guidelines and international standards in the field of herbal medicine, and to introduce measures for the regulation and control of medicinal plant products; and to identify those medicinal plant or products derived from them, which have a satisfactory efficacy/side-effect ratio. They are includes in national formularies. The Ministry of Health and the Ministry of Agriculture have good relationship about the cultivation, collection and preservation of medicine plants. As part of this Program the National Regulatory Authorities of Drug (NRAD) defined the traditional medicine strategy, especially about herbal medicines, aimed at to develop regulatory and legal framework to ensure good practice, the authenticity, safety and efficacy of these medicines and to promote the rational use. The NRAD has established a National Expert Committee on Traditional Medicine with functions and activities for the development and implementation of the medicine traditional.

## INVITED LECTURE

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Specialist in registration and control of drugs.

# **IDEAS AND METHODS OF MODERN RESEARCH ON TRADITIONAL CHINESE MEDICINE**

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## **INTRODUCTION**

The material basis of Chinese compound formula is the complex compositions of different drugs and the mechanism through which it achieves effectiveness is the multiple target points. Based on years of researches on Traditional Chinese compound formula, we have raised some ideas and methods for research on traditional Chinese compound formula and provide reference to study on traditional medicine.

## **METHODS**

Traditional Chinese compound formula were investigated by modern molecular biological techniques.

## **RESULTS AND DISCUSSION**

The major components of Panax notoginseng of GuanXin Danshen Pill are saponins acting mainly on myocardium, while the major components of Salvia miltiorrhiza including salvianolic acid A, B and tanshinone mainly showed protective effects on hemodynamics and vascular endothelium. The main components of lignum acronychiae--flavonoids act as antioxidants and show significant protective effects on oxidative stress-induced cardiac myocyte apoptosis, the mechanisms might be associated with its antioxidative effects, maintaining mitochondrial function and modulating JNK and P53 pathways. Furthermore, lignum acronychiae is the adjuvant and messenger drug in the compound formula, volatile oil from which nonspecifically facilitates the transportation across biomembrane, the absorption and distribution of major components of Salvia miltiorrhiza by enhancing dissolubility of liposoluble compounds, increasing the lip solubility of water soluble components and temporally decreasing the extent of tight junction. Volatile oil from lignum acronychiae shows no effect on major active efflux transporters in intestinal epithelium. Flavonoids from lignum acronychiae may promote the absorption of components of Salvia miltiorrhiza specifically by decreasing the protein expression and functional activities of major active efflux transporter P-gp.

## **CONCLUSION**

Present studies have shown that the main components of Traditional Chinese Medicinal Formulas can have an overall therapeutic effect on one particular disease through different ways on various levels. In fact, the onset and development of any kind of disease are caused by more than one factor. The functional action of drugs is also not limited to one certain single target. In modern Western medicine, the application of combination of different drugs is also ubiquitous to achieve better therapeutic effects, shorten the duration of treatment, relieve the suffering for the patients, and prevent further damage to patients. Research on Traditional Chinese medicinal formula can be achieved by the combination of multiple subjects and various kinds of techniques. It will promote the development of traditional medicine tremendously and contribute more to the health of mankind.

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# THE GUIDELINES FOR CULTIVATION AND QUALITY CONTROL OF MEDICINAL PLANTS IN JAPAN

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The crude drugs used for Kampo medicine in Japan mostly depend on the imports. As a demand of the crude drugs is increasing, not only the steady supply and higher quality of the drugs but also the training for cultivation of medicinal plants are in great demand as well. In order to meet the demands, the Ministry of Health, Labour and Welfare launched publishing a series of monographs on the guidelines for cultivation and quality control of medicinal plants in 1988 about the species cultivable in Japan. The Part I of the series was published in 1992, followed by the 10 volumes including 58 species of medicinal plants (Table 1).

The monographs are structured along the following lines:

1. Name of medicinal plant
2. Part to be employed as the medicinal plant material
3. Characteristics of the medicinal plant
4. Characteristics of the medicinal plant material and major production areas
5. Characteristics of strain (s) for cultivation
6. Cultivation methods
7. Quality evaluation of the medicinal plant material
8. Comparative summary table of the characteristics of different cultivated strains
9. Cultivation calendar
10. Background data and other information

The Part 12 is in progress, which includes 5 species: *Epimedium grandiflorum* var. *thunbergianum*; *Corydalis turtschaninowii* forma *yanhusuo*; *Artemisia annua*; *Glechoma hederacea* var. *grandis*; *Benincasa cerifera*. Other species included in the further volumes are as follows: *Acanthopanax senticosus*; *Cimicifuga simplex*; *Dioscorea japonica*; *Sophora flavescens*; *Glehnia littoralis*; *Prunus persica*; *Evodia rutaecarpa*.

**Table 1** Cultivation of medicinal plants and quality control. Part 1-11

Volume	Year	Plant
Part 1	1992	<i>Coptis japonica</i> , <i>Rehmannia glutinosa</i> , <i>Rheum palmatum</i> , <i>Angelica acutiloba</i> , <i>Bupleurum falcatum</i>
Part 2	1993	<i>Curcuma zedoaria</i> , <i>Platycodon grandiflorum</i> , <i>Cnidium officinale</i> , <i>Coix lacryma-jobi</i> var. <i>ma-yuen</i> , <i>Carthamus tinctorius</i>
Part 3	1994	<i>Cassia obtusifolia</i> , <i>Uncaria rhynchophylla</i> , <i>Schizonepeta tenuifolia</i> , <i>Perilla frutescens</i> var. <i>acuta</i> , <i>Paeonia lactiflora</i>
Part 4	1995	<i>Curcuma longa</i> , <i>Valeriana fauriei</i> , <i>Crocus sativus</i> , <i>Atractylodes lancea</i> , <i>Lithospermum erythrorhizon</i>
Part 5	1996	<i>Rauwolfia serpentina</i> , <i>Atractylodes ovata</i> , <i>Panax ginseng</i> , <i>Gernium thunbergii</i> , <i>Paeonia suffruticosa</i>
Part 6	1997	<i>Matricaria chamomilla</i> , <i>Asiragolus membranaceus</i> , <i>Gentiana lutea</i> , <i>Scutellaria baicalensis</i> , <i>Houttuynia cordata</i>
Part 7	1998	<i>Trichosanthes bracteata</i> , <i>Phellodendron amurense</i> , <i>Lycium chinense</i> , <i>Arctostaphylos uva-ursi</i> , <i>Polygala senega</i> var. <i>latifolia</i>
Part 8	1999	<i>Gardenia jasminoides</i> , <i>Swertia japonica</i> , <i>Saposhnikovia divaricata</i> , <i>Aconitum carmichaeli</i> , <i>Foria cocos</i>
Part 9	2000	<i>Ariemisia capillaris</i> , <i>Zanthoxylum piperitum</i> , <i>Cassia angustifolia</i> , <i>Plectranthus japonicus</i> , <i>Saussurea lappa</i> , <i>Ephedra sinica</i>
Part 10	2002	<i>Fritillaria verticillata</i> var. <i>thunbergii</i> , <i>Asiasarum sieboldii</i> , <i>Prunella vulgaris</i> var. <i>tilacina</i> , <i>Plantago asiatica</i> , <i>Glycyrrhiza uralensis</i> , <i>Lindera strychnifolia</i> , <i>Achyranthes fauriei</i>
Part 11	2005	<i>Foeniculum vulgare</i> , <i>Simomenium acutum</i> , <i>Patrinia scabiosaeifolia</i> , <i>Pimellia ternata</i> , <i>Angelica dahurica</i>

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# **Cultivation and Conservation of Medicinal Plant in ASEAN Countries and Japan**

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Medicinal Plants are cultivated in the botanical garden and in the field for medicines in hospital or pharmaceutical products and education materials. Quality of medicinal plants is controlled by the Good Agricultural and Collection Practices (GACP). GACP is constituted Good Agricultural Practices of medicinal plants (GAP) and Good Field Collection Practices of medicinal plants (GFCP).

GAP is following : 1. Selection of medicinal plants for cultivation, 2. Selection of propagation materials, 3. Selection of cultivation site, 4. Environmental conditions, 5. Soil, 6. Climates, 7. Temperature, 8. Length of day, 9. Methods of cultivation, 10. Standard operation procedure, 11. Maintenance and pest managements and 12. Methods of harvest.

GFCP is following: 1. Selection of medicinal plants and their parts for collection from wild population, 2. Assessment of availability of wild population of target medicinal plant and parts. 3. Selection of collection site, 4. Authorization for collection

Consider for conservation, 5. Concentration level of toxic constituents

Convention on International Trade of Endangered Species (CITES) is for medicinal plant materials intended for export from the country of collection, export permits, phytosanitary certificates.

WHO draft Conservation is following : 1. Health care, development and conservation (Importance of traditional health care system), 2. Policy frame works and legislation to support medicinal plant conservation, 3. Research and information, 4. Conservation strategies, 5. Sustainable production and harvest, 6. Equity Bonn Guidelines, 7. Responsible trade and business practices, 8. Promoting public awareness.

The information of The 2nd ASEAN Conference on Traditional Medicine was held in Hanoi, Viet Nam on 31 Oct. to 2nd Nov. 2010. The purpose of conference is the development of traditional medicine in ASEAN. It is same purposes of the Western Pacific Regional Forum for the Harmonization of Herbal Medicines (FHH).

## INVITED LECTURE

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### **Occupation:**

Guest Professor, Toyama University, Institute of Natural Medicine (2009-present)

Guest Professor, Ochanomizu University, Science for Human Life (2007-present)

Professor, Ochanomizu University, Science for Human Life (2002-2007)

Senior Managing Director, Japan Bath Assistive Industry Association (2002-2002)

Adviser, Japanese Pharmacist Education Center (2001-present)

Director, Department of Pharmacognosy and Phytochemistry, National Institute of Health Sciences, Japan, (1992-2000).

Director, Tsukuba Medicinal Plant research Station, National Institute of Health Sciences, Japan, and (1985-1992).

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Laboratory Staff of Pharmacognosy and Phytochemistry, National Institute of Health Sciences, Japan, ( 1964-1980).

## WHO's policy and activities relating to the sustainable use of medicinal plants and quality of herbal medicines



Traditional Medicine  
Department for Health System Governance and Service Delivery  
World Health Organization  
November 2010



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## WHO Traditional Medicine Team

- *Organizational change, since December 2009*
- *WHO's work in the field of traditional medicine has been carried out under the **Department for Health System Governance and Service Delivery** at WHO Headquarters*



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## Six-Points in WHO's Agenda for the Next 5 Years (2006)

1. Health and development
2. Health and security
3. Health systems
4. Information, knowledge
5. Partnerships
6. Performance

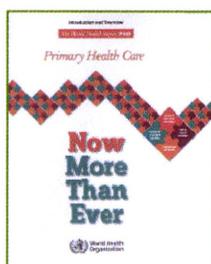


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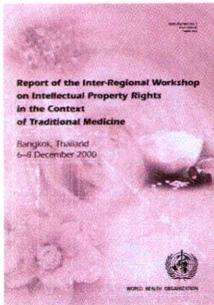
3

## Renewing Primary Health Care (PHC) through 4 Areas of Reform (2008)



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## Global strategy and plan of action on public health, innovation and intellectual property (GSPOA)



- *Discussion at the Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property*
- **Resolution on Global strategy and plan of action on public health, innovation and intellectual property (WHA 61.21), adopted at the 61<sup>st</sup> World Health Assembly, May 2008**
- **Quick start programme 2: Traditional Medicine**
  - **Supporting Research and Development and promoting standard setting for traditional medicines in developing countries**

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## WHO Congress on Traditional Medicine

Date: 7 - 9 November 2008

Venue: Jiu Hua Hotel, Beijing, China

- Over **70** Member States attended the WHO Congress
- Satellite symposia were held to discuss related technical topics presented by 4 NGOs - In total, approximately **1500** people present at all the events.
- The "**Beijing Declaration**" was adopted, **promoting the safe and effective use of traditional medicine**, and calling WHO Member States and other stakeholders to **take steps to integrate TM/CAM into national health systems**.
- Member States shared national experiences and information in five areas, which will aid countries in taking further action in the future:
  - National Policy on TM/CAM
  - National Regulation of Traditional and Herbal Medicines
  - TM in Primary Health Care
  - National Regulation of TM/CAM Practice
  - Research on TM/CAM

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## WHA resolution on traditional medicine adopted at WHA 62 (WHA62.13, 2009)



- Referred to the "Beijing Declaration"
- Requested WHO to continue providing
  - **technical guidance** to support countries in ensuring the safety, efficacy and quality of traditional medicine
  - **policy guidance** to countries on how to integrate traditional medicine into health systems
- Requested WHO to **update the WHO traditional medicine strategy**

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## Traditional Medicine - strategic objectives and priority area -

1. Capitalizing on the potential contribution of Traditional Medicine to self-care and to people-centred primary care
2. Modality for integration of Traditional Medicine into health systems
3. Promoting agreement and consensus on criteria for endorsement, integration, and evaluation of Traditional Medicine as a subsystem of national health systems.
4. Strengthening research to promote the quality, safety and efficacy of traditional medicines and products

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## Traditional Medicine

### - strategic objectives and priority area -

#### 1. Capitalizing on the potential contribution of Traditional Medicine to self-care and to people-centred primary care

*WHO to provide better advice to Member States on:*

- the potential of developing and adopting **multiple appropriate models and forms in the use of traditional medicine, and its contribution to primary care**, based on accessibility, affordability and availability at the community level;
- **appropriate self-care using Traditional Medicine**, particularly at the community level.

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## Traditional Medicine

### - strategic objectives and priority area -

#### 4. Strengthening research to promote the quality, safety and efficacy of traditional medicines and products

*WHO to provide better advice to Member States on:*

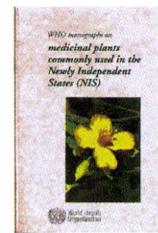
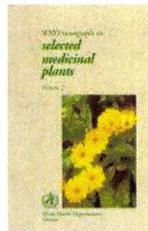
- the **use of appropriate research methods and approaches** for developing traditional and herbal medicines;
- establishing appropriate standards and requirements to ensure and endorse the **quality safety and efficacy of traditional medicines and products**;
- implementing the Global strategy and plan of action on public health, innovation and intellectual property (**GSPOA**), particularly the parts related to traditional medicine in the plan of action.

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## Medicinal plants are supplied through

- Collection from the wild population
- Cultivation



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WHO Informal meeting on methodologies for quality control of finished herbal products  
Ottawa, Canada, July 2001

### Objectives:

- To identify needs and gaps for quality control of finished herbal products
- To outline key technical issues and analytical methods/techniques for quality control of finished herbal products

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WHO Informal meeting on methodologies for quality control of finished herbal products

Ottawa, Canada, July 2001

**Major Recommendations to WHO:**

*Herbs, and Herbal materials*

- To prepare a series of technical guidelines:
  - on good agricultural and collection practices for medicinal plants
  - on processing raw materials (after harvest) and extracts
  - on use of herbal materials produced by using recombinant DNA techniques
- To establish new standards and update existing standards for contaminants and residues including, micro-organisms, mycotoxins, heavy metals and chemicals used in agriculture

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WHO Informal meeting on methodologies for quality control of finished herbal products

Ottawa, Canada, July 2001

**Major Recommendations to WHO:**

*Herbal preparations, and Finished herbal products*

- To prepare series of technical guidelines:
  - on quality control methods for materials at different stage of the manufacturing process, i.e. starting materials, intermediates and finished products
  - on identifying constituents in finished herbal products
  - on the techniques available for analytical purposes

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## General guidelines on quality control methods for finished herbal products

1. **Guidelines on Good Agricultural and Field Collection Practices (GACP) for medicinal plants (2003)** – ensure the safety and quality at the first and most important stage of production of herbal medicines
2. **Guidelines on good processing practices for herbal materials (in preparation)**
3. **Guidelines on assessing quality of herbal medicines, with special reference to contaminants and residues (2007)**
4. **Guidelines for selecting substances for quality control of herbal medicines (in preparation)**



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## WHO Guidelines on Good Agricultural and Field Collection Practices (GACP) for Medicinal Plants

### Source of herbal materials

- Collection from the wild population
- Cultivation

### Quality assurance measures

- Good Field Collection Practices (GFCP) for Medicinal Plants
- Good Agricultural Practices (GAP) for Medicinal Plants

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