



**WORKING GROUP ON  
MEDICINAL PLANTS  
II MEETING  
29-31 March 2006  
Curitiba, Brazil<sup>1</sup>**

**Participants:**

**Members:**

**Bolivia:** Vanesa Mejia Loza

**Brazil:** Eduardo Machado Netto

**Canada:** Michael Smith **Unable to attend**

**Jamaica:** Princess Osbourne

**Mexico:** Rosalia Reyes Pérez

**Panama:** Pablo Solis **Unable to attend**

**ALIFAR:** Carlos Silva

**Observers<sup>2</sup>**

Laura Padula, ANMAT, Argentina

Beatriz Luna, MOH, Uruguay

Bernarda Torres, MOH, Paraguay

Edith Rodriguez, MOH, Venezuela

**Secretariat:**

Rosario D'Alessio, OPS/OMS

James Fitzgerald, OPAS, Brazil

Xiaorui Zhang, Coordinator TRM, World Health Organization

**AGENDA & MINUTES**

**1. Participation at the Round table: The Pan American Experience in Medicinal Plants.**

The Round Table Session was organized by ANVISA as an pre-meeting activity of the WG on Medicinal Plants. See report in Annex 1.

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<sup>1</sup> The meeting was financed by ANVISA/Brazil

<sup>2</sup> Regulators from MERCOSUR countries were invited to participate at the WG meeting, taking advantage of their meeting the day before.

**2. Welcome and greetings from ANVISA, PAHO Brazil and the WHO.**

**3. Background and Update on the work of the PANDRAH and Rules and Regulations for the operation of the Working Groups**

See pp in separate file

**4. Current situation on Regulation of Medicinal Plants in participating countries**

All four Observers attending the Working Group Meeting and ALIFAR representative in the WG were invited to make brief presentations on the current situation regarding Medicinal Plants in their respective countries. The presentations are listed in separate file.

**5. Background activities related to Medicinal Plants in the Region of the Americas**

The Conclusions and recommendations arising from two previous regional activities on Medical Plants and Traditional medicines were reviewed. Both events as well as the previous meeting of the WG/MP were relevant to the objectives of this meeting. Issues reviewed included:

- a. A proposed definition for medical plants to be adopted by all countries;
- b. A proposal for the harmonization of registration activities for medicinal plants based on scientific data;
- c. The need for the assurance of quality control, safety and efficacy of medicinal plants;
- d. Promotional and educational needs for prescribers and consumers;
- e. Agreements of the first meeting of the WG/MP.

See pp in separate file

**6. Review and discussion of the Mission Statement and Objectives of the WG/MP**

The Working group was asked to review the existing Mission Statement and Objectives which were approved by the IV Pan American Conference, and make changes that would more appropriately reflect the purpose and tasks of the Working Group. Changes were made as follows:

Mission. Previous Version:

To promote a common understanding regarding the types of herbal products, definition of terms used, identification of procedures, and minimum requirements for the registration of herbal products towards the harmonization of regulation of herbal medicines, within the framework of the Pan American Network of Drug Regulatory Harmonization (PANDRH).

Mission: Revised Version To foster a common understanding of MP in the Region of the Americas and to develop recommendations to promote regulatory harmonization taking into consideration the traditional and sustainable use of Medicinal Plants.

Objectives. Previous Version

- To create a Network for the exchange of information
- To collect terms & definitions for different types of registration and to develop harmonized proposal for each of them;
- To share regulatory experience for control Q in HM
- To identify practical mechanisms for harmonizing HM in particular regulatory, and Quality standards for HM

Objectives. Revised Version:

1. To promote and strengthen the exchange of information about MP
2. To promote the assurance of quality, safety and efficacy of MP in the Americas, including the development of programs for vigilance and control;
3. To develop proposals for harmonized regulatory activities in the area of MP; and to support countries in the implementation of these activities once they have been adopted by PANDRH;
4. To promote activities and educational programs on MP for health care providers, consumers, and the public in general.

**7. WG/Plan of work. Setting of priorities**

See separate document

**8. Closure of Working Group Meeting on Medicinal Plants**

The representatives from ANVISA and from the PANDRH Secretariat performed the closing exercise. In their closing statements they thanked the WG members and the Observers who participated for their fruitful work and commitment towards regional cooperation in the area of Medicinal Plants.

## **ANNEX 1: Report from ROUND TABLE on: The Pan American Experience in Medicinal Plants. Curitiba, Brazil 29 March, 2006**

The PANDRH Working Group on Medicinal Plants met in Curitiba, Brazil from March 29-31, 2006. The meeting commenced with a round-table session on March 29. The opening exercise included greetings from the Director of ANVISA, the Coordinator for the Program on Traditional Medicines from the World Health Organization, and The Regional Advisor in Medicines and Pharmaceutical Services from PAHO, Washington.

The National Agency for Health Surveillance of Brazil (ANVISA) organized the round table to discuss the Pan American Experience with Medicinal Plants, as part of the program for the "Eighth Ordinary Meeting of the Parties of the Convention on Biological Diversity", which was organized by the United Nations. The Convention, took place in Curitiba, Brazil from March 20-31, 2006. ANVISA invited all the participants to the PANDRH Working Group on Medicinal Plants, to take part in the round-table session held at the Convention venue.

ANVISA planned the round-table based on the fact that the sustainable use of medicinal plants is an important issue for those countries and regions of the Americas rich in biodiversity. ANVISA's interest is that the traditional use of these medicinal plants be preserved in such a manner so as to favor greater access to therapeutic treatments with products that are safe, effective and of good quality.

The Regional country representatives to the round table included the, the drug regulatory authorities of Bolivia (Andean Community), Jamaica (Caribbean Community, CARICOM), and Mexico (North America). Panama should have represented the countries of Central America, but was unable to participate.

The Round Table concluded with a presentation from the WHO representative on International Regulation on the good use of Traditional Medicine. It was pointed out that various working groups are working in forums on initiatives in the area of harmonization in various regions of the world. The support provided by WHO in these processes was highlighted. Special mention was made of the recent agreement in establishing a global initiative on International Cooperation in Regulation of Herbal Medicines (IRCH), the main goal being to promote and facilitate the safe use of the herbal medicines worldwide, through regional initiatives, exchange of information and dialogue.

Regional perspectives were presented and it was clear that greater discussion on some areas highlighted by presenters was needed. These were:

### **1. The need for Legislation for the registration or approval of medicinal plants**

Some countries are developing specific legislation for use of medicinal plants and finished products obtained from plant source. World Health Organization facilitates the development of legislation, through the preparation and dissemination of technical and scientific documents.

## 2. Definitions and terminologies

The terminologies used in the classification of herbal medicines are not standard among the countries of the region. They are diverse and the range includes: Finished Herbal Products, Herbal Remedies, natural drugs and herbal drugs. In addition, other terms utilized include herbal medicines, phytotherapeutics and phytomedicines. There is also no common definition for a phytotherapeutic drug.

The use of different terminologies to describe equivalent preparations in different countries makes it necessary to work towards harmonizing the terms and definitions. This would facilitate the development of policies that are consistent between countries, hence make harmonization achievable.

## 3. Categories

The presentations showed that medicinal products or products made from medicinal plants in each country and regional blocs are classified differently, and there are also different criteria for safety and efficacy.

### Bolivia:

Four categories were identified:

- i. Artesan Craft Natural Drug
- ii. Homeopathic Natural Drug
- iii. National Natural Drug
- iv. Imported Natural Drug.

All of them require regulatory registration with different requirements for each category.

### Jamaica:

Five categories were identified:

- i. Herbs (material of raw plant origin)
- ii. Herbal Material (in addition to herbs include juices rubber resins, essential oils, etc.)
- iii. Herbal Remedy (botanical product with therapeutic properties and include both the traditional and new). These need to be registered.
- iv. Finished Herbal Product (mixture of two or more herbs and can contain excipients in addition to active ingredients). May also require registration
- v. Nutraceuticals or Health Foods.

### Mexico:

Two categories were distinguished:

- i. Herbal Drug - Needs to be registered. The presentation of national or international literature which endorses that the therapeutic effectiveness and safety have been confirmed scientifically is necessary

- ii. Herbal Remedy - should be registered. These cannot claim to have therapeutic use, and can only be indicated to assist clinically based on the knowledge of the traditional use.

Dietary Supplements also exist in Mexico. These should be notified since although found in the food category and the purpose for use is to increase the total dietary intake, can contain medicinal plants and in its labeling use therapeutic claims.

#### 4. Quality

The need for developing monographs for native medicinal plants, which exist in the countries of the various geographical blocs, was highlighted. Monographs will allow the harmonization of technical requirements necessary to assure the identity, quality, safety, and efficacy of medicinal plants. Whilst medicinal plant monographs exist in some of the countries it was noted that their formats differ.

## **ANNEX 2: Country presentations on Current situation of Medicinal Plant Regulations**

### **Argentina**

- The ANMAT establishes the figure of Phytomedicines (*Ministerial Resolution 144/98*) by which it is defined as the drug formed by pure plant drugs or mixtures of these and their derivatives (extracts, juices, discharges, etc) traditionally used for medicinal purposes; and that they do not contain chemical substances defined or its mixtures, even if they were constituents isolated from plants, except for the cases that thus are acceptable.
- The regulation *Resolution ANMAT 2671/99* includes the qualification of manufacturing establishments, packaging plants/packers and importers of phytomedicines, defining each of these categories and stipulating the requirements of the qualification of these establishments.
- The regulation *Resolution 2672/99* is the Guide of the Good Manufacturing Practices and product control fitoterápicos.
- *Resolution 2673/99* regulates the necessary requirements for the drug registration fitoterápico. It includes the Annex of traditional medicinal plants and criteria for acceptability for being registered.
- *Resolution 1788/00* constitutes a list of medicinal plants that are excluded in the phytomedicines figure.
- The label and prospect preparation, regulated by *Resolution 2673/99*, does not exclude other regulations of prospects that involve: To- Condition of sale. B- Groups phytochemistry defined. C- Groups pharmacotherapeutic.
- Phytomedicines are regulated by *Law N°16.463, Decree 150/92* as well as the rest of the drugs and medicinal specialties.
- National or imported drugs are classified in accordance with their similarity evidence (definitions described in the Decree) in its formulation with a product registered and marketed in Argentina or countries of high health surveillance. Those formulations that do not have similarity consonant with *Decree 150/92* request, for their approval, a more exacting regulation.
- The ANMAT has regulation on Drug Surveillance. The adverse events corresponding to medicinal plants are reported and evaluated as any drug.
- Currently in ARG this beginning to speak about modifications of the figure of drugs fitoterápicos.
- It has Good Agricultural Practices, but also recognizes the existences of collection of wild plants that derive Drugs P. En this sense need more internal organization.
- There exist several Research centers.
- They are trying to develop a Database of indigenous plants.

## **Brazil**

- Phytotherapeutic drugs are regulated. These are produced by the pharmaceutical industry, and satisfy Good Manufacturing Practices.
- Brazil is beginning to look at regulation for registration that permits product marketing with informed, traditional based effectiveness. Only products made from plant derivatives are registered. Plant drugs are not registered, but can be marketed in *herboristerias*.
- Safety and efficacy can be verified by presenting international and/or national literature.
- A point system exists for validation of product effectiveness. Upon gaining a specified number of points, product effectiveness is considered achieved. The points are based on references of the product in the scientific literature used as reference (e.g. WHO, ESCOP, Komm. E). The effectiveness can also be determined from local research. The world bibliography can also be used on the recommendation of the WHO.
- Medicinal Plants do not require registration in Brazil. It is possible to market them in pharmacies and *herboristerias*. However their labels are not allowed to carry therapeutic indications.
- Brazil does not have a category equivalent to dietary products.
- Legislation exists for phytotherapeutic products in both prescription and non-prescription categories.
- GMP is required for quality acceptance. The derivatives of vegetables also have to be defined in terms of recognized of chemical markers
- There is no specific program for Drug Surveillance for phytotherapeutics. The drug surveillance is part of the national programs for pharmaceutical products.

## **Paraguay**

- The derivatives of Medicinal Plants are regulated by Decree of 2000. Herbal medicines are included in the group of products classified as phytotherapeutics
- Quality control is based on established Monographs.
- There is no difference between the GMP used for phytotherapeutics and those used for drugs in general. Quality Control is necessary for finished drugs from plant origin that has been used traditionally.
- Laboratories are inspected according to GMP requirements. There are twenty-one national laboratories that produce phytotherapeutic products and brand name drugs, five of which conform to GMP. There are six (6) national laboratories that produce phytotherapeutics only, and of these only one satisfies GMP.
- There are 180 phytotherapeutic products registered.

## **Peru**

- Peru has the General Law of Health \*No. 26842, published on 20 July 1997, which establishes the guidelines for registration of pharmaceutical products and control and monitoring for natural resources among others.
- The law indicates, "The promotion of traditional medicine is of interest and preferential care of the state".

- Chapter III of the law focuses on pharmaceutical products, medicines, and natural therapeutic resources.
- The health authority established a list of medicinal plants, the use for which is restricted or prohibited based on their toxicity and harmful effects.
- Medicinal plants that make no therapeutic claims can be marketed freely, subject to the requirements and conditions established in the regulation.
- Regulation \*No. 010-97 was issued on 23 December 1997 and regulates the registration, control, and health monitoring of pharmaceutical and related products. In Article 69 natural therapeutic resources are classified in natural RESOURCE of use in health and in natural PRODUCT of use in health.
- Natural Resource is any material that comes from live organisms or minerals, has pharmacological activity that has been verified, is presented for marketing without undergoing artificial processes that alter its natural composition and is not packaged in a pharmaceutical form.
- Natural Product is any medicinal product with verified pharmacological activity, prepared from the natural resource of use in health, whose active substance corresponds to some of the parts of this resource or results from associations, combinations or mixtures of resources in natural state, that is presented in dosage form and that is used for therapeutic purposes.
- The technical requirements for Natural Products include:
  - The qualitative and quantitative formula of the product.
  - Depending on the form to be registered the information is standardized.
  - Taxonomic classification of the natural resource
  - Presentation of the Dosage Form
  - Route of administration
  - Dosage Material recommended
  - Use and type of mediate and immediate containers
  - The system of coding used for the lot numbers for imported products
  - Shelf -life
  - Condition of therapeutic sale
  - Protocol for analysis, including technical specifications and analytical methods
  - Labeling for the mediate and immediate container, including package insert
  - Certificate of Fee Sale
  - Stability Study,
  - Monographs verifying the pharmacological activity of the product. This has to be authenticated by a university accredited in Peru for this purpose. The Monograph should include the type of resource utilized in the formula as well as ethno botanic physicochemical, toxicological and clinical features.

## **Uruguay**

- Medicinal plants are registered by the Department of Drugs
- These preparations are subject to the same terms for authorization, as for conventional drugs.

- Phytotherapeutic Drug: drug whose active ingredients are produced from plant raw materials (plant drug and/or its derivatives).
- Products combined with chemically defined active ingredients are not considered phytotherapeutic.
- Three types of Phytotherapeutic Drugs are categorized: new, similar, and traditional. The proposed definitions are as follows:
  - New: those whose efficacy, safety and quality are verified scientifically and may act as reference for those classified as similar.
  - Similar: these contain the same plant raw materials, with the same concentration of active ingredients or markers and have similar routes of administration, dosage forms, dosages, and therapeutic prescription for phytotherapeutic drugs considered as reference.
  - Traditional: those from plant raw materials with use rooted in popular tradition. Their medical, historical, and ethnological use reveals no evidence of harm. Their effectiveness is endorsed by their prolonged use documented in medical and/or pharmaceutical bibliography.
- Whilst some manufacturers follow the guidelines On Good Agricultural Practices, there are wild herb collectors who do not conform.
- There is a quality control program for post-marketing through which the quality of all the drugs consumed in the country is assured. This is done approximately every two years for all products.

## **Venezuela**

Registration of natural products is legislated through Ministerial Resolution SG 1329 dated 06-09-1995; Official Gazette N° 35,837 dated 14-11-1995. It includes health standards for natural products, which are defined as those of vegetable, animal or mineral origin, in original form or which have only been subjected to compulsory physical, chemical or biological treatment for their good manufacturing, packaging, preservation or provision, destined by man for different therapeutic ends through ingestion, inhalation or application on the surface of the skin and mucous membranes.

The products cannot have properties that are different from the characteristics of its active ingredient.

Natural Products should display the following characteristics:

- They demonstrate biological activity for which limits were previously established.
- They do not contain active ingredients, which due to their therapeutic activity, potential for toxicity, and possible contraindications, require medical surveillance.
- They contain only excipients or additives of synthetic origin that are indispensable and complementary to the utilization of modern manufacturing techniques and are acceptable from a sanitary standpoint.
- Excipients, and additives included in the standards of the Office of the
- Director of Drugs and Cosmetics must be declared on the product label.

- They cannot be combined with synthetic drugs or with active ingredients of natural origin that have been synthesized.
- They can be combined with vitamins, amino acids, and minerals, when it is shown that these items are necessary in order to complement the proposed therapeutic indication.
- Combination of active ingredients with antagonistic pharmacotherapeutic effects is not acceptable.
- Combinations of natural substances or botanical species with heterogeneous indications are not acceptable.
- The proposed indication for a natural product should correspond with the therapeutic actions of the botanical species as presented in the Qualitative and Quantitative formulation.
- Natural Products should be sold to the public as "Over the Counter", by establishments authorized to such end, as: Pharmacies, Sale of Medicines and Houses Naturopaths.
- For botanical products, a Certificate of analysis on the raw material and the methodology for producing it are required.

Venezuela is presently working on the development of standards that will allow for broader classification of the products as well as implementation of a national surveillance and control system.