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W01 The European Pharmacopoeia and quality standards for herbal drug preparations: An update

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The fourth edition of the European Pharmacopoeia contains more than 120 monographs on herbal drugs whereas only a small number of monographs deal with herbal drug preparations such as extracts, tinctures, fatty oils and essential oils.

Since general monographs on extracts, fatty oils and essential oils have been finalized it might be expected that the more than forty monographs on these herbal drug preparations, which are currently under study, will be finished in the near future.

In this way it will become possible to improve the quality standards of many commercial herbal medicinal products in Western Europe, especially since a harmonisation of the quality criteria of these products has been realised with the ones set up by the regulatory authorities. The different specifications for herbal drug preparations such as extracts, tinctures, fatty oils and essential oils will be reviewed.

W02 Harmonised assessment criteria for efficacy and safety of herbal medicinal products

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ESCOP, the European Scientific Cooperative on Phytotherapy, was founded in 1989 as an umbrella organisation of national scientific associations on phytotherapy. Within its objective to establish harmonized criteria for the assessment of herbal medicinal products, ESCOP has prepared monographs on important plants and their medicinal use taking into consideratioin relevant scientific literature and different viewpoints from all countries involved. The format is in line with the European guideline on Summaries of Products Characteristics (SPCs). In terms of definition of the plant material and quality requirements, reference is made to the European Pharmacopoeia or to national pharmacopoeias. In the pharmacological part, all relevant *in vitro* and *in vivo* data as well as clinical studies have been evaluated, each statement being supported by references. Six fascicules including a total of 60 monographs on efficacy and safety of medicinal plants and their preparations have been published, and further ones as well as revisions of the existing ones will soon be available.

Based on the "Guidelines for the Assessment of Herbal Medicines" which define basic criteria for the evaluation of quality, safety and efficacy, WHO's Traditional Medicine Programme (TRM) has prepared a document entitled "Model Monographs of Widely used Medicinal Plants". These monographs include summaries of the botanical characteristics and chemical constituents as well as clinical applications, pharmacology, etc… Two volumes, each consisting of approx. 30 model monographs have already been finalised, and a third and fourth volume are in preparation.

The EMEA Working Group on Herbal Medicinal Products expressed its opinion that the monographs drafted by ESCOP and WHO "offer a valuable and updated overview on published scientific literature, which together may be used in support of the demonstration of the safety and efficacy of a medicinal product". The group is currently evaluating these monographs in order to develop official assessment criteria for herbal medicinal products.

W03 Efficacy, safety and quality monographs of Iberoamerican herbal medicinal products

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The biodiversity of Iberoamerica is well known as a potential source of new drugs. The traditional use of hundreds of plants for medicinal purposes is documented. Although some of these plants are widely used and preliminary data on validation is available, international information on efficacy, safety and quality is still lacking.
After a survey on the needs for technification of the phytopharmaceutical industry in Iberoamerica, it was evident a diverse legal situation of herbal medicinal products in the region, and the lack of reliable information on the native American plants. In the framework of the Iberoamerican Network on Phytopharmaceutical Products (RIPROFITO), the first problem conducted to the publication of a compilation of specific legislations from 17 countries, and the second was tackled by organizing international teams to elaborate monographs from specific plants. These should be: Native to the American continent, proven efficacy, lack of toxicity, knowledge of its agrotechnology, matter of commerce, and should not be included in any known pharmacopoeia. The monographs are of the mixed type, including: botanical and pharmacognostical descriptions, quality control, preclinical and clinical information, including therapeutic indications.
Since 1998, 24 plants were selected as fulfilling the characteristics required. After information compilation, preliminary preparation of monographs, and a review of the potential of each plant, eight species were selected for international evaluation and validation of analytical methods: *Achyrocline satureidoides, Croton lechlerii, Maytenus illicifolia, Mimosa tenuifolia, Phlebodium aureum, Psidium guajava, Smilax* spp. (*S. chiriquensis, S. domingensis*), and *Uncaria tomentosa*. Based on this information, an international project was submitted to CYTED, waiting for its approval.

Acknowledgements: The financial support from the Program for Science and Technology for Development (CYTED) is appreciated, as well as the participation of experts from different academic, public and private sectors, particularly Marlene Porto (Cuba) and Martha Gattuso (Argentina).

W04 Challenges in the establishment of pharmacopeial standards for botanicals and their dosage forms

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Establishment of pharmacopeial standards for botanicals and their dosage forms marketed in the United States as dietary supplements are receiving greater emphasis in the standards –setting program at the United States Pharmacopeia since 1995. USP Council of Experts's approach thus far has been to identify those are widely used and do not present safety risk associated with their use. Acceptable articles, recognized as having fitness for use, could be defined adequately only by a full range of standards-identity, strength, quality, purity, packaging, labeling and where necessary absorption. The standards should be established with reference to the intended use. In the standardization of botanical dosage forms, the USP approach has been to establish standards first for the plant materials and their extracts. This three–pronged approach to botanicals has been time consuming and long. Challenges in the establishment of limits for pesticides, microorganisms and other closely related but unwanted contaminant species will be discussed. Further USP's approach to establishment of *in vitro* dissolution standards for oral solid botanical dosage forms will be discussed.

W05 HPTLC in stability testing of herbal medicinal products

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In herbal medicinal products (HMP's), the entire herbal drug or a herbal drug preparation is regarded as the active substance (API), regardless of whether or not constituents with defined therapeutic activity are known. In stability testing of these products, it has to be shown by means of appropriate fingerprint chromatograms, that substances present in extracts and finished products are stable and that their proportional content remains constant over a defined period of time. For analysing fingerprints of herbal drugs or herbal drug preparations, validated methods e.g. concerning robustness, reproducibility and selectivity methodology are a major prerequisite. In this context, HPTLC offers the advantage of different visualised fingerprint. By using different detection reagents and detection wavelength selectivity in HPTLC is superior to other chromatographic techniques.

According to the EU guidelines "Note for Guidance on Specifications: Test Procedures and Acceptance Criteria for Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products" (CPMP/QWP/2820/00) and "Note for Guidance on Quality of Herbal Medicinal Products" (CPMP/QWP/2819/00) all test methods (assays) must be validated with appropriate methods according to the EU-guidelines "Note for Guidance on Validation of Analytical Methods: Definitions and Terminology" (CPMP/ICH/381/95; ICH Topic Q2A) and "Note for Guidance on Validation of Analytical Procedures Methodology" (CPMP/ICH/281/95; ICH Topic Q2B). In order to fulfil the requirements and instructions given in the latter guidelines, special analytical features of plant derived multi-component mixtures have to be considered. According to the advantages of HPTLC given above, this methodology is suited for analysing these mixtures.

Using starting materials and preparations form *Urtica* as an example, appropriate approaches for demonstrating selectivity, robustness and reproducibility of HPTLC methods for quality and stability testing are presented.

W06 Stability of flavonoids by TLC analysis in Hawthorn leaf and flower, Passion flower herb, Hypericum herb and Chamomile flower fluid extracts

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Thin layer chromatography (TLC or HPTLC-quantitative TLC) is a widely used chromatographic method from which is possible to obtain basic information about the identity, purity and stability of active or marker substances in drugs and their preparations. Adulterations and decompositions can be easily detected using this technique because you can see in one line (from the start to the end of the plate) all possible substances by different possibilities (UV 254 nm, UV 366 nm and the possibility for colouring the substances and detecting them again by UV 366 nm or daylight). By this way you can provide semi-quantitative (TLC) or quantitative (HPTLC) information on the major constituents or marker substances of drugs, extracts or finished preparations.

In this work TLC is proposed as a technique to follow the stability of several common extracts containing flavonoids. Hawthorn leaf and flower, Passion flower herb, Hypericum herb and Chamomile flower were used to prepare fluid extracts which were examined by TLC, using typical mobil phases and detection systems for flavonoids.

The fluid extracts were submitted to a stability program at 25ºC and 40ºC following the behaviour of the C-O-glycosides and aglycone forms of flavonoids present in the studied extracts by the proposed chromatographic method.

If there is a decomposition may be from rutosid to quercetin it has to be discussed if this is important of a pharmaceutical and medical view.

W07 Method validation for stability testing of *Boswellia* species and its preparations by HPTLC

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The exudates of Boswellic trees (Olibanum and Salai Guggul) belong to the group of gum resins. At the present time these gum resins are important commercial sources for pharmaceutical formulations. The active principles are the tirucallic acids (TA) and the boswellic acids (BA). They belong to the group of tetra- and pentacyclic triterpenes.

As there exists no actual monograph of Olibanum, according to the latests developments in science, the pharmaceutical companies have an interest in analytical methods for stability testing.

Gum resins belong to sticky materials and are not easy to handle. We propose HPTLC methods for the determination of the ketoBAs without derivatization by UV_{254} light and of BA's and TA's after derivatization. HPTLC - Fingerprints clearly differentiate one species from the other by the marker compounds. Multiwavelengthscans offer the possibilty to observe alterations, caused by the chromatographic process or by the manufacturing method, whereas 2- D –TLC in one single solvent system is suitable to attach the related compounds (of alteration) to each other.

W08 Qualification of TLC-systems for stability testing of *Vitex agnus-castus*-extracts

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TLC is one of the main issues to test stability of herbal medicinal products (HMP's) in future. The complex composition of HMP's can be documented with TLC. Newest guide-lines ask for tests, who characterise compounds of high, medium and low polarity of HMP's on several levels. This is a regulation more which overcomes the strategies of Ph Eur, which identifies herbal drugs with one specific TLC. Probably, a lot of additional TLC's will have to be developed in future.

Concerning stability testing, a main problem is the system qualification. Forced degradation tests are proposed to qualify TLC. The clinically approved (1) ethanolic dry extract of *Vitex agnus-castus* (Ze440) has been exposed to day-light, heat (50°C), hydrochloric acid, ammonium and humidity. Furthermore the extract has been dissolved in methanol and treated with light, 3% H_2O_2, 0,1 N trifluoro-acetic acid (TFA), 0.1 m dimethylamine (DMA) and heat (50°C/30 minutes). Iridoids disappeared completely under hydrochloric acid atmosphere. On the diterpene-TLC (2) rotundifuran disappeared under hydrochloric acid atmosphere, H_2O_2 and light. Linoleic acid was not detectable anymore after exposure to hydrochloric acid atmosphere and reduced under TFA und DMA. Hydrochloric acid atmosphere destroyed two further diterpenes, vitexilactone and 6β,7β-diacetoxy-13-hydroxy-labda-8,14-diene, meanwhile casticin was quite stable: Weaker peaks but not a complete decomposition have been observed under hydrochloric acid atmosphere and H_2O_2. C-glycosidated flavonoids, especially isoorientin, remained unchanged under all conditions, but chlorogenic acid was influenced into of the extract as well as a pure compound by hydrochloric acid atmosphere. The experimental work with forced degradation proved that chemical instabilities can be analysed by TLC and qualify the systems. Furthermore the results showed a relatively high robustness of the extract against physico-chemical influences.

Acknowledgements: The work was done in co-operation with CAMAG AG, Muttenz, and University of Basle (E. Reich, F.Wahli, W.Schaffner)

References: 1. Schellenberg R. (2001 British Medical Journal 322, 134-137. **2.** Dold U. (2000) HPTLC-Screening von Vitex agnus-castus-Früchten aus verschiedenen Herkünften. Diploma work, University of Basle.

W09 Advances in clinical research of phytopharmaceuticals

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Clinical research in phytopharmaceuticals has improved a great deal especially with regard to complaints with GCP-guidelines and requirements. Phytotherapeuticals are generally used for the treatment of chronic and/or less severe diseases.
Very often – in spite of its reputation –, the demonstration of efficiency is scientifically more demanding than "standard therapeutical agents". Minor pharmacological effects require a high level of sophistication and scientific dedication to be detected in unambiguous way.
Very often completely new human pharmacological models have to be developed for these purposes.

W10 An new developed extract from butterbur (*Petasites hybridus* L.) is clinically efficient in allergic rhinitis (hay fever)

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Butterbur (*Petasites hybridus* L.) has traditionally been used against complains in intestine, urogenital tract, asthma and migraine. The extract (Ze 339) has been developed from leaves instead of roots by means of a new extraction technique. A particular clone is used to highly guarantee identity of the starting material (Petzell). The new, patented extraction procedure with carbon dioxide is twofold of advantage, first the active constituents are highly enriched and second the pyrrolizidine-alkaloids are loss. By the pharmacological action of this extract, the release of the inflammation mediators is blocked and the symptoms of allergic rhinitis (sneezing, rhinorrhoea, itching, nasal congestion) disappear. This action occurs within 30 minutes after oral administration. In addition the arachidonic acid cascade becomes interrupted, i.e. the leukotriene-synthesis is inhibited (1). The petasins are the active constituents in the extract, which modulate the leukotriene (2). The bio-availability of the active constituents is shown in a pharmacokinetic study. In a proof of action study the pharmacodynamic profile has been demonstrated (3). Clinical trials to demonstrate efficacy in allergic rhinitis follow different approaches, either by reduction of symptoms severity or by improvement in quality of life. The symptoms severity has been assessed using two different dosages of Ze 339 vs. placebo. Both arms with the active medication have been superior to placebo. Furthermore, 3 tablets have been superior to 2 tablets, indicating a dose-relationship. In a quality of life study, the efficacy of Ze 339 has been compared with cetericine (Zyrtec). Both active compounds were comparable effective (4). For the benefit risk evaluation, both the safety data from the trials and data from toxicological investigations have been assessed. Taken together, with new developed extract Ze 339 the allergic rhinits (hay fever) can efficiently and safely be treated.

References: 1. Thomet OAR et al. (2001) Clin. Exp. Allergy 31:1310-1320. **2.** Thomet OAR et al. (2001) Biochem. Pharmacol. 61: 1041-1047. **3.** Thomet OAR et al. (2002) Int. Immunopharmacol. 293. **4.** Schapowal A. (2002) BMJ 324: 144-146

W11 Double-blind, randomized, placebo-controlled clinical trial with a *Polypodium leucotomos* extract in senile dementia

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Impairment of cognition is the key clinical feature of senile dementia (SD) of both, Alzheimer disease (AD) and vascular type (VD). In spite of clinical, neuropathological and etiological differences, some pathogenic mechanisms of immuneneurodegeneration are shared between both diseases. An special extract obtained from *Polypodium leucotomos* (Anapsos), has shown immunomodulating activity on different cells and proteins of the immune system, and to be efficient as a neuroprotective and procognitive substance on AD animal models. The aim of the present work was to evaluate the effect of two doses of this extract, vs. placebo, in mild to moderate SD (Alzheimer and vascular).

Forty-five patients with SD (Global Deterioration Scale: 3-5), were included in a double-blind randomized placebo-controlled clinical trial. After a 2-week wash-out period with placebo, patients which entered the double-blind running-in period, received extract (360 or 720 mg/day) or placebo for four weeks. ADAScog test, brain mapping and doppler ultrasonography were performed at baseline and after the four week treatment period.

Patients receiving 360 mg/day of Anapsos, showed a significant improvement in cognitive performance (ADAScog score $p<0.05$, vs baseline) that was not observed with the highest product dose. As compared to placebo, Anapsos (360 mg/day) induced a significant improvement in ADAScog scores in mild SD patients ($p<0.01$) and in the subset of patients with AD ($p<0.05$). Anapsos (360 mg/day) also increased cerebral blood flow velocities in left and right middle cerebral arteries in the AD subgroup, and showed a shift from δ towards θ and α brain bioelectrical activitiy (BBA) frequencies, indicating an acceleration of the EEG pattern.

In conclusion, Anapsos, at the dose of 360 mg/day, improves cognitive performance, cerebral blood perfusion and BBA in patients with SD, being these effects more marked on patiens with mild mental deterioration of the AD group.

W12 CYTED, a unique program of exploring Iberoamerican biodiversity for novel natural compounds

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The Iberoamerican Program of Science & Technology for Development (CYTED) is a multilateral program of cooperation aimed fostering scientific and technological integration of 21 participating countries. The Subprogram X of Fine Pharmaceutical Chemistry since 1990 has been uniting over 1300 natural products scientists in different R&D Centers and industries in Latin America, Spain and Portugal through 5 Thematic Networks and 7 Collaborative Research Projects to discover lead compounds with immunomodulatory, chemotherapeutic, cardiovascular, antiparasitic and anti-inflammatory properties. During this period over 570 scientists have been trained in different facets of natural products drug discovery through workshops, scientific exchanges, and training courses. Some of the results of this collaborative program will be presented along with the research on Panamanian Flora.

Acknowledgements: CYTED, SENACYT, and Organization of American States.

W13 CYTED-X.A: Iberoamerican network for collaborative research on medicinal natural products. Configuration, activities and results.

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This Network was constituted at the beginning of the last decade and presently involves more than 1250 scientists belonging to more than 200 research groups of some 140 Institutions in 21 CYTED member countries.
The Network mainly focuses on the generation of multidisciplinary Cooperative Research Projects related to a number of diseases, the most significant by their mortality/morbidity within the Region, namely, infectious, parasitic, inflammatory and gastro-intestinal diseases, as well as on the organization of courses, workshops and scientific exchanges to improve the scientific and technological level of the scientists and to facilitate the knowledge transference among the participating research groups and industries.
This has resulted in many collaborative research publications related to chemical, and pharmacological aspects of medicinal plants and natural products, as well as many BS, MSc and PhD theses, data bases, tutorials and handbooks on research techniques.
A summary of the activities of the Network and some examples of collaborative investigations will be presented.

W14 Contribution of CYTED's herbal medicinal products network in the upgrading of phytopharmaceutical products in Iberoamerica

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Within the framework of the Fine Pharmaceutical Chemistry Suprogram of CYTED, the Iberoamerican Network on Phytopharmaceutical Products (RIPROFITO) was started in 1996, with the aim to encourage international cooperation among industry, academic and regulatory sectors to stimulate cultivation and industrialization of medicinal plants and optimize the use of in health care. To date it has coordinated activities among 125 private and public institutions with 685 participants, which have resulted in the organization of 18 international training courses on agrotechnology, industrialization, quality control and phytotherapy involving 600 professionals, participation in 40 international meetings and workshops; various scientific exchanges, and initeation of monographs of regional plants, and over 20 publications.
Survey of status of phytopharmaceutical industry in Latin America has also been prepared. Selected cases of technology transfer will be presented.

Acknowledgements: CYTED & National Council of Science & Technology (CONCYT)

W15 Search, evaluation and obtention of new antiparasitic agents in Iberoamerica

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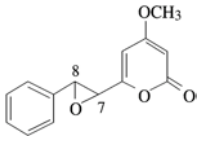
This international cooperative project aims to discover new natural antiparasitic agents for the treatment of: malaria, leishmania and chagas disease, through bioguided isolation and structural determination of the active compounds obtained from medicinal plants as well as chemical transformations and *de novo* synthesis, to establish SARA total of 19 research centers from Bolivia, Brazil, Chile, Colombia, Guatemala, Mexico, Panama, Peru, Paraguay and Spain, are engaged in this objective. Of over 100 extracts, the genus *Piper yielded* the most active compounds together with compounds obtained from *Lonchocarpus xuul* and *L. yucatanensis*. A new epoxide kawapyrone derivative with leishmanicidal properties has been isolated from *Piper rusby*. Several diterpenes with unique structures have been isolated from Andean species *Mulinum crassifolium, Laretia acaulis, Azorella madreporica* and the structures with azorellane and mulinanae skeleton being the most active against *Trypanosoma cruzi*. Naphtoquinone semisynthetic derivatives showed strong activity against *Plasmodium falci - parum*. The most important results with wide range of activity against malaria, leishmania and chagas have been obtained from stilbene derivatives.



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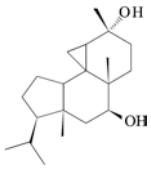
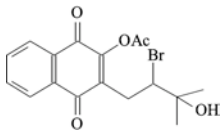
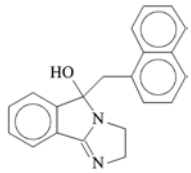
IC_{50} PH8 < 5 µg/ml
IC_{50} M-2903 < 5 µg/ml



IC_{50} T. cruzi < 50 µg/ml



IC_{50} F32 < 1 µg/ml



IC_{50} F32 < 1 µg/ml
IC_{50} T. cruzi = 1.8 µg/ml
IC_{50} PP75 = 5 µg/ml

Acknowledgements: CYTED, Subprogram X. Project X.5, and Organization of American States.

W16 Controlled and sustainable wild collection of medicinal and aromatic plants for rural income generation in Bosnia and Herzegovina

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In Bosnia and Herzegovina (BiH), the Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) is promoting the income generation in rural areas by diversification of the traditional systems of sustainable wild collection of Non-Wood Forest Products (NWFP), and by value addition in rural areas. GTZ is collaborating with SIPPO, the Swiss Import Promotion Program, for the training of collectors, organic certification and marketing of certified products from sustainable wild collection in regional and international markets.

Special emphasis is placed on controlled and sustainable wild collection, which is considered by companies and returnees as their first option for generating cash income after resettlement. The numbers of collectors affiliated to the companies, participating in the GTZ-programs, is ranging from 50 collectors to estimated 10.000 collectors with established companies, including co-operatives and company organised collection schemes.

Serious conflicts of interests have developed with the individual collectors sourcing raw material for direct and illegal sales to foreign companies. There is the need to regulate these conflicts. The first efforts had been taken to improve the documentation, and to rise awareness for controlled and sustainable wild collection involving international organic certifiers.

The sustainable use of bio-diversity can be supported through the application of different management tools, to increase the level of documentation of the chain of production and processing. Starting at the resource base, all levels of production, processing and marketing are subject to monitoring through certification. Based on sustainable use of the wild resources, and accompanied by proper management plans, certification leads to an innovative marketing package, including the product and proper documentation of the same, ready to fit in the GMP-systems of the potential clients.

W17 Medicine and species conservation: Challenge for Man and Nature in the new millennium

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In every corner of the world, medicinal plants are harvested from the wild to cover the local supply or to be traded on the international market. The global sales amounted to about USD 6 million by the mid-90s. The increasing demand for medicinal herbs puts nature's scarcer resources under constant pressure. According to the Medicinal Plants Specialist Group of IUCN, about 9000 species of medicinal plants are endangered world-wide. Medicinal plant specialist Dr. Dagmar Lange assumes that about 10% of the European plant species used for medicinal applications (about 150 species) are endangered.

The protection of these species in the wild is only possible if harvest and trade are sustainable. Excessive use of certain species has to be identified early in order to initiate conservation steps in time. Sustainable use can be ensured by: 1) controlled and considerate gathering from the wild, 2) organic farming and 3) restrictions and prohibitions, where necessary. The joint endeavour of science, industry, governmental and non-governmental organisations will be crucial. This process will decide if future generations are still able to use the remedies of nature.

For these reasons, WWF and TRAFFIC have started the initiative '"Medicine and Species Protection" on the occasion of the 2000 EXPO in Hanover, Germany. Meanwhile, over 100 organisations, companies and persons have signed a common declaration committing themselves to actively contribute to the protection of natural, medicinal resources. A platform has been created to exchange ideas and start co-operation programmes between the industry, trade, health sector stakeholders, political institutions and organisations involved in nature conservation. Anyone who would like to join this working-group is most welcome.

W18 Certified wild crafting of medicinal plants?

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The aim of this work is to give a statement point of view about contamination and quality of wild plants, protection's possibilities of natural resources and its sustainable use. We have tried to give an idea about which is the actual situation of the amounts of wild medicinal plants harvested in Spain and the possibility of changing to cultivation for each one. At the same time we have introduced the situation of medicinal plants cultivation in Spain, and the possible collaboration with suppliers and cultivation research institutions, for some wild medicinal plants used in big quantities or in dangerous situation. In the same line, we have talked about the legal situation in Spain. In that sense, we have made an analysis of production, trade and market bibliographic researches and a poll of wild medicinal plant rural collectors.

The results allows us to conclude that the quality of these medicinal plants are according to Pharmacopeia normally. In Spain, there is a decreasing tendency regarding the number of wild medicinal plants harvested and the wild rural collectors, as well. The contrary situation is happening in South and East of Mediterranean countries. Only some medicinal plants are harvested in big amounts (more than a ton/year) in Spain, like *Equisetum ramosissimum* Desf. ssp. *ramosissimum* or *E. telmateia* Ehr., *Lepidium draba* L., *Juniperus communis* L., *Taraxacum officinale* Weber., *Arctostaphylos uva-ursi* Spreng., *Gentiana lutea* L., *Malva sylvestris* L., *Viscum album* L., *Rosmarinus officinalis* L., *Thymus* spp., *Salvia* spp., *Lavandula* spp., *Paronychia* spp., *Jasonia glutinosa* De Cand., *Centaurea aspera* L., *Artemisia campestris* L., *Spiraea ulmaria* L., *Capsella bursa-pastoris* Medik., *Santolina* spp., *Sideritis* spp., and *Satureja* spp. For some ones is really necessary certified wild crafting of medicinal plants.