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Form 1: Proposal for a new field of technical activity

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Proposer: ISIRI	**ISO/TS/P** TS/P 264

A proposal for a new field of technical activity shall be submitted to the Central Secretariat, which will assign it a reference number and process the proposal in accordance with the ISO/IEC Directives (part 1, subclause 1.5). The proposer may be a member body of ISO, a technical committee, subcommittee or project committee, the Technical Management Board or a General Assembly committee, the Secretary-General, a body responsible for managing a certification system operating under the auspices of ISO, or another international organization with national body membership. Guidelines for proposing and justifying a new field of technical activity are given in the ISO/IEC Directives (part 1, Annex C).

The proposal (to be completed by the proposer)

Title of the proposed new committee (The title shall indicate clearly yet concisely the new field of technical activity which the proposal is intended to cover.)

Medicinal Plants

Scope statement of the proposed new committee (The scope shall precisely define the limits of the field of activity. Scopes shall not repeat general aims and principles governing the work of the organization but shall indicate the specific area concerned.)

Standardization in the field of medicinal plants as well as medicinal plants propagation materials, in particular terminology, sampling, test methods and analysis, product specifications, safety and quality requirements for packaging, storage and transportation. Medicinal plants substances with regard to safety and quality such as content of active material, values for physical, chemical specifications and microbial contaminants, chemical residues and heavy metals etc., must be based on recognised international standards or deliverables and should be laid down in written form.

Excluded from its scope are products covered by ISO/TC 54 Essential oils, ISO/TC 245 Traditional Chinese Medicine and ISO/TC 215 Health Informatics.

Proposed initial programme of work (The proposed programme of work shall correspond to and clearly reflect the aims of the standardization activities and shall, therefore, show the relationship between the subject proposed. Each item on the programme of work shall be defined by both the subject aspect(s) to be standardized (for products, for example, the items would be the types of products, characteristics, other requirements, data to be supplied, test methods, etc.). Supplementary justification may be combined with particular items in the programme of work. The proposed programme of work shall also suggest priorities and target dates.

Medicinal plants committee is mainly responsible for making medicinal plants development plan of international standards, developing and revising the international standard. Initial work programme in the proposal as follows:
-Basic standards such as “Terminology of Medicinal Plants”;
-Hygiene requirements for Medicinal Plants;
-Safety requirements for Medicinal Plants;
-Technical requirements for Medicinal Plants;
-Quality control standard for Medicinal Plants;
-Characterization and specification requirement for Medicinal Plants;
-Transportation and storage requirements for Medicinal Plants;
-Packaging requirements for Medicinal Plants;
Medicinal Plants terminology is fundamental for standard development in the field.
Hygiene and safety requirements can be used by medicinal plants handling and processing system to provide assurance to consumers on safety and quality of products.

The priority of work will be establishing Terminology, classification, cost and productivity standards that will resonate with the market place and provide immediate value to consumers

Indication(s) of the preferred type or types of deliverable(s) to be produced under the proposal (This may be combined with the "Proposed initial programme of work" if more convenient.)

The deliverables from this work would include ISO standards.

A listing of relevant existing documents at the international, regional and national levels. (Any known relevant document (such as standards and regulations) shall be listed, regardless of their source and should be accompanied by an indication of their significance.)

The relevant existing documents are as follows:
WHO: Guideline and EC directive on traceability of Herbal raw material:
ISO standards: ISO 17351:2014, ISO 15378:2011
Iran national standards: IS 5103:2000, IS 5310:2001, IS 2599:2003, IS 3741:2005, IS 410:2000, IS 6399:2001, IS 438:2000, IS 433:2001, IS 2459:1989, IS 3277:1991, IS 11078:2000, IS 2815:1988, IS 251:1995, IS 3358:1998, IS 3359:1998.

British national standard: BS EN 16679:2014.

A statement from the proposer as to how the proposed work may relate to or impact on existing work, especially existing ISO and IEC deliverables. (The proposer should explain how the work differs from apparently similar work, or explain how duplication and conflict will be minimized. If seemingly similar or related work is already in the scope of other committees of the organization or in other organizations, the proposed scope shall distinguish between the proposed work and the other work. The proposer shall indicate whether his or her proposal could be dealt with by widening the scope of an existing committee or by establishing a new committee.)

There will be no work scope and deliverable overlap or conflict between the proposal and other technical committees or sub-committee of ISO and IEC.

A listing of relevant countries where the subject of the proposal is important to their national commercial interests.

This proposal will be commercially beneficial to all countries that manufacture or use medicinal plants, especially to those countries that produce large numbers of medicinal plants, such as China, USA, India, Iran, Germany, Britain, Japan, Turkey, Italy, South Africa, Australia, Pakistan, Afghanistan, etc. Those countries that export large numbers of medicinal plants, such as China, UAS, Iran, India, Italy, South Africa, Australia, Canada, Spain, Pakistan, etc.

A listing of relevant external international organizations or internal parties (other ISO and/or IEC committees) to be engaged as liaisons in the development of the deliverable(s). (In order to avoid conflict with, or duplication of efforts of, other bodies, it is important to indicate all points of possible conflict or overlap. The result of any communication with other interested bodies shall also be included.)

Medicinal technical committee will actively seek opportunities to coordinate and liaison with many international organizations below. As propose of this proposal does not overlap or conflict with work scope or deliverable of any technical committee of ISO.
However, Medicinal plants are used in the production of medicine. Medicinal plants also requires development of special safety and quality standards, thus the proposal would seek contact with the following technical committee or subcommittee for communication in the study of standardization:

ISO/IEC Technical committees:
ISO/TC 34, Food products;
ISO/TC 54, Essential oils;
ISO/TC 84, Devices for administration of medicinal products and catheters;
ISO/TC 215, Health informatics;
ISO/TC 217, Cosmetics;
ISO/TC 249, Traditional Chinese Medicine;
ISO/TC 276, Biotechnology;
ISO/TC 34/SC 7, Spices;
ISO/TC 34/SC 8, Tea.

The proposal would seek contact with the following international organizations in the study of standardization:
WFAS (World Federation of Acupuncture and Moxibustion Societies);
WHO (World Health Organization);
FAO (Food and Agriculture Organization);
UNESCO (UN Economic and Social Council);
UNDP (United Nations Development Program);
UN (United Nation);
WFPMM(World Federation of Propertary Medicine Manufactures);
WWF(World Wild Fund for Nature);
IUCN(International UNION for Conservation of Nature and Natural Resources);
IHTSDO (International Health Terminology Standards Development Organization).

A simple and concise statement identifying and describing relevant affected stakeholder categories (including small and medium sized enterprises) and how they will each benefit from or be impacted by the proposed deliverable(s).

All medicinal plants at stakeholders, including consumers, industries, governments/regulatory organizations, national and international traders and researchers will benefit from and be affected by the proposed deliverables.
Medicinal plants obtained from wild habitats are found in different natural ecosystems of the forests, grasslands, woodlands, wetlands, in field margins and garden fences, as weeds and in many other microhabitats from where they are harvested when the need arises. These are free access resources to all who want to use them for practicing traditional medicine or for sales. Today, as many as 80% of the world's people depend on traditional medicine for their primary health care needs, according to the World Health Organization(WHO). The greater part of traditional therapy involves the use of plant extracts or their active principles.
The preliminary results of a study on behalf of WHO has shown that the number of individuals using medicinal plants is large and on the increase, even among young people. It is not just in developing countries that medicinal plants are important. In the USA, for example, 25% of all prescriptions from community pharmacies between 1959 and 1980 contained materials from higher plants.

As harvesting of natural resources is an economic activity recognized both locally and internationally, the use and commercialization of traditional medicinal plants can improve income and living standards in developing countries where rural people are economically vulnerable. As far as SMEs are concerned, both national and international trades in this category are affected by the standardization of medicinal plants, because standardized products are more welcomed by consumers and comparing with other products, they are taken more confidently.

In the absence of regulatory control, product quality is too variable to accept. Inadequate post-harvest storage and processing techniques often lead to high levels of biological/no biological contamination and significant stock/losses. Little attention is paid to product packaging and marketing, and the most significant value-adding takes place when the remedies are prescribed. Consumers' safety is also an issue, although largely unmonitored at present. On the other hand, implementing such technical committees and new standard development will result in market expansion, valid analytical methods for researchers and the authorities, composition and active component uniformity and a value added product for the industries, in addition to protecting health and preventing commercial fraud.

An expression of commitment from the proposer to provide the committee secretariat if the proposal succeeds.

ISIRI is willingly to undertake the secretariat work of "Medicinal Plants Technical Committee" when the proposal is accepted by ISO.

Purpose and justification for the proposal. (The purpose and justification for the creation of a new technical committee shall be made clear and the need for standardization in this field shall be justified. Clause C.4.13.3 of Annex C of the ISO/IEC Directives, Part 1 contains a menu of suggestions or ideas for possible documentation to support and purpose and justification of proposals. Proposers should consider these suggestions, but they are not limited to them, nor are they required to comply strictly with them. What is most important is that proposers develop and provide purpose and justification information that is most relevant to their proposals and that makes a substantial business case for the market relevance and the need for their proposals. Thorough, well-developed and robust purpose and justification documentation will lead to more informed consideration of proposals and ultimately their possible success in the ISO IEC system.)

Medicinal plants have been used in treating human diseases for thousands of years. It appears that Neanderthal man (about 60,000 years ago) valued plants as medicinal agents; this conclusion is based on a grave in Iran in which pollen grains of eight medicinal plants were found (Solecki and Shanidar, 1975). With the constant increase in the use of herbal medicines worldwide and the rapid expansion of the global market, the safety and quality of herbal materials and finished herbal products have become a major concern for health authorities, pharmaceutical industries and the public. The safety and efficacy of herbal medicines largely depend on their quality. Requirements and methods for quality control of finished herbal products, particularly for combining/mixing herbal products, are far more complex than for chemical drugs. The quality of finished herbal products is also influenced by the quality of the raw materials used.

The latest World Health Assembly resolution on traditional medicine (WHA56.31) requested WHO to provide technical support to develop methodology to monitor or ensure the quality, efficacy and safety of products. In answer to WHO's call, health authorities in developing countries have decided to take traditional medicine more seriously and to explore the possibility of utilizing them in primary health care. The quality of herbal medicines can directly affect their safety and efficacy.

Member States face complicated technical issues in the quality control of herbal medicines. In order to promote and improve the quality of herbal medicines and also to reduce the proportion of adverse events attributable to the poor quality of herbal medicines, WHO has committed to the development of a series of technical guidelines related to quality assurance and control of herbal medicines, as well as to updating existing guidelines.

It appears to the health authorities that defining medicinal plants from cultivation to end product (both dried and liquid extracts using different solvent composition), tablet has a great necessity. Monitoring and surveillance of the promotion of the use of medicinal plants is another issue that needs upstream documentation which will be achieve by implementing this committee and developing the standard protocols(even developing a comprehensive document on medicinal plants). To promote traditional use of medicinal plants based on the latest scientific findings about such plants, transferring the technologies and developed countries are other benefits of the proposed deliverables. Theorizing and future frontiers of knowledge in all aspects of plant medicine and aromatic plants will be achieved through this technical committee.

Unlike conventional pharmaceutical products, which are usually produced from synthetic materials by means of reproducible manufacturing techniques and procedures, medicinal plants are prepared from materials of herbal origin, which are often obtained from varied geographical and/or commercial sources. As a result it may not always be possible to ascertain the conditions to which they may have been subjected. In addition, they may vary in composition and properties.

The list of the experts whose disciplines can contribute most to the conservation and utilization of medicinal plants as follows:

To improve techniques for cultivating medicinal plants;
To persuade the public of the need to conserve medicinal plants;
To understand the ecosystems in which medicinal plants grow;
To identify the use of plants as medicines in traditional societies;
To include conservation and utilization of medicinal plants in their policy and planning;
To cultivate medicinal plants;
To develop effective legal mechanisms that ensure that collection of medicinal plants is at levels;
To study the application of medicinal plants;
To evaluate the patterns of use and the economic values of medicinal plants;
To understand the germination and storage requirements of the seed of different medicinal;
To protect the cultivated medicinal plants from pests and diseases without using dangerous;
To identify the medicinal plants accurately;
To provide information on the uses and availability of medicinal plants.

The economic and industrial environment in the medicinal plants field is changing, since due to economic requirements their production is moving to less developed countries, while quality control and consumption occur in more developed ones. Moreover, it should be considered that markets tend to globalization and dropping of some trade barriers. In this respect, the new committee contributes greatly, by developing International Standardization of methods of analysis and specifications, to facilitate trade and commercial exchanges in the Medicinal plants sector, as the above mentioned globalization has involved a growing demand of International standards on medicinal plants.

Note: The scope and deliverables of this proposal aim at specific work of medicinal plants characterizations and do not overlap or conflict with any scope or deliverables of ISO/IEC committees.

Signature of the proposer ISIRI

Further information to assist with understanding the requirements for the items above can be found in the Directives, Part 1, Annex C.