Forum: UNODC
Issue: Regulation of drugs involved in traditional or natural medications
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Introduction:

Before the advent of modern medicine, diverse communities' folk beliefs developed over many centuries into the medical parts of traditional medicine, commonly referred to as indigenous or folk medicine. Traditional medicine is described by the World Health Organization (WHO) as "the body of knowledge, skills, and practises based on theories, beliefs, and experiences that are indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement, or treatment of physical and mental illness," whether these are based on explanations or not. Scientific medicine and traditional medicine are frequently compared to one another, some believing that they may or may not show the same results as forms of treatment.

Up to 80% of the population in several Asian and African nations turns on traditional medicine for their basic medical requirements. Traditional medicine is frequently viewed as an alternative type of medicine when it is practised outside of its original cultural context. Traditional European medicine, traditional Chinese medicine, traditional Korean medicine, traditional African medicine, Ayurveda, Siddha medicine, Unani, traditional Iranian medicine, and ancient Iranian medicine are some examples of traditional medical practises. Herbalism, ethnomedicine, ethnobotany, and medical anthropology are among the scientific fields that research traditional medicine.

However, according to the WHO, "wrong use of traditional medicines or practises might have negative or harmful effects" and "more study is needed to verify the efficacy and safety" of such activities and the medicinal plants employed by traditional medicine systems." The WHO created a comprehensive nine-year approach in order tohelp the member states create proactive policies and implement action plans. This would be in order to highlight and try to take advantage of the role that traditional medicine plays in maintaining population health. However, due to the lack of relevant standards, the development of TCM is undermined and the progress of internationalization and modernization of TCM is seriously influenced

Definition of Key Terms:

1. **Folk medicine:** Folk medicine is a term used to describe practises that may coexist with established, scientifically founded, institutionalised systems of medical practice, or conventional medicine, in many different nations. Folk medical practises include, among others, traditional Chinese medicine, Iranian traditional medicine, traditional Korean medicine, indigenous Arabic medicine, Uyghur traditional medicine, Japanese Kamp medicine, traditional Aboriginal bush medicine, Native Hawaiian Lau lapaau, and Georgian folk medicine.
2. **Traditional medicine:** It is the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.
3. **Phytotherapy:** Phytotherapy is the practice of using medicines derived from plants or herbs to treat or prevent health conditions. Although increasing in popularity throughout the world, phytotherapy still needs more research to determine its effectiveness and potential side effects.

Background Information

History

Traditional medicine practices have existed for millennia and the Sumerians, who are mentioned in the written record as early as 5,000 years ago, documented well-known medical uses for plants and are the first people to study herbs. The Ebers papyrus, which dates to around 1552 BC, contains a list of traditional treatments and magical medicinal procedures used in Ancient Egyptian medicine. Regarding Kashrut, the Old Testament also makes reference to the cultivation and usage of herbs.

Ancient Indian herbalists like Charaka and Sushruta wrote descriptions of several plants and minerals utilised in Ayurveda throughout the first millennium BC. The Shennong Bencao Jing, which was originally written during the Han Dynasty but dates back to a much earlier period, was the earliest Chinese herbal literature. It was later expanded as the Yaoxing Lun (Treatise on the Nature of Medicinal Herbs) during the Tang Dynasty. Pythagoras and his disciples, Hippocrates, Aristotle, Theophrastus, Dioscorides, and Galen are a few of the early known Greek compilers of existing and contemporary herbal knowledge.

Pliny the Elder's Natural History and Celsus's De Medicina were two Roman sources. For his De Materia Medica, Pedanius Dioscorides drew from and corrected earlier writers while providing a significant amount of new material. The work was translated into other languages, and over time, names in Turkish, Arabic, and Hebrew were added. Latin copies

of De Materia Medica were inserted into the Anglo-Saxon codex Cotton Vitellius C.III together with a Latin herbal by Apuleius Platonicus (Herbarium Apuleii Platonici). These early Greek and Roman collections, which were translated by the Persians Avicenna (Ibn Sn; 980–1037), Rhazes (Rzi; 865–925), and the Jewish Maimonides, served as the foundation for European medical thought.

Current Situation

The ways Traditional Medicine are usually made (Just for some insight)

Herbs (13 species, 30.95%) and shrubs (23 species, 54.76%) were the two life forms that were used the most frequently. The leaves and roots of medicinal plants were the most commonly used components. Various methods, including drenching, dropping, smearing, chewing, wrapping, fumigating, and washing, were used to administer prepared medicines.

The Ecological concern of animal products in traditional medicine

Regrettably, one of the reasons for the overexploitation of the wild population of many animal species is the demand created by traditional medicine. Due to the widespread acceptance of popular medicine, the use of animals in popular medicine undoubtedly puts strain on the natural resources that are exploited through conventional ways of collection . In terms of medicine, this trend's one main drawback is that there will effectively be less options for the creation of new medications [19]. Currently, roughly 40% of all prescription medications come from materials that were once found in plants, animals, fungi, or microbes .

Unfortunately, one of the factors contributing to the overexploitation of many animal species' wild populations is the need for traditional medicine. A major contributing factor to the demand on natural resources utilised through traditional means of collection is the use of animals in popular medicine. There will effectively be less options for the future creation of drugs, which is the one significant drawback of this trend from a medical standpoint. Approximately 40% of all prescription medications currently on the market were first derived from plants, animals, fungus, or microbes.

The cultural concern of animal products in Traditional Medicine

There is a growing interest in the knowledge that traditional populations have regarding the use of animals for medicinal purposes, in part because the empirical foundation established over many years may have scientific support in many cases, but also because of the practice's historical, economic, sociological, anthropological, and environmental implications.

Due to the low level of harvesting, healers and indigenous people have been gathering remedies from local plants and animals for generations without endangering the population dynamics of the species. Modern medicine's advancement is impacted by the loss of traditional knowledge.

In light of globalisation and the rising demand for natural resources globally, it is especially important to safeguard traditional knowledge and its cultural environmental resources. Traditional knowledge is useful for modern medicine, agriculture, and other fields in addition to people who are directly associated with it. Protection of traditional knowledge can also be utilised to increase awareness of the knowledge and those who hold it. This has ramifications not only for the preservation of customs inside communities, but also for the relationships (such as economic and ecological interactions) created outside of groups.

The economical concern of using animal products in Traditional medicine

Pharmaceutical corporations have carefully evaluated using animals as test subjects for compounds used in modern medicine, and a sizeable portion of vital medications are currently produced using animal sources. 11.1% and 8.7%, respectively, of the 252 important compounds chosen by the World Health Organization come from plants and animals. Additionally, 27 of the 150 prescription medications currently being used in the United States of America are derived from animals.

Traditional medicine is included in the trade in wildlife body parts and goods, and it is generally known that the annual global trade in medicines derived from animals is worth billions of dollars [31]. But in nations like Brazil, where most collectors are illiterate, underpaid, and believe their work is clandestine or semi-clandestine, the trading of animals for medical purposes has had less of an influence on their social standing. At each level of trade, the value of animals traded in the nation for therapeutic purposes rises, and the socioeconomic makeup of traders alters proportionately.

The advent of drugs in traditional medicine

Traditional medication has existed for beyond decades, passed down from generation to generation with many forms of it existing all over the world. However, with the introduction of drugs and narcotics into the system of treatment and even before that, drugs in traditional medicine have become a rising concern for many governments around the world, questioning the ethicacy as well as the effectiveness of these drugs.

One such case is Homeopathy. Homoeopathy is a system of medicine based on the observation that high doses of pharmacologically active substances cause symptoms when

administered to healthy individuals, which is now facing regulations in the US. When synthesized in a very diluted form, the same chemicals may alleviate comparable symptoms in illnesses caused by various etiologies. Homoeopathic medicines are governed by FDA regulations and the Food, Drug, and Cosmetic Act, unlike nutritional supplements. Premarket approval for homoeopathic medications is accomplished through monograph approval by the Homeopathic Pharmacopoeia Convention of the United States rather than by the new drug approval procedure (HPCUS). The Homeopathic Pharmacopoeia of the United States includes monographs (HPUS). For a homoeopathic medicinal product to meet the requirements for inclusion in the HPUS, it must first be deemed safe and effective by HPCUS and created in accordance with the guidelines of the HPUS general pharmacy section. The established and lengthy history of homoeopathic medicine regulation may offer a model for the regulation of dietary supplements. Homoeopathic drugs in the United States are now subject to well-defined regulatory processes that more closely resemble those that apply to allopathic medications than to dietary supplements.

The specific regulations that major countries around the world have in relation to this issue are explained in more detail in the following subtopic.

Major Parties Involved and Their Views

China

As the country of origin and application of TCM, China has a unique TCM theoretic system and effective treatment methods. In recent years, after the constant transformation of concepts and methods, great breakthroughs and remarkable achievements have been made in terms of the standardization of TCM, but some problems remain. China has written 27 articles in the Endangered species import and export act in 1993. This was an act to implement the Convention on International Trade in Endangered Species of Wild Fauna and Flora by regulating the import, export, re-export, and introduction from the sea of specific animals and plants, as well as the import, export, and re-introduction of their parts and derivatives, and for matters related thereto. In 2009, the State Council of China issued Several Opinions on the State Council on Supporting and Promoting the Development of Traditional Chinese Medicine, in which “promoting the standardization of TCM” was included.

India

On the 25th of March 2022, the World Health Organization (WHO) and the Government of India signed an agreement to establish the WHO Global Centre for Traditional Medicine. This global knowledge centre for traditional medicine, supported by an investment

of USD 250 million from the Government of India, aims to harness the potential of traditional medicine from across the world through modern science and technology to improve the health of people and the planet. The Prime Minister and Government of India are supporting the establishment of the WHO Global Centre for Traditional Medicine in Jamnagar, Gujarat, India, as a global good and in the spirit of Vasudhaiva Kudumbakam: the world is one family. India has many ancient forms of traditional medicine such as Ayurveda, homoeopathy etc.

Brazil

It is up for debate to what degree a historic usage of a plant guarantees the safety of a similar herbal medication. The Brazilian National Health Surveillance Agency (Anvisa) recently issued a new draught regulation that put this contentious subject front and centre. The "phytotherapeutic medicines" and "traditional phytotherapeutic products" (TPTP) categories of herbal pharmaceuticals are defined in the draught rule, which has recently completed a public consultation for reviews and comments (Anvisa, 2013). A substance falls under the latter category if it has been determined to have a long-standing (traditional) usage that hasn't been shown to be harmful, is acknowledged in the literature, and is supported by ethnopharmacological and/or ethnobotanical investigations. Safety and effectiveness data from pre-clinical and/or clinical trials are no longer necessary to receive authorisation for commercialization after the conventional use has been identified.

Europe

The proposed new regulations for Brazilian herbal medicine licencing are somewhat reminiscent of those announced by the European Parliament in 2004. Traditional herbal medicine products (THMPs), as described by Calapai (2008), Quintus and Schweim (2012), and Silano et al., can be categorised as "traditional herbal medicine products" (THMPs) in accordance with EC Directive 2004/24 even if they do not have a recognised degree of efficacy (2004). A medication or its corresponding products, which are those with the same active ingredients, the same or similar intended uses, equivalent strengths and posologies, and the same or similar route of administration, must have been in use as a medication for at least 30 years in order to be classified as a THMP. In the THMP category, the registration process for herbal medications is streamlined. The traditional usage of a herb must be shown for aspirant herbal goods; however, if the product complies with the European positive list created by the Committee on Herbal Medicinal Products (HPMC), this condition is waived (Knöss and Chinou, 2012). Herbal monographs created by HPMC are not legally binding, and member state agencies may not concur with all of the monograph's recommendations. For instance, applicants who cite an HPMC monograph might need to provide further information on safety (e.g., on genotoxicity).

United States

The United States Food and Drug Administration (US FDA) does not differentiate between herbal and conventional medications in regards to the standards for pre-marketing demonstration of safety and efficacy, in contrast to European and Brazilian authorities (Wu et al., 2008). Due to this, herbal items that have therapeutic benefits are typically not approved as medications and instead are sold as dietary supplements in the USA. It is debatable whether or not herbal medications require less thorough and rigorous safety and effectiveness investigation. There is no scientific basis for assuming that plants, their components, and/or their derivative products, including those with a long history of widespread use, are inherently safe and/or beneficial, or that, in comparison to conventional medicines, they would necessitate fewer and easier pre-clinical and/or clinical studies. For the sake of consistency in drug laws, all medications, regardless of where they were developed and where they came from, must pass the same exacting safety and effectiveness requirements in order to receive marketing authorisation.

The fact that herbal medical goods with inadequate or even no testing have not been taken off the market in the USA is now the greatest argument against applying the same criterion to herbal and conventional medications. In actuality, these goods are nonetheless widely distributed and eaten as herbal and dietary supplements (HDS), a class of consumer goods that the US FDA regulates less strictly. A declaration of thorough and exact pre-marketing medication safety and efficacy is not a prerequisite for HDS. Dietary supplements (HDS) manufacturers are required by the US Dietary Supplement and Health Education Act of 1994 and the Final Rule for Current Good Manufacturing Practices for Dietary Supplements of 2007 to define dietary ingredients as vitamins, minerals, herbs, and amino acids, provide standards for identification and purity, and make sure that product claims are truthful and not deceptive. HDS is used in concert with conventional medications or on their own to treat a number of morbid disorders, despite legal limits on listing supposed therapeutic characteristics on the product label. On the basis of this, proponents of maintaining a distinct category of phytotherapeutics for regulatory purposes contend that this particular class of medicines, as opposed to dietary supplements, undergo a more in-depth evaluation of safety and at least some assessment of efficacy and are also subject to more stringent rules regarding quality assurance and manufacturer adherence to GMP.

Singapore

The Singapore government states that “TM are not subject to approvals and licensing by HSA for their importation, manufacture and sale. HSA prohibits the addition of medicinal ingredients such as steroids in TM. HSA also sets strict limits on toxic heavy metals in these

products. Dealers (importers, manufacturers, wholesale dealers and sellers) have the obligation to ensure that their products are not harmful or unsafe and that they conform with the following guidelines before supplying TM into Singapore."

Malaysia

In order to include traditional medicine within the current official healthcare system, Malaysia wants to create traditional healthcare regulations and legislation. An international trend is the rising use of traditional medicine. Malaysia serves as a good example. The regulation of traditional medicine there has not, however, kept up with this development. The main focus of this thesis is how this might be performed in the most efficient way possible. Currently, the national healthcare policy on traditional medicine is being formulated and implemented, but legislation is not yet in place. The policy challenge is how best to cultivate a standard policy across the various traditional systems. This involves such issues as follows:

- The definition of legal power,
- The framing of rules and regulations, and
- The standardisation of a traditional medicine education system

UN Involvement, Relevant Resolutions, Treaties and Events

- WHO Traditional medicine strategy (2014-2023)
    - The WHO Traditional Medicine (TM) Strategy 2014–2023 was developed in response to the World Health Assembly resolution on traditional medicine. The goals of the strategy are to support Member States in harnessing the potential contribution of TM to health, wellness and people-centred health care; promoting the safe and effective use of TM by regulating, researching and integrating TM products, practitioners and practice into health systems, where appropriate. The strategy aims to support Member States in developing proactive policies and implementing action plans that will strengthen TM's role in keeping populations healthy.
- WHO Global Centre for Traditional Medicine opening in India
- The purposes of WHO's current traditional medicine strategy:

1) harnessing the potential contribution of traditional and complementary medicine to health, wellness, people-centred health care and universal health coverage (UHC)

2) promoting safe and effective use of traditional and complementary medicine through the regulation, research and integration of traditional and complementary medicine products, practices and practitioners into the health system, as appropriate.

- WHO Expert Meeting on Evaluation of Traditional Chinese Medicine in the Treatment of COVID-19 (2022)

Possible Solutions

1) **Existing treaties**

- During the debate, delegates should discuss the different treaties written by the different countries and how they can be improved and/or made more effective.

2) **Legal Action**

- Delegates should work towards creating solutions that provide better law enforcement to allow for stricter monitoring of importing, exporting as well as producing contraband items in relation to traditional medicine. Ways to help mitigate the use of taxidermy or animal produce for the use of human treatment.

3) **Educating more on the study and production of traditional medicine**

- Delegates should look at how different countries could come together and help to form a global framework to help educate more on the dangers of using drugs and contraband in traditional medicine as well as the ways in which traditional medicine can be safely and effectively produced and administered to keep ancient traditions alive.

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Useful Links

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