Challenges of Law Related to Indigenous Medical Research for Drug Innovation in Sri Lanka in the Context of the New Normal: A Critical Analysis

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Abstract - With the prevailing condition of the world, the World Health Organization (WHO) activated a blueprint for research and development for accelerating diagnostic, improving coordination between scientists and global health professionals, research and development process, and therapeutics for severe acute respiratory syndrome Coronavirus 2 (Covid-19). The humans who have been infected and are suffering from chronic illnesses and elders are at a high risk of fatality. Therefore, human immunity power boosting is the best solution to fight Covid-19. With this atmosphere, the world's attention was drawn to indigenous medicine to innovate a cure. In Sri Lanka, a controversial situation has arisen on the traditional treatment for enhancing immunity, questioning uniformity, and transparency. Considering the medicine production procedure, there should be adapted standards unless neither the doctors will recommend, nor people will trust and consume the medicine. The objective of this study is to find the reasons for the controversial issues that occurred when the traditional cures were introduced in Sri Lanka. This study explored the relevant laws and their defects and how to adapt all indigenous medical practices to one formula regarding drug innovation of indigenous medicine and the authorities who are responsible for drug innovation of indigenous medicine. The researcher followed a systematic literature review method to analyze the provisions of Ayurveda Act No. 31 of 1961 (hereinafter referred to as "Act") and regulations as well as other relevant documents.

Keywords— indigenous medicine, research, responsibility, authorized bodies, Ayurveda Act

I. INTRODUCTION

Covid 19 is a virus that is not cured by any available drug. This virus can spread from droplets that are generated from coughing and sneezing, among humans, and rapidly converted according to the environment in which it formulating. The virus can be affected not only the respiratory system but also the cardiac, renal, brain, eyes, gastrointestinal, skin, and psychologically. This is a virus that can fatal any person having a weak immune system. The WHO has taken steps to implement the vaccination program worldwide months later. (WHO, 2021) The vaccine artificially enhances immunity. The vaccine is belonging to an allopathic medical system among the various medical practices across the world deviate from allopathic medicine and there is an Ayurvedic medical system in Sri Lanka. (WHO, 2019). Although it is generally referred to as ayurvedic medicine, it is a combination of Ayurveda (which came from Hindu Veda treaties of India),Siddha (from Indian religion and culture), Unani (originated in ancient Greece, and now practicing in India), and Deshiya Chikitsa (Sri Lankan traditional treatment). Sri Lankan traditional treatment or medicine is inherited with its own remarkable indigenous knowledge system as evident by its impact on the earlier inhabitants (Medicine, 2013). In 341 AD King Buddadasa's "Sarartha Sangrahaya", the first medical treaty in Sri Lanka, which was contained the ethnicity and medicine of "Hela". This knowledge comes through passing the evolutionary process which has evolved in the cultural environment and that has been a transmission from generation to generation (A.D. Zoysa, C.D. Palitharathna, 1992). (CK Gamage, 2019).

The Covid-19 pandemic was impacted Sri Lanka from March 2021. Sri Lankan Traditional Medical Practitioners(TMP) are also trying to contribute their knowledge to innovate the cure. Although there are authoritative bodies to help and direct them, citizens of Sri Lanka witnessed that the health authorities

tried to legalize the cures without clinical trials or even without acknowledge of ingredients containing in the introduced drugs. Therefore, it is punctual to find out why the National Medicine Regulatory Authority, Ayurvedic Medical Council, or Ministry of Indigenous Medicine pr any responsible authority did not come forward to regulate this situation.

II. OBJECTIVES.

There is a comprehensive legal framework to regulate and observe every aspect in relation to drug innovation under National Medicine Regulatory Authority Act no. 5 of 2015in Sri Lanka. Despite all rules and regulations, there couldbe able to see the controversial situation that arose in Sri Lanka with the syrups introduced by many persons without the approval of any responsible authority, while the western practitioners submitted their research proposals to the National Research Council of Sri Lanka. (Jayasiri, 2020) None of them reveal the all ingredients of the syrup and they started distributing among the people for free and sell later. However, the Sri Lankan government or any authoritative body did not interfere to stop that immediately.This is a very problematic situation just in case if the syrupimpacts negatively on the human, then the ayurvedic or allopathic doctors will not be able to give treatments without knowing what was in the syrup. In addition to that many medical professionals have tried to adapt TMPs to the accepted methodology by pointing out the deficiencies of the methodology in which these drugs were introduced, these TMPs who introduced the cure have arbitrarily rejected those ideas. The TMPs are breaching their existing contractual liability with the patients. It is not uncommon for cases to extend beyond the civil liability to criminal liability. While the experts were up against the syrup, some responsible authorities including the Ministry of Health, believed that the syrup should be approved. (Bandara, 2020) However, the Health Minister, who consumed the Covid syrup, was positive for Covid-19. (BBC, 2021)

When Sri Lanka is making such futile efforts, with the recognition gained on the results of clinical trials conductedsince 2000, the World Health Organization allows scientifically proven traditional medicine for Covid-19.(WHO, 2020)

Thus, it is very clear that although there are laws and regulations in this regard, in Sri Lanka such as the NationalMedicine Regulatory Authority, there should be some reasons for not being functional. The reasons may be a flaw or a weakness of the laws and regulations. There is a requirement to identify what are the loopholes in the law, that allows them to do so. These are the research question I used for that. What are the relevant laws and the defects ofrelevant laws? how to adapt all indigenous medical practitioners to one formula regarding drug innovation of indigenous medicine and what are the authorized bodies have responsible for drug innovation of indigenousmedicine?

III. DISCUSSION CONCLUSION

The WHO identified key objectives of the Traditional Medicine Strategy in 2005, aims to support member states, to integrate traditional medicine within national health care systems, where feasible, by developing implementing national traditional medicine policies and programs, to promote the safety, efficacy, and quality of traditionalmedicine by expanding the knowledge base, and providing guidance on regulatory and quality assurance standards, to increase the availability and affordability of traditional medicine, with an emphasis on access for poor populations,to promote therapeutically sound use of appropriate traditional medicine by practitioners and consumers in South - West Asia Region. (WHO, 2013). Simultaneously, Sri Lanka also had been a party to the Delhi Declaration onTechnical Matters of Traditional Medicine (Delhi Declaration). Regional Committee is willing to support member states to the promotion of national policies for equitable development and appropriate use of traditional medicine in health care delivery; to development of an institutionalized mechanism for information exchange; andto exchange of views, experiences, and experts forintegration of traditional medicine into national health systems in accordance with national policies and regulations (WHO, 2014). WHO launched the Implementation of Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property in 2015 for the development of indigenous medicine (Sri Lanka, WHO, 2015). The protocol for phase III clinical trials of herbal medicine for Covid-19 has been endorsed by Regional Expert Committee on Traditional Medicine forCovid-19 established by the WHO Africa Centre for Disease Control and Prevention, and the African Union Commission for Social Affairs. Additionally, a charter and terms of reference for the establishment of a data and safety monitoring board for herbal medicine clinical trials. (WHO,2020). The African government adopted the

resolution of the WHO Regional committee as a member country and implemented from the year 2000 and undertake relevant research and require national medicines regulatory agencies to approve medicines in line with international standards, which include the product following a strict research protocol and undergoing tests and clinical trials. There is a piece of evidence for research going in the unity of four countries on herbal medicine. (Dâmaris Silveira, Jose Maria Prieto-Garcia, Fabio Boylan, Omar Estrada, Yris Maria Fonseca-Bazzo, Claudia Masrouah Jamal, Pérola Oliveira Magalhães, Edson Oliveira Pereira, Michal Tomczyk, Michael Heinrich, 2020).

With this background, need to look at the Sri Lankan context. In Sri Lanka, the Government College of Indigenous Medicine was established in 1929. In 1961, theAyurveda Act No. 31 of 1961 was enacted by repealing theIndigenous Medical Ordinance No.17 of 1941. The Ayurveda Act intended to provide for the establishment of an ayurvedic medical council to register ayurvedic practitioners, ayurvedic pharmacists, and ayurvedic nurses, and deal with matters relating to their professional conduct;for the establishment of as ayurvedic college and hospital board to discharge certain functions in relation to the college of ayurvedic medicine, the central hospital of Ayurveda and the pharmacy, herbarium, and dispensary attached thereto; for the establishment of an ayurvedicresearch committee to discharge certain function in relationto research in Ayurveda. This Act is the main area that should investigate to find why it is not coming into operation in this controversial situation.

Paragraph (b) of section 18 of the Ayurveda Act No.31 of 1961 as amended, provides for the registration of ayurvedicpractitioners. As a basic law relating to indigenous medicine, under Section 11 (1) of the Ayurveda Act constituted an Ayurvedic Medical Council (AMC). AMC is the authoritative body for the registration of ayurvedic medical practitioners according to Section 18 of the Act. However, the AMC is constituted including not more than three members appointed by the Minister, persons who are not registered as ayurvedic practitioners according to section 11(1) (f) (i), out of seventeen members, and at least three from the members of the All Ceylon Ayurvedic practitioners' Congress. Although one can argue this amount out of seventeen is a very small percentage, according to Section 16 quorum of the council is six. They can register the practitioners on the authority of Section 18(b) and make rules for the Regulation and control of the professional conduct of ayurvedic practitioners and any of the matters referred to cancellation, or suspension of such registration. According to this structure of the Ayurvedic Medical Council, it seems that the Act itself allows the emergence of unregistered traditional practitioners. Part VII of the Act provided the provisions for the registration of ayurvedic practitioners *inter alia.* There is a general register and a special register. Section 55(1)(e) provides Sri Lankan citizens who have sufficient experience and skill inany particular branch of Ayurveda can be registered in thegeneral registry and non-registration is an offence according to Section 69(3). If all TMPs are registered AMCwill no longer exist. This conflict between Section11(f) and Section 69(3) of the Act constitutes *exclusive ad invicem*.

The Registered Ayurvedic Medical Practitioners' (Professional Conduct) rules issued by the Minister under Section 18, on 15.10.2014 from No.1884/36 ExtraordinaryGazette for manipulating the medical responsibility of ayurvedic medical practitioners. The responsibilities assigned to the medical practitioners of research and innovation of drugs and the production of drugs shall havecomplied with all applicable laws for the time being in force relating to the same. These rules are not strong enough to be enforced and there is a question of whether there are applicable laws for the time been. There is no recognized mechanism for implementation on the malpractices of the TMPs because of the interpretation clause of the gazette notification, these rules apply only to the registered ayurvedic medical practitioners. As well as there is no provision to punished irresponsible acts ofTMPs. That may leads to malpractices.

There is a provision for refusal of the registration on the grounds that, he has been convicted by a competent court of any offense which shows him to be unfit to be such practitioner, he has guilty of any misconduct in his capacity as such practitioner in Section 57 of the Act. However, this provision could not impact the unregistered TMPs since the entire Section dealt with registered practitioners. The Act also does not provide a clear definition of "any offense which shows him to be unfit" or "any misconduct". Therefore, the legal authorities could not be able to TMPs take into the regular legal framework. There must be included the clear definition for"any offense which shows him to be unfit" and "any misconduct" in the Act.

Order No.6 of Gazette Notification No.1884/36 of 2014 issued by the Minister stipulates that Ayurvedic Medical Practitioners who engage in the production of Ayurvedic drugs shall comply with all applicable laws for the time being in force. Even so, no regulations have been devised by the minister for how to conduct or what is the accepted methodology of the research in indigenous medicine although there is an Ayurvedic Research Committee. Compared to the way allopathic medicine is being researched, no accepted uniform methodology can be found in traditional medical research. Part V of the Act provided provisions for the establishment of The Ayurvedic Research Committee (ARC). Section 41 of the Act conferred the duties to the committee as follows; to advisethe Minister as to the carrying out of research in all branches of Ayurveda for, ayurvedic literature; fundamentals in ayurvedic doctrine; ayurvedic clinical treatment and ayurvedic drugs, pharmacology, and pharmacopeia. The scope of ARC should not be limited tothe advice. The additional power can be added to ARC to make rules and regulations on research methodology. If there were such by-laws TMPs drug innovations can be taken into the legal framework. The Bandaranaike Memorial Research Institution (BMRI) of Ayurveda is theonly institution that, established outside of this Act, is accommodated to research new drugs using traditionalknowledge. However, there are no pieces of information available about the ongoing or completed research of BMRI on cure for Covid 19.

The notion of the prescriptions or the formulas of traditional medicine have been time tested and need not be researchedis unacceptable on two grounds in the present context. Since those formulas are hereditary and they cannot be avertimented from change with the individual affiliation in a timely manner. On the other hand, if the constituents of herbs change according to chemicals and environmental changes, it will affect the drugs produced by those plants. Therefore, an argument of time-tested can be ruled out. (P. Ahamadpour, F. Ahamadpour, T.M.M.Mahmud, Arifin Abdu, F.Hosseini Tayefen, 2014)

There is an Ayurveda Pharmacopoeia which was documented raw materials and medicinal system by the Department of Ayurveda. Sri Lanka Ayurvedic Drugs Corporation was incorporated under the State Industrial Corporation Act No.49 of 1957 and the private institutions (including most of the practitioners) manufacturing the ayurvedic drugs according to Ayurveda Pharmacopoeia and they do not try to do research for drug innovation.

In 2015, the legislature of Sri Lanka passed Act No.5 to repeal The Cosmetic, Devices and Drugs Act No 27 of 1980, and provide for the establishment of the National Medicines Regulatory Authority (NMRA) which shall be responsible for the regulation and control of, registration, licensing, manufacture, importation and all other aspects pertaining to medicines, medical devices, borderlineproducts and for the conducting of clinical trials in a manner compatible with the national medicines policy. There had been established National Medicines Quality Assurance Laboratory to ensure the good quality of the medicine. It is a comprehensive law regarding drugs in Sri Lanka. The NMRA has the power to encourage the manufacturing of good quality medicines in Sri Lanka witha view to assuring the availability of essential medicines ataffordable prices and regulates all matters pertaining to conduct clinical trials. The appropriate regulations with regards to the manufacturing and clinical trials published in2019 and part II of the Gazette provide how to manufacturethe drugs. (Gazette, 2019) But this law is also silent whenthe TMPs introduced their Covid syrups. Section 146 of theNational Medicines Regulatory Authority Act, "Medicine" interpreted from the interpretation clause *inter alia*including a product made out of medicinal herbal extract but excluded an Ayurvedic or Homoeopathic medicine. Therefore, the National Medicines Regulatory Authority Act does not have the capacity to interfere and control the acts of TMPs. There should be enacted a comprehensive and absolute law pertaining to indigenous medical research.

The project report related to Sri Lanka in 2015, which is linked together with the World Health Organization has revealed several facts on this issue. (Perera, Pathirage Kamal, Manisha Shridhar, 2015). According to the AnnualReport of AMC 2017, there are 8908 traditional ayurvedic medical practitioners out of 23206 ayurvedic medical practitioners. TMPs practicing medicine who are having secret formulae received from their ancestors apart from registered physicians at the Ayurveda Medical Council. The report (Perera, Pathirage Kamal, Manisha Shridhar, 2015) suggested preserving these manuscripts for future research to develop health products through digitalizing and outlined from India as an ensample. The TMPs in Sri Lanka hesitate to reveal their secrets formulae or prescriptions which had been inherited from their ancestors. And traditional medicine may

die because it is passed down from generation to generation unless taking the measure toprotect the intellectual property rights of the TMPs. The existing literature review on Current Status and Challengesin Research and Development on Traditional Medicine in Sri Lanka identified current states and challenges. (Perera, 2019). When we discuss the intellectual property rights of the indigenous medical practitioners, there is a question of whether TMP's intellectual property rights are protected in Sri Lankan Law? Although Sri Lanka had been signed the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Sri Lanka did not implement concerning the indigenous part through the Intellectual Property Act No. 36 of 2003 although having section 24 forsui generis form of expression of folklore, according to the interpretation clues. Therefore, Sri Lankan Traditional Medical Knowledge cannot be included for that. This leadsto endangering the intellectual property rights of TMPs. Therefore, TMPs are reluctant to publish the prescriptions they have researched.

Existing literature on "Traditional Medicine and Primary Health Care in Sri Lanka: Policy, Perceptions, and Practice" (Matgaret Jones, Chandani Liyanage, 2018) revealed that the conflict between western and TMPs and policies are required to reduce the gap between the two systems. (Arseculeratne, 2002)

The Ayurveda (Disciplinary) Regulation, 1973 was made under section 82 of the Ayurveda Act and there is no provision in relation to the TMP's research. Similarly,Medical ethics is also a theme that should draw attention to when discussing the challenges. Robert M. Veatch,emphasis that, professional ethics is to emerge as an independent discipline, it is as a special case of the universal norms of ethical 99ehaviour and not as a special professional ethic. (Veatch, 1972). In that sense, TMPs do not bound by "The Ayurveda (Disciplinary) Regulation, 1973".

The National Research Council (NRC) established according to the Section 2 of the National Research Council of Sri Lanka Act No.11 of 2016. This Act invites researchers in public sector, who are willing to do the research in science and technology. Therefore, no venue for TMPs to conduct their research even under this Act.

The issued National Assessment Report Sri Lanka by the World Health Organization on Implementation of Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property in 2015 revealed that Sri Lanka does not have drugs innovation capacity on allopathy, and the World Health Organization endorsed the WHO Global Traditional Medicine Strategy 2014-2023 to help for strengthening the research capacity in the traditional medicine of the member states. National Science and technical policy of Sri Lanka;2008, identified a lack of research and document of the scientific basis of indigenouspractices including traditional medicine. Comparatively assessed to the steps taken by WHO, Sri Lanka is unbaled to step up with them.

IV. CONCLUSION

For preserve traditional medicine, which is a very valuable medical resource in Sri Lanka, change or make laws need to be accordingly. The practitioners of traditional medicine must be adopted to the legal framework while protecting their intellectual property rights. For that purpose, Ayurveda Act No.31. of 1961 which is older more than 50 years, must be amended in line with the present requirements and as much as possible for the future with effect to the Intellectual Property Act No.36 of 2003. Thereafter, Sri Lankan Indigenous Medicine will be able toachieve full recognition of the World Health Organization with the implementation of WHO strategies and achieve the pathways to trade benefits of the world market.

The sole penal Section of the Act is Section 80. According to that Section, the fine is not exceeding five hundred rupees. First of all, there must be amend the penal Section of the Act possible to punishment can be imposed separately for each offence. In addition to that, should be enhanced the sentence on the offence of non-registration which referred to in Section 69(3). Section 11(1) (f) (i) should be amended accordingly to avoid the conflict between Section 69(3) and 11 (1) (f) (i) of the Act. The law become null and void and neglected by the people on account of such conflict. The appropriate and specific interpretation of "any offense which shows him to be unfit" and "any misconduct" referred to in Section 57 of the Act must be included.

That should be introduced a research methodology and provides the accepted research criteria. In addition to that, the intellectual property rights of the TMPs must be protected by making necessary amendments to the Intellectual Property Act. It would be more effective if thelegislature could bring in a new bill that has similar provisions to the NMRA with regard to indigenous medical research. Then only can be TMPs adapted into the legal framework and encouraging them to fulfill their responsibilities

and obligations on behalf of the patients aswell as protect their rights.

VI. AVENUES FOR FUTURE RESEARCH.

This study is limited to critically analyze the Challenges of Law relating to Indigenous Medical Research for Drug Innovation in Sri Lanka, in the Context of New Normal regarding the TMPs only on sources that are currently available within the period of travel restrictions due to pandemic situation. The same study can be extended with the interviews of expertise of the relevant areas. Therefore, many avenues will be open to future research for how to amend or create other affected areas of law, when researching Strengthening the Laws Relating to the Indigenous Medical Research for Drug Innovation in Sri Lanka.

ACKNOWLEDGEMENT

The author would like to thank scholars who were referred in this study for their excellent efforts to contribute new knowledge for this research and to General Sir John Kotelawala Defence University. The author highly appreciates the valuable advice given by Maj. Dilantha P. Aluthge for encouragement.

CONFLICT OF INTEREST

The author declares that no conflict of interest.

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