RECOMMENDATIONS FOR REFORMING THE REGULATORY FRAMEWORK FOR THE AYUSH SECTOR

The COVID-19 pandemic has clearly brought out that although India has a rich tradition of Indigenous System of Medicine; its use for prophylactic purpose has remained sub-optimized. Moreover, accessibility to quality healthcare for all still remains a big challenge due to lack of infrastructure and support system, which includes trained and qualified manpower. For managing pandemics like COVID-19, it is observed that we have a strong indigenous medicine system, based on the principles of AYUSH, which offers affordable, effective and holistic healthcare solutions for our 1.3 billion citizens. It is also observed that the interventions have to start from the doorstep of the citizens, involving the Sub-Centres, Primary Health Centres, Health and Wellness Centres and Community Health Centres. The biggest lesson learnt from the current Pandemic is the urgent need to increase investment in the public healthcare system of our country and improve accessibility of health workers to the citizens through technology. We should make use of telephone (Call Centre), internet facility (Smartphone and Apps), Telemedicine and consultation with qualified medical practitioners with access to prompt diagnostic tools for ensuring preventive care and avoidable disease burden.

At a recent International Conference organised by the Faculty of Ayurveda, Institute of Medical Sciences (IMS), Banaras Hindu University (BHU) on AYUSH and COVID-19 along with Quality Council of India (QCI), Federation of Indian Chamber of Commerce and Industry (FICCI) and Patient Safety & Access Initiative of India Foundation (PSAIIF) examined this matter. The Conference adopted MAHAMANA DECLARATIONS ON AYUSH on 2nd May 2020 by identifying NINE game-changing key concepts of AYUSH for making AYUSH popular through its preventive use. One of the Key Concepts identified, deals with Setting up of a Strong Regulatory Body exclusively for AYUSH, having an Independent Regulator.

The following recommendations deal with challenges at the ground level, changes required and benefits which can be derived from a Strong Regulatory Body for AYUSH:

1. Current D & C Act lacks clarity for granting permission to develop and manufacture AYUSH products, trained manpower for implementing Rules and has grossly inadequate regulatory Infrastructure for reaching the target set by Hon. Prime Minister of India to achieve the turnover of INR 1,00,000 Cr for the AYUSH industry, from present INR 10,000 Cr by 2024.

2. Traditional medicine relies almost 90 per cent on the use of medicinal plants supplemented by minerals and metals and animal and marine products like corals and shells. Health systems and health administrators have perforce to get involved with the raw material aspect if traditional medicine is to be taken seriously. Without this the quality of medicine suffers, affecting the credibility of traditional systems and practices. Medicinal plants comprising thousands of species of plants constitute a vast, undocumented and over-exploited resource. The growth and cultivation of such plants, their collection, storage, distribution, processing and marketing are now gaining importance as they all have an impact on quality. For traditional medicine to get a foothold on a sustained basis, the quality of the medicine has to be assured. There is a world of difference between the efficacy of a medicine made from plants cultivated and harvested using Good Agricultural Practices and that derived from plants uprooted from the wild.

3. It is for this reason, availability of good quality raw materials and materials of plant origin has remained a challenge for the manufacturers who are not being provided with good quality of raw materials and materials of plant origin. The Hon. Finance Minister has recently allocated INR 4,000 Cr for Medicinal Plant Cultivation as an incentive for farmers and allowed farmers to do a direct Marketing and Sale of their produce. Accordingly, Training and Motivation to farmers in Good Agricultural and Collection Practices, Minimum Support Price for purchase of good quality herbs, Crop Insurance Cover and Guaranteed Buy- Back Schemes to incentivize the farmers to cultivate medicinal plants need to be introduced. At the same time,

standards for Identification and Authentication of materials should be institutionalized. NMPB-QCI certification scheme for medicinal plant produce based on Good Agricultural and Collection Practices is already available. Its promotion, adoption and training to farmers/collectors need to be incentivized.

4. In spite of having Schedule T within the D & C Act, for almost two decades, there is no compliance by majority of Manufacturers to the provisions of Schedule T. Regulators should ensure strict implementation of such provisions of Schedule T in a time bound manner for which regulatory infrastructure and manpower should be augmented. Further, Schedule T should be revised on the lines of WHO-GMP within a time frame of maximum of 5 years and thereafter, it should be adopted as Indian GMP standard, rather than WHO-GMP, for manufacturers of AYUSH products

5. To meet GMP requirements for domestic Manufacturers, AYUSH Standard Mark and for exports, AYUSH Premium Mark are available. All Manufacturers should be encouraged to comply with the provisions of these GMP requirements and get Certification which should be deemed to be compliant to Schedule T. The reduced regulatory oversight in case of certified manufacturers will go a long way in incentivising manufacturers.

6. The Indian AYUSH Pharmacopoeia Lab at Centre should be upgraded and equipped with modern infrastructure, testing facilities and competent manpower to develop Methods, Standards and Specifications for raw materials and finished products.

7. Likewise, separate AYUSH Labs should be established and/or existing Labs should be upgraded to manage the need for testing and made operational at State level to ensure compliance to quality standards for AYUSH products in the next 3-5 years. Given that the States find it difficult to operate labs efficiently, it is recommended that the PPP model should be adopted in state AYUSH labs on the lines of FSSAI with only Reference labs being managed by Ministry of AYUSH.

8. All the testing laboratories should get accredited as per ISO 17025 NABL in order to meet the international guidelines for which Ministry of AYUSH should provide necessary financial support and competent technical resources.

9. A major issue with AYUSH products is absence of proper guidelines for their Storage, Transportation, Distribution and Sale. Guidelines should be framed and implemented for AYUSH Products Storage and Distribution Practices and a Cadre of AYUSH Pharmacists should be placed to supervise the establishments. One time registration of all these players in the value chain should be made mandatory, which is simple and user-friendly.

10. Traditional systems which are highly documented and which are backed by statute and by regulatory and enforcement mechanisms are bound to be taken more seriously than those which depend only on the faith of the consumer or the confidence generated by word of mouth, howsoever convincing it may be. Since the medication of an individual can lead to all kinds of effects years from now, governments have a responsibility to ensure not only the efficacy of the medicine but, more importantly, its safety. This can only be done by making available quality medicine and registering the practitioners who can be held accountable. However, what is essential is strong policy support to give the system a national stature, resources to conduct evidence-based research and to include practical strategies for different traditional medical practices to provide an alternative or to complement the work of the normal health system. They require investment in time and resources to understand where traditional medicine can contribute most meaningfully, resulting in better health outcomes. But, most important of all, stakeholders require an open mind to the development of health systems which rise above the ordinary, an end to the hubris that surrounds traditional medicine today and the strength to determine what can be offered to a hungry and curious public with a sense of legitimacy that the situation demands. Now is the time to make better use of the traditional system to augment access to health care, based on empirical evidence, public demand and cost effective studies.

11. Above all, today the trust of Consumers is lacking in Quality, Safety and Efficacy of AYUSH products. Rules should be framed to ensure that the medication being developed and manufactured are of Standard Quality, free from contaminants and adulterants. Here, the Regulator should develop, communicate and ensure implementation of appropriate GCP Guidelines to carry out authentic Clinical Trials

befitting the very nature, principles and concepts of AYUSH systems. Any new claim of existing product or any new product should be first defined and then validated through clinical studies as per these GCP guidelines. The claims of existing products which are documented in classical texts should remain excluded from the ambit of clinical trials.

12. It is understood that Clinical Development Services Agency under DBT is developing a system of certifying GCP professionals and accrediting training institutions. This system may also cover AYUSH sector suitably.

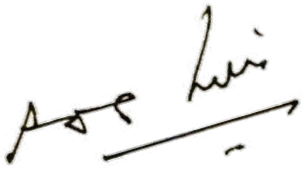
13. To facilitate the Research and Development on a scientific basis, mandates of existing Agencies such as CCRAS, CCRUM, CCRYN, CCRH under the Ministry of AYUSH should be reviewed and their capabilities brought up at par with ICMR.

14. The Regulatory Agency under Ministry of AYUSH should also examine the Registration, Promotion and Advertisement of AYUSH products at State levels for their Claims, in the manner similar to Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and frame Process and Guidelines for soliciting and handling feedback from all stakeholders under an independent Pharmacovigilance program.

In conclusion, all of the above have not got formalised and AYUSH industry remains fragmented. Consumer perception regarding AYUSH products also remains poor, where citizens don't see these products as of standard quality, safe and efficacious. The D & C Act, in the current form, is more focused on regulating pharmaceuticals and has not been able to exercise effective control on AYUSH products and its value chain. The only possible remedy is setting up of a Strong Independent Regulatory Oversight for AYUSH with adequate Infrastructure and competent Manpower. This requires enactment of a law exclusively for a Robust Single Window Regulatory Authority for AYUSH. I urge the members of the Reform Committee to seriously consider above recommendations for setting up of a Strong Regulatory Body exclusively for AYUSH, having an Independent Regulator.

Hence, it is essential to prepare a Bill to be placed before the Hon'ble Members of the Parliament consolidating the laws relating to indigenous system of traditional medicines which include Ayurveda, Unani, Siddha, Homeopathy (other than allopathy) and Yoga/Naturopathy to establish an independent Authority for laying down science based standards for AYUSH system and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe, efficacious and standard quality medicines for human consumption. The relevant provisions from existing Drugs and Cosmetics Act and Rules may be adopted with suitable amendments under this Authority to enforce the same.

Thank you.



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Under Mahamana Declarations on AYUSH, (a joint partnership initiative)