

## SIG 9 DOCUMENT

# LEADERSHIP IN SHAPING POLICIES FOR AYUSH

The UN Sustainable Development Goal (SDG) 3 mandates *Good Health & Well-being* for all at all ages and lists out measurable targets to be achieved by 2030, in the area of maternal, neonatal and child health, communicable diseases' epidemics and non-communicable diseases, amongst others. These healthcare targets can be met globally, only when modern and traditional medicine systems work in tandem, recognizing and complementing their respective areas of strength.

AYUSH system has been traditionally strong in preventive & promotive health care, diseases and health conditions relating to women and children, non-communicable diseases, stress management, palliative care, rehabilitation etc. Strengthening the host immune system and increasing resistance to infections and diseases, have been the *forte* of AYUSH medicines. The inherent strengths of the AYUSH system are *in sync* with a good part of the key thrust areas listed under SDG 3. The National Health Policy 2017 also recognizes the need for a pluralistic approach, and envisages a three dimensional mainstreaming of AYUSH. AYUSH can be India's offering to the world for promoting and building *Good Health & Well-being*, provided the system and products are taken upto international standards.

There is therefore, this immediate need to design an effective Leadership matrix and formulate a good policy statement for the AYUSH sector as a whole, in order to even out the grey areas and build up a robust system that is able to provide quality, safe and efficacious healthcare solutions to the current public health challenges. Leadership should be in areas which will create evidence – based policies, that are also in consonance with the global policy structures, in order that AYUSH systems and products get world-wide acceptance. In order to achieve this, there is the need to position AYUSH and modern systems of medicine on an equal footing within the healthcare system and create a convergence that is acceptable and can win the trust of the community. It is not just integration of AYUSH with the modern system of medicine, but also integration of the six streams within AYUSH and the folklore, tribal, ethnomedicine and traditional systems that is imperative, for attaining global acceptance of these systems and mandates common metrics, common documentation, common educational and training modules for these systems, in languages including the national language, vernacular languages of respective states and global link language i.e. English. Putting in place a robust and sound

policy framework is a prerequisite for achieving these goals, and calls for a new governance system, with improved and effective coordination mechanism between the various government ministries and adequate tracking, monitoring and measurement system for periodic course correction.

**1. Mapping infrastructure in AYUSH domain:** There is this need to upgrade infrastructure in the manufacturing sector of the AYUSH industry. Industry needs to invest in state-of-the-art, WHO-GMP grade manufacture facilities; right from technologically advanced medicinal plants' extraction units to modern formulation manufacturing setups. Strict compliance with GMP guidelines with respect to facility, personnel and operations ought to be made mandatory. Accreditation systems on the lines of NABH need to be developed for AYUSH hospitals and clinical care settings. Establishing state-of-the-art, NABL-accredited AYUSH testing laboratories is an absolute necessity. As for products of modern medicine, a WHO prequalification system / a national prequalification system ought to be put in place for AYUSH products, so that these can be globally purchased and accessed. With respect to clinical trials for AYUSH products, there is the need to ensure and enforce implementation of GCP guidelines and audit of trials. All AYUSH clinical trials need to be approved by duly registered Ethics Committees and registered with CTRI, so that the information is available in public domain. Mapping available infrastructure with respect to number of certified manufacturing units, number of accredited hospitals and testing laboratories and number of practising physicians in the AYUSH system will help provide an estimate of the actual size of the sector. Encouraging public - private partnership in setting up clinics and diagnostics infrastructure would go a long way in tackling the inadequacy of facilities, especially in the rural setups. Additionally, there is this need to improve infrastructure in epidemiology, modern diagnostic methods and their interpretation, clinical management and public health, modern sciences of statistics, drug discovery; these are principles that aren't taught and need to be structured in the AYUSH system. These basic tenets are also enshrined in the National Education Policy 2020, that recommends an integrative healthcare education system, whereby all students of AYUSH would be imparted basic understanding of allopathic system of medicine and *vice versa*. The policy calls for re-envisioning of all forms of healthcare education, including AYUSH, with greater emphasis on preventive healthcare and community medicine.

**2. Creating Data Analytics structure:** The application of data analytics in healthcare has today, become almost indispensable, particularly in handling, reviewing and analyzing big data generated in / from epidemiological studies, clinical studies, wearables and point-of-care

devices. Big data makes it possible to provide better quality and more personalized patient care in a more cost-effective manner and therefore, makes it imperative for AYUSH systems to be equipped with the facility and competence to handle and analyze big data and artificial intelligence. There is the need to create a Geographic Information System (GIS) in the AYUSH matrix, in order to extend and ensure equitable distribution of medicines and healthcare to all segments of the population including those under migration. Access to community health data in AYUSH systems, as also data sets from wellness clinics, which provide basic health information like hemoglobin, blood pressure, thyroid etc. should be created so that these can be interpreted, in synergy with Ayurgenomics, for gauging the health status of the individuals. As in the modern hospital system, Laboratory Information System (LIS) and Hospital Information System (HIS) with Electronic Health Record of patients should be built within the AYUSH system, with data on digital imaging system, also made available. Use of the already available Pharmacogenomics and Pharmacovigilance data by AYUSH physicians should be encouraged, with efforts to build an independent Pharmacovigilance network for the AYUSH system. Surveillance data for communicable as well as noncommunicable diseases and epidemiological data should be made available in the AYUSH system as well. With regards to access to data, there ought to be a national policy on data sharing, with provisions for a central data repository which can be used interchangeably by anonymizing the identity of the subject. Ensuring data security and confidentiality through appropriate measures like data encryption and firewalls will be of utmost importance. The AYUSH system should be integrated with the National Health smart card under the Rashtriya Swasthya Bima Yojana. Finally, it is absolutely imperative to familiarize AYUSH practitioners with the new health programs or initiatives being announced in the country.

**3. Creating world – class documentation & archiving facility:** Documentation and archiving of all available resources is an absolute essential if misappropriation and usurping of the traditional Indian medicinal knowledge is to be prevented. CSIR's Traditional Knowledge Digital Library (TKDL) has been scientifically converting and structuring the available contents of the ancient texts on Indian Systems of Medicines i.e. Ayurveda, Siddha, Unani and Sowa Rigpa as well as Yoga, into five international languages, namely, English, Japanese, French, German and Spanish, with the help of information technology tools and an innovative classification system - Traditional Knowledge Resource Classification (TKRC). As on date, more than 3.6 lakh formulations/ practices have been transcribed into the TKDL database and this continues to be work in progress. TKDL is available to 13 patent offices, for search &

examination purposes only, and protects against wrongful misuse of traditional knowledge. This being more of a defensive protection, there is this need to buildup patents by way of new formulations / entities and actively secure protection of intellectual property rights. AYUSH practitioners should be trained in global patenting laws so as to encourage greater number of patents from the sector.

**4. Fostering education, training and research in the AYUSH system :** As envisaged by the National Education Policy 2020, an integrative healthcare education system needs to be put into place, with a modern medicine intern to compulsorily do a two - month internship in AYUSH system and *vice versa*.

- Like the IAS, there is the need to create Indian Medicinal Services, where AYUSH and modern medicine practitioners are integrated into the service and can opt for postings across the country. There is the need to create policies that make it attractive for healthcare practitioners to get into any postings that may go into a rotation system, with career progression opportunities for the practitioners as well as their families.
- There should be greater emphasis on quality publications in peer- reviewed journals in the AYUSH system.
- Knowledge about best practices for environment protection and preservation should be provided to AYUSH practitioners; harmful effects of indoor air pollution, microwave and cell phone radiations for unborn babies, neonates and growing up children should be highlighted.
- Training and knowledge about public health protective measures and practices against major outbreaks to be made available to AYUSH practitioners; some of the devices and instruments like PPEs, oxygen cylinders ought to be made available and their correct usage taught to them.
- AYUSH practitioners should be familiarized with the social development indices. Enhancing social development indices and poverty alleviation measures are the major initiatives that contribute to successful implementation of any healthcare program.
- AYUSH practitioners should be made aware of labor laws, Child Labor Act etc.
- AYUSH practitioners acquire knowledge about animal health, given that most of the contagions of recent times have been of zoonotic origin.
- AYUSH graduates should be exposed to organized courses in Disaster Management Training, so as to be able to handle epidemics / other public health concerns, post-

traumatic stress disorders, supply chain disruptions, interventions require to be done during calamities, wars and mass migration of populations.

Setting up suitable skill - development programs for paramedics in the AYUSH system is the need-of-the-hour. Common nursing schools may be set up for both AYUSH and modern systems of medicine nurses whereby trained nurses can be deployed in both the systems.

Fostering and enhancing research in AYUSH system of medicine is important for the system to grow and thrive. Handling the Health Technology Assessment (HTA) system, as in the modern system of medicine, should be an integral component of research in AYUSH system.

**5. Creating biobanks and repositories in the AYUSH system :** There is the need for creating biobanks for storing serum, plasma, tissues, immortalized cells, stool samples etc. which could be used by AYUSH practitioners. Internationally registered biobanks and repositories, including microbial and cell repositories that are already functional in the country should be mapped so that research in AYUSH can prosper.

**6. Building world-class testing laboratories & setting standards for AYUSH products:**

World-class, NABL-accredited testing laboratories, equipped with state-of-the-art testing and analytical instrumentation need to be established, for accurate identification and authentication of medicinal plants, and testing ingredients used in production of AYUSH medicines and finished AYUSH products. Private sector should be encouraged to participate more actively in building more world-class testing laboratories. The AYUSH testing laboratories' network need to be integrated with the other testing systems of modern medicine. Developing protocols for identification of contaminants and adulterants is essential for ensuring quality and safety of the products. Akin to the modern system of medicine, repositories for chemical entities and impurities need to be built for the AYUSH system as well. For assuring quality of AYUSH medicines, there is also this need to create standards for both ingredients and finished products, that are on par with the internationally laid down specifications for phytoactives, excipients and finished products. Innovative testing protocols need to be developed to confirm compliance with these standards. Advanced analytical instrumentation, including hyphenated techniques can be used for designing testing protocols that are accurate, sensitive and discriminatory and conform to stringent international standards, providing assurance of quality, safety and efficacy of AYUSH products.

**7. Integration of sciences together:** A trans-disciplinary approach, with integration of sciences together is essential otherwise actual coalition may not build up. A case in point would be joint clinical trials for non-communicable diseases including oncology, joint and rheumatic diseases and kidney diseases where AYUSH can help provide better quality of life / ambulatory care. With medical pluralism being preferred by the public and also encouraged by the government, clinical studies providing evidence of the same, would be most useful. With modern science becoming more and more interdisciplinary, knowledge of biology, genomics, proteomics, metabolomics, transcriptomics, biotechnology should also be incorporated into the AYUSH system of medicine. A case in point is Ayurgenomics, which has further strengthened personalized medicine in the AYUSH system.

**8. Creating a modern and responsive regulatory system:** Creating a modern and responsive regulatory system in AYUSH that intercalates with the regulatory system of modern medicine as well as regulatory system of food standards and safety so that the grey areas are handled appropriately. The independent regulatory body should be empowered to issue licenses for conducting clinical trials and give an opinion about marketing and postmarketing surveillance, when the trials have been conducted successfully. It should also create a separate category for orphan diseases, rare diseases, modern medicines, modern interventions and formulations. On the lines of the D&C Act, of the modern system, we should have a similar Act, named as D&C Act, so that the regulatory oversight can be carried out for AYUSH systems, especially given that AYUSH systems have so many cosmetics. Many of the AYUSH products are administered through the skin, which is a relatively new concept, but has always been in existence in AYUSH. Formulations form the backbone of the drug delivery & AYUSH systems of formulations are unique in nature & this can be developed through regulatory oversight in the AYUSH systems. Some of the newer formulations in the AYUSH system that are treated as drugs & may not be phytopharmaceuticals & so preclinical toxicological data needs to be generated for these. Endeavour should be made to set up preclinical toxicological assessment systems in the AYUSH family. However in the meanwhile, the existing current preclinical toxicological systems that are available in the private sector can be used. The regulatory system should strengthen labelling laws so that false claims regarding efficacy and use of AYUSH products can be effectively tackled & made more robust and converted into enforceable legislation.

**9. Creating robust financial infrastructure:** This is the most important architecture and creating a robust financial infrastructure for the sector is important to attract investment in critical areas. Sub-optimal financing could prove harmful for the system but even as there is increased financial allocations to the sector, it is imperative to build adequate safeguards and innovative technological mediations within the system that ensure transfer of resources right upto the 'last-mile of the targeted section, plugging any possible leakages in delivery. The sector would grow only there is wealth-creation for all stakeholders including extract and finished product manufacturers, packagers, exporters and medicinal plants' farmers, who form the most financially-vulnerable link in the chain. Assisting farmers with training in modern agrotechnology, helping them establish backward linkages for establishment of nurseries for supply of quality planting materials and forward linkages for post-harvest management, processing, marketing infrastructure, fixing attractive Minimum Support Price (MSP) and setting up medicinal plants' processing clusters are some of the measures that can support farmers, encouraging them to take up medicinal plants cultivation. Of the around 10,000 licensed AYUSH manufacturers in the country, almost 85% belong to the MSMEs and SMEs section, with minimum resources and manufacturing facility not upto the mark. Support to this segment is important for upgrading their infrastructure, with ultimate impact on improved product quality.

**10. Communication & Advocacy:** Creating public trust for the AYUSH system and products is very important, cutting across the spectrum, both within the country as well as globally. Responsible and factually - correct communication with all stakeholders would go a long way in debunking many of the myths / fallacies associated with the system and products. Continued advocacy with the government would help effect conducive policy changes that can prove beneficial for the sector. Appropriate labelling of the products is most important, with no misquoting & wrong claims that are not based on evidence generated through established scientific studies would only do more harm than good to the credibility of the industry & sector as a whole. The collateral damage to the genuine products by such illegal acts would be irreparable. The system would be rendered significantly more effective if a platform for voicing communities' and patients' experiences was created, whereby the data so generated could be collated, analysed and appropriate action points decided.

**11. Better coordination between ministries:** With various elements of the AYUSH sector being governed by different Ministries like AYUSH, Health & Family Welfare, Chemicals &

Fertilizers, Women & Child Development, Nutrition, Department of Empowerment of Persons with Disabilities, better coordination between these stakeholders would go a long way in improving ease of doing business and thus stimulate growth in the sector. 'One Health' concept should be adopted, particularly in areas of outbreak, given that most of the contagions of recent times have been of zoonotic origin.

**12. AYUSH system in Geriatric and Palliative care:** Geriatric and palliative care have been one of the strengths of the AYUSH system, where there are formulations of *Bacopa monnieri*, Ashwagandha and the likes, for dementia, memory loss and ageing, functional foods for metabolic disorders like diabetes, kidney diseases, autoimmune diseases, cardiac conditions and enhancement of quality of life in cancer patients. Yoga system, meditation and *Pranayam* also improved complete physiology and mind - body- soul connect with improved overall health.

**13. Food & Nutrition:** Food & Nutrition forms the central fulcrum of all healthcare systems. The basic tenets of successful nutritional intervention through food supplementation and fortification should be introduced in the AYUSH system. Some of these food elements have been part of the AYUSH system, for instance karela and jamun for diabetes, iron in the form of bhasmas, where the nanoparticulate form of the bhasmas shows remarkably improved absorption. Nutritional database of the country and nutritional practices and tenets should be taught to the AYUSH practitioners, who should also be encouraged to contribute their own experiences in nutritional additives, supplements as well as food prescription practices in the AYUSH system. Awareness about Vitamin D and iodine deficiency and their impact on general public health and wellbeing, ought to be highlighted. National Nutrition Policy & all policies that improve mother and child health through public health measures should be included in AYUSH. For instance, flax seeds for omega 3 fatty acids, Vitamin B12 that is not found in plant sources, microbiota that are often prescribed to mothers, are relatively newer interventions for modern system of medicine also and should be included under the overall umbrella of nutrition & food supplementation. Improved maternal and child survival ultimately reflect the entire spectrum of social development.

All AYUSH practitioners should promote vaccination and counter misinformation about vaccination and the anti-vaccination lobbies. Vaccinations have been available since ancient times in various traditional communities across the globe and are effective tools for tackling many of the common yet lethal infections.