EXPRESS PHARMA

Sanjeevani for AYUSH

By Lakshmipriya Nair on June 20, 2017

AYUSH could be the answer to India's unmet medical needs but only if it is backed by scientific validation and credible evidence

This Sanskrit prayer is also a goal that India has been striving to ensure for its citizens and enabling universal healthcare access (UHC) is a pivotal step towards achieving this noble objective. Yet, it remains a distant dream due to unequal health access, threat of existing and emerging diseases, lack of trained medical professionals and rising costs of healthcare.

The patient-centric approach of India's alternative and traditional systems of medicines that comprise Ayurveda, Yoga & Naturopathy, Unani, Siddha & Sowa-Rigpa and Homoeopathy (AYUSH), has led the government to look at them as a panacea to India's public health challenges. Spurred by the belief in the potential of AYUSH to alleviate the crises within Indian healthcare, the government has been trying to promote and popularise alternative systems of medicine with an aim to integrate it with modern systems of medicine.

However, despite myriad actions to promote and popularise AYUSH, it hasn't taken off the way it was expected to. A health survey conducted by National Sample Survey Office (NSSO) in 2015 revealed that 'inclination towards allopathic treatment was prevalent (around 90 per cent in both the sectors). Only five to seven percent usage of 'other' including AYUSH was reported both in rural and urban area.'

Clarion call for evidence

So, what's hindering the growth of AYUSH and preventing its widespread acceptance? In answer to this question, experts and industry veterans cite various reasons on all fronts: education, research, clinical practice, industry, and regulation.

But, all of these are interconnected and seems to be linked to one mammoth hurdle: lack of scientific validation and evidence.

This has often led to the rampant misuse of herbal and traditional medicines and thereby the negative outcomes are often reported. Though traditional medicines have been in use for a long time, there has been limited quality control and negligible documented evidence of their safety and effectiveness. This, in turn, has negatively impacted the development of regulations and legislation in this arena. Hence, building trust in the traditional medicine systems through validated data and irrefutable evidence has emerged as an urgent need to leverage the true potential of these systems.

Are clinical trials the answer?

Fortunately, paying heed to the increasing clamour for evidence-based AYUSH, regulators and the government have been mulling over measures, systems, policies and processes to ensure better documentation and validate the drugs and practices of these alternative systems of medicine. Clinical trials for AYUSH drugs is one of them. In 2016, Indian Council of Medical Research (ICMR) released guidelines for conducting testing medicines from AYUSH to provide more clarity on testing ayurvedic formulations and other traditional medicines.

While there is unanimous accord on the good intent of the government, the industry is divided on its impact. Many believe that it would undoubtedly lead to better safety and efficacy of AYUSH drugs, but there are many dissenting voices who argue that such a step, if implemented with proper thought and planning, would not only curb the growth of the industry but also do it unforetold harm.

Dr Ali Mehdi

Dr Ali Mehdi, Fellow & Project Leader, Health Policy Initiative from Indian Council for Research on International Economic Relations (ICRIER), a leading policy research institution supports the intent to mandate clinical trials for AYUSH drugs and states, “The AYUSH industry cannot sustainably thrive on faith! It has to be based on sound scientific and management principles.”

Opining that clinical trials are in the best interests of the AYUSH industry, he believes that it would empower the practitioners to feel more confident – and probably incentivised – to prescribe AYUSH medicines once they are convinced of their scientific value. He says, “Right now, they are unable to take ownership and leave it to the patients to take them at their own risk.”

However, he believes that the move will meet with resistance from at least some segments of the AYUSH industry and recommends the government to engage with the industry and clearly explain the merits of the move.

VK Dhawan, CEO, Planet Herb Lifesciences also speaks in support of clinical trials. He says, “It will certainly help to build trust and authenticity amongst doctors and patients for herbal medicines. Today, many doctors, mainly practicing in Western medicines doubts and do not trust on herbal medicines due to lack of clinical studies done on these products. Once thorough studies are carried out it will help to support clinical claims about the brand/ products. It will certainly encourage those organisations that are sincerely involved in research-based manufacturing activities and ready to spend good amount on R&D activities to develop quality product.”

He further states, “It will help in manufacturing quality medicines and to make clinical claims for these products. Only those manufacturers/ brand owners will stay in the field who really have good research based formulations available. Quality and efficacy of herbal medicines will go high and reliability of herbal medicines over allopathic medicines will improve a lot. Additionally, companies who really want to stay in the market shall be forced to set up their own R&D set up to deliver research based products. Copying of branded formulation will stop.”

However, he is also aware of the challenges that need to be tackled. He outlines, “Clinical trials are quite expensive, they require huge investment. Only those companies who are really sincere about conducting research based activities will survive once the clinical trials are made mandatory. Development of formulations will also be a big challenge to meet efficacy standards as per the clinical claim of products. All new formulation development will require thorough compliance to parameters tested to generate clinical data. Another challenge will be to develop more infrastructure and instrumentation to cater to huge volume of clinical studies of herbal products at a economic costs.”

Shaheen Majeed

Shaheen Majeed, Director, Sami-Sabinsa Group also feels that clinical trials can usher credibility in the sector but also foresees challenges. He points out, “The AYUSH market would be more valid for its strong claims if clinical trials are performed but there are a lot of grey areas such as standard protocols or trial designs to be followed w.r.t each clinical trial. The scope of it would be much more impressive but the costs of investing on clinical trials would slow down the product launch, which in turn can hit the manufacturers. Ultimately, consumers lose out on a potentially beneficial product.”

He also points out that the move might also give rise to more employment opportunities in the sector but that too has its flipside. He predicts, “This can also spring up the employment opportunities to the upcoming AYUSH doctors both in government and private sectors. Different streams of learning for clinical research would erupt like short term diplomas, degrees and certificate exams to conduct the clinical trials. Again, the challenges would be standardisation in training and providing skillsets to match the level of research in other sectors. Initially, the investment in such areas would also be a challenge as to take risk-based chance.”

Jayesh Chaudhury

Jayesh Chaudhury, CEO, Vedic Lifesciences is however very sceptical of the effectiveness of mandating clinical trials for all AYUSH drugs. He is of the view that ensuring it for propritary medicines might be a good move, but enforcing it on Shastrokta drugs (medicines made as per the approved ancient texts) are not really necessary and would lead the players to incur heavy costs, which in turn will adversely effect the growth of the industry. Thus, it might prove to be a counterproductive step.

Dr Surendra Chaudhary

Dr Surendra Chaudhary, District Ayurvedic and Unani officer, Government of Uttar Pradesh and President, Uttar Pradesh, Vishva Ayurveda Parishad is also opposed to the step as it may kill the small manufacturers since clinical trials are costly and lengthy processes. Though he agress that it will provide a certain amount of credibility to the drugs, especially in the case of international users, he also draws attention to the fact that the approval process of ASU drugs, already makes provisions to ensure safety and efficacy of drugs. After amending the rule 158 B of Drugs & Cosmetics Act vide G.S.R. 663(E) dated 10 August 2010, safety and efficacy proof are well defined.

Thus, though the industry lauds the intent behind making clincial trials compulsory, many doubt its effective implementation. This highlights the urgent need to devise better startegies to mainstream AYUSH and prove them as credible systems of medicines without any doubt. The need for effective steps to make AYUSH more evidence-based is more urgent than ever before.

Envisioning a starring role for AYUSH

Fortunately, the government has realised this urgent need, and several measures have been initiated by the to drive access to affordable, reliable and easily accessible medical facilities to the masses through AYUSH. Programmes to increase research and MOUs to augment cooperation with other nations in the field of traditional systems of medicine have also been undertaken.

The report of the Steering Committee on AYUSH for 12th Five Year Plan had envisioned a significant role for the sector. In a foreword in the report, Dr Syeda Hameed, who chaired the Steering Committee of the Commission on Health which reviewed the National Health Policy of 2002, till its dissolution in 2015, outlines, “AYUSH and allopathic, both systems, often provide solutions to a common set of problems. Many times both systems complement each other also. Our endeavour during the 12th Five Plan period will be that both systems expand and progress together, based on their core competencies and inherent strengths. We must ensure that the healthcare delivery system in the country is designed and developed in such a way that, both, AYUSH and allopathic systems are available to every patient and the choice of system of treatment is the patient’s choice, based, of course, on set protocols.”

She further states, “AYUSH has presence in all parts of the country. In addition it has near universal acceptance, available practitioners and infrastructure. The strength of AYUSH system lies in preventive and promotive healthcare, diseases and health conditions relating to women and children, non-communicable diseases, stress management, palliative care, rehabilitation etc. AYUSH has very little side effect, has a soft environmental footprint and is engrained in local temperament. It can play an important role in achieving the National Health Outcome Goals of reducing MMR, IMR, TFR, malnutrition, anaemia, population control and skewed child sex ratios. Its huge resource of hospitals beds and health workers need to be efficiently utilised to meet the National Health Outcome Goals.”

The current government, under the aegis of India’s PM Narendra Modi, has also offered strong support to the alternative medicines industry and introduced a number of noteworthy measures to fortify the sector. Forming a separate ministry of AYUSH and declaring a National AYUSH Mission have been some of them. Mainstreaming of AYUSH has been a fundamental strategy under the National Rural Health Mission (NRHM) as well. Under NRHM, drug kits of ASHAs include AYUSH medications as well. Moreover, AYUSH formulation also form a part of the additional supply of generic drugs for common ailments at SC/PHC/CHC levels. The AYUSH ministry has been allocated Rs1,428.65 crores in the Union budget for the fiscal 2017-18. The total outlay for the ministry in last year’s budget was Rs 1,326.20 crores.

Thus, the government is engaged in several activities to improve our AYUSH systems and mainstream it. However, it is undeniable that a lot more needs to be done on different fronts to accelerate the pace of progress.

Recommendations from industry representatives:

I would say there are four main factors hindering the growth of AYUSH – lack of scientific validation, innovation, public trust and marketing.

Both the government and the AYUSH industry need to take measures to address the above four concerns. And I think it’s important to also enable new players to come into this industry, players who can bring in scientific, technical and marketing expertise.

Another important measure could be the promotion of international cooperation – connecting Indian players in the AYUSH sector with their international counterparts and scientific associations so that they can benefit from best practices from around the world. I am sure India is not

the only country trying to promote traditional medicines. From my perspective, alternative medicines enhance the choice-set of patients, which is neither a topic of discussion in India nor of serious consideration for policymakers.

A very important feature from a regulatory perspective would be transparency, something which even regulation of modern medicines needs badly in this country. There are a whole lot of trust issues, especially when it comes to critical illness, and without addressing them, the AYUSH industry stands little chance of emerging as a significant player in the pharma sector.

Then obviously, they need to have strong marketing muscle which modern pharma companies are well-known for.

Dr Ali Mehdi, *Fellow & Project Leader, Health Policy Initiative from Indian Council for Research on International Economic Relations (ICRIER)*

Vasudha Wattal

At present, Rule 158 B of the Drugs and Cosmetics Rules, 1945, lays down the regulatory requirements, including submission of proof of safety and effectiveness for licensing of AYUSH drugs. Enforcement of these provisions is under purview of the state licensing authorities appointed by the state governments. For mainstreaming AYUSH – clear regulatory pathways would serve as a strong foundation. Hence, in promoting quality and credibility of AYUSH, carefully calibrated regulatory definitions, elaborative guidance documents for requirements to establish safety, efficacy and quality, and dedicated efforts are required for effective enforcement of legislation.

Pallavi Joshi

The need for further evidence based studies regarding the various complementary systems of medicines is a prerequisite for strengthening the AYUSH sector as a whole. Doing so would strengthen prescribers' understanding of the implications of various drugs and therapies, as well as the interaction of treatments from across different systems. However, it should be borne in mind that creating a pool of scientific literature based on rigorous studies will further require that certain guidelines and standards be put in place first (such as the Ayurvedic Pharmacopoeia of India which was released last year by the Ministry of AYUSH) in order to ensure that among other things, the trial design is appropriate and the data is reported in a standardised manner.

Vasudha Wattal and **Pallavi Joshi**, *Research Associates, Health Policy Intiative, ICRIER*

To make AYUSH more evidence-based, there is a need to work aggressively on devising new research strategies to corroborate facts in a scientific way. This includes instituting regular clinical trials to assess impact and efficacy of drugs, and finding out the right dosage and duration of treatment. In recent years, some research have been conducted to gauge the effect of AYUSH medicines which are essentially based on herbs on diseases such as diabetes and blood pressure etc. This needs to be implemented on a large scale to bridge the division between Western and AYUSH systems. Journals must be maintained to collate all data and figures. A more practical approach is of mutual co-existence of all these systems. For this to happen, we need studies and clinical trials to find out how well can supplementing patients with Ayurvedic or Unani medicines along with western medicine can aid their recovery.

Dharminder Nagar, *MD, Paras Healthcare*

All AYUSH physicians working with NHM must treat patients only with their respective expertise – be it Ayurveda, Unani or Homeopathy.

Specialty clinics for Panchkarma, anorectal surgeries be setup at primary healthcare centres (PHC) level and full time specialists be recruited to man these centres

Set up of good quality educational institutes

Making stringent check points to curb substandard educational and treatment centres through monitoring of GMP certification process. If a manufacturer doesn't have the required analytical facilities, we must have MoUs for drug testing facilities with AYUSH-certified laboratories.

Control over raw material quality should be strengthened

There must be clear guidelines about use of excipients- colouring agents, flavouring agents, sweeteners etc.

The D&C is a central act and its rules should be followed uniformly across the country with a few changes as per state requirements. Granting of ASU manufacturing license and drugs approval process is so different with state to state.

Dr Surendra Chaudhary, *Ex District Ayurvedic and Unani Officer, Government of UP & President, Uttar Pradesh, Vishva Ayurveda Parishad*

Quality of education, lack of research, non-transparency, lack of standardisation of product manufacturing, finished products and the treatment protocols, and lack of documentation, are some of the hindrances facing the promotion of AYUSH.

Collaborations between educational institutes, research centres and industries can bring a lot of changes to uplift AYUSH. National programmes held by the states and central government to promote AYUSH systems can also bring awareness about these systems and their potential. Let it have information exchange programmes conducted even by small sectors. Though a lot of exercise has been done on these lines, what we need is to one consolidate medicinal system under AYUSH which can be integrated with mainstream medicine to benefit the population of the country.

Shaheen Majeed, *Director, Sami-Sabinsa Group*

We should ensure quality by enhancing our quality montiroing systems and ensuring that cGMP is ensured at all the drug manufcturing centres

We should fortify our data collection systems and processes. Hospitals are a great place to collect data. We can do retrospective research by looking at case files and the progress during the treatment of patients to collect evidence. It will give great information about the effectiveness and efficacy of the drugs and help build credible data to support the AYUSH systems.

If the government is looking at clinical trials as a way to make AYUSH evidence-based then the government should help the SME players in this segment by setting up clinical trial centres and subsidising the compnay to carry out these trials.

Pooling of resources by SME players with the same Shastrokt products to create and collect data could also be a way forward to promote evidence-based AYUSH.

Jayesh Chaudhary, *CEO, Vedic Life Sciences*

The way forward

AYUSH is garnering considerable attention and recognition globally. Reports reveal that the country’s export of AYUSH and value-added products of medicinal plants in 2015-2016 stood at $358.60 million. A research report, ‘Ayurvedic-Global Market Outlook (2016-2022),’ published by OrbisResearch.com, the global ayurvedic market accounted for $3,428.0 million in 2015 and is expected to reach $9,791.0 million by 2022 growing at a CAGR of 16.2 per cent from 2015 to 2022.

Thus, it is time that we created a strategy which will use a multifarious approach to ensure natural and safe medicines, which are time-tested, accessible and affordable to leverage the true potential of AYUSH.