Vol. 1 | No. 1 | October 2021

Traditional Medicine Review

Volume 1 Number 1 October 2021

EDITORIAL

Message from Secretary, Ministry of AYUSH

FITM
Forum on Indian Traditional Medicine

(Continued on back cover)

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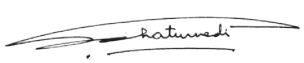
The prevailing pandemic has drawn global attention on the immense potential of Traditional Medicine (TM). It has enabled acknowledgement of both preventive and curative aspects of healthcare for sustainable wellness. Today, these systems are not limited by demand within the countries of origin. As visible in the substantial growth in international export of Ayurvedic and other TM products, it has been witnessing a growing interest worldwide. A growing body of clinical research is further adding to its validity.

Traditional medicine in healthcare, being more prevalent in the Global South, is also a significant tool for South-South Cooperation, as is evident in several strategic regional co-operations with and within Africa, BIMSTEC and ASEAN. Protection of TM has also brought the common concerns of the Global South at several international platforms such as WIPO, WHO and WTO.

RIS has been on the forefront to bring TM to become a legitimate player in the world trade by meeting with global standards in manufacturing and quality and safety standards. It has already initiated several studies in the area of medicinal plants and TM trade. At a time when TM systems across countries are making serious efforts at trade, research and information exchange on commerce, economy and sociology and policy, dissemination of this information becomes imperative. With these objectives in mind that RIS and the AYUSH Ministry joined hands to launch the Forum for Indian Traditional Medicines (FITM) in 2017.

Through the Traditional Medicine Review (TMR) our endeavour would be to bring out academic outputs to generate debate on economy, trade, IPR, international healthcare cooperation, legislation and policy responses in the field of traditional medicine. This will definitely connect the wider, emerging community of TM enthusiasts to bring about greater clarity in domestic and international policy and strategy formulation. Ultimately, we hope the TMR would emerge as a Journal of peer reviewed research papers.

The encouraging support from Vaidya Rajesh ji Kotecha, Secretary, AYUSH and his team and the Board Members of the FITM are major source of strength for this effort. I would also like to use this opportunity to compliment the FITM Team, led by Prof. T.C. James and comprising Dr. Namrata Pathak and Mr. Apurva Bhatnagar, for their commendable effort.



Sachin Chaturvedi

MESSAGE FROM SECRETARY, MINISTRY OF AYUSH

वैद्य राजेश कोटेचा
Vaidya Rajesh Kotecha

सचिव
भारत सरकार
आयुष मंत्रालय
आयुष भवन, 'बी' ब्लॉक, जी.पी.ओ. कॉम्प्लेक्स,
आई.एन.ए, नई दिल्ली–110023

Secretary
Government of India
Ministry of Ayush
Ayush Bhawan, B-Block, GPO Complex
INA, New Delhi-110023
Tel. : 011-24651950, Fax : 011-24651937
E-mail : secy-ayush@nic.in

MESSAGE

The world is witnessing a paradigm shift from medical services to healthcare wherein, significantly, a holistic approach towards health and wellness is being adopted. This is likely to increase and in this changing healthcare scenario, traditional medical healthcare has a significant role to play. This initiative by FITM in bringing out the Traditional Medicine Review is praiseworthy. It will bring out academic debates and discussions on policy, economy and other important developments on traditional medicine in India and across the globe.

I wish this initiative a great success and look forward to subsequent publications of this Review.

(Rajesh Kotecha)

New Delhi,
Dated: 27th October, 2021

Ayurveda and Health Insurance- Status and Opportunity

Rajiv Vasudevan*

Rajiv Vasudevan

Introduction

At 4.2 per cent of GDP India has the lowest healthcare spend amongst BRICS countries, with the Government spending a mere 1.1 per cent of GDP.[1] Of India's total population of about 1.3 billion, around 950 million were covered under various health insurance schemes as of 2019.[2] Government schemes accounted for 630-650 million (Ayushman Bharat-PMJAY- 500 million and State schemes- 130-150 million). Other Government Group schemes such as ESIC, ECHS, CGHS covered another 150-180 million. Private insurance accounted for another 120 million.[3] Close to 400 million Above Poverty Line (APL) individuals by inference from the 1350 million Indian population are not covered currently under any scheme.[4]

Although, as inferred from data provided by the CII[5], 70 per cent of the population is covered under one or the other payer backed schemes, it is quite intriguing that out-of-pocket expenditure accounts for 64 per cent of total health expenditure.[6] This is attributed to the fragmentation of service provision and lower levels of risk pooling. Today, small health service providers perform more than 64 per cent of health service provision.[7] More than 98 per cent of all health service providers in the country have less than ten employees.[8] A fragmented provider market with unclear referral pathways, weak strategic purchasing, and weak or no regulatory/insurance oversight has made the provider-customer relationship transactional, with limited accountability for continuity of care and improved

* MD & CEO, AyurVAID Hospitals, Bengaluru.

outcomes over time, resulting in delayed care and unnecessary expenditures, with sub-optional overall outcomes.[9]

This article attempts to provide an overview of healthcare funding with reference to existing healthcare challenges. It highlights the need, scope, and significance of Ayurveda coverage within the larger payer-backed healthcare system in India and suggests the way forward to realise the full potential of Ayurveda as a mainstream, payer-backed, system of medicine within the pluralistic, universal health coverage paradigm that is envisioned by Indian health policymakers.

India's Epidemiological Transition to Non-Communicable Diseases (NCDs)

There is an increase in the contribution of Non-Communicable Diseases (NCDs) from 30 per cent of the total disease burden, i.e. Disability-Adjusted Life Years (DALYs) in 1990 to 55 per cent in 2016 and also an increase in the proportion of deaths due to NCDs (among all deaths) from 38 per cent in 1990 to 62 per cent in 2016.[10] This shows a rapid epidemiological transition with a shift in disease burden to NCDs.[11] cardiovascular diseases, cancers, chronic respiratory diseases, diabetes, and other NCDs are estimated to account for 61.8 per cent of all deaths in India, making them the leading cause of death, ahead of injuries and communicable, maternal, prenatal, and nutritional conditions.[12] Furthermore, NCDs account for about 40 per cent of all hospital stays and roughly 35 per cent of all recorded outpatient visits.[13] India stands to lose $4.58 trillion before 2030 due to NCDs and mental health conditions. Cardiovascular diseases, accounting for $2.17 trillion, and mental health conditions ($1.03 trillion), will lead the way in economic loss.[14] Notwithstanding, the entire focus of the private healthcare sector continues to be on tertiary-quaternary care. Unfortunately, the Government's own flagship programme, Ayushman Bharat-PMJAY also primarily focuses on acute-emergency care and pays scant attention to the treatment of NCDs unless they have evolved to an acute presentation.

This as we continue to contend with Maternal, New-born and Child Health (MNCH) related morbidity and mortality, particularly among the poor, and the burden of infectious diseases. The current Government strategy to roll out 150,000 Wellness Centres across the country to focus on preventive and promotive health interventions, vaccination, contraception, safe delivery, nutritional interventions, infectious disease control, sanitation, clean air and water and health education among others[15] to some extent addresses this lacuna. To tackle the middle belly of NCDs the Ministry of Health and Family Welfare (MoH&FW), GOI has implemented the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular disease and Stroke (NPCDCS) with the objective to increase awareness on risk factors, to set up infrastructure (like NCD clinics, cardiac care units) and to carry out opportunistic screening at primary health care levels. Integration of NPCDCS with the National Health Mission (NHM) resulted in augmented infrastructure and human resources particularly in the form of frontline workers, i.e. the ANM and the ASHA. With the active participation of these frontline workers, the population-

based periodic screening of hypertension, diabetes, and common cancers (oral, breast, cervical cancers) is initiated to facilitate the early detection of common NCDs. Prevention and management of chronic obstructive pulmonary disease (COPD) and chronic kidney disease (CKD); and better management of co-morbidities such as diabetes and tuberculosis are also considered under the programme.[16]

Integration of AYUSH with NPCDCS is a further step for promoting healthy lifestyle changes among the population. Health promotion through social media is also being used to generate awareness about prevention and control of NCDs, such as the use of mobile technology in applications called 'mDiabetes' for diabetes control, 'mCessation' to help for quit tobacco, and 'no more tension' as a support for mental stress management.[17] But, if these interventions are really working in arresting and reversing the trend is yet to be seen .

Emerging Definition of Preventive Healthcare

Over the years the concept of preventive healthcare has evolved significantly. However, preventive healthcare has been reduced to an undifferentiated, crude concept that is well intended but is rarely effective anywhere in the world and particularly in India. To attempt to move towards a more inclusive, accessible, affordable, and acceptable system of healthcare for all it is incumbent on policymakers to take into account the life cycle of disease and the different roles that disease prevention would seek to achieve

Figure 1

Source: Author's compilation.

at each stage of life and each stage of the disease. Figure 1 highlights levels of prevention in the spectrum of healthcare services that enables a fresh paradigm of healthcare- moving away from mere disease management to lifecycle health management at individual/community level.

Levels of prevention are mainly categorized as primal/primordial, primary, secondary, and tertiary prevention. Primal/Primordial prevention consists of actions to minimize future hazards to health and hence inhibits the establishment of factors that are known to increase the risk of disease. It addresses broad health determinants rather than preventing personal exposure to risk factors, which is the goal of primary prevention. A reductionist, one-size-fits-all approach by the Government has led to India having one of the highest prevalence of underweight/stunted children apart from extremely high maternal and child mortality rates.

Primary prevention seeks to prevent the onset of specific diseases via risk reduction by altering behaviours or exposures that can lead to disease or by enhancing resistance to the effects of exposure to a disease agent. Better sanitation, access to clean air-water, disinfection, vaccination, meeting primary nutritional needs, etc. fall into this category of prevention. Further, in the modern-day context, annual medical check-ups, periodic testing of one's biomarkers to identify emerging risk factors is a ritual that is taken quite casually by almost all concerned. Thus, for all practical purposes, from the common man to the serious healthcare sector investor to the policymaker preventive healthcare is reduced to optional, periodic rituals that are limited in intent. Further, the role of appropriate diet-lifestyle keeping in mind person-place-time is totally missing notwithstanding the sea change in dietary habits of all Indians.

Secondary prevention includes procedures that detect and treat preclinical to early-stage pathological changes and thereby control disease progression. Screening procedures are often the first step, leading to early interventions that are more cost-effective than intervening once symptoms appear. Unfortunately, the symptom(s) alleviation approach prevalent in conventional medicine ignores the root cause of disease and allows it to grow and spread and, in turn, leads to other systemic co-morbidities.

Once the disease has developed and has been treated in its acute clinical phase, tertiary prevention seeks to soften the impact caused by the disease on the patient's function, longevity, and quality of life. For reversible conditions, tertiary prevention shall reduce the population prevalence, whereas for incurable conditions it may increase the prevalence if it prolongs survival. While where the condition is not reversible, tertiary prevention focuses on rehabilitation, assisting the patient to accommodate to his disability.[18]

Interestingly, a new term 'Quaternary Prevention' has emerged[19]: as "action taken to identify the patient at risk of over-medicalization, to protect him from new medical invasion, and to suggest him interventions ethically acceptable." The concept of quaternary prevention makes it easier to "identify patient at risk of over-medicalization. Quaternary prevention has become an essential component of

the prevention concept and it should be applied as a prevention tool in the current scenario in many disease conditions, pertaining to classical "*primum non nocere*" meaning "first, do no harm."

Promotive health is a collaborative, patient-centered process that promotes trust and recognizes patients' self-directed roles and responsibilities in maintaining health. Effective elements of this process may include educating and motivating patients regarding healthy lifestyle, helping patients by assessing their needs, preferences, and readiness for change and recommending appropriate preventive care measures[20]. Beyond the classical definition of tertiary prevention, promotive health should include restoration of positive health in convalescents, in elders, and for rehabilitation at physical-mental levels at any age with a focus on functional health at a whole person level, i.e. enabling the virtuous cycle of good health with good quality of sleep, appetite, metabolism, excretion, state of mind, and vitality- the positive definition of good health as opposed to the mere absence of disease symptoms, in accordance with the ancient, classical definition of a healthy person in Ayurveda.

It is appropriate in the context of the current pandemic to reiterate the critical role that Ayurveda can play in preventive and curative mental health interventions. Stress, anxiety is at an all-time high, not ignoring more severely debilitating mental health conditions. The holistic approach of Ayurveda is ideal in complementing modern medicine.

Ayurveda's evolving role in preventing, mitigating, treating, and rehabilitating COVID patients over the last one year has led to a huge public trust build-up in the system nationwide. This should be cautiously and prudently leveraged with evidence-based products and services for not only COVID but also other Communicable Diseases such as Dengue, TB, etc. that are widely prevalent in the country.

Thus, in developing a public health strategy and an insurance coverage strategy the exclusive focus on management of the acute-emergency stage of disease, and cosmetic focus on primordial and primary prevention, repudiating the finer aspects of life-cycle health assurance- from cradle to grave - is a serious omission that has serious consequences at socio-economic-political levels. This is precisely where Ayurveda has a significant, breakthrough role to play.

Public Healthcare Insurance Schemes in India

Rashtriya Swasthya Bima Yojana (RSBY) and Ayushman Bharat-Pradhan Mantri Jan Arogya Yojana (AB-PMJAY)

The Rashtriya Swasthya Bima Yojana (RSBY), launched on 1 April 2008, was the flagship health insurance program for BPL patients managed by the Ministry of Labour & Employment. The coverage for hospitalization expenses was up to Rs. 30,000/- for a family of five on a floater basis. Transportation charges were also covered up to a maximum of Rs. 1,000/- with Rs. 100/- per visit. At its peak, it covered 36 million families or about 180 million individuals[21]. In 2013, the scheme for the 1st time included Ayurveda treatments under the scope of coverage but restricted it to Government Ayurveda hospitals and medical college hospitals. Practically, this restricted inclusion did not make any significant difference to

the adoption of Ayurveda by the masses since both- service providers and patients- were relatively unaware of this inclusion. Further, with cross-referral from one system of medicine to another, particularly from conventional to Ayurveda, being virtually non-existent in the public health domain, this policy change was effectively stillborn.

The RSBY scheme was dormant for a couple of years and was subsequently subsumed into the Ayushman Bharat-PMJAY scheme in 2018. However, Ayurveda has not been included till date in the scope of coverage of the scheme. In mid-2020, the National Health Authority in conjunction with the Ministry of AYUSH, Government of India, has initiated steps to explore andevaluate the inclusion of Ayurveda/AYUSH systems of medicine under the AB-PMJAY program.

Other Payer Backed Programs (CGHS/ SGHS)

The Central Government Health Services (CGHS) scheme provides free healthcare to the entire base of Central Government and their employees situated across India for which a specific empanelment process exists with a uniform, pre-notified tariff structure for services availed. In 2008 after a tender process the tariff structure was fixed based on a L1 (lowest) quote basis which turned out to be a non-serious quote at about 15 per cent of the actual cost of service provision leading to virtually no Ayurveda hospital seeking empanelment[22]. Effective October 2015, after a fresh tender was called for from AYUSH hospitals that were technically pre-certified by NABH[23], a new set of rates was announced and 21 Ayurveda and five Yoga & Naturopathy Hospitals were empaneled by CGHS[24]. An egregious anomaly in the current CGHS tariff structure is that the room rates for Ayurveda hospitals remain unchanged from rates applicable in 2008[25], although the rates have since more than doubled for equivalent category rooms in Allopathy hospitals- a clear, discriminatory step against the AYUSH sector.

Only by exception, with highly restrictive tariffs, do some State Governments cover Ayurveda treatments for their employees and their families. The Railways and the Indian Armed Forces have initiated some pilot projects to evaluate the provision of Ayurveda/ AYUSH medical care in some of their nodal facilities. Comprehensive Ayurveda medical care with full-scale Panchakarma treatments on an in-patient basis may be absent at most if not all facilities. It must be said that there has been considerable progress in opening up different closed health systems to Ayurveda over the last 6 years consequent to a determined effort from the independent Ministry of AYUSH set up in 2014. Some of the Public Sector Units have visiting Ayurveda/AYUSH doctors but with a limited scope of service.

It must be appreciated that unless the payer backed healthcare system opens up fully to Ayurveda medical care the scope for the Ayurveda sector to scale will be limited.

Scope of Ayurveda Medical Care

Multiple studies[26] have reported that a significant majority of deaths in India are on account of chronic diseases- systemic diseases such as heart disease, cancer, COPD, diabetes, etc. Disability is also caused by a large prevalence of muscle-bone-joint disorders and mental disorders. Chronic diseases (CDs- diseases that subsist

in an individual for at least 3 months) more often than not precedes or succeeds the need for tertiary-quaternary care. Non-Communicable Diseases (NCDs) often are also CDs. Modern medicine is almost entirely focused on symptom suppression/ alleviation. Ayurveda, on the other hand, posits an aetio-pathogenesis framework, at a whole person level, that enables root-cause diagnosis and targeted therapeutic framework encompassing personalised, diet-lifestyle-medicine-therapy 'black-box' prescription that, as per Ayurveda science, seeks to reverse the pathogenesis right up to the aetiology to attain true disease reversal and to establish sustained wellbeing. At established, mature Ayurveda hospitals across the country, one can see this black-box therapeutic approach delivering exceptional health outcomes arising from the reversal of the aetio-pathogenesis.

Ayurveda's aetio-pathogenesis reversal strategy is rare and possibly unique amongst the medical systems of the world. Being the oldest system of medicine in the world, with time-tested proof of safety and efficacy and an uninterrupted record of practice for about 3 millennia, it is sad that today a patronising attitude towards Ayurveda prevails amongst many policymakers in the country of its origin without in the least taking the effort to understand the highly evolved, 'systems thinking', 'many causes-many effects' approach of Ayurveda in stark contrast to the predominantly reductionist 'single cause-single effect' symptom suppression/ alleviation approach of modern medicine.

The strategy to tackle NCDs/ CDs must be to focus on primordial/ primary/secondary/ tertiary/quaternary prevention and promotive health rather than solely invest in capacity for tertiary-quaternary care (surgical/emergency care). This lopsided policy framework and budgetary provision at central and state government levels, compounded by a health insurance sector that focuses almost entirely on the surgical/ emergency care aspects has deprived the policy holder of access to effective, root cause Ayurveda treatments that are less harmful in collateral side-effects, and go beyond disease to whole-person positive health and wellbeing.

Current Status of Ayurveda Coverage in Indian Health Insurance

In October 2015 after a gap of approximately seven years the IRDA encouraged Insurance companies to extend the benefit of 'cashless' Ayurveda treatments to Quality Council of India/NABH accredited hospitals as well as at medical college hospitals. Subsequently, in 2016, the Ministry of AYUSH in discussion with the insurance sector notified benchmark rates for various therapies/intervention, along with guidelines for insurance coverage and claims settlement[9]. However, the implementation of this order was largely been kept in abeyance by different insurance companies.

The four PSU Insurance companies had subsequently developed their own PPN (Preferred Provider Network) consisting of Allopathy hospitals who had agreed to an exclusive tariff framework. This PPN tariff was applicable for the top 10 cities in India. Since there is no PPN Ayurveda tariff announced PSU Insurance companies deny cashless Ayurveda treatments to their policyholders in the top 10 cities: a clear case of apathy, if not discrimination, against Ayurveda and

against the best interests of their own customers. In 2019 IRDA has redefined AYUSH Hospital as having at least five inpatient beds, with a full time AYUSH doctor, and with dedicated therapy sections- essentially opening the gates for small AYUSH hospitals to enter the insurance network[27]. Once again, while the notification has been issued, in reality, insurance companies have not heeded this government notification.

Further, significantly, on 1st January 2020, the IRDA notified 'Guidelines on Standard Health Insurance Product[28]' wherein the foundational, base terms and conditions applicable to all new health insurance products to be launched by different health insurance companies have, at the least, to offer this minimum scope of coverage, and which minimum scope includes by default coverage for Ayurveda and other systems of AYUSH fully, without sub-limits, up to the full policy coverage amount. This is a breakthrough stipulation and starting October 2020 new health insurance products to be approved by IRDA shall mandatorily have this benefit.

Many private insurance companies such as HDFC Life, Max Bupa, Star, Future Generale, etc. cover Ayurveda care with varying levels of restrictions- from none to drastic sub-limits and limiting clauses.

OPD Cover

OPD or Out-patient Department Cover is a relatively new feature offered as a novel value add by several private health insurance players as a differentiated offering that includes coverage for doctor's general consultation, pharmacy bills, health check-ups, diagnostic tests, etc. Often a flat rate is paid by the insurance company to the empanelled doctor covering consultation and medicines.

The OPD feature is a strategic move by companies to detect early the policyholders at higher health risk and in turn higher risk of needing hospitalization in the near to medium term. The relative depletion of General Practitioners makes this model difficult to scale. Further, there are clear risks of fraud- by policyholders or service providers. Technology is seen as the way out to authenticate transactions and to ensure an audit trail that prevents fraud. The cost of such technology upgradation, maintenance has to be weighed against potential benefits in attracting more customers and lower average claims.

AYUSH systems of medicine offer an affordable, accessible, and acceptable mode for OPD healthcare. While modern medicine doctors gravitate to specialities a large number of graduate AYUSH doctors may invest in their own clinic-pharmacy outlets that take care of symptom alleviation, patient triaging-referrals. A true patient-centric care model can be created with personalised diet-lifestyle-medicine prescriptions. This is a model that is waiting to happen at scale across the country with one or more organised players coming in and setting up large chains of branded clinics with standardised protocols, billing systems, training, etc. However, insurance companies may not be willing to entirely foot the bill for building this AYUSH service category and the Government of India must engage with the insurance sector to work out a model that is large scale and benefits all stakeholders. Further, Government may be called upon to commit its resources to and to invest in building the AYUSH physician/clinic national network required to service the load.

Recently, CGHS has on a pilot basis permitted Ayurveda OPD treatments in Delhi NCR region for a period of one year.[29] This is a positive step for the AYUSH sector.

International Health Insurance

Several foreign countries offer universal health coverage, with no restriction on the choice of medical system, for every citizen/resident. UAE is a case in point. On the other hand, in Maldives, an adjoining SAARC nation, UHC exists with patients able to come to India for tertiary-quaternary medical care, but the scheme does not currently include Ayurveda. Also, multi-lateral, global organisations (under the United Nations, e.g.) offer medical coverage without restriction. International Health Insurance covered patients offer an excellent opportunity for Indian Ayurveda medical care providers- to tie up with overseas Insurance companies and TPAs (Third Party Administrators) for 'cashless' or reimbursable Ayurveda medical care. This can be a precursor to setting up full-fledged Ayurveda hospitals in select overseas geographies.

Opportunities for Ayurveda

The National Health Policy 2017 posits a pluralistic, integrated health system for India that is visionary in approaching the major health issues that our nation faces today. In practice, however, this integration continues to elude implementation. The issue of fragmentation of healthcare delivery with the private sector playing a major role has been a major barrier. In the Government-run public health system cross-referrals between systems of medicine is largely absent.

The opportunity for Ayurveda lies in offering a mainstream treatment option for approximately 2/3rd of healthcare demand, i.e. as primary treatment (secondary, tertiary, quaternary prevention) for NCDs/CDs, and as complementary treatment (primordial and primary prevention) for fundamental disease prevention. Districts/communities that have a long history of malnutrition may be targeted with an Ayurveda based local strategy that is consistent with age-old practices and customs of the community geography.

With over 25,000 Ayurveda doctors graduating each year and over 4,000 post-graduates in multiple medical specialities qualifying each year, adding to an existing base of an estimated 400,000 Ayurveda doctors[30], doctor scarcity will not be an issue particularly in manning the large number of Wellness Centres (150,000) planned to be rolled out across the country offering primary care that triages-escalates, is predominantly Ayurveda based but leverages modern medicine for management of acute symptoms. Integrated medicine is possible at the Primary Healthcare level leveraging mutual strengths of the two major systems of medicine in India, in the best interests of patients. Thereafter, at higher levels of care, depending on the disease, co-morbidities, severity, and optimal line of management, the patient may be referred to either an Ayurveda or Allopathy tertiary-quaternary care facility.

India can show the way to the world in a cost-effective, just, equitable, gentle healthcare system that is in the best interests of the common man-woman-child, from cradle to grave, from disease reversal to sustained wellbeing.

The Way Forward

Several initiatives can be taken towards building an effective and resilient insurance programme in Ayurveda:

- AB-PMJAY must include Ayurveda hospitalised medical care for secondary and tertiary prevention of diseases. This will accelerate Ayurveda hospital capacity creation in the private sector as also enable Government hospitals and medical college hospitals to upgrade the quality of services. Further, the maturity of the entire Ayurveda sector (products and services) will leapfrog with this one enabling step. This will be a great win-win because it will have a significant impact on DALYs, and on the total cost of healthcare in the country enabling a continuum of care from primary to quaternary care that is pluralistic and in the best interests of the citizen.
- The Ministry of AYUSH must intimate the GIC Council to take corrective steps forthwith to direct the 4 PSU insurance companies to fix and announce PPN rates for Ayurveda hospitalized care.
- CGHS must revise its room rates for Ayurveda hospitals and make it identical on an on-going basis to that applicable for a given room category (private/semi-private/ward) in Allopathy hospitals, in the same geography.
- In this case too, the Ministry of AYUSH must intimate the CGHS administrators to take corrective steps forthwith.
- In general, it would be fair to say that while several progressive policy measures have been announced in recent years by the Ministry of AYUSH and IRDA, in reality, insurance companies have been relatively indifferent to implementing the same.
- Decision makers amongst different players in the health insurance sector- insurance companies, brokers, TPAs, regulator, MoH&FW, NHA- need to be oriented to authentic Ayurveda *chikitsa* (medical management) at established Ayurveda hospitals across the country. Direct, in-person, perception of *chikitsa* in action and interaction with a cross section of patients by this set of insurance sector leaders alone shall enable right perception and understanding leading to implementation of policies in letter and spirit. The Ministry of AYUSH should enable this process of orientation/interaction and premier Ayurveda hospitals in the government and private sector to play their part in transformation of prevalent stereotypical mind-sets about Ayurveda.
- Three diseases where elective surgery is the prevalent choice (OA-Knees, Sciatica on account of IVDP, Cervical Spondylosis, for e.g.) may be taken up for a robust, longitudinal, comparative study on cost versus benefit (objective clinical outcomes in addition to quality-of-life parameters) on a short- and medium-term bases. This study is expected to reveal the significant reduction in pay-outs for Payers with significantly happier patients on a sustained basis, i.e. to establish the socio-economic benefit rather than trying to prove the mechanism of action or building evidence for Ayurveda which may be a secondary objective or may demand targeted research for this specific purpose. If the Ministry of AYUSH were to take the

initiative the insurance companies are likely to welcome and partner in this longitudinal compilation of data that is in the best interests of all stakeholders-most importantly, the patient.

- A public awareness campaign must be initiated by the Government to educate the general public, the insurance sector, and medical professionals from other systems of medicine on the true and complete scope of Ayurveda medical care- of Ayurveda as '*chikitsa*' or medical/health management system that diagnoses and treats the root cause of disease, at whole person level, for disease reversal and sustained wellbeing.
- Ministry of AYUSH must engage with the insurance sector to open up Ayurveda/AYUSH OPD insurance coverage. It is likely that insurance industry shall expect the government to share the cost of building the clinic network, development of standard protocols, training, and finally to build awareness of the insurance product and its benefits. This could be a great win-win for all stakeholders.
- An Ayurveda based Nutrition-Primary Health-Wellbeing strategy must be tested and validated in the most vulnerable communities-districts. The proposed 12,500 exclusive AYUSH Wellness Centres that are currently under rollout must be used to demonstrate a new paradigm of community health at the grassroots level. This implies that the Vision, Objectives, Key Performance Measures must be defined in advance and adequately resourced-supported.

Conclusion

Ayurveda is the potent *Brahmastra* weapon that India is fortunate to have. For India to meet its health goals, including the UN SDG 3.0 overarching goal by 2030, i.e. 'To ensure healthy lives and promote wellbeing for all at all ages' Ayurveda (and Yoga) is mandatory to be mainstreamed and leveraged. All healthcare stakeholders must not lose this opportunity due to short-sightedness or arrogance. Policymakers need to go beyond shibboleths and take concrete steps to leverage the potential of Ayurveda with a well-considered strategic plan. Ayurveda's time has come. All stakeholders must work together with an open mind in the best interests of the Indian citizen.

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Integrative Medicine in India: Need for an Inclusive Health Policy

N. Srikanth*

N. Srikanth

Introduction

Integrated Medicine is an approach to health and healing that provides patients with individually tailored health and well-being programs. These are designed to address the barriers to healing and provide the patient with the knowledge, skills and support to take better care of their physical, emotional, psychological and spiritual health. Rather than limiting treatments to a specific specialty, integrated medicine uses the safest and most effective combination of approaches and treatments from the world of conventional and complementary/alternative medicine.[1] These are selected according to, but not limited to, evidence-based practice, and the expertise, experience and insight of the individuals and team members caring for the patient. As defined by the National Center for Complementary and Alternative Medicine at the National Institutes of Health, Integrative medicine combines mainstream medical therapies and CAM therapies for which there is some high-quality scientific evidence of safety and effectiveness.[2] The term integration is widely used to express the formalization and official incorporation of TRM into national health services. However, the term has a more specific meaning. Historically, the relationship between modern and traditional medicine has taken four broad forms:[3] (i) Monopolistic system- Modern medical doctors have the soul right to practice medicine. (ii) Tolerance system- One of co-existence system where traditional medical practitioners, while not formally

* Director General In-Charge, Central Council for Research in Ayurvedic Sciences.

recognized, are permitted to practice in an unofficial capacity. (iii) Parallel or dual health care system- As in India, where both modern and traditional medicine are separate components of the national health systems (iv) Inclusive Integrated model- Modern and traditional medicine are integrated at the level of medical education and practice (e.g. China, Vietnam). India is one such country which enjoys great antiquity of health practices backed by strong base of its indigenous Traditional Knowledge (TK). It has been increasingly understood that no single health care system can provide satisfactory answers to all the health needs of modern society. Evidently, there is a need for a new inclusive and integrated health care regime that should guide health policies and programs in future. India has an advantage in this global resurgence of interest in holistic approach as it has a rich heritage of indigenous medical knowledge coupled with strong infrastructure and skilled manpower in modern medicine. Medical pluralism can bloom here. Thus AYUSH sector has a critical role to play in the promotion of AYUSH drugs as standalone and as add on therapy for various ailments. Certain studies examine the efficacy of AYUSH intervention as standalone therapy and also as add on therapy to conventional medication for various ailments. It is high time to further promote the same at much bigger platform so that the benefits can reach among masses. Currently Traditional and Complementary Medicine (T&CM) or Complementary and Alternative medicine (CAM), and conventional medicine are practiced in almost all countries in the world. CAM is in increasing demand by patients and is also studied in universities (e.g. the Academic Consortium for Integrative Medicine & Health in the USA). According to the "Traditional Medicine Strategy: 2014–2023" of the World Health Organization (WHO), the public and consumers of health care worldwide continue to include TM in their health choices. This obliges Member States to support them in making informed decisions about their options.[4] As the uptake of T&CM increases, there is a need for its closer integration into health systems. Policy makers and consumers should consider how T&CM may improve patient experience and population health. Integrating T&CM into conventional medicine will provide an additional knowledge and interventions on preventive and curative health promotion.[5] The integration can therefore contribute to current issues in public health and healthcare such as developing strategies of healthy ageing, promoting self-management, and controlling healthcare expenditures.[6,7]

Health Policies in India : Integrating Health Care Systems

The Government of India has included AYUSH in many major health policies and made strategies for optimal inclusion and mainstreaming of AYSUH in mainstream healthcare services in India. The policy and strategies of Government during different periods opened avenues for integration of AYUSH and conventional medicine at Research as well as Clinical practice. The core recommendations of policies encompass mainstreaming of AYUSH in the National Reproductive and Child Health (RCH) Program in the National Population Policy-2000; Re-orientation, prioritization of research in AYUSH and to validate therapy and drugs in

Chronic and Life Style Related Diseases in National Health Policy on AYUSH -2002 and National Health Policy-2002; Health conditions and disability - adjusted life years (DALYs) lost in India results from Communicable diseases, Reproductive and Child Health conditions and Life style related disorders in National Commission on Macro-economics and Health-2005. Further, the recent three major documents related to health policy viz. National Health Policy (NHP) 2017; Situation Analyses – Backdrop to NHP 2017, Ministry of Health and Family Welfare, Government of India; and Three-Year Action Agenda 2017–2020, NITI Aayog, Government of India highlighted on prevention through lifestyle advocacy, health care delivery through integration, co-location, and medical pluralism.

To understand the real challenge of integration of diverse systems, let us briefly review the genesis of the conflict. In 1938, largely as a result of the freedom struggle and emphasis on '*swadeshi*', the National Planning Committee (NPC) set up by the Indian National Congress took a decision to absorb practitioners of Ayurveda and Unani systems into the formal health set-up of independent India. In 1946, the Health Minister's Conference adopted the NPC proposals and resolved to make appropriate financial allocations for: (i) Research based on the application of scientific methods in Ayurveda and Unani; (ii) The establishment of colleges and schools for training in diploma degree courses in indigenous systems; (iii) The establishment of postgraduate courses in Indian medicine; (iv) The absorption of *vaidya* and *hakims* as doctors, health workers etc. and (v) Inclusion of departments and practitioners of Indian medicine on national health committees. As a result of the conference resolutions, the government set up the Chopra Committee (1948) on the Indigenous Systems of Medicine to work out guidelines for the implementation of the above proposals. The Chopra Committee eventually came out in support of a synthesis of the Indian and Western systems through integrated teaching and research. It recommended that the curriculum be designed to strengthen and supplement one system with the other, with each making up for the other's deficiencies, while research should be concentrated on removing useless accretions to Ayurveda and making it intelligible to modern minds since a large portion of the texts were in Sanskrit. The ultimate objective of the research ought to be a synthesis of Indian and Western medicine which was suited to Indian conditions. The Chopra Committee was followed by the Dave Committee which went into the issue of establishing standards in respect of education and regulation of practice in ISM. The Committee recommended an integrated course of teaching and some states in the Indian Union in fact started integrated colleges which taught both modern medicine and Ayurveda. Eventually, the supporters of a pure system of education and training for Ayurveda, homeopathy and Unani system gained political support in the country's political circles. This led to the formation of several independent Councils for looking after the research, development, training and regulatory aspects relating to ISM. The Sixth Plan (1980-84) was influenced by two policy documents: The Alma Ata Declaration and the ICMR/ICSSR report on 'Health for All by 2000'. The ICMR/ICSSR Report (1980) was in fact a move towards articulating a national health

policy that was thought of as an important step to realize the Alma Ata Declaration. It was realized that one had to re-define and re-articulate and get back into track an integrated and comprehensive health system that policy-makers had wavered from. It reiterated the need to integrate the development of the health system with the overall plans of socioeconomic and political change.[8]The Declaration recommended that primary health care should include at least education concerning prevailing health problems and methods of identifying, preventing and controlling them; promotion of food supply and proper nutrition, and adequate supply of safe water and basic sanitation; maternal and child health care, including family planning; immunization against major infectious diseases; prevention and control of locally endemic diseases; appropriate treatment of common diseases and injuries; promotion of mental health and provision of essential drugs. It emphasized the need for strong first-level care with strong secondary-level and tertiary-level care linked to it. It called for an integration of preventive, promotive, curative and rehabilitative health services that had to be made accessible and available to the people, and this was to be guided by the principles of universality, comprehensiveness and equity. It also recognized the need for a multi-sectoral approach to health and clearly stated that primary health care had to be linked to other sectors.[9] The emphasis of the first health report i.e. Health Planning and Development Committee's Report, 1946 (popularly known as the Bhore Committee Report)[10] on the role of the State was explicit. The Report was based on a countrywide survey in British India. It is the first organized set of health care data for India. It considered that the health program in India should be developed on a foundation of preventive health work and proceeds in the closest association with the administration of medical relief. The Committee strongly recommended a health services system based on the needs of the people, the majority of whom were deprived and poor. It felt the need for developing a strong basic health services structure at the primary level with referral linkages. This integration of preventive and curative aspect can only be achieved by bringing true medical pluralism with effective cross referral system in India by bringing all system of medicine on one platform so the best of all can be utilized in its full potential. Most of the policy reports miss out on the importance of a strong referral system.

Exploring Integration Models

Integration of various system of medicine in India can be done in various aspects to achieve true medical pluralism and thus providing better and comprehensive health care services to every citizen. (i) Integration of AYUSH system with Allopathic system and Intra AYUSH integration (ii) Integration of all the systems by identification of their strengths and improving cross referrals (iii) Integration in Research field, combining positive leads of two or more system of medicine to bring out the best treatment modality for the patients.

There are two schools of thoughts in this regard. The first school views traditional systems as based on fundamentally different assumptions about human life, health and illness, which, in no way can reconcile with the theories of

biomedicine. The traditional medicine systems attempt to restore the balance of mind-body-soul and treat patients holistically. The conventional medicine approach, on the contrary, treats a patient as a passive subject and focuses only on bodily aspects of the health problem.[11] Thus, those who subscribe to the first school consider western and traditional medicines irreconcilable and prefer them being practiced rather independently. The second school though acknowledges the differences in the two medicine system approaches and sees many possibilities of developing a unified health care delivery system. The vast local resources of health care need to be mobilized into the crumbling public health services where different medicinal systems can work under one roof.

The Self-Care Approach as an Integrative Tool

Both the traditional and western biomedicine represent theory and practice for managing human health, the approaches differing in basic concepts but also converging on many aspects of healthy lifestyle and public health. Self-care is one such dimension. A people empowering self-care approach requires that (i) general public not only have access to, but also learn to digest and critically evaluate health-related information (from advertisements, newspapers, books, journals, internet, etc.) that could inform their activities; (ii) appropriate information about all available systems would be useful for rational decision making; (iii) sharing of experiences and information within the community and between sufferers of specific problems.[12]

Evidence -Based Approach for Integration

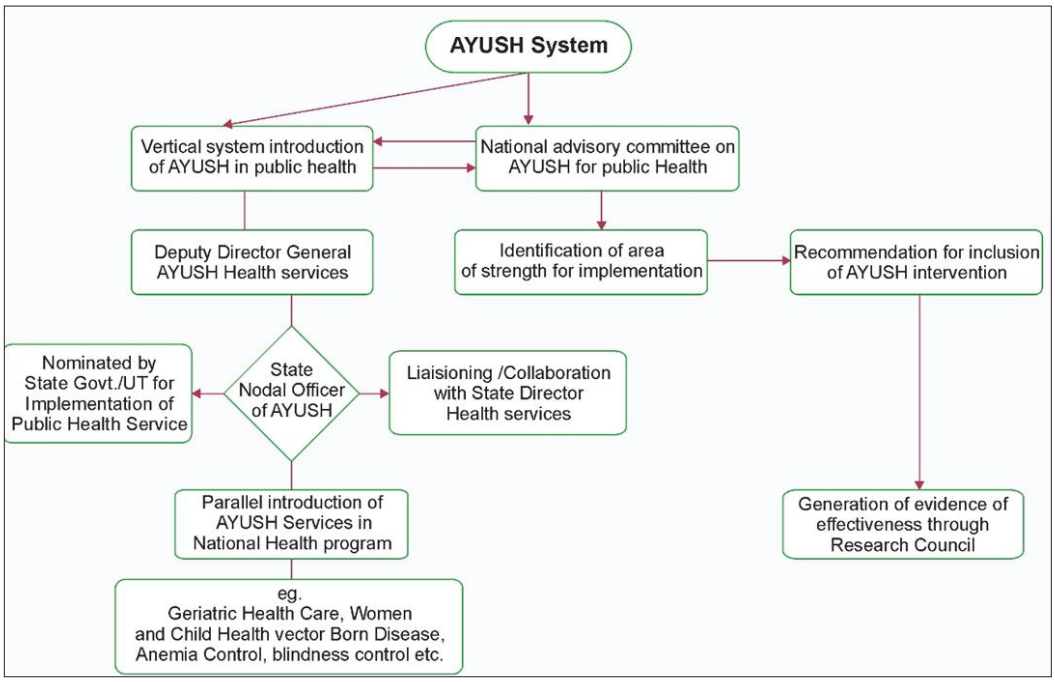
Certain studies have been conducted to assess the feasibility of integration of AYUSH systems in primary and tertiary level of health care. Central Council of Research in Ayurvedic Sciences (CCRAS), Ministry of AYUSH, Govt. of India in collaboration with the Directorate of Health Services of different Indian states conducted a study to assess the feasibility of Integration of AYUSH (Ayurveda) with NPCDCS program. The study reveals that integration of AYUSH with NPCDCS program at grassroots level will be a useful tool for future action plan and to take appropriate policy decisions for integration, which will further help to control and manage the disease burden.[13,14] In a collaborative study to assess the feasibility of integration of Ayurveda in Reproductive and Child Health program at primary health care level conducted in collaboration with ICMR demonstrated the feasibility of introducing Ayurveda in mainstream and effectiveness in the ante-natal and post-natal care in primary health care setups. Significant improvement in various outcome indicators such as Hemoglobin%, minimal complications during pregnancy, achievement of full term pregnancy and no still birth and neonatal death were observed in the study. An operational Study entitled feasibility of integrating Ayurveda with conventional system of medicine in a tertiary health care hospital to the management of Osteoarthritis-knee (OA) was conducted in Ayurvedic unit of Safdarjung Hospital, New Delhi, a multispecialty conventional medical hospital in collaboration with the World Health Organization, India office.[15] The

study initiated a functional linkage between Ayurvedic and Orthopedics Departments in terms of continued communication and referrals of the suitable patients. The study created awareness among practitioners of Department of Orthopedics about the benefits of Ayurvedic treatment for OA. Ayurvedic treatment was proved to be effective in the management of OA knee with respect to reducing the symptoms, improving the quality of daily activities, and reducing the use of non-steroidal anti-inflammatory drugs as rescue medication. The study created awareness among the patients visiting the hospital about the availability of Ayurvedic services in the premises. It is apparent from the experience with the study that the continued communication and scientific approaches will usher actual integration and a rational cross-referral system is the practical effective way to integrate Ayurveda with allopathy.[16] Further, an international collaborative research project with Charite University to study management of Osteoarthritis through Ayurveda evaluated the effectiveness of Ayurvedic treatment compared to conventional conservative care in patients with knee OA.[17] The study results suggest that the Ayurvedic treatment is beneficial in reducing knee OA symptoms. For the study, the protocol was developed in an international consensus process with Ayurveda and orthopedic experts from three countries (India, Germany and Italy) using a Delphi approach.

In order to integrate Traditional Systems of Medicine in India, the major task is to standardize the terminologies of these systems which will be in accordance to the WHO ICD (International Classification of Disease). A landmark work is being done in this direction by the Ministry of AYUSH by development of National AYUSH Morbidities and Standardized Terminologies E- Portal[18] (NAMASTE Portal) which is an AYUSH Informatics Initiative for centralized collection of morbidity statistics pertaining to various systems of medicine under the Ministry of AYUSH.[19] AYUSH need to be developed as a sustainable healthcare system instead of mere gap filling measure. Independent AYUSH health service infrastructure at State and Central level parallel to Allopathic health services may be established through an inclusive or parallel system of AYUSH based health care program. There is a need of introduction of AYUSH based National programs for Health care delivery on the line of program implemented by Ministry of Health and Family welfare either as inclusive or parallel or vertical healthcare delivery system. Expert level steering committee /group of clinicians may be given the task to decide the treatment levels of care. Thus channelizing AYUSH care for inclusion in various health care program at different levels. **(Figure 1)**

Integrated healthcare approach may be adopted instead of integrative medicine through promotion of Cafeteria approach in a hospital where one gets all facilities under one roof so that the patients have the choice for the suitable treatment under one roof and will also promote cross referrals (Integrative medicine combines Complementary and Alternative medicine (CAM) with conventional medicine).[20] Whereas, integrated healthcare system is the organization and management of health services so that people get the care they need, when they need it, in ways that are user friendly, achieve the desired results and provide value for money.

Figure 1: Suggested Implementation Strategy of AYUSH based Health Services in Public Health Parallel to Conventional Health Services



Source: AYUSH in Public Health: Strategy and Framework. Brainstorming Session (Background Note). CCRAS, Ministry of AYUSH, 2018).

This system provides right care in the right place.[21] Further, systematic research is needed to establish standardization, efficacy and safety of classical AYUSH medicines as actively done by CCRAS.[22]

The National Consultative Meet on Intra AYUSH Collaboration explored various strength areas where a particular system of AYUSH medicine can be beneficial as standalone and as add on therapy to showcase the notable achievements of AYUSH Research Councils and possible areas of collaboration. A document titled "AYUSH systems - A focus on core achievements and potential areas of strength" has been released to draw a future roadmap for integration among these systems and following are few suggestions such as introduction of inclusive or parallel vertical healthcare delivery along the lines of conventional framework and AYUSH based public health initiative to attain the goal of the National Health Policy 2017, aspects of AYUSH to be included in programs aimed at achieving Universal Health Coverage and necessary steps involved in fructifying vision, regulatory barriers, which if overcome could enable AYUSH to serve the society more efficiently and, steer it closer to the goal of the National Health Policy 2017, a public health task force may be created under Ministry of AYUSH that may work as an Advisory body to develop research programs, which should aim at fine tuning this program as culturally sensitive, locally available and low cost public health program and ASHA workers and ANMs may also be trained in AYUSH systems as they are working in the grassroots level. [23]

The dream of healthier 'New India' can be achieved only with collaborative efforts by bringing the scientists of all system on one platform. It is the duty of the stakeholders of all the system of medicines to have esteem for each other and to identify the areas of collaboration and integration so to develop a stronger and consolidated platform for medical pluralism in its true form. Thus, AYUSH systems plays a key role in the health care system, however its positioning with respect to National Health Policy 2017 needs to be augmented.[24,25]

Conclusion

A comprehensive health policy is essential to promote integrative health care in the country making provision for expanding the scope of integration in medical education, research and development, clinical practice and public health. While integrating AYUSH and mainstreaming it into the healthcare system in India, some of the important aspects that needs to be addressed: (i) developing standard integrative treatment protocols validated through research studies (ii) initiation of integrative health services of AYUSH and conventional medicine based on the standard integrative treatment protocols (iii) developing standard operative procedures for functional integration (iv) examination of integrative treatment approaches for compliance within the ambit of biomedical ethics (v) building an ethos of trust and mutual respect between AYUSH and conventional medicine practitioners which can be achieved by feasibility studies on functional integration (vi) cafeteria approach i.e. co-location of different system of medicines under one roof (vii) sensitization through development of AYUSH educational module for conventional medicine system students can also be planned.

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Ayurveda Sector Profile: Exploring the Untapped Potential

Ranjit Puranik*


Ranjit Puranik

Introduction

'Ayurveda' has become a buzzword of sorts in COVID-19 pandemic times. The Government of India has made some important recommendations in preventive health solutions emerging from this medical heritage. The Ministry of AYUSH on its part has initiated many validation studies and the interim reports indicate a fair advantage benefiting society, frontline COVID-19 medical staff and others in combating exposure to this virus. The attention received has also led to the Ministry of Finance announcing an INR 4000 cr. package for the cultivation of medicinal plants as part of a larger economic stimulus for the economy.[1] This is a much-needed initiative to be managed by the National Medicinal Plants Board, an autonomous body dedicated to backward integration efforts and sustainable supply of medicinal plants for the AYUSH Sector in India.

AYUSH, an acronym for Ayurveda, Unani, Siddha, Yoga, Naturopathy, Sowa Rigpa & Homoeopathy, is a loosely put together indicator to sometimes describe everything that is not allopathy *ala* modern science-based pharmaceuticals or health care delivery. Ayurveda as a sector occupies a majority of this AYUSH aspect. Its profile has many dimensions which emerge from a traditional medicine standpoint. Ayurveda, like everything traditional and history-rich is glory personifying a bygone era. Its romance includes an era when gods walked Earth and their interaction led to miracle cures, nectar and elixir in common life. But unlike all things mythological and historic, Ayurveda is here, codified and documented, it's now in practice and is a fledgling sector awaiting recognition. With

* Managing Director, Shree Dhootapapeshwar Ltd, Mumbai and Vice-President (West), Ayurvedic Drug Manufacturers' Association (ADMA), India.

the advent of modern medicine in India, Ayurveda a mainstream primary health care monopoly of a pre-independence era, has seen the challenge, labelled an alternate and even sometimes relegated to a status of a probationary complementary health option, blasphemously called a placebo. Systematic policy neglect, urgent national health concerns, and a shift to quickly embrace the 'new' resulted in the country setting aside its medical heritage to something being a cultural nuance. A combination blend of Ayurveda and modern medicine to the advantage of society and mankind was not followed by a curriculum that ingrains the two. Hence, whilst the glory of Ayurveda is an accepted great, its current status has not been credibly documented nor its interventions pronounced in health policy. The economic slowdown of this sector was but natural and a renaissance in Ayurveda is only on account of modern medicine's failure to live up to promise of being truly a 'primary health solution'. Modern medicine's failure has led to a sprint for a return to roots, whilst Ayurveda is caught muddled in an identity crisis, trying to configure the signals of this newfound attention. The era-based upgrade that has served Ayurveda well since its inception in 3000 BC, is yet to happen for this cycle. As a consequence, the sector is yet to emerge as a true comparator to modern medicine. Translational science fails this traditional sector. A profile or its absence now mars its progress.

This article is an attempt to provide an overview of the sector through a profile, with the objective of providing a broad outline of the potential it holds for the economy. This overview is provided with aid of measurements of economic components within the sector. Importantly, this article limits itself to an understanding of the Ayurveda dimension only.

Figure 1: Stakeholders in this 'Ayurveda Profile'

Source: Author's compilation.

Gross Domestic Product (GDP)

A normal exercise of estimating a sector's economic footprint includes comparison with the GDP of the country to assess the weightage associated with the particular sector.

Tapping into public information database like World Bank, various Ministry reports, trade reports, press statements and statistics published, we have put together some comparators to attempt an 'Ayurveda Profile'. Assumptions are transparently placed to draw inference and not to claim exactitude or any semblance of factual position.

India's GDP estimated is US$ 1875.14 Billion[2] for FY 2019-20 and is ranked 5th in the world. India is on a fast track looking at 50 years of economic boom with a challenge and a boon - extending this growth story to over 600 million[3] citizens awaiting inclusion in India's economic upturn. Ministry of Finance has targeted a US$ 5 trillion GDP[4], next to only USA and China by 2024. Important to note is that a former agrarian economy is now well balanced with a 24.9 per cent contribution from an emerging Manufacturing sector.[5] This is a huge plus when it comes to achieving the US$ 5 trillion targeted growth leap by 2025 and including 600 million citizens to this largesse.

The modern pharmaceutical industry of India brands itself to be the 'pharmacy of the world' and true to its claim boasts of a phenomenal last decade of growth with exports of over INR 1.50 lac crs., and a total size of INR 2.77 lac crs.[6], with a GDP footprint of 1.15 per cent. India also boasts of over 44 per cent of all Abbreviated New Drug Applications (ANDA) approvals by US FDA in 2018.[7] The growth of the modern pharmaceutical industry in India has a special meaning, a precursor, to the future potential of the Ayurveda industry and its emergence globally. Can the country use this credibility to provide medicines from its own medical heritage to the confidence of regulators world-wide? We have an immense science and technological base in pharmaceuticals and it shows that the same can be established for Ayurveda as well. We are received in markets as proven manufacturers of quality pharmaceuticals, competently employing scientific rigour

Figure 2: Components of GDD

Source: Author's compilation.

and it's time we wrote our own new drug paradigm emerging from Ayurveda medicine. To do that it is important to question the readiness of the country, policy makers, scientists and the Ayurveda industry to make it happen. The main areas of focus should be disease, disorder, cure & management.

There is currently no official estimate of the Ayurveda industry size, although a CII report published in 2018 estimated the size of Ayurveda industry to be INR 30,000 crore.[8] Even if one argues that the estimate is inflated, we can place a realistic assumption that Ayurveda Industry is INR 25,000 crs in market size and just 0.10 per cent of GDP for the financial year 2019-20. There is no quantitative basis for this assumption, there is no database that has a validated estimate for the market size of the Ayurveda industry. It's merely a conservative estimate vis-a-vis quotes of it being INR 30,000 crs., and is as good a guess as any.

Per Capita

The second aspect of profiling is to understand earnings within the sector. There is no relevant database but we do know that there are approximately 7494[9] licensed Ayurveda manufacturers in India, as per the Ministry of AYUSH estimates. A rule of thumb would indicate an average economic size of INR 3.34 crs. for a typical industry unit. But based on estimates drawn from industry experience we do know that 200 companies control almost 85 per cent of the market share and this would mean that 7294 units would share an assumed INR 3750 crs. of commerce, resulting in an unviable economic size of just INR 51 lacs per unit. This is unviable sustenance, for any development agenda and for any competency to emerge in the coming years. Associated with such unviability are some of the glaring negatives we see in Ayurveda sector – amplified claim benefit, inconsistent quality offerings, packaging, compliance issues and sale at any cost strategies. This

Table-1 Estimating Work Force in Ayurveda

Unit	Estimated workforce per unit**	Total Estimated workforce
Medium and Large Ayurveda Co's – 200**	250 Employees per Company	50,000
Small and Micro Ayurveda Co's – 7,294*	10 Employees per Company	73,000
Medicinal Practitioners (Vaidya's)*	478450	478,750
Add: Assistants of Vaidya's	2 assistant per Vaidya	957,500
PHCs – 15,118*	5 employees per centre	75,590
Colleges- 254*	150 employees per college	38,100
State Govt's - 29*	500 employees per state	14,500
Medicinal Plant Traders	50 per state x 5 per trader	7,250
Total Sector Employment		**16,94,690**

Source: *Estimates taken from Ministry of AYUSH website, **Author's estimates based on minimalistic assumption drawn from industry experience/association.

per capita assessment, however one resets it statistically, reality will be in an around this malady. It's therefore given that new capital would be needed for extension of India's economic boom to the Ayurveda sector, new champions will have to emerge and in the short- term with a firm foot of Drug Control - shrinkage in number of units is inevitable.

Employment

On a very conservative and minimalistic base it is estimated that Ayurveda sector will have an economic impact on approximately 1.7 million workforce (Table 1). This would not include the medicinal plant farmers and forest communities who cultivate and collect the natural resources, hitherto undocumented and a little difficult to segregate and estimate this large group of stakeholders. A growing focus on sustainable sources for medicinal plants from agriculture and afforested areas would mean a very large impact on employment opportunities from this upstream activity. The National Medicinal Plants Board recently claimed to have over 6 lac of hectares under conservation activity and over 10 lac hectares under cultivation activity with an annual budget of a paltry INR 60 crs.[10] We must imagine the INR 4000 cr. stimulus in this activity to be god sent and boom as far as employment in this sector is concerned even at a low assumption of impact – 1 worker per hectare.

Given the size of India's workforce, it can be claimed that with even a marginal encouragement from Government – State & Central -- we would see Ayurveda sharing its economic boom with 1 per cent of the total workforce that India employs, i.e 5 million strong engagement in allied activities of medicinal plants cultivation and collection, in the medium term.

Agriculture

Sustainable sourcing of medicinal plants is a challenge for the Ayurveda sector. Hitherto Ayurveda industry has sourced its need for medicinal plants from forests. In recent years with the growth of phyto-chemicals, which source medicinal plants for the extraction of pure compounds used in modern pharmaceuticals (it is reported that almost 25 per cent of modern pharmaceuticals still source their pure compounds from plant resources), the pressure on the natural cycle of regeneration from the forests has been disturbed. This has led to the cultivation of medicinal plants on a larger scale and we estimate this global demand coupled with boom from within the Ayurveda sector has afforded agriculture to be a primary source of such herbs. Industry sources indicate that even today 90 per cent of the medicinal plant species are sourced from the forests but in volume, the picture would be inverse with over 80 per cent of the volume coming in from farms. Firms usually report the cost of medicinal plants as raw material at around 12 per cent [11] of the total cost to the industry. With an economic sector size estimate of INR 25,000 crs., this would mean INR 2,400 crs. worth of medicinal plants are sourced from farms. Here lies a huge opportunity to make a difference with higher volumes being sourced from Agriculture and sustained Afforestation. Commensurate to this activity is a huge potential for impacting livelihoods of forest communities and providing an alternative crop for farmers. Medicinal plant sourcing should be one of the greenfield sectors for global trade from Ayurveda sector. Value

addition and like economic activities can only spell greater value realization to communities and farmers.

Industry

Indian Industry accounts for around 25 per cent of GDP which nears to around USD 468.8 Billion and employees around 26 percent workforce which account for around of 130.5 million people.[12] To estimate the size of Ayurveda economic footprint, Table 2 attempts a very basic minimal summary of INR 57,117 crs. Ministry of AYUSH, Government of India enjoys a budget of INR 2,122 crs.[13], we should safely say that this relegates AYUSH sector to still being a 'cultural nuance' and not a coparcener in the National Health Programme.

The incomes of Ayurveda Physicians have been assumed at a very subsistence level of existence.[14] Some knowledge regards gross budget of an Ayurveda teaching institution with a basic minimum capacity of 60 UG students per academic year has been relied upon for the above estimate. The State budgets for Ayurveda or AYUSH have not been factored in. The incomes of all employees in the Ayurveda Industry, related trade channels and commerce from medicinal plant trade have been assumed to be within the gamut of assumed industry annual turnover.

Global Trade

Export statistics from PHARMEXCIL have been relied upon in Table 3. We understand PHARMEXCIL have their source from DGFT HS Code data. The sector exports have been collated to be US$ 423.12 million or INR 3173.42 crs for the year 2019-20.

Export data from PHARMEXCIL for the past 10 years shows a US Dollar stagnant export amount. No phenomenal growth or demand is seen here. The

Table 2: Ayurveda Commerce

Sector	Estimated Size per unit	Total
AYUSH Industry	25,000 crore**	25,000 Crs.
254 Colleges*	5 crore per college per annum**	1,270 Crs.
Vaidya's 478750*	6 lakh per Vaidya per annum**	28,725 Crs
Ministry of AYUSH Budget 2020-21	2,112 crore*	2,122 Crs.
Total Minimum Commerce		**57,117 Crs**

Source: *Ministry of AYUSH, Govt. of India. **Author's estimates based on minimalistic assumption drawn from industry experience/association.

Table 3: Global Trade

Ayurveda Sector	Exports (USD Million)	Exports (INR Crore)
Medicines for Retail Sale	126.06	945.50
Medicines in Bulk	16.15	121.12
Herbal Extracts & Crude	280.92	2106.90
Total	**423.13**	**3173.42**

Source: PHARMEXCIL.

incidence of export efforts in medicinal plants or standardized herbal extracts have met with some global interest but over the years there has been no monumental addition to export trade. It is also known that the export of medicinal plants is driven hugely by global demand for *Isabgol* and *Senna* pods, almost 80 per cent of the exports[15]. These two medicinal plants have nothing in common with the Ayurveda element in exports; it's purely dietary and phyto chemical demand from overseas buyers. There is no real export drive for medicinal plants or standardized herbal extracts emerging from Ayurveda, which have borne fruit.

The export of medicines, dietary supplement, herbal powders, put up for retail sales or exported in bulk for repackaging has also remained stagnant. Lack of regulatory recognition for Ayurveda is a major factor that impedes the exploitation of this global interest in all things natural and non-pharmaceutical. The recent acceptance of traditional medicine in countries like Switzerland, Canada, Oman and in some measure in ASEAN Trade block, are opportunities for exports from the Ayurveda sector. Very often Traditional Chinese Medicine (TCM) has been a comparator with regards Ayurveda potential for global trade. There is no real study of what the comparative trade statistics would show.

Exports from the Ayurveda sector can be divided into two types: i) demand for medicinal plants and standardized herbal extracts for their phytochemical compounds ii) Ayurveda medicaments. Given the absence of any blockbuster 'drug' from Ayurveda in India as yet, Ayurveda exports would have to be in the paradigm of 'whole sector' approach of science, diagnosis, health delivery, services and medicine. This approach riding on an extended 'Yoga' fad world over can have early reception but for 'medicine', 'medical service', disease – disorder treatment to Cure & Mitigate, there is a lot of traditional science to be translated into modern syntax. This is not impossible though this has not been attempted till date. The faster India adopts a 'whole systems' approach for exports and global propagation of Ayurveda the earlier it can realise its potential to global health care. For this domestic preparedness is the key, and inter-ministerial cooperation and coordination essential. The reference here would include the Ministry of AYUSH and Ministry of Health and Family Welfare working in sync to address many reasons of mortality and disease affecting the population. Recent experience with reference to COVID-19 Protocols shows that whilst 're-purposed' chemical molecules were 'tried' for their treatment of COVID-19, even celebrated, only to be withdrawn, there was little opportunity or no interest in Ayurveda 'empirical' treatment approaches. The lack of support as mentioned above would mean that the bloom of global trade from Ayurveda or its contribution into a robust GDP US$ 5 trillion would be a deferred realisation. The policy framework in the health sector of India is not encouraging for the growth and emergence of Ayurveda.

Research & Development (R&D)

India spends 0.70 per cent of its GDP on R&D.[16] Budget for CCRAS is INR 276 crs.[17] With the assumption that almost 50 per cent of this budget is for salaries and wages, it implies very little developmental

capacity in this premier research institution. It is to be noted that several clinical trials are registered with CTRI for "Ayurvedic" interventions. Recently all allied Government departments and research organisations were asked to develop their revival of 'swadeshi' science mandates. With regards to Ayurveda, not much is seen on the horizon or not much is going on. In the private sector, there is no real estimate of R&D spending. We do know that the industry is engaging in validation studies for its drug rationale translation in modern medical terms but a disease treatment or cure protocol is still absent. Ayurveda drugs in market are - 'good for …', 'aid in management of …', adjuvant palliation in disease management but there is no real claim statement of benefit that the medical fraternity relies upon for Ayurveda medicines. Despite INR 25,000 crs. of commerce, the appreciation of Ayurved as a science and the attribute of 'cure' is continually denied by modern medicine lobbies. 'Wellness', 'Preventive' and 'Promotive' are surrogate pluses bestowed to Ayurved, but 'drug' for 'cure' is denied, it's a crafted side-lining in stature with substantial influence on health policy diktat. The whole approach of research in Ayurveda must recognize its 'empirical' stand point of being a 'whole systems approach'. Systems biology is an approach that recognizes this approach and medical research in developing protocols with multi drug interventions, sometimes including treatments like Panchakarma or even Yoga, need to be considered. There is no monetary exclusive gain in generic classical approaches for industry and quest for being pioneer for a drug discovery phenomenon has not yielded any success so far, one must admit it may not be possible. Ayurveda classical approach that has seen its relevance through the ages is on basis of a 'whole system' approach and not a blockbuster drug discovery commercial success. Given even the meagre attention of research to Ayurvedic medicinal plants, scientists prospecting flora for compounds for decades, the plight of waning pipelines of 'new drugs' in modern pharmaceuticals, can indicate 'not much to report here'. Its best India's research policy and Ayurveda sector reflect on its traditional standpoint and in earnestness undertake era relevant translational science to present itself on its own pharmacology rather than be hopeful applicants for a 'new drug' source.

Broadly, little or no research reflecting the core essence of Ayurveda approaches which has added experiential wisdom to the principles through the ages is taking place. Ayurveda the manner in which it is practised in clinics every day, is not the subject of much Research agenda today. For Ayurveda to emerge as an active coparcener in the National Health Program such protocols are the need of the day.

Potential Economic Impact of growth in Ayurveda Sector

Ministry of AYUSH, CII, FICCI and some other industry associations have touted a target of the sector emerging to an economic size of INR 1 lac cr. by 2025. Even if the start point is INR 25000 cr. or INR 57000 cr. the achievement would be manifold and of high impact. Even if the target is delayed from 2025 to 2027, the analysis carried above that shows the potential for growth in AYUSH and what it means for sectors such as agriculture, employment, global propagation of Ayurveda, education and vocational options to students, and availability of

medical practitioners to our population. All the numbers projected above have not been modelled on any economic growth matrix but simply forecasted as a possibility based on bare minimum and realistic assumptions.

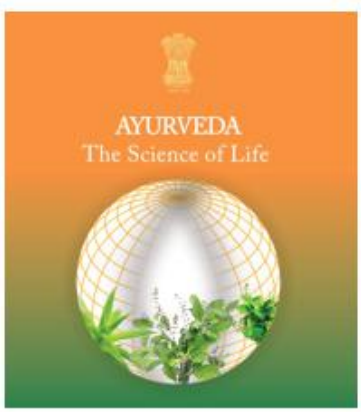
The Way Forward

A slight indication of benefit by Ministry of AYUSH echoed by the office of the Prime Minister saw phenomenal growth in certain product segments in the Ayurveda industry. Basic research and validation of a 'whole systems approach of Ayurveda' is also being brought to the fore. The focus could be protocols in managing chronic and non-communicable diseases and disorders, which have been strong points of experience from Ayurveda treatment throughout the ages. Modern medicine admittedly has little or nothing to offer in such medical segments. Ayurveda in principle can make and does make a difference in primary health care. Ayurveda is a science that employs basic principles to deliver benefit at the discretion of the practitioner. It has been misunderstood to be 'individualistic medicine', which it is from a modern medicine standpoint but not in absolute terms. There is every possibility of assessing standard groups, degree of disease progressions and prescribing standardized treatment and medicine protocols. The more we employ basic principles of diagnosis, document, review and refine the better will be our ability to employ this in public health. A cursory listing of national disease burden and Ayurveda strong points indicates a huge role Ayurveda can play in managing these health challenges.

'National Dossiers' is a validated approach to disease & disorder treatment and cure. This should be an end to end compendium of standards and norms for managing disease and disorder. Such protocols being the subject of curriculum in Ayurveda colleges would see patronage, data and refinement over time. This economic benefit will flow to every stakeholder in the Ayurveda sector. National Dossiers will also address a much-needed standardization in manufacturing for industry, alignment of

Figure 3: National AYUSH Dossiers

- Mother & Child Health
- Malaria, Dengue & all types of *Jwar*
- Cancer palliative care
- Cardiac Care
- Diabetes Management
- Thyroid & Blood Pressure management
- Sports Medicine
- COPD & Asthama
- Geriatric medicine



Note: This table is a cursory listing and not a comprehensive scope.

efforts to bridge the gap between supply and demand of medicinal plants, validated claim statements, medical integration with cross referencing or adoption of Ayurveda across medical practitioners

The faster we pursue a 'whole system' approach for Ayurveda acceptance the easier it would be to enjoy the benefits of this traditional medicine towards healthier, wholesome, longer and happier lives.

Database exists in national and state charts regarding direct and indirect taxation, public expenditure, regulatory licensing, EXIM trade, census and many more such and like data charts. However, data on the Ayurveda sector or AYUSH as sector have not been captured in these data charts. This is a serious lacuna that impacts any further effective policy strategy for growth. Going forward 2020 for a sector like Ayurveda or AYUSH, an absence of 'Profile' cannot be stressed more.

Further clarity on the several traditional components that have been included in AYUSH as a result of policy compulsions is required. Inclusion of Homeopathy as component of 'Indian systems of medicine', is a caveat as it originates from Germany. This complex milieu needs its own paradigm for a deeper understanding and in coming times the phenomenon called – AYUSH, would need an intense detailing on advantages and standpoint, for India first and its global echo thereafter. The fine line of indigenous systems, homoeopathy, and the advantages of each stream of traditional medicine is not very clear. Even to policy maker and Ministry of Health or Ministry of AYUSH, it would still be an unknown 'potential', medical heritage at best.

This is where the need for a Profile becomes imperative. It brings out the core syntax of this colossus called 'AYUSH' with the objective of further streamlining of the sector.

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Traditional Medicine in India: Regulations and Trade

T. C. James*

T. C. James

In recent years, there has been an upsurge in the global interest in Traditional Medicine (TM) as an effective alternative to the modern system of medicine. The World Health Organisation (WHO) has also been taking a keen interest in the development of TM. India is one of the few countries that had introduced regulatory systems for TM quite early. It had national laws and regulations on TM from 1940 onwards which were updated several times. The AYUSH/ISM industry is also quite large. There are 8,954 manufacturing units registered with the Ministry of AYUSH.[1] A 2018 industry report by the Confederation of Indian Industries (CII) estimated the Gross Market Size of just the Ayurveda sector to be Rs. 30,000 crore. During 2017-18, India exported USD 330.18 Mn worth of herbs and USD 456.12 million worth of AYUSH and Herbal products.[2] With the spread of Indian diaspora in other countries, the demand for ISMs has grown in those countries. Most of the traditional system formulations are based on plants. India is estimated to use around 7500 plants. However, the easy availability of medicines and herbs gets hampered by regulations within India and the export destinations. In this paper, a brief review of such regulations that have a material effect on trade is being made.

Regulations and Standards

Of late, issues of "safety and efficacy, as well as the quality control, of traditional medicine and complementary and alternative medicines have become important concerns for both health authorities and the public" (WHO, 2005). The

* Visiting Fellow, RIS and and Member Secretary, Forum on Indian Traditional Medicine (FITM)

latest WHO Traditional Medicine Strategy, 2014-2024 shows that quite a good number of countries are now recognising TM as an integral part of healthcare and bringing out rules and regulations on the same. There are as many as 124 countries that have laws and regulations on herbal medicine. In the USA and Europe, herbal medicines form a major chunk of over-the-counter (OTC) drugs. In Germany, the pharmaceutical companies sell almost one third of all non-prescription drugs as herbal medicines (Vasisht and Kumar, 2002). As of 2018, around 65 per cent of member states corresponding to 125 countries reported having a registration system in place for herbal medicines. In 60 countries, herbal medicines are sold as prescription medicines, whereas in 79 countries they are sold as OTC or self-medication drugs. Generally, TM does not find a place in the list of national essential drugs in most countries. However, herbal medicines are included in the list by 34 countries.

Regulations in India

The Drugs and Cosmetics (D&C) Act, 1940[3], the Drugs and Cosmetics Rules, 1945 and the Drugs (Control) Act, 1950[4] contain the drug regulations of India. They prescribe the legal requirements for the manufacture, import and sale of medicines in Ayurveda, Siddha and Unani systems, among others. They relate to regulating the quality, safety and efficacy of the medicines. The D&C Act has very specific provisions regarding quality, standards, branding and regulations of manufacture. It also provides for an Ayurvedic, Siddha and Unani Consultative Committee to advise the governments and a Technical Advisory Board to bring uniformity in the matter of administration of the Act throughout the country.[5] It defines misbranded, adulterated and spurious drugs.[6] Labelling has to be in the prescribed manner. Manufacture, sale and distribution of any drug against the licence conditions and standards are prohibited.[7] Under the D&C Act, the Central Government has also the power to prohibit in the public interest the manufacture, sale, etc., of any ISM medicine, which does not have the therapeutic value claimed for the same. The Act also empowers the central and state governments to appoint inspectors for ISM drugs.[8] Manufacture for sale or distribution in contravention of the provisions of the Act is punishable with imprisonment for upto to one year and in the case of spurious drugs, upto three years.[9] The Drugs and Cosmetics Rules, 1945 lay down the details, that include, among others, standards such as of strength, quality and purity.[10] The manufacturing units have to comply with Good Manufacturing Practice (GMP). Approximately 7488 units have complied with GMP by 2017.[11]

There are also very specific provisions in the Rules regarding labelling, packing and limit of alcohol in Ayurvedic (including Siddha) or Unani drugs.[12] The label should display the true list of all the ingredients used in the manufacture of the preparation. In the case of drugs for export, (a) name of the Ayurvedic, Siddha and Unani drug (single or compound formulations); (b) the name and address of the manufacturer and the number of the licence under which the drug has been manufactured; (c) batch or lot number; (d) date of manufacture, along with the date for "Best for use before"; (e) main ingredients, if required by the importing country; and (f) the words "for export"[13] are to be included. Expiry dates have to be prominently stated on the labels/containers of drugs.[14]

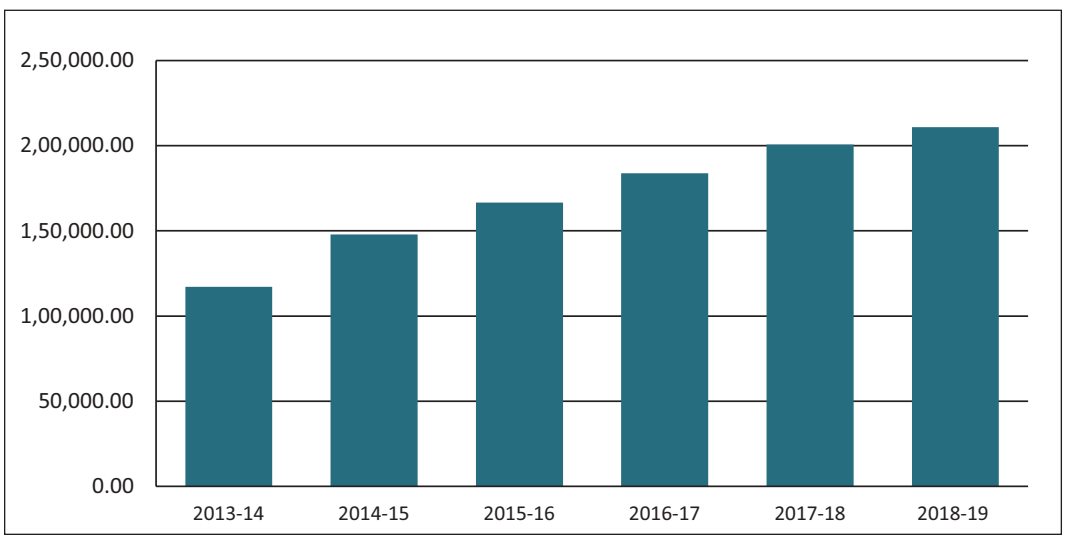
Production and Trade

The sale of medicinal plants is taken as a fair indication of the production and trade in medicinal formulations, medicinal plants being the resource base. India has approximately 15,000 medicinal plants of which about 6000-7000 plants are used in Indian Systems of Medicine; 960 of these have been recorded in trade and 178 are traded in high volume, i.e. in quantities exceeding 100 Metric Tonne (MT), per year, according to the Ministry of AYUSH. The market size of medicinal plant in 2019 was estimated to be Rs. 4.2 billion.[15] But these medicinal plants could also be used for the preparation of crude drugs and extracts also used as raw material by the pharmaceutical industry. It has been estimated that about 880 medicinal plants are involved in the Indian trade. Of these, 42 species are imported and 48 species are exported (Sen and Chakraborty, 2015).

Indian exports of 'TM' generally comprise three categories: the first one is the medicinal plants and herbs as such, the second one, saps and extracts and the third one, formulations. The first category generally includes raw materials without any value addition and one does not know how the products end up, whether in medicinal preparations or in some other form. In some cases, they may be used as such, for example, as spices in food preparations, but mostly end up in industrial use. A major item in this category is Isabgol (psyllium husk and seeds). The second category comprises herbal juices and vegetable saps. This involves some value addition. The third one is supposed to be the real TM export. From India, mostly Ayurvedic and Unani preparations are exported. But the large exports are in the categories of vegetable saps and extracts and raw plants. (see Figure 1).

The exports of Medicaments of AYUHS systems saw a decline from the year 2013-14 to 2014-15 (Figure-2). This

Figure 1: India's Exports of Medicinal and Aromatic Plants



Notes: Value in Rs. Lakh (1 lakh = 100,000). Values reported for export of items under HS 1211.

Source: Export Import Databank, Ministry of Commerce

fall was in line with the general decline in exports of pharmaceuticals in that year. But from thereon, the exports of AYUSH medicaments have shown a general increase.

In the case of imports of raw MAPs, we have seen a huge increase in terms of value in the year 2018 and 2019 (Figure-3). It should be noted that India generally runs a trade surplus in the exchange of medicinal plants, but that gap has been vastly reduced in the past two years.

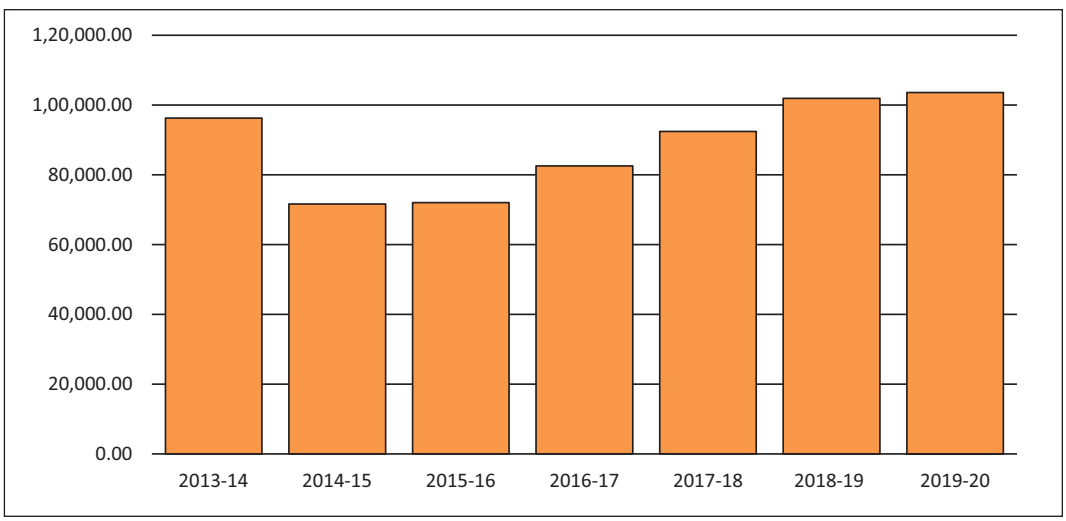
Trade Classifications

Trade classifications for TM remain a major bottleneck in trade data. The four-digit and six-digit HS code classifications have global acceptance but they do not provide targeted data on TM exports and imports. HS code 1211 relates to botanical drugs but includes plants and plant parts used in perfumery, pharmacy or for insecticidal, fungicidal or other similar purposes. In the sub-categories, they refer to certain commonly traded commodities such as Liquorice roots (1211.10), Ginseng roots (1211.20), etc. Even within these formats, there is no universal availability of trade data on all TM products. India has been following an eight-digit classification model, which includes TM systems such as Ayurveda, Siddha and Unani besides biochemical compositions and others.[16] The issue starts with evolving comprehensive classification codes for biological resources, including plants and their parts, since the trade in raw materials is both as whole plants and as parts of a plant, and many of them are TMs in themselves.

Trade Barriers

European Union (EU) and the United States of America (USA) are the major markets for trade in TM products outside BRICS. In herbal products, they have a market share of 41 per cent and 20 per cent, respectively in value terms

Figure 2: India's Exports of Medicaments of AYUSH Systems



Notes: Value in Rs. Lakh (1 lakh = 100,000). Values reported for export of items under HS 30039011-14 and 30049011-14.

Source: Export Import Databank, Ministry of Commerce

(Deshpande, 2015). Hence the regulations in these two trade zones are material to any consideration of international trade barriers.

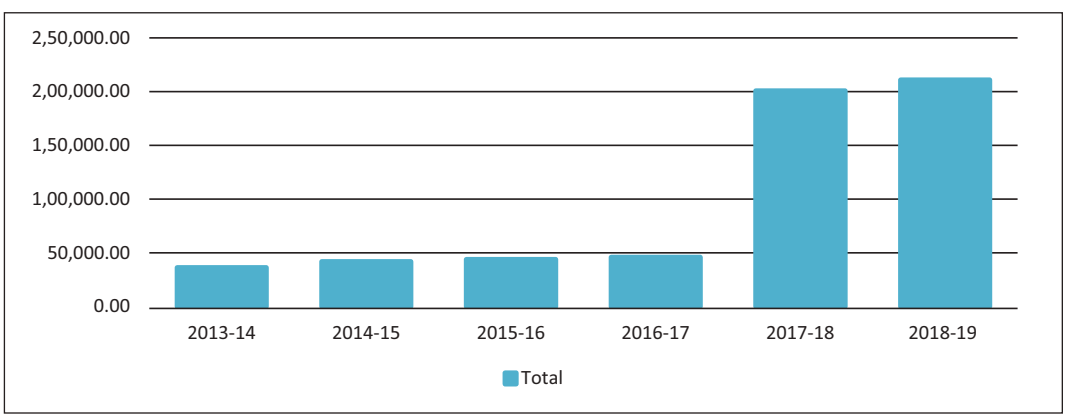
European Union

Europe regulates herbal medicinal products under the European Directive 2001/83/EC. The European Union Directive 2004/24/EC on traditional herbal medicinal products amended the provisions of the 2001 Directive to provide for a simplified regulatory approval process for herbal products. This Directive has added the following categories in the definitional article: traditional herbal medicinal product, herbal medicinal product, herbal substances, and herbal preparations. The Directive has provided for the establishment of a Committee for Herbal Medicinal Products (HMPC). Although, in 2004 the regulations simplified the registration procedure there are still many regulatory barriers where ISM products may not be able to get the registration. Some of the ISM products may contain mineral components or animal products or herbal constituents, which will debar them from registration as traditional herbal medicinal products. The requirement for registration is that the products are to be taken without supervision by a medical practitioner. Most ISM drugs are to be used under the supervision of a medical practitioner of that branch.

United States

The US is using the term complementary and alternative medicine (CAM).[17] The National Centre for Complementary and Alternative Medicine (NCCAM) defines CAM as "a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine." Complementary medicine is used together with conventional medicine, whereas alternative medicine is used in place of conventional medicine. Botanical products, depending on the circumstances may be regulated as drugs, cosmetics, dietary supplements, or foods. The US was the first country to introduce Global Manufacturing Practice (GMP) regulations covering herbal medicines through the

Figure 3: India's Imports of Raw Products



Notes: Value in Rs. Lakh (1 lakh = 100,000).

Source: Export Import Databank, Ministry of Commerce.

Drug Amendments of 1962.[18] In 2007, the FDA issued mandatory current good manufacturing practices (cGMP) for dietary supplement manufacturers and distributors.[19] Most of the developed countries prefer to have standardisation of herbal drugs, as to quality, efficacy and safety. Many of the exporters to those countries face issues on these grounds,[20] but adaptation to the changed conditions will have to be made and responsible governments will have to reassure their people that marketing permissions are given only for medicines, drugs or food items which are safe for human or even animal consumption.

The Way Forward

The global herbal market is projected by different agencies to grow to $ 5 trillion by 2050. The goods for trade include medicinal formulations, medicinal and aromatic plants, plant material extracts, plant materials, spices, herbs and cosmetics and dietary supplements. This throws open wide opportunities for countries with vast biological resources like India. According to data available from the Ministry of Commerce, Export- Import Databank, India's export of medicaments in AYUSH constitute less than 1 per cent of India's total export of pharmaceuticals in value terms. Moreover, the exports of Medicaments of AYUSH registered a Compounded Annual Growth Rate (CAGR) of just around 1 per cent between 2013-14 and 2019-20 compared to CAGR of 7.99 per cent registered for the total pharmaceutical sector. That would mean the export of Indian TM is not a significant proportion of India's pharmaceutical exports.

If TM systems have to emerge as alternative or complementary to conventional systems, they will have to be put on an even keel with the conventional system in human resource and infrastructure. For this, it should ensure the availability of qualified practitioners, researchers and regulators of TM. For this, more educational and research institutions will have to be established. With industrialisation and wide spread use of insecticides and pesticides, the quality and purity of raw materials, viz. plants and plant parts, used in TM formulations is emerging as a subject that may affect the quality of the medicines. Not being laboratory created or industrially produced synthetic chemicals, maintaining the same quality in TM formulations with raw natural or semi-processed natural ingredients is a challenge in itself.

An issue in the raw material sector is the shortage of genuine and uncontaminated herbs and plants that go into the making of medicinal formulations. This can be met only by incentivising farmers to grow more medicinal plants, maybe on a commercial scale. The creation of reliable and comprehensive statistical databases on raw materials is a *sine qua non* for the TM formulation industry. It will also be a boost to the agricultural sector. Drug master files and national dossiers on each plant need to be developed to convince the world that TMs are not mere hearsays but proper and time-tested systems.

The major difficulties in regulating herbal medicines identified in the WHO Survey are to some extent applicable to the TM sector as a whole. These include lack of research data, lack of appropriate mechanisms for control of herbal medicine, lack of education and training and lack

of expertise within the national health authorities and control agencies. These are issues that are amenable to solutions with adequate governmental or regulatory interventions. Legislative and executive initiatives are required. Educational and research institutions will also have to be strengthened.

In order to get wider acceptance globally for TM, countries like India should first integrate its own TM systems such as Ayurveda into the mainstream. TM manufacturers and traders will have to adjust to current regulations and standards in all countries. This includes ensuring quality and safety standards for products, processes and practices. GMP certification is increasingly becoming a necessity. Proper documentation, certification of quality and standard analysis, etc., are required increasingly. Along with such measures, they also need to press for international trade classifications that recognise different medicines in different systems, raw materials, etc. separately.

Standardisation faces many hurdles on account of difficulties in the identification of plants, genetic variability, variations in growing conditions, diversity in harvesting procedures and processing of extracts, and lack of information about active pharmacologic principles (Kumar et al., 2016). But with the development of a proper database these issues can be successfully addressed.

In order to satisfy quality concerns, clinical trials using modern technology are also required to obtain marketing approvals as medicines in countries, which are not countries of origin of such TM. However, new and separate protocols for such trials will have to be developed since current ones are essentially for synthetic chemical or biomedicines. As the TMs are mostly proven therapies through long usages and without serious adverse side effects, though no clinical trials in the modern sense had been done in the past, the risks for volunteers are much less than in the conventional pharmaceutical sector.

As a trade strategy, the priority will have to be on those items that have less difficulty in getting registration and marketing approvals in other countries. This will help in establishing market presence and once that is achieved, spread and penetration will be easier.

Conclusion

India can significantly improve its healthcare by exploring the scope of the traditional systems of medicine), which are cost-effective compared to the modern medicinal system. The TM's general approach is to aim at comprehensive and wholesome wellness of the patient by removing the infirmities in the individual's system caused by the impact of environment, food and habits. To achieve that, the medicinal formulations industry, including the raw material sector, has to be developed and sustainable access and trade in the products have to be encouraged. While ensuring quality and standard, the regulations have to take into account the differences and distinctions with the conventional health care sector and the peculiarities of the TM systems.

Endnotes

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2 PIB, 2019. Export of Herbs and Herbal Products. Press Information Bureau of India: https://pib.gov.in/Pressreleaseshare.aspx?PRID=1558955

[3] Drugs and Cosmetics (D&C) Act. No. 23 of 1940. The Act has been amended a number of times, the last one being of 2008.

[4] Drugs (Control) Act, No. 26 of 1950.

[5] Drugs and Cosmetics (D&C) Act, 1940, Section 33D.

[6] Ibid, Section 33E, Section 33EE, and Section 33EEA.

[7] ibid, Section 33EEC.

[8] Ibid, Section 33F and Section 33G.

[9] Ibid, Section 33(1)b.

[10] The Drugs and Cosmetics Rules, 1945. Rule 111

[11] Outlook India. 2017. 1,179 ASU&H drug manufacturers not compliant with GMP: Govt. Online at: https://www.outlookindia.com/newsscroll/1179-asuh-drug-manufacturers-not-compliant-with-gmp-govt/1212369

[12] The Drugs and Cosmetics Rules, 1945. Part XVII

[13] Ibid, Rule 161A

[14] The Drugs and Cosmetics Rules, 1945. GSR 764(E) dt. 15.10.2009.

[15] Muringatheri, M. 2019. Medicinal plants in good demand. The Hindu. Online at: https://www.thehindu.com/news/national/kerala/medicinal-plants-in-good-demand/article30239519.ece

[16] ITC is an 8 digit product classification code used in India only which is a modification of 6 digit HS code (also known as HTS Harmonized Tariff Schedule) used all over world.

[17] Public Health Service Act [42 U.S.C. 262 (a)(1)]. Section 351 (a)(1)

[18] FDA. Guidance for Industry: Current Good Manufacturing Practice in Manufacturing, Packaging, Labelling, or Holding Operations for Dietary Supplements; Small Entity Compliance Guide; 2010.

[19] Therapeutic Goods Administration, Department of Health, Australian Government. 2012. Pan Pharmaceuticals Limited: Regulatory action & product recall information. Online at: https://www.tga.gov.au/product-recall/pan-pharmaceuticals-limited-regulatory-action-product-recall-information

[20] Some of the suggestions in this section are based on the discussions in an informal consultation organised by RIS in preparation to the BRICS Wellness forum in which many prominent AYUSH industry people and academics participated. We are especially thankful to the suggestions made by Dr. R B Puranik, Dr. D C Katyar, Dr. Ashok Pandey, Dr.Vaidya Vinod and Dr Ramanathan.

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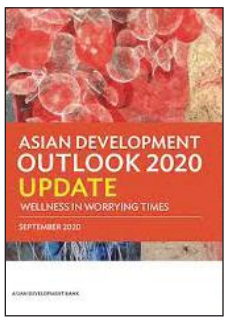
Wellness in Worrying Times – The Asian Development Outlook 2020 Update



Unnikrishnan Payyapallimana *

Unnikrishnan Payyappallimana

https://www.adb.org/what-we-do/economic-forecasts/september-2020/theme-chapter

"Wellness in worrying times", a report released by the Asian Development Bank in September 2020 is part of the Asian Development Outlook 2020 Update. One of the key focus areas of the Outlook is the GDP contraction rate of 0.7 per cent in the region for 2020, owing to the pandemic, which the report claims is first of its kind for the region since the 1960s. In this context, the theme chapter explores the concept of wellness during the pandemic and possible pathways to wellness in the post-pandemic recovery period in Asia. The report discusses wellness both as a driver of economic growth, recovery and sustainability as well as a desired outcome.

What is of relevance to the Forum on India Traditional Medicines (FITM) as well as the AYUSH community is that the report highlights traditional medicine and allied knowledge practices as key resources for rebuilding the economy and society in the region. In 2016, RIS came out with a publication, "Health, Nature and Quality of Life – Towards BRICS Wellness Index" which defined contours of wellness as "a unified paradigm that looks at quality of life, covering aspects of access to material resources, opportunities, conditions of healthy living, and environmental sustainability…" (RIS, 2016). This publication had a series of well-articulated perspectives

* Visiting Fellow, United Nations University-International Institute for Global Health, Kuala Lumpur

and experiences from countries such as Brazil, Russia, India, China and South Africa. It also proposed a framework for a wellness index for these countries. In July 2019, FITM also brought out a policy brief titled "Special Wellness Zones for Wellness Tourism - Exploring prospects of creating dedicated ISM hubs" which highlighted the increase in lifestyle diseases and the potential of traditional medicine in wellness tourism in developing countries as a major driver of growth (FITM, 2019). It extensively discussed the strategic potential of wellness and various related pathways for the country from the perspective of AYUSH and other rich cultural health traditions. The ADB report should be read in the context of these parallel efforts that were taken in India in the recent years. It also assumes importance when the Ministry of AYUSH has taken up key initiatives to convey the message of wellness in COVID-19 times through national advisories and protocols.

In Asian countries, wellness economy forms 11 per cent of the economic output with an annual growth of 10 per cent in the recent years (ADB, 2020). The ADB report starts by highlighting the public health impacts, both physical and mental, during the pandemic. It showcases how the pandemic has accentuated the importance of engaging with wellness, or "the deliberate pursuit of activities that bring holistic health, happiness and wellbeing." This report analyses how wellness had assumed a critical position in the Asian economy even before the pandemic due to the growing relative affluence and disparities in the region, attendant lifestyle changes, and health issues. It more specifically dwells on the new vulnerabilities, physical, mental as well as the socio-economic, in the wake of COVID-19. Interestingly, the report calls attention to the rich traditional health practices and productive cultural assets of the region which form a key resource for wellness and the need to revitalize these practices in a strategic, science-policy-practice approach. The report offers four policy domains to be addressed such as: healthy environment and liveable places; enabling improved physical activity; healthy diets and enhancing workplace wellness. It also touches upon the poor and the marginalized populations who have limited opportunities for wellness engagements and how governments should take affirmative actions for the benefit of such communities.

The first chapter starts with an extensive discussion on the conceptualization and definition of wellness, its links to social, environmental, and economic dimensions of sustainability, and how it has been toppled due to the unprecedented impacts of the pandemic. In the following section it quantifies multiple sectors (ten of them) related to wellness and extensive cross-country comparison of the wellness economy in the region. The third section on 'holistic pathways to physical wellness' highlights the emerging regional public health challenges in terms of physical inactivity, unplanned workplaces, infrastructure and planning, and malnutrition (both undernutrition and obesity). The next section on mental wellness describes the strength of Asian wellness traditions and the need to capitalize on them. The subsequent two chapters focuses on wellness as a development indicator and inclusive growth and key policy directions towards advancing it.

The report compares various indexes such as the HDI, OECD Better Life Index, Indigo Wellness Index, Social Progress Index, Happy Planet Index, and Inclusive Green Growth Index. The report says that Asia's wellness indicators are close to the world average yet fall below OECD countries as well as Latin America and the Caribbean states. In South Asian Wellness Index coverage and scores, India (38.96) appears weak just above Afghanistan and Pakistan in comparison to more progressive countries like Sri Lanka (69.29) and Bhutan (67.03).

The ten sectors reflected upon extensively with systematic data include Personal care, beauty, and anti-aging; Physical activity; Healthy eating, nutrition, and weight loss; Wellness tourism; Preventive and personalized medicine and public health; Traditional and complementary medicine; Wellness real estate; Spa economy; Thermal and mineral springs; Workplace wellness. These are mostly very relevant to the AYUSH sector as well as the Indian economy in general. It estimates that more than 50 per cent of the Asian population utilizes traditional medicine (TM) habitually and the usage is higher in rural than urban areas. Interestingly, in relation to TM usage it talks of a bimodal curve high at both extremities but lower in the middle, examined by income and educational factors. More affluent and educated have better appeal for promoting health, prevention and wellness. By highlighting the exclusive nature of knowledge systems and challenges in the model of care, it calls for a better integrative model of traditional and modern medicine in Asian countries to maximize synergies and potential of the two. By quoting GWI (2018), it says "Wellness tourism expenditure in the region, for example, grew by 11% annually in 2015–2017 to $136.7 billion. The industry directly employed 3.74 million in India, 1.78 million in the PRC, and 530,000 in Thailand."

Excitingly the report has a significant focus on "the ancient spiritual traditions, healing modalities, and life philosophies—including yoga, ayurveda, traditional Chinese medicine, tai chi, reiki (energy healing), meditation, herbal medicines, and ikigai (Japanese "reason for being")—which are deeply ingrained in culture and daily life" of the region. By contrasting the medical (which is reactive) and wellness (proactive) paradigms, it says that what is desired is not just a disease-free neutral state but an advanced stage of prospective optimal health. It also highlights the issue of the relatively low subjective (self-reported) happiness in the Asian region. It comprehensively touches on the gender dimension of wellness sector and inclusive growth and says women have better stake in the sector as consumers, service providers, knowledge holders, and drivers of growth.

On the flipside, the report harps much on the documents of the Global Wellness Institute while giving limited focus on the national and subnational efforts of the States in the region. It has a dearth of focus on the broader areas such as structural determinants of health and wellness, other socio-political dimensions such as freedom, capabilities, plurality, equity, access, rights, social security, all of which are factors that empower individuals towards wellbeing as articulated sustainability discussions. It is rather reticent over the direct negative drivers such as unclean water, sanitation, air, tobacco, alcohol, unsafe roads which are critical for optimal health. The report is also silent on the broader emerging

intersectoral perspectives of global public health which are squarely relevant to wellness such as the one health, eco-social health, planetary health, biodiversity and health, and so on. While there are critical discussions on localizing SDGs it would have assumed additional value if it had a slightly more detailed analysis from the framework of SDGs. While discussing the policy environment the report is also silent on the WHO 2023 strategic goals such as the triple billion goals where "1 billion more people enjoying better health and well-being" and Healthy Life Expectancy are key aspects. Most importantly though the report in passing refers to the growing socio-economic disparity in the region, it is largely silent on specific pathways to address them even hinting at an affluence bias of the wellness sector

As per the FITM policy brief, "India's wellness market, estimated at INR 85,000 crore, is expected to grow at a CAGR of 12 per cent between 2015 and 2020. With this growth rate the wellness industry in India will reach at INR 1,50,000 crore by 2020" (FITM, 2019; FICCI, 2016). In light of this newly emerging interest in wellness, it is noteworthy that many Indian national policies have wellness as a key focus - the National Health Policy 2017 (*Health and Wellness Centres – AYUSH Wellness clinics as part of Ayushman Bharat*), National Education Policy (*Health and wellness in education and educational facilities; medical education and wellness*), National Mental Health Policy 2014, National Policy for Skill Development and Entrepreneurship 2015, National policy for Women 2017, to name a few. It is also important to note that the Ministry of Tourism, Govt. of India has created a "National Wellness and Medical Tourism Board to act as an umbrella organisation to promote wellness tourism in India in an organised manner (FITM 2019)".

In conclusion, by bringing out this report at a critical time of the pandemic, ADB should be able to create better cross cutting imagination and traction of an 'adaptive lifetime framework for wellness policy' as well as more broadly towards building health and wellbeing for all at all ages!

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Traditional Medicine

Core IV-B, Fourth Floor, India Habitat Centre
Lodhi Road, New Delhi-110 003, India.
Ph. 91-11-24682177-80 Fax: 91-11-24682173-74-75
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