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Recent global health crises have demonstrated that achievement of universal health care (UHC) is critically dependent on resilient and people-centred primary healthcare system (PHC). A PHC that emphasises on wellness and not merely an absence of infirmity, that takes a holistic integrative approach utilising traditional health practices, greatly reduces the burden of secondary and tertiary care through effective utilisation of infrastructure and human resources. However, the efficacy of traditional medicine in strengthening PHC would be dependent on the degree of integration in national health systems, innovations in product development and compliance to safety standards and regulations.

This issue focuses on the emerging narratives on the relevance and mechanisms for strengthening the traditional medicine sector for attaining health goals. Ritu Priya in her article reviews the approaches to PHC and traditional medicine in the current global health discourse specially in context of the Astana Declaration of 2018. She proposes some shifts in conceptualisation of health related knowledge and its pluralism, and how the concepts and operational dimensions of PHC should be updated for more sustainable and people empowering health systems. Taking the concept of plurality of health systems further, T.C. James provides the historical policy and advocacy of integrating locally available health systems and practices with modern health care in India's national health programmes. He also provides a glimpse of policy status in other countries. The plurality of health systems is reflected in the thriving systems of Sowa Rigpa and Unani in addition to Ayurveda , Siddha and Yoga, that emerged in India. Harilal Madhavan reflects on the complexities of integration of Sowa Rigpa, a cross- cultural medical system into the Indian systems of medicine. He argues that Sowa Rigpa warrants some initial state support in terms of knowledge codification efforts, mechanisms to recognize the frugal heterogeneous innovations in practices and also in utilizing the alternative protection mechanisms other than patenting. Farah Ahmed and Ghazala Javed bring out the strengths of Unani medicine and its integration in mainstream healthcare in India. With the recent strides in education, research and development and quality control enabled through the strong push for traditional medicine systems, India is emerging as a global leader in Unani systems of medicine. Anil Jauhri and Namrata Pathak highlight how strengthening of health systems with use of traditional medicines will be best served with conformity assessment

subscription attained through global voluntary standards in goods and services. Finally Krishna Ravi Srinivas's book review of Vergehse et al (edited) 'Conservation through Sustainable Use: Lessons from India' points out the key issues of inclusivity, biodiversity conservation and community rights at a time when medicinal plants sourced from forests still constitute a large proportion of raw material for the herbal industry.

I hope readers will find this issue of Traditional Medicine Review in expanding their understanding traditional medicine in the context of national and global health governance.

Sachin Chaturvedi

Traditional Medicine in Global Health Systems Approaches: A Review that Calls for Drafting of a PHC 2.0

Ritu Priya*

Ritu Priya

Introduction

In international Public Health discourse, Traditional and Complementary Medicine (T&CM) is closely linked to the Primary Health Care approach (PHC approach). Now that health care world-wide is in crisis, PHC and T&CM are gaining in salience again. It was global crises in the 1970s that preceded the spelling out of the PHC approach, again in the 2000s before the COVID-19 pandemic led to its recognition, and aggravation of the crisis during this biggest public health disaster in a century has enhanced the present resurgence of interest. This provides an opportunity to advance the integration of T&CM in health systems globally. However, we need to learn from the past achievements and limitations in approaches adopted when such opportunities had arisen in earlier times. Identifying the limitations, we must address their causes in order to maximise attainments as we chart our way for the future.

This paper reviews the approaches to PHC and T&CM in the current Global Health discourse in light of analyses of the past, to highlight the opportunities and barriers. Over the decades since the Alma Ata declaration there has been some forward movement in shifting the power of medical knowledge from doctors alone to nurses, paramedical

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cadre and communities. There has also been enhanced acknowledgement of the relevance of knowledge pluralism. Yet continuing bottlenecks in democratising the politics of knowledge in health care is identified as a dimension that requires greater attention. Demonstrating this, the paper proceeds to propose some shifts in conceptualisation of health related knowledge and its pluralism, and of how the concepts and operational dimensions of PHC should be updated for more sustainable and people empowering health systems.

Primary Health Care (PHC), Universal Health Coverage (UHC) and Traditional Complementary and Integrative Medicine (TCIM)

The 1970s and '80s

It was the Primary Health Care approach, as spelt out in the Alma Ata declaration and its report of proceedings (WHO and UNICEF, 1978) that first provided an official international approval to the inclusion of traditional medicine practitioners in community and national health systems. In the forty years since Alma Ata much literature has been generated on the benefits to people's access to health care through PHC initiatives (Dodd et al, 2019; Labonte et al, 2017; Banerji, 1999). There is also a large body of published research on efficacy studies of T&CM therapies for specific health problems or effects. This literature belies the understanding of PHC and T&CM as merely compromise options.

The PHC of Alma Ata (1978) was a strategy for reaching the goal of 'Health for All by 2000'. The PHC approach was about improving health of populations through comprehensive development and about healthcare services 'closest to home', with 'appropriate technology' that is effective, safe, cheap, and simple to use, so as to limit the need for doctor and hospital centred care. Adoption of the Alma Ata declaration led to introduction or strengthening of primary level services in large parts of the world, with a shift from the hospital and doctor centred understanding of health care to paramedics and community based outreach services becoming a prominent part of health systems especially in low and middle income countries. However, these became add-ons to the dominant hospital and doctor centred institutional care in most countries and remain peripheral to them even after four decades.

Reasons for this limited operationalisation of PHC have largely been identified as lack of political will in governments, lack of funding and lack of professional interest. As the 'causes of causes', pressures of the medical industrial complex and its commercial nexus that has promoted technology-centred and specialist services to detriment of the perception of importance of PHC and distraction from it, have been the major explanation for the above lack of salience to PHC (Navarro, 2008).

However, it has also been argued that in addition to these political economy analyses, there is the politics of knowledge emanating from the colonial history of the 18th-20th centuries that gives supremacy to the biomedical expert knowledge underlying the medical industrial complex, thereby undermines the very spirit of Alma Ata. The limitations of conventional bio-medicine that have not

been acknowledged or dealt with, the medical industrial complex referred to almost in passing, and medical pluralism not at all, reveals that the implications of the politics of knowledge have been ignored in the Alma Ata report itself (Priya, 2018). Health systems discourse still does not acknowledge this politics of knowledge which is most pertinent for PHC and integration of medical pluralism in national health systems. Therefore this is the dimension that is the focus of this paper.

In the Alma Ata report the traditional medicine practitioners were recognised as having influence on health matters within communities and "It is therefore worthwhile exploring the possibilities of engaging them in Primary Health Care and of *training them* accordingly (WHO-UNICEF,1978a, p.63; emphasis added). The intrinsic value of other knowledges than conventional biomedicine that the traditional healers practiced were not given due acknowledgement, and the issue of integrating them into national health systems was absent.

This was not due to the lack of information or thinking on the subject. An international expert group met on the subject of traditional medicine towards the end of 1977. The WHO published a detailed report of the meeting in 1978 before the Alma Ata Conference as Technical Report Series No. 622 titled 'The promotion and development of traditional medicine' (WHO, 1978). It starts with discussion on the role of traditional medicine in health care and the rationale for its promotion, including the strengths of its knowledge content as holistic and culturally rooted, which '"can and does freely contribute to scientific and universal medicine." As rationale for the utilisation of TM in national health care systems and the integration of traditional and modern medicine it cites both the 'intrinsic qualities' of the knowledge of TM and the operational reason that "it is one of the surest means to achieve total health care coverage of the world population, using acceptable, safe and economically feasible methods by the year 2000." (WHO 1978, p13-14). Discussing the challenges to integration in some detail, it makes operational recommendations including for manpower development and research in traditional medicine.

One is led to the logical questions. Why did the Alma Ata documents not pay heed to the knowledge component of TM despite such a detailed report? The examples of primary level innovations from countries such as China and India were used for drafting the Alma Ata documents, picking up the community health worker/barefoot doctor concept from there. But it ignored their experience of promoting TM in the national health systems—Why?

Evidently, the global public health community was not ready for addressing the politics of knowledge. While the Alma Ata declaration speaks of 'self-reliance' and 'acceptable health care', it does so in respect of only conventional bio-medicine. Any challenge to the knowledge supremacy of bio-medicine and its practice was not acceptable. In attempting to make the health care system more affordable and accessible to all, it was amenable to letting community health workers and paramedical workers use and promote 'appropriate technology' at primary level, thereby shifting ownership of a basic level of knowledge to them. However when they

referred higher care needs to secondary and tertiary care there was no explicit redefining of the structure and practice at these levels. The secondary and tertiary level practitioners and institutions were the unquestioned leaders of the health service system. The Alma Ata articulation of PHC seems to have refrained from explicit operational correctives for the ills and limitations in the practice of conventional medicine, inspite of strong articulation of it by that time, Illich's 'Medical Nemesis' being a well known book that put together a cogent argument based on a huge collection of evidence of the negative effects of the medical system (Illich, 1977).

In the Alma Ata articulation, despite its intent of placing 'the community' as the focus of PHC, the secondary and tertiary level practitioners and institutions were called the 'centre' of the health system from which the community health workers and communities were 'at the periphery' (Priya et al, 2019). As the quote below shows, the social periphery also becomes the health service periphery rather than its centre-point when the leadership is firmly placed in the hands of the secondary and tertiary level doctors, with the expectation of a benevolent paternalism.

"The consequence for health policy is the preferential allocation of resources to people at the social periphery in order to satisfy first and foremost their essential health care needs, for experience has shown that overall improvements in national health situations depend on improving the health status of these people. Fortified by additional resources, communities will be in a better position to accept greater responsibility for their own health, and to fulfill this responsibility through primary health care. The more specialized needs of this care will influence the type of service that has to be provided by the more central levels of the health system. The result should be stronger links between the more centrally placed health institutions and the communities they are intended to serve." (WHO and UNICEF, 1978, p.40).

This internal contradiction allowed for a continuing 'business as usual' in the secondary and tertiary services, which also remained the major image of quality health care. Without acknowledging the politics of knowledge, even PHC remains a top down approach rather than a bottom up one. For the latter, the vantage point is the community and primary level services are close to them while secondary and tertiary institutions are at the periphery (Priya, 2018; Ghodajkar, et al 2019).

In the following decades, the PHC approach itself got short shrift. The Comprehensive PHC approach that highlighted the importance of access to health care for all, from womb to tomb and addressing the wider determinants of health through other sectors of the economy, was reduced to a selective PHC approach with a package of selected interventions (Qadeer, 1995; Chen, 1988). Therefore, even while paramedic based primary level health services were developed in most Lower and Middle Income Countries (LMICs), the allopathic doctor and hospital remained the centre of the dominant vision of quality health care. PHC and TM continued to be perceived largely as second rate options included in health care systems for reasons of affordability and feasibility rather than desirability. A significant body of literature also demonstrates the lack of adequate

health systems research and development on the T&CM component of health care with only a few countries taking any initiatives in this regard, with only 23 countries having any national programme for T&CM even by 1999 (WHO, 2019).

The 1990s-2000s

The health sector reforms promoted by the IMF and World Bank undergirded by the economic development policy approach of globalisation and privatisation further consolidated the medicalised understanding of health systems. The medical technology versus public health hierarchy got aggravated over the decades of the 1980s and 1990s (Qadeer et al, 2001). This is why, in the 2000s, UHC could be conceptualised as the approach to health systems strengthening focussed on medical care alone. UHC gained wide policy acceptance, while it completely ignored the PHC approach.

In the year 2000, responding to the health care crisis of rising inequities and unaffordable costs of medical care, the international agenda became 'health systems strengthening' and the approach popularised for for this has been 'Universal Health Coverage' (WHO, 2010). Responding to the environmental, economic and social crises facing humankind, the Sustainable Development Goals (SDGs) were adopted by the UN and SDG-3 stated as: "Ensuring healthy lives and promoting well-being for all at all ages". For achieving this too, UHC has been adopted as the strategic approach (UN, 2015). However, three years later the world community that had come together in Astana in Kazhakistan acknowledged the severe limitations of UHC and reiterated the importance of Primary Health Care as an essential complement to UHC if SDG-3 is to be met.

The UHC strategy has largely been viewed as ensuring access to conventional bio-medicine based healthcare through coverage by medical insurance to 'prevent catastrophic medical expenditures' (WHO, 2010). This thereby aligns the healthcare coverage to be largely of conventional medicine provided through secondary and tertiary level hospitals. It neither addresses the determinants of health, nor does it include strengthening of the primary level care that is required for a much larger proportion of ill-health than the requirement of secondary and tertiary services. It has been shown that even the financial repercussions on out-of-pocket expenditures are more of outdoor services relative to indoor services, because of the larger scale of resort to outdoor services relative to the indoor care. While rationality of clinical care is addressed to some extent by insurance mechanisms that assess claims based on laid down guidelines of patient management for specific conditions, the USA's experience with their insurance based health system has shown that at the macro level such a system results in over-medicalisation and escalating medical expenditures (Woolhandler, 2003; Investopedia Team, 2022; Montero et al, 2022). Finally, that it tends not to include TM in its conceptualisation of health systems and health systems strengthening is of conern. While several countries have attempted to include TM services to fulfill the UHC mandate, there are strong barriers which prevent implementation of this, thereby leaving out a major health care resource from planned health systems development.

The Astana declaration attempts to fill these gaps of the UHC strategy by aligning health systems to UHC-with-PHC. The Astana declaration (2018) avers: "We are convinced that strengthening primary health care (PHC) is the most inclusive, effective and efficient approach to enhance people's physical and mental health, as well as social well-being, and that PHC is a cornerstone of a sustainable health system for universal health coverage (UHC) and health-related Sustainable Development Goals" (WHO and UNICEF, 2018a).

The WHO and UNICEF document of 2018 that provides a vision for reframing PHC as per the Astana declaration defines PHC as: "PHC is a whole-of-society approach to health that aims equitably to maximize the level and distribution of health and well-being by focusing on people's needs and preferences (both as individuals and communities) as early as possible along the continuum from health promotion and disease prevention to treatment, rehabilitation and palliative care, and as close as feasible to people's everyday environment." (WHO and UNICEF, 2018b, p. xii). It brings focus on the PHC approach:

"PHC has three inter-related and synergistic components:

- Meeting people's health needs through comprehensive promotive, protective, preventive, curative, rehabilitative, and palliative care throughout the life course, strategically prioritizing key health care services aimed at individuals and families through primary care and the population through public health functions as the central elements of integrated health services;
- Systematically addressing the broader determinants of health (including social, economic and environmental factors, as well as individual characteristics and behaviour) through evidence-informed policies and actions across all sectors; and
- Empowering individuals, families, and communities to optimize their health, as advocates for policies that promote and protect health and well-being, as co- developers of health and social services, and as self-carers and caregivers." (WHO and UNICEF, 2018b, p. xii)

The Health Sector Reforms of the 1990s and focus on UHC also distracted official attention from the ills of conventional medical practice and resurgence of TM globally. Despite that, momentum of the previous decades led to policy attention to T&CM by WHO and national governments for UHC-with-PHC. Three surveys conducted by WHO in 2005, 2012 and 2018, show that there had been movement in the official national efforts at integrating traditional medicine in the national health care systems (WHO, 2019). Yet Global Health / Public Health and Health systems research have paid scant attention to this component of health systems.

While stating its approach to PHC-with-UHC, the strategy the Astana declaration lays out on knowledge is unexceptionable:

> "We will apply knowledge, including scientific as well as traditional knowledge, to strengthen PHC, improve health outcomes and ensure access for all people to the right care at the right time and at the most appropriate level of care, respecting their rights, needs, dignity and autonomy." (WHO and UNICEF, 2018a, p.8).

In the WHO-UNICEF vision document for UHC-with-PHC, T&CM is placed as one of the several health care needs for PHC and traditional healers as one of the human resources (WHO and UNICEF, 2018b, p.xiii). Its focus is on people-centred health care and integration across the three tiers of primary, secondary and tertiary services. It elaborates on this by drawing on studies to highlight the role of T&CM as source of health care, for self-care, and integrated into primary level care for better outcomes and lower cost.

> "Traditional medicine draws on and enhances societal knowledge of health preservation and management, supporting the vision of a knowledge-based healthy society equipped for self-care *(76,77)*. In many countries, traditional medicine has been effectively integrated with allopathic interventions. Traditional medicine has been shown to be effective in areas such as NCD management, palliative care, rehabilitation, several neglected tropical diseases, mental health and the care of the elderly *(78,79,80,81)*." (WHO and UNICEF, 2018b, p.15)

Two advances in conceptualisation of PHC and health care systems that these statements indicate have to be noted.

- Acknowledgement of traditional 'knowledge' and not only involving the products, practices and practitioners. T&CM can then be integrated at the level of knowledge content to bring benefits of its intrinsic value and not only where its economic value lies.
- Linking primary, secondary and tertiary tiers of the health services together for consideration of the appropriate care at the appropriate level. This allows opening up of the secondary and tertiary levels to application of the PHC approach, ie rather than primary level alone as isolated from the secondary and tertiary. If this gets translated into real life policy and operationalisation, it will mean a major rationalisation of the hospital and specialist services in relation to patient need. The gate-keeping role of primary level services is already well acknowledged though operational challenges are obvious.

Thus, while the recent approaches to PHC-with-UHC provide the opportunity to open up the health care system to democratisation of its knowledge processes, how far the secondary and tertiary levels will incorporate PHC principles and strategies will shape the health service system of the future. This strategic shift is what has to be worked out by each country to develop integrative health systems in coherence with its own context. A major shift in mindsets and thinking about health care systems is essential to operationalise this at any appreciable scale.

Diverse Translations of the PHC Approach

Analysing the PHC discourse and experience of its implementation since the Alma Ata declaration, one finds what a previous analysis had also shown, that the Alma Ata articulation of PHC has allowed its translation into three versions of the PHC approach: (i) Primary level care with a feasible, affordable, 'essential health care' package that has become known as Selective Primary Health Care, based on primary level care and 'community mobilisation' through the campaign mode, as adopted for the RCH

and Polio Eradication programmes (Chen and Cash, 1988). (ii) Comprehensive Primary Health Care (CPHC) with primary level care as central to the general HSD and appropriate secondary and tertiary care to support it, including medical and non-medical interventions that are preventive, promotive, curative and rehabilitative. based on the bio-medical understanding of health issues, and addressing comprehensive socioeconomic development in other spheres than health services for improving population health, and (iii) CPHC as in (ii) that additionally incorporates medical pluralism including the local folk knowledge based home and community care at primary level, backed up by the institutional primary, secondary and tertiary levels (Priya, 2018). It is the advocacy and action based on the third interpretation, largely by networks of T&CM practitioners, users, and civil society supporters, that has led to the progress made by 2018 globally.

The 2020s

Post-Astana, the COVID-19 pandemic provided another opportunity for T&CM to exhibit its value and generate evidence of effectiveness (Huang et al, 2021; Lyu et al, 2021; Sujatha 2021; Sujatha and Payyappallimana, 2022). However, the World Bank, recognising the value of PHC subsequent to the experience of the COVID-19 pandemic, brought out a document on Reimagining PHC (IBRD/ World Bank, 2021) which does not even mention TM. Probably for the first time, a World Bank document specifically denounces the translation of Alma Ata's Comprehensive PHC approach into Selective PHC in the 1980s. It also refers frequently to the WHO-UNICEF vision of 2018. Despite its focus being more on the financing of personal health care and the role of PHC as a low cost option, it also discusses issues of 'integrating' PHC and public health towards building resilient health systems for dealing with pandemics in the future. Yet it does not recognise T&CM's role at all. Its 'reimagining' of PHC still seems to be closer to the Selective PHC it critiques rather than Comprehensive PHC. Meanwhile the WHO-UNICEF vision is coming closer to the CPHC-with-knowledge pluralism approach.

This difference of approaches to T&CM within global health reflects the divide between more holistic care-oriented perspectives, as of WHO and UNICEF, and the narrower economistic perspective of the World Bank. The learnings from past experience seem to have been drawn differently by the two. While the financial and governance issues are important, what kind of public health, its content and politics of knowledge are critical too. How to strengthen the conceptualisation and implementation of the WHO-UNICEF 1978 and 2018 visions is the challenge.

Integrating T&CM in National Health Systems

The two documents explicating the WHO Strategy on TM (WHO 2002; WHO 2013) provide guidance to assist countries in undertaking the process of integrating T&CM in national health systems. However, they too do not explicitly address the issues of epistemological diversity and the politics of knowledge. The operational guidance provided by them is very much in line with the mainstream systems development, as the stated goals set for the T&CM strategy themselves illustrate:

"The goals of the strategy are to support Member States in:

- harnessing the potential contribution of TM to health, wellness and people-centred health care;
- promoting the safe and effective use of TM by regulating, researching and integrating TM products, practitioners and practice into health systems, where appropriate." (WHO, 2013).

These are extremely useful measures for the process of promoting utilisation of T&CM through planned systems, for regulation of quality and safety of products and roles performed by T&CM practitioners. However, besides their 'products, practitioners and practices' there is their knowledge base, methodologies of new knowledge generation and diverse organisational approaches that makes each one a different knowledge tradition with its own strengths and limitations. Just like bio-diversity or economic diversification provide resilience to eco-systems and economies, the complementarity of knowledge forms is what can lead to more resilient, sustainable and empowering health systems globally. This epistemological complementarity needs to be appreciated and a sensitive nurturing of it will then occur through the processes of integration.

The WHO strategy approaches and recommendations, without sensitisation to the value of epistemological complementarity and attention to it in the guidance given for various relevant measures, raises concerns about the long term implications for the future of the T&CM streams themselves. Whether they will grow and develop as knowledge traditions or become mere additions to the mainstream pharmacopeia and wellness procedures? Will they only contribute to the 'medicalisation' and commercialiston of T&CM or to evolving sustainable health systems and empowering individuals, families, and communities?

Implications for Sustainable and Empowering Health Care Systems: Democratising the Politics of Knowledge

The brief narrative review presented in the previous sections makes it evident that T&CM can be formally acceptable globally and Integrated Health Systems (IHS) generated and implemented in full when the PHC approach is what becomes the dominant paradigm in health systems thinking. This must be not only for the primary level of care but for all its dimensions. And this requires a shift in the dominant knowledge paradigm for health systems.

On one hand, worthy of note is the globally increasing acceptance of medical pluralism in operational practice from individual and households to national and global levels (WHO, 2019). This is reflected in the changing terminology, from TM and Alternative Medicine of the 1970s, to T&CM and then to Integrative Medicine, and now Integrative Health Systems (NCCIH, undated; WHO, 2013). The increasing utilisation at individual and family level is a response to the growing disillusionment with the conventional medical system, as much as it is a documenting and formalisation of what was already in practice in all societies but had been invisibilised by the formal health data, research and policy regimes (Priya and Shweta, 2010). On the other hand is a continuing strong resistance to incorporating T&CM in national health

systems and programmes from quarters that espouse a mechanical positivist approach to science and to scientific evidence of what works and how.

'Big data' on health of populations collected through macro surveys or service delivery and insurance systems have become a major source of health services data. However they are unable to capture the extent of use of TM since much of it happens outside institutions in the household and community domains. These sources of data are, therefore systematically exclusionary and under-report the use of knowledge other than of conventional biomedicine. Even community based household surveys need innovative methods to elicit the use of T&CM from respondents, since laypeople often give what are considered socially accepted answers and the contemporary socialisation is that conventional medicine is the only legitimate health seeking behaviour (Priya and Shweta, 2010). Since Global Health policy generation is based on big data analyses of health problems, services and behaviours, this systematic exclusion has precluded consideration of T&CM.

However, even more difficult to overcome is the demand for 'certainty' of 'proof' of efficacy and effectiveness of T&CM health interventions as required for 'evidence-based medicine'. The reductionist approach of positivist science does not allow for validity of 'practice-based evidence' or 'whole system thinking'. It is predicated on there being only one true and 'objective' version of reality, which can be reached only by 'value-neutral' pursuit of knowledge (Yong et al, 2021). This limited view of science itself has been challenged from within the modern knowledge system through inter-disciplinary approaches, for instance those that are generating 'systems biology', those examining the links between the physical body, mind, social and spiritual dimensions such as in psychoneuroimmunology and in consciousness studies, and those that are studying health care systems as complex adaptive systems (Paina and Peters, 2011). Trans-disciplinary approaches that draw linkages between diverse ontologies and epistemologies of various sections of society are developing knowledge based options for practical solutions to contemporary human and environmental problems (Stirling and Scoones, 2009),

Practitioners and researchers of T&CM who are attempting to make linkages with modern science and technology for strengthening T&CM must understand this diversity within the scientific enterprise itself, and align not with the reductionist positivist science but with the much more holistic approaches that also exist and are growing and evolving (Priya, 2021). It is only when the widely propagated view of knowledge shifts from the present dominant positivist version of science to its more emergent versions based on realist and critical holist philosophies (that acknowledge social diversity and knowledge pluralism), will a contextually rooted approach to health care become possible as a formal systemically legitimised and preferred approach. We must be able to view the various knowledges as co-existing 'diverse traditions of health knowledge' known by their specific names rather than the common divide indicated by the use of the terms 'traditional medicine' and 'modern medicine' (Priya, forthcoming).

Within health systems thinking, the PHC approach being the closest to such a holistic, open, contextually rooted and plural conceptualisation of health care, must provide the theoretical basis for UHC. Thereby its application to the health care system as a whole is required. It also needs to link to emergent issues of the 21st century. Ecological sensitivity, social justice and equality, as well as cultural pluralism and 'appropriate' technological regimes underlie much of the emerging trans-disciplinary science. The PHC approach needs to be re-articulated, building on the Alma Ata declaration and making more explicit the critique of exclusively positivist conventional biomedicine based health care systems, the diverse contextual needs across and within communities, as well as addressing issues of the secondary and tertiary levels of care.

For operationalisisng the PHC approach in letter and spirit, the politics of knowledge has to be addressed at several levels. Patient-centred approaches require granting validity to the patients' knowledge about their health; community-centred approaches need granting validity to the community's knowledge and the frontline community workers' knowledge' sustainable development requires openness to ecological world-views; decolonisation of public health and health systems thinking requires an appreciation of diverse ontologies, epistemologies and methodologies of knowledge generation so that multiple knowledge traditions can co-exist with equal legitimacy. An inclusive, sustainable and people empowering health care system requires all of these. All these constitute the politics of knowledge that is relevant for implementation of the PHC approach in letter and spirit. The global community, therefore, needs to come together to articulate a PHC 2.0 that presents the operational conception of an Inclusive, Sustainable and People Empowering Health System. Pluralism of health knowledge will then organically have to be an integral part of the system.

In Conclusion

Health Systems Research (HSR) and practice need to address the politics of knowledge if a significant movement is to be made towards operationalising the PHC approach and developing national integrative health systems. Contemporary developments in the scientific domain, with more inter-disciplinary and trans-disciplinary research being institutionalised especially in relation to development studies and sustainability can lead to a different knowledge generation for health systems development. This paper proposes that research and practice in T&CM must draw more from the holistic approaches in contemporary science and not only from the conventional positivist frames. Various traditions of health related knowledge could then not only remain more rooted in their own fundamentals but also contribute to the societal shift in the dominant knowledge paradigm, from mechanical positivism to critical holism. This means a moving away from the paradigm of one knowledge tradition as the 'true' or most valid knowledge, whether developed as a singular science or as an integration of more than one tradition. Acceptance of the legitimacy of co-existence of epistemological diversity and pluralism of health knowledge traditions would strengthen the theoretical bases of acceptance of PHC and T&CM as significant components of national health

systems that are in constant interaction with the other components and form a complementary continuum on the spectrum of health care. Only then is it possible to develop inclusive, sustainable and people empowering health care systems for the 21st century.

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Integrated Healthcare: India and Other Countries

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Introduction

After food, the primary concern of early humans might have been warding off illnesses. This they might have done initially by consuming plants or herbs randomly. Once they found out the healing and analgesic properties of certain plants probably through a process of trial and error, they might have used the same plants in similar situations later and that is where the medicine systems began (Schafflinger: 2018). In various parts of the world, such systems emerged differently and later got influenced by the metaphysical concepts that developed among each group. The Hellenic medicine system developed around the 5th century BC lays claim to being based on 'natural sciences' and later formed the foundation of western medicine. In India, Ayurveda developed and found its metaphysics in the Vedic philosophy. In China and Persia (present-day Iran) also medical systems grew from observing nature and later fitted into philosophies such as the Ying and Yang principles of China. Though based on plants, minerals, etc., each of the systems developed in its independent way and created its own specific therapeutic principles. Ayurveda looks upon illness as a consequence of loss of balance, both internally and externally, among the three *doshas* or humours (*Vata, Pitta, Kapha*) and the five elements (ether, air, fire, water, and earth). Scientific developments during the 19th century led to the emergence of modern western medicine which now approached illnesses based on the germ theory and bacteriology pioneered by Louis Pasteur (1822-1895), Robert Koch (1843 – 1910) and others.

Western medicine spread throughout the world on the back of colonialism. It did not adopt an accommodative attitude towards the existing medicine systems in the countries and

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remained aloof initially, possibly because of the perception that medical systems must be based on scientific reductionism, on which modern medicine is built. As time progressed, it has been realised that instead of an exclusionary approach what is desirable and advisable is an inclusive attitude, leading to an integrated healthcare system that accommodates different systems and makes the best of each of them. This paper explores the policy approaches toward integrated healthcare in India in the past and the current efforts. By integrated healthcare is meant healthcare in which modern medicine is supplemented with Indian Systems of Medicine in India and local traditional and complementary systems in other countries. It also briefly explores the situation in other countries. Knowledge by whatever name it is called and developed by whoever is for the whole humanity and should accordingly be used. That is the fundamental principle of integrated healthcare.

India's Health Policies and Integration: Evolution of a Concept

India has a very rich heritage of what is commonly referred to as traditional medicine and has also been a beneficiary of the early introduction of modern medicine. However, it is a late starter in an integrated policy approach to healthcare where all available and robust medical systems are employed to meet the objective of the health and wellness of its people. A brief look at the health policy evolution brings this out. Folk medicine and the medical systems Ayurveda and Siddha remained the main healthcare practices for a long time in South Asia including India. Of these, the Siddha system was predominantly in use in Tamil-speaking areas of South India only. The Hellenic contact in the third century BC and later inroads made by the Turks and Arabs into India led to the introduction of Unani. During the Mughal era, it appears that both Ayurveda and Unani received state protection. Public health was not considered as part of State responsibility until the emergence of modern medicine and nation-states. India's first encounter with Modern Medicine was through the Portuguese who had established 'hospitals' in their forts, Kochi in 1505, Kannur in 1506 and Goa in 1510. These were for their military personnel only (Abreu:2020). However, the Portuguese had no explicit policy in the 16th century to endow the colony with healthcare workers from Portugal. Some religious outfits like the Jesuits had set up healthcare facilities such as the Poor Hospital with its leprosy ward. (Abreu:2020). The Portuguese later through the Bye-law of Physicians, Surgeons, Bloodletters and Apothecaries, 1618 recognised the existence of two categories of healers, namely, the Indian *vaidyas* and the western physicians (Abreu:2020). Since the Portuguese dominance was essentially limited to Goa, it did not have a salutary effect on the rest of India.

It was during the British times that modern medicine made its real presence in India[1]. The British, like the Portuguese, opted for western medicine and medical departments were set up in 1785 to treat the British military and British civilians working in India (Anshu and Supe: 2016). In 1822 the Native Medical Institution was established in Kolkata to provide medical training to Indians and in this institution, parallel instruction was given in both

western and indigenous medical systems; classes on Unani medicine were held at the Calcutta *madrasa*, while the Sanskrit college conducted classes in Ayurvedic medicine (Anshu & Supe:2016). Thus, in the initial period, Indian systems were also part of overall healthcare. But these classes in Indian medicine were discontinued following Macaulay's Minute in 1835; Macaulay did not favour government funding of teaching Sanskrit and Arabic, which were part of Ayurveda and Unani education respectively, and favoured only English education which was the medium of instruction of modern medicine. It was after the crown took over India in 1857 that serious steps were taken to provide public health services with modern medicine. Even then, in 1877, among the 8,000 medical practitioners, only 450 were trained in western medicine. The rest were practitioners of indigenous systems of medicine. The inter-group relationship between the two groups of practitioners was not smooth and there were cultural clashes between them (Anshu & Supe: 2016). The government had accorded official status to modern medicine only and indigenous systems were ignored or discriminated against. The Ayurveda graduates were registered as Class B practitioners while modern medicine graduates were Class A practitioners. Given the background and training of the officials of the colonial government, this was not surprising.

The early twentieth century witnessed demands for giving due recognition to the Indian systems of medicine and making an integrated system of health care. To begin with, these demands were part of the freedom struggle. In the Nagpur session of the Indian National Congress held under the presidentship of Shri C Vijayaraghavachariar, a resolution was adopted that unambiguously asked for an integrated healthcare system. The resolution read: "There should be an Integrated System of Medicine and Research which should be a combination of both our Ayurveda, Unani Tibb, Siddha, and Modern medicine system choosing the best out of all and thus supporting one system by another to serve mankind to its best".[2] The approach adopted was that all systems have their places in healthcare and depending on the situation the best one or a combination of many should be practised. Ultimately, the health and wellbeing of the subjects of treatment should be the objective of any medical treatment. All health care systems are for the benefit of the entire humankind.

Many committees were set up during the early twentieth century to investigate the use of Indian Systems of Medicine (ISMs) in healthcare and education and training in those systems. Most were at the provincial level. The Report of the Chopra Committee of 1948 gives a list of such committees.[3] Most of these committees explored the issues from the narrow perspective of stand-alone promotion of ISMs and some from a purely regional angle. Of the above, the report of the Committee on Indigenous Medicine, Madras (the Usman Committee after the name of the chairman of the committee) deserves special mention since that appears to be the earliest available report on the promotion of indigenous systems from the government perspective. The Committee which was appointed on 17th October 1921 by the Government of the Madras Presidency[4] was to report "on the question of the recognition and

encouragement of the indigenous systems of medicine". The committee afforded opportunities to the practitioners of the indigenous systems to justify the case for state encouragement of these systems[5]. The committee after elaborate surveys, research and deliberations concluded that it is incumbent upon the State to explore to the full the possibilities of the Indian systems of medicine to make them wholly self-sufficient and fully efficient in both its medical and surgical branches and that the government should make an immediate declaration that of its policy to accord State recognition and State encouragement to the Indian systems of medicine.

At the pan-India level, a committee under the chairmanship of Sir Joseph William Bhore was set up in 1943 to provide a broad survey of the then position regarding health conditions and health organisation in British India and to make recommendations for future developments (Bhore:1946). An overwhelming majority of the twenty-four members of the committee had been trained in medicine in Britain and this seemed to have an impact on the committee's views and recommendations on ISMs that they are static and have not kept pace with scientific research. While the committee admitted that the indigenous medicine systems are in great use and have great acceptability among the people, it felt that the indigenous system was static in conception and practice and does not keep pace with the scientific discoveries and research at the global level and, therefore, cannot hope to give the best available ministration to those who seek its aid.

This was based not on any genuine knowledge about the ISMs as the report made statements like the indigenous systems of medical treatment do not deal with subjects like obstetrics, gynaecology, advanced surgery and some of the specialities (Bhore:1946. Para. 281). Based on this notion it concluded that public health or preventive medicine, which must play an essential part in the future of the medical organisation, is not within the purview of the indigenous systems of medical treatment. The Bhore Committee thus took an approach that excluded Indian systems of medical care from public health care. The recommendations of the Bhore Committee were not unanimous. Three members of the committee (Dr A.H. Butt, Director of Public Health, Punjab, Dr Vishwa Nath, Member, Medical Council of India and Dr U.B. Narayanrao, Member, All-India Medical Licentiates Association) were not in agreement with the recommendations on traditional medicine. They were for unrestrictedly (freely) using the services of persons trained in the indigenous systems of medicine for developing medical relief and public health work in the country. (Bhore: 1046. para 284.). These three members also suggested that the state should regulate the teaching and training in indigenous systems of medicine. They stated: "We are of the opinion that the teaching of indigenous systems of medicine should be regulated by the State. The Bombay Medical Practitioners Act, 1938, represents in regard to registration, the medical curriculum and examinations preliminary to registration, a step in the right direction. Practitioners trained and registered under the requirements of the above Act, or similar legislation, should be freely utilised for promoting public health and medical relief in India." (Bhore 1946: II, 461, §13)

The Bhore committee's recommendations were in sharp contrast to the present National Health Policy 2017 (NHP 2017). The 2017 Policy unambiguously states that "Promotion of healthy living and prevention strategies from AYUSH systems and Yoga at the work-place, in the schools and in the community would also be an important form of health promotion that has a special appeal and acceptability in the Indian context."[6] Interestingly, this reflects the minority viewpoint in the Bhore Committee, but which came to be accepted as national policy after seven decades only.

The approach of the Bhore committee was also not in accordance with the general sentiment of the freedom struggle and did not consider the reports of the several committees set up by various provincial governments since the 1920s. Therefore, in 1946 the Government of India appointed the Indigenous Systems Inquiry Committee, under Sir Ramnath Chopra as Chairman, and three Hakims, three Vaids, Dr B. N. Ghosh Professor of Pharmacology and Mazhar H. Shah as members. The committee was required to make recommendations on (a) the provision for research in Ayurveda and Unani Tibb, (b) Improvement of facilities for training, (c) desirability of state control, (d) increasing usefulness of these systems, and (e) holding enquiry as to whether the three systems – Ayurveda, Unani and Modern – could be combined into one comprehensive system. (Shah 1966: vii):

The Chopra Committee (1948) felt that the Indian Systems of Medicine (ISMs) were capable of making many valuable contributions to modern medical science. They held that if the aim of all the systems of medicine, be it Indian or western, is the maintenance of health and prevention and cure of disease, they should all be "integrated in the form of a single system which should be capable of suitable alteration and adaptation in accordance with time and other conditions"[7]. This was exactly on the lines of the Usman Committee recommendations in 1923.

Apart from the Chopra Committee, many other committees were also appointed by the Government of India since independence from time to time to study various aspects of the up-gradation of Indian systems of medicine and their wider use in the public health care systems. These include the following: (1) Committee Appointed to Advise on the Steps to be Taken to Establish a Research Centre in the Indigenous Systems of Medicine and Other Cognate Matters (The Pandit Committee), 1951. (2) Committee to Study and Report on the Question of Establishing Uniform Standards in Respect of Education & Practice of Vaidyas, Hakims and Homoeopaths (The Dave Committee) 1956. (3) Committee to Assess and Evaluate the Present Status of Ayurvedic System of Medicine (The Udupa Committee), 1959. (4) The Shuddha Ayurvedic Education Committee ("The Vyas Committee), 1963. The recommendations of these committees led to the development of ISM infrastructure for policymaking research and development over the years. For example, the Pandit Report was the basis for the establishment of the Central Institute of Research in Indigenous Systems of Medicine and the Postgraduate Training Centre for Ayurveda, both in Jamnagar in 1952 (Jaggi 2000: 312, Shankar 1992: 146). The Dave Report presented a model integrated syllabus to be used in colleges that would teach

only physicians of indigenous systems of medicine (ISM). The Udupa committee recommended the establishment of a Council of Indian Medicine (to regulate educational standards) and a Council of Ayurvedic Research. An integrated education with a common syllabus was the target of these. But the Mudaliar committee (1961) took a different view that once fully trained, indigenous physicians could be separately trained in modern medicine. The Committee felt that the practitioners of Ayurveda be offered a specific course of 2-3 years of training covering preventive medicine, obstetrics and gynaecology and principles of surgery. It also recommended making available post-graduate training in Ayurveda to modern medicine graduates. The Mudaliar committee recommendations led to the establishment of the Central Council for Research in Indian Medicine and Homoeopathy in 1969[8].

An independent committee headed by Professor V. Ramalingaswami, a former Director of the All-India Institute of Medical Sciences, and also a former Director-General of the Indian Council of Medical Research, in its report titled *Health for All: an Alternative Strategy* (1981) identified the non-recognition of indigenous systems of medicine as the case of public healthcare deficiencies in India and it blamed the British colonial rulers for the same. The report explained this in very lucid terms:

"*These [health] services were first organised by the British administrators who totally ignored the indigenous belief systems, lifestyles and health care institutions and practices which formed an organic unity. Instead of building on these foundations and evolving a new system more suited to the life and needs of the people with the help of modern science and technology, they decided to make an abrupt and total change by introducing the Western system of medicine in toto. This decision created a wide gulf between the culture and traditions of the people on the one hand and the health services on the other. It also deprived the latter of several valuable contributions which the Indian tradition could have made.*" (Ramalingaswami 1981: 81 f.)

This observation brings out what integrative health care could have achieved for India for that would have greater acceptability and adaptability and the people would not have to face a cultural shock.

National Health Policies

Despite so many committees and commissions recommending the promotion of Ayurveda and other traditional systems of medicine and despite it being one of the planks of the national movement, integrated health care or even due recognition of ISMs was slow to emerge at the national level. For one, health itself was a low priority item for the national government being a subject in the State List in the Constitution. The total public expenditure on health care was generally less than one per cent of the GDP. The first National Health Policy was announced in 1983. This was in the background of the 1978 Alma Alta Declaration on Health for All by 2020. This Policy noted the large stock of health manpower in the non-allopathic sector and also recognised that the traditional medicine practitioners enjoyed high local acceptance and respect. It accepted the need for initiating organised measures to enable each of the various systems to develop in accordance with its genius. The Policy also made a specific statement

in favour of integrated health care. It stated: "Simultaneously, planned efforts should be made to dovetail the functioning of the practitioners of these various systems and integrate their services, at the appropriate levels, within specified areas of responsibility and functioning, in the overall health care delivery system, specially in regard to the preventive, promotive and public health objectives."[9] It also recognised the need to launch well-considered steps to move towards meaningful phased integration of the indigenous and the modern systems. This is the first unambiguous statement in a national policy document for integrated health care. While that statement is there, there is another observation that raises doubts about the government's confidence in traditional health practitioners. As part of maternal and child health services, the policy recommended the continuation of providing refresher training for orientation to the traditional birth attendants. But at the same time, the policy considered it as a stop-gap arrangement only and recommended the launching of new schemes and programmes so that deliveries should be conducted by competently trained persons [para 12 (vi)].

The National Health Policy 2002 too accepted that alternative systems of medicine like ISMs have a substantial role in national healthcare. The Policy considered the advantages of these systems as diversity, modest cost, low level of technological input and the growing popularity of natural plant-based products. In view of these advantages, it is considered that these alternative systems can be used in the underserved, remote and tribal areas. While it made the main components of the Policy applicable to the alternative systems, the Policy features specific to them were left for a separate Policy document. Beyond that, it did not make detailed recommendations for the integration of the alternative systems with the national programme.

One of the objectives of the first National Policy on Indian Systems of Medicine & Homoeopathy-2002 was to Integrate Ayush into the health care delivery system and National Programmes and ensure optimal use of the vast infrastructure of hospitals, dispensaries and physicians. Towards this it had chalked out a number of strategies including AYUSH wings in PHCs, setting up of ISM speciality centres at district hospitals, assistance to speciality hospitals to establish *Panchkarma* and *Ksharshutra* facilities for the treatment of neurological disorders, musculoskeletal problems as well as ambulatory treatment of anal fistula, bronchial asthma and dermatological problems.

The National Health Policy 2017 made recommendations for integration. It, however, emphasised developing a protocol for mainstreaming Ayush as an integrated medical care since Ayush has a huge potential for effective prevention and therapy that is safe and cost-effective (4.6). It also recognised the need for developing integrated courses for the Indian System of Medicine, Modern Science and Ayurgenomics. A welcome feature of the Policy was that it put focus on sensitizing practitioners of each system to the strengths of the others (para 9). The Policy stated unambiguously that patients would have access to Ayush healthcare practitioners through co-location in public facilities. The Policy advocated a policy shift from stand-alone to a three-dimensional mainstreaming in the case

of Ayush systems. One of the strategies envisaged for this was linking Ayush systems with ASHAs and VHSNCs. It advocated a mandatory bridge course for Ayush practitioners to give them competencies with respect to allopathic remedies. The policy also envisaged the integration of Ayush systems at the level of knowledge systems. Validation of the therapies was considered essential for the integration. Thus, now, at a policy level, India has a document that clearly advocates the integration of Ayush systems in mainstream healthcare.

Status in Other Countries

Many countries have integrated traditional medicine in some form or other into their formal national health care programmes, such as Bhutan where gSo-ba Rig-pa (traditional Bhutanese medicine) is part of the formal stream and China which has a separate stream of Integrated Medicine consisting of both Traditional Chinese Medicine and Western Medicine. The national policies of many countries have provided for the practice of both herbal medicines and modern medicine. In a survey (2019) of integrated medical care by the WHO, the following 13 countries said that they had an existing national plan for integrating T&CM into their national health service delivery: Benin, Bolivia, Brazil, Cuba, Democratic People's Republic of Korea, Ghana, Guatemala, Haiti, India, Mali, Mexico, Nicaragua and Thailand. Other countries, apart from India and China, stated to have fully integrated certain traditional systems into healthcare are, the Democratic People's Republic of Korea, the Republic of Korea and Vietnam (Shang: 2018). Most Japanese physicians (84 per cent) use *Kampo* (Japanese traditional medicine) in daily practice (Shang: 2018). Many African countries such as Burkina Faso, Cameroun, Cote d'Ivoire, Equatorial Guinea, Guinea, Mozambique, Niger, Nigeria and the Republic of Congo besides those mentioned above have made efforts to integrate Traditional Medicine into formal health streams through policy formulation and creation of traditional medicine councils, but the integration has not been successful (Amponah, *et al*: 2020). Park and Canaway observe that among the 37 countries in the WHO Western Pacific Region, countries such as China, Japan, and the Republic of Korea have well-established integration policies, Malaysia and Cambodia are in-process of developing integration within their national healthcare systems, in New Zealand, attempts are being made to integrate Māori traditional medicine, while Australia has government-led regulation of Traditional Medicine products, but in most Pacific Island Countries indigenous traditional medicine is practised outside the national healthcare system (Park and Canaway: 2019). The USA has also taken a positive approach toward integrated healthcare as indicated by its decision to rename National Centre for Complementary and Alternative Medicine to The National Centre for Complementary and Integrative Health (Patwardhan: 2014).

China is a special case in the matter of the development of an integrated healthcare system involving both traditional medicine and modern medicine. Modern medicine made a very late entry into China. In the 1950s, some modern medicine practitioners were trained in Traditional Chinese Medicine (TCM) and some TCM practitioners were trained in Modern Medicine and thus the Integrative

Medicine model started in China (Lu. 2008). The IM slowly got expanded and in 1981 the Chinese Association of Integrated TCM and WM got established (Lu; 2008). The Chinese government policy was to encourage equally TCM and Modern Medicine. The 2003 Regulations[10] while reiterating that TCM should be protected and supported, encouraged doctors in both steams to learn from each other and complement each other for developing IM. The Chinese health care system evolved into using three kinds of health care: One purely Modern Medicine, another purely Traditional Chinese Medicine and a third Traditional Chinese Medicine integrated with Modern Medicine, but this Integrated Medicine (IM) largely remained a part of the TCM (Pan Weidong, *et al*. 2016).

The challenges in having an integrated system of healthcare differ from country to country. While many countries have policies proposing the integration of complementary and alternative systems of medicine with modern medicine there is a huge gap in implementing the same as in the case of Sri Lanka (Jones and Liyanage: 2018). The policy administrators mostly belong to the conventional system and are not enthusiastic about the other systems, probably because of epistemological differences in the therapies. This may, many a time, affect, the allocation of funds as well as the facilitation of integrated healthcare.

In most countries, the local health tradition, while being used by local people, is not organised into 'systems' or has its own authoritative texts or *Materia medica*, unlike the case with Ayurveda or Siddha or Unani. In the absence of systematised knowledge with well-established and commonly accepted foundational texts, those local traditions are not easily amenable to proper study discipline and practitioners of modern medicine find it well nigh impossible to explore complementariness. The ISMs are proper study disciplines and have regular modern educational institutions like universities and medical colleges imparting education in them. India, however, faces a different set of challenges. For one, the multiplicity of such systems is an issue. Integrative health care means giving due recognition to each of these systems. Apart from such well-established systems, India also has local health traditions outside the organised systems. Incorporating them in an integrated healthcare will pose many challenges.

Conclusion.

No single system of healthcare can address successfully all the healthcare needs of modern society (Pan *et al*: 2016). Anti-microbial resistance, reactions to chemical drugs and so on are factors that lead to patients and practitioners of modern medicine exploring other more herbal-based systems of medicine to address their health issues. The WHO *Traditional Medicine Strategy 2014-2023* envisages integrating T&CM into national health systems and that WHO will facilitate the development of national policies in that regard. Another strategic objective of the WHO Traditional Medicine Strategy 2014–2023 is "To promote universal health coverage by integrating T&CM services into health care service delivery and self-health care". As WHO itself says, "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (WHO 1948). The recent Covid 19 pandemic has underscored the need for using all available resources for human

health programmes. Complementary and Alternative Medicines (CAM) have come to be used along with modern medicine by people in most parts of the world. Seetharaman, *et al* identify the following reasons for the same: the rise of chronic diseases, high rates of adverse side-effects of modern medicine, and high cost of modern medicine-based health care. The paper points out that there is high interest among medical professionals in CAM education and that CAM practices are getting included in new clinical practice guidelines. One can say that there is a bright future for IM but national governments, especially in countries with strong traditional medicine systems should come up with proactive policies to encourage the use of CAMs and modern medicine appropriately.

Endnotes

1 These include, among others, the following: (1) The Committee on Ayurvedic and Unani Systems, Bengal, set up in August 1921, (2) The Committee on Indigenous Systems of Medicine, Madras, set up in October 1921, (3) The Committee on Ayurvedic and Unani Systems, United Provinces, set up in 1925, (4) The Committee appointed to Examine the Indigenous System of Medicine, Central Provinces and Berar, set up in 1937, (5) The Indigenous Medicine Enquiry Committee, Punjab, set up in 1938, (6) A Committee to go into the question of encouraging the Indigenous Systems of Medicine, Mysore set up in 1942, (7) The Utkal Ayurvedic Committee, Orissa, set up in 1946, (8) The Indian Systems of Medicine Enquiry Committee, Bombay, set up in 1947, (9) Scheming Committee to report on the steps to be taken for the development of Ayurveda in Assam, set up in 1947, and (10) The Ayurvedic and Unani Systems Reorganisation Committee, United Provinces set up in 1947. See Report of the Chopra Committee. Pp.25-26.

2 Report of the Steering Committee 12th FYP. The Chopra Committee (1948) quotes the resolution as below: "This Conference is of the opinion that, having regard to the widely prevalent and generally accepted utility of the Ayurvedic and Unani Systems of Medicine in India, earnest and definite efforts should be made by the people of this country to further popularise Schools, Colleges and Hospitals for instruction · and treatment in accordance with Indigenous Systems." It also mentions that the recommendation was reiterated by the Working Committee in 1938.

3 These include, among others, the following: (1) The Committee on Ayurvedic and Unani Systems, Bengal, set up in August 1921, (2) The Committee on Indigenous Systems of Medicine, Madras, set up in October 1921, (3) The Committee on Ayurvedic and Unani Systems, United Provinces, set up in 1925, (4) The Committee appointed to Examine the Indigenous System of Medicine, Central Provinces and Berar, set up in 1937, (5) The Indigenous Medicine Enquiry Committee, Punjab, set up in 1938, (6) A Committee to go into the question of encouraging the Indigenous Systems of Medicine, Mysore set up in 1942, (7) The Utkal Ayurvedic Committee, Orissa, set up in 1946, (8) The Indian Systems of Medicine Enquiry Committee, Bombay, set up in 1947, (9) Scheming Committee to report on the steps to be taken for the development of Ayurveda in Assam, set up in 1947, and (10) The Ayurvedic and Unani Systems Reorganisation Committee, United Provinces set up in 1947. See Report of the Chopra Committee. Pp.25-26.

4 The Report of the Committee on the Indigenous Systems of Medicine (Madras 1923)

5 Ibid. p.7.

6 NHP.2017. pg. 10.

7 Report of the Chopra Committee 1948. P. 7.

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Integration of a Heterogeneous Medical Tradition: Some reflections from Sowa Rigpa in India

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Introduction

Since 2005, the major policy support to indigenous systems in India has been mainly facilitated by the National (Rural) Health Mission (NHM), which claimed 'to carry out necessary architectural correction in the basic healthcare delivery system' and 'to mainstream' the codified systems of medicines commonly known as AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha, Homeopathy and recently added Sowa Rigpa medicine) and 'revitalize' the local health traditions (LHTs). The basic strategy was shifting the role of AYUSH from a parallel system to a possibility of an integrated system in infrastructure, manpower and medicine to strengthen the public healthcare delivery systems at all levels. Most states have been facilitating increased pluralism in health system delivery through activities like establishing co-located AYUSH facilities alongside biomedicine (Albert et al 2015), incorporation of AYUSH formulations along with the generic drugs for common ailments at district, primary and Community Health centres and inclusion of AYUSH drugs in the accredited health activists' drug kits. But studies had pointed out that there are multiple levels of confusion and discrepancies exists in bringing these systems together (Josyula et al 2016). The difficulties of integration are evident at various points especially in cross practices

This essay talks about the varied complexities of integration of Sowa Rigpa into the category of Indian systems of medicine.

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As a cross-cultural medical system, with its petty commodity nature of the industrial production, Sowa Rigpa warrants some initial state support in knowledge codification efforts, mechanisms to recognize and promote frugal innovations in practices and also in utilizing the alternative protection mechanisms other than patenting. A public good approach would be beneficial for the system as such for two reasons: one, to tap the strong potential of innovations in both knowledge and pharmaceutical component and two, to deal with the exclusions and challenges that the modern industrial structure may offer.

Complexities of Medically Pluralism

Various systems of medicine have monopolistic presence in various states along with biomedicine, for example, Ayurveda in Kerala, Gujarat and many other north Indian states, Siddha in Tamil Nadu, Sowa Rigpa and Ayurveda in parts of Jammu and Kashmir, Himachal Pradesh and West Bengal, tribal local traditions in Meghalaya, Chhattisgarh etc. However seemingly, the current budgetary allocation at times undercuts this health seeking behavior in some places. In Ladakh for example, though the demand for Sowa Rigpa is much higher than that of Ayurveda and Unani, the financial allocation favors the other systems, and hence the infrastructure to support this demand is poor and pharmaceuticals are largely under-supplied (Blaikie 2016). In fact, any pluralistic attempts, which envisages the redistribution of medical staffs, infrastructure and pharmaceuticals, has to take care of the regional demand and supply gaps.

Even though the entry of Sowa Rigpa into this pluralistic ground of India is not recent, its incorporation within the framework of Indian Systems of medicine is recent with the notification of the Indian government in 2010[1]. This, to an extent justifies the cultural and geographical demand of certain northeastern states in India and trans-Himalayan region. Sowa Rigpa had medically served Indians for decades, and in the Himalayan regions even for centuries without gaining recognition. Central Tibetan administration, the medical community in exile and Himalayan amchi community in Ladakh were the main stakeholders of this recognition. Beyond the public health aspects, its acceptance particularly makes sense in the current boom of pharmaceuticalization and industrialization in Asian medical stream. The herbal pharmaceutical industry in Asia invents remedies through multiple translations from formulations and descriptions of plant properties in the ancient texts (traditional and reformulated drugs) or from traditional tacit knowledge to create new medicines for the treatment of common ailments. This is quite evident in the case of codified systems of medicines as we have many explanations in the case of Indian and Chinese medical systems (Bode (2009), Banerjee (2009), Madhavan (2009), Pordie and Gaudilliere (2014) and Scheid (2001), Kloos et al (2020) among many others). Kloos (2016) situates Sowa Rigpa's official recognition within this larger context of growth of the indigenous pharmaceutical industry. It was argued elsewhere that only when Ayurveda was transformed into a mass-produced 'product' for the market in the late nineteenth century that it eventually able to gain legal recognition during the latter half of the twentieth century (Banerjee

2009). In contrast to this, Sowa Rigpa's recognition in India has a much shorter, while almost a century passed between the beginnings of Ayurveda's industrialization and its official recognition, Sowa Rigpa undertook the same journey in only a little over a decade.

Counting these twin forms of identity- public health and pharmaceutical, in the complex pluralistic background of India, the process of recognition gives an opportunity to have a status check and the way in which Sowa Rigpa may confront- both national and international policy regime. In the process, Sowa Rigpa also needs to undergo strong regulations, stipulations of standardization, and the effort for further centralized codification, many of which are clearly peripheral to the systems until recently. Hence, not only just wider acceptance, but its sustained usage, and systematic support to codify, test and publicize this knowledge is part of creating this global public good.

This essay discusses this new pluralistic atmosphere in India and Sowa Rigpa's formal entry into the system, where it may require an unusually new approach of global public good (GPG). Under this framework, the loss of such kind of knowledge will have significant impact across countries, not only for the communities, which own them, but also in terms of the lost possibilities of market for derivatives, which the knowledge can supposedly generate. In the following sections, we explain the complexities of pluralism in India and how the entry of Sowa Rigpa into the picture necessitates a direct dialogue with the domestic and international policy instruments. The third section discusses the systemic changes that are required to deal with heterogeneous systems like Sowa Rigpa before we conclude with some inferences.

Sowa Rigpa: A Cross Cultural Medicine

Here we visualize the development in Sowa Rigpa through a global public health lens and see the potential and challenges of the same. Given that, the Sowa Rigpa is in its early stages of development and petty industrialization face in India, the attempts of a public good approach (Smith 2003; Moon 2008; Stoll 2011) would be beneficial both in therapeutic development and industrial development. It is relevant with the fact that the growth of Sowa Rigpa is uneven in different countries, where in China has seen significant growth of patent filing (Madhavan, 2018), while in Bhutan, it's a single firm dominates the production, mostly enabled by the government financing. A recent article has shown that there is a tenfold growth of the Sowa Rigpa pharmaceutical industry in Asia between 2000 and 2017 (Kloos et al 2020). In 2017, the industry had a total sales value of 677.5 million USD, and constituted an important economic and public health resource in Tibetan, Mongolian and Himalayan regions of Asia. 98% of this pharmaceutical sales in Sowa Rigpa emerges from China, while India has a contribution of little above 1% with the contribution of production units like Men-Tsee-Khang. But generally most of the Sowa Rigpa pharmaceuticals are still under a petty commodity production mode, manually produced in small scale by traditional amchis/physicians in most of the Indian regions.

Hence, within the complex co-existence of pluralistic medicines, Sowa Rigpa may face certain difficulties to get absorbed into

the existing system of official plurality. It is apparent that the nature of the rights of this knowledge cannot be easily put into the straight jacket of private appropriation, as the knowledge is associated with specific community or a geography of cultural identity. Hence, the State may offer funding for recording, codification and dissemination of such knowledge and for further research and sustainability (Ghosh 2002). In the case of Sowa Rigpa, there can be two major global challenges: first, as a trans-migratory medicine rooted in varied cultural traditions (China, India, Mongolia, Buryatia in Russia, Bhutan etc), the domestic policies of one national stakeholder may create exclusions to its co-owners/practitioners elsewhere through intellectual appropriation, in addition it may pose rivalry through threatened extinction of bio-resources, for example one may refer to the discussions regarding Chinese initiative of intangible cultural appropriation of Sowa Rigpa (Madhavan 2017). Second, as a semi-codified knowledge, Sowa Rigpa has strong reformulation possibilities and hence proprietary and patent ownerships. This calls for revision of existing norms and regulations of Sowa Rigpa.

To entwine this medical system effectively into the national health delivery schema, require changes not only in presentation of knowledge (the codification and institutionalized training), but in health system (integration and tenability of petty production) and in the regulations and norms that suit the public good like a) intellectual property rights and patent legislation b) turning knowledge in to practice: the importance of capacity strengthening - R&D, ethical, legal, social and policy c) International bodies to organise, advocate and regulate input for national governments & other players.

The reformulation of Asian medicines is influenced by market mechanisms and regulations. In India, manufacturers can register their products as a traditional medicine so long as they can refer to ancient texts that contain the elements presented in the recipe. Regulations permit the reformulating and branding of multiple versions of the drug (Madhavan and Gaudilliere 2020). It is an attractive mechanism for manufacturers to get their plant-based products onto the market much more quickly and cheaply than if they had to fulfil the requirements of clinical testing and evidence needed for a pharmaceutical based on molecular isolates. But many of these issues with regards to the compatibility of these peripheral systems in mainstreaming goes broader than just the national strategies alone, and many a times they are increasingly influenced and determined by the international regimes. This forces Sowa Rigpa to follow the rubric of commercial pharmaceuticals like good manufacturing and clinical practices, where it has to deal with domestic economic exigencies, albeit reshaping its systemic uniqueness.

Issues in Pharmaceutical Regulations and Property Rights

In the last few decades, the institutional structure of Indian Systems of Medicine has progressed extensively and now is ready to deal with the leading aspects of the drug research, licensing and regulations through a parallel institutional support both in centre and the states (Abraham 2009, Banerjee 2009). Still, the state level implementing apparatus are in the process

of taking shapes, hence the facilities and infrastructure of the mainstream pharmaceutical sector also sought after especially in deciding the drug standards, new drug licensing etc. This is equally true for any indigenous medicines, though some state-wise initiatives are better serving selected systems. As a new entrant into the system, Sowa Rigpa is bound to deal with many of the laps and lacks in the institutional structure.

While large and medium firms in a system like Ayurveda do conduct serious research (Dabur, Himalaya, Kottakkal Arya Vaidyasala are examples) large investment in Sowa Rigpa R&D is absent in the private sector (may be some initiation by MTK) and hence to be initiated by the government or the community. Government also controls the monopoly pricing (through drug price control order (DPCO) and essential drug lists), saving the small-scale production units (through infant industry subsidies) and other drug regulatory policies through Central Drug Standards Control organization (CDSCO), which is controlled by Drug Controller General India (DGCI). The drug control cell of the department of AYUSH created the essential drug list in Indian medicine in 2000, and updated the list in 2013[2] after the NRHM initiative, which include 277 drugs in Ayurveda, 247 in Homeopathy, 302 in Siddha and 288 in Unani and recently in 2022 with more than 200 drugs from each systems. Unlike the list in modern medicine, the essential list is mainly for priorities for need-based procurement in district and primary health centres and not for any kind of ceiling or price control. But these drugs were given preference in production in the government co-operatives and other pharmacies. Sowa Rigpa would also have an essential drug list and funding in due course.

Even though the new drugs applications and the pre-cilinical and clinical trials are monitored by the CDSCO, many of the licensing activities regarding the drug research and manufacturing is solely under the State Drug authorities[3]. And the State Drug authorities are susceptible to the local political influence and there are cases of deviousness. This is more in the case of indigenous medical drugs, as the reformulation system within the Indian medical system is largely unknown to many of the drug controllers who are trained in the modern medicine. It is only very recently that some of the states have appointed the drug controllers, who has fair knowledge in Indian medicines.

In Ladakh, practitioners of Sowa Rigpa (*amchi*) have made medicines on a micro scale and distributed them to local patients for many centuries. Over the last 20 years, several *amchi* also started producing drugs commercially, prescribing them in private clinics as well as selling them to other practitioners. In the absence of any official status for Sowa Rigpa, this industry existed in a grey area, lacking legal status, external investment or regulation. However, the recognition of Sowa Rigpa made a profound change. *Amchi* are now working in hospitals and Primary Health Centres across the region and large numbers are engaged in institutional training in pursuit of such jobs. Government-funded projects are aiming to both expand and improve the quality of medicine supply, while investment is growing alongside awareness of internal and external market potential (Blaikie and Madhavan 2015).

Even though the State recognition can leverage Sowa Rigpa's market expansion

and transnationalisation for the exiled Tibetans (especially in Dharamshala) and a sustainable market and livelihood enhancement for the Indian Himalaya *Amchis* (Blakie 2016), it also matters whom the new wave of government patronage and institutionalization will help. The exponential growth in the demand for Sowa Rigpa both in the domestic market and among the international community, the task before the government is how to frame a public action in the pharmaceutical regulations and enforce a strong mechanism to check the biopiracy issues, while effectively dealing with the narratives of exclusion of oral traditional segment within Sowa Rigpa.

Rather than the transnational patenting, what requires for Sowa Rigpa given its stage of commercialization, nature of knowledge ownership, the situation of political environment and status in relation to other systems of medicine in India is, how effectively we can use the other mechanisms of protections like Trademarks and Geographical Indications etc. India has not made use of these rules effectively until now, in most of the officially recognized Indian medical systems. The Trademarks Act- 1999 in India includes protecting the distinctive signs, logos, marks and so on used on goods and services by firms in trade and commerce. Even though, the Act does not have any specific provision for protection of drugs, the provisions of the Act could be used for protecting the brands and marks of traditional medicine producers. The brand name 'Ayush' got into controversy in the beginning itself as the name of the brand was already in the market for the products marketed by a private company.

India and China have Geographical Indications as a method of property rights protection; there is a good possibility of some traditional medicine products acquiring special qualities, which are linked to the region where they are manufactured (James 2013). For example, now the efforts are active to get the GI tag for *Marayoor Sarkara*, a special kind of jaggery, which has medicinal properties. In such cases, they can be registered as geographical indications. However, as of December 2015, no traditional medicine product appears in the list of 256 registered Geographical Indications in India. While China is far ahead in utilizing the geographical indications and intangible cultural heritage applications for protection, India opted for only the sui-generis model of defensiveness (Madhavan, 2017). How best we can utilize these options may be considered in the case of Sowa Rigpa. The apex institute like National Institute of Sowa Rigpa (NISR) formed by the central government expected to do further research on such possibilities.

In the current situation, the sui generis version of IPR is in use. The Drugs and Cosmetics Act of India, 1940 has detailed regulations regarding manufacture for sale of the ISM drugs as well as for their safety and quality standards. The Act has a special category for patent or proprietary medicines in the ISMs. The Act categorizes the ISM drugs into: (i) classical preparations; and (ii) patent or proprietary medicines[4]. There are 57 Ayurvedic books recognized as authoritative texts in the First Schedule to the Drugs and Cosmetics Act of India. Preparations in these texts provide detailed recipes of the herbs/

ingredients, levels of usage, process for manufacture, dose, indications and other relevant information. Such preparations manufactured as per the textual recipe are generally referred as classical Ayurvedic drugs. Proprietary medicines are those formulations, which are produced and packaged, changing the combinations used in the classical texts, but not included under the classical formulations (Madhavan 2014). The proprietary medicines are leading the market of herbal pharmaceuticals. This is in close similarity with the development of process patenting in generic pharmaceuticals in India to enhance the access and affordability, the proprietary options give possibility for frugal innovations in the field of Sowa Rigpa. The production segment called 'sorig beauty preparations and skin products' of the largest Sowa Rigpa manufacturing company Men-Tsee- Khang (MTK) is a found opportunity, which makes use of the sui generis patent possibility. In the transformation and development of Indian medicine as an Industry, these proprietary products are significant in terms of capturing the middle class market (Banerjee 2009), and Sowa Rigpa is in the initial phase of this process. Schwabl and Vennos (2015) mentions that the task of bringing an ethno-pharmacological based preparation within the modern medical and regulatory framework expands the question about the 'potency' to topics such as justification of the composition, clinical efficacy and safety. The multi-compound mixtures or any inclusion of animal origin or precious metals even if purified makes any formulations will face increasing regulatory difficulties. But, the success of gabur-25 (a Tibetan formula for curing the heat disorders) gives ample hope to Tibetan pharmaceuticals of dealing with regulations and competes with many herbal counterparts in the global market (Schwabl and Vennos 2015).

The key issue in terms of dissemination of this medical knowledge is excludability. Two types of exclusion are relevant: (a) exclusion of traditional amchis from the medical knowledge itself, due to wrongly assigned ownership in countries); and (b) exclusion from the products resulting from such knowledge, such as medicines or other medical techniques (due to monopoly pricing). Obviously, the emergence of new knowledge or even new drugs and therapeutic techniques is in itself not enough to ensure universal access.

The existing support systems under AYUSH are mainly expedite the protection and production techniques of the derivatives of the indigenous knowledge than the knowledge itself- e.g. Pharmacopeia preparation, the D&C Act, Magical remedies Act etc. While this largely gives a framework for Sowa Rigpa to develop as an Industry, the public action should ideally include the basic research in Sowa Rigpa and further codification efforts too. In this context, some of the questions raised by the international workshop on 'the essentiality of developing an interdisciplinary and multilingual digital base of Tibetan formulas' (Schrempf 2015) seems to be more relevant: Which texts are important for understanding Tibetan *materia medica* and formulas produced today? Who produces these formulas using what kind of knowledge and production technology, and how is this connected to (biomedically defined) efficacy and safety issues? Which ingredients are we actually talking about

in a specific formula and how do we identify them botanically while addressing their regional diversity at the same time? How and why are certain *materia medica* ingredients in a formula substituted? Many of these questions also addresses the industrial paradigm of Sowa Rigpa in terms of bringing homogeneity, safety and efficacy issues etc. and it underscores the need for an epistemological clarity for practical purpose of production and validating the source of knowledge.

The theoretical scope of any intellectual property protection is limited, because the patent system only protects the knowledge embodied inventions, but the pure knowledge is not protected and this in turn drives the knowledge holders or practitioners out of business as happened in the case of China. Importantly what patents are also not covered is innovations in methods for diagnosis and methods for treatment of diseases. The heterogeneity in Sowa Rigpa practice explains these frugal innovations in practice. Due to these theoretical limitations and legal exclusions, the patent system will not protect the existing knowledge of Sowa Rigpa, as it's not novel (Benjamin Liu 2003). This raises questions regarding the use of support systems only for the protection of derivatives. This difference between unpatentable products of 'nature' and patentable derivatives is ambiguous. This reconfirms the argument that what the recognition aims is the pharmaceutical market and multiplier potential of the capital invested in production. The petty industries like Sowa Rigpa, probably within the national boundaries can gain monopolies by inventing close to the existing technology (as in the case of proprietary medicines), through a relaxant property right system.

Addressing 'Local' Frugal Innovations

Sowa Rigpa is often presented as a rather monolithic cultural tradition being ancient and unchanged, and therefore 'authentic'. While the *Rgyud-bzhi* (Gyushi)is invariably cited as the standard source and legitimate text for Tibetan medical knowledge as though it is a uniform and unchanging text, in reality it has been constantly edited, revised and reinterpreted by many different users. Gerke (2018) referred to it as an 'epistemic genre' where the recipes of Gyushi is a result of collective authorship and remain open for further reformulations, and hence work as a built-in mechanism for preserving the heterogeneity of practices and to endogenize the contingencies regarding availability/non availability of some substances / geographical variations/ constitution of patients (Gerke 2016). Gerke argues that the possibility of reformulation is more open for revisions in a formula and the way substances are listed matters. The recipes were generally learnt and reformulated in practice, sometimes with the help of written knowledge, and handed down among family members, or within networks of specialists, from healers to apprentices. Blaikie examined the multiple recipes of the Sowa Rigpa still used by healers in non-industrial, small-scale settings (Blaikie 2016).

Thus, a gradual and attentive comparison of a wider variety of medical texts and practices, and by careful research on its social history, that we can gain a clearer picture of Sowa Rigpa in all its complexity (Schrempf 2007). This includes the influences from other medical traditions of Indian and Chinese provenience, as well as its variety of localized traditions, its

interference with other Tibetan healing practices, and finally its increasingly complex relationship with biomedicine.

Sowa Rigpa also undergoes transformation in its theory and practice engaging with various cultural context and geographical specificities. Socio-political and historical factors, such as colonialism, state policies and polices of the exile government etc. are also important forces that have transformed and shaped the theory and practice of Sowa Rigpa into the 21st century. Examination of these factors and their influence will inform us much more about how Tibetans have understood and engaged with issues of health, illness and healing in any particular time and space (Schrempf 2007). Tibetan medicine emphasizes environmental, dietary and seasonal changes as primary factors in disease. This emphasis is strengthened in the context of exile, where Tibetans are confronted to drastic changes in their environment.

Role of the Dharamshala MTK in addressing the problems of public health in the Tibetan exile community is significant (Prost 2007). The implication of place-specific contagion in common diseases is unsurprising when one considers that places and land scape are a powerful source of imagery and identity in Tibetan cultural areas (Buffetrille and Diemberger 2002). Prost mentions that Sowa Rigpa is particularly apt at dealing with what could be called 'diseases in exile' (TB, arthritis, diarrhea etc) because of its emphasis on localized aetiologies that links diseases to oraganisms or spirits pertaining to particular places. Sowa Rigpa has excellent treatment offers for these ailments and hence the regional public health aspect is even more proved in its entirety. This reveal that Sowa Rigpa is very attentive in the public health issues of the local specificities and regional epidemiology to a larger extend. This might be the reason why the demand for this medical system is excellent over the decades and reflected in the growth of MTK- which, between 1964 and 2010, develop from a small medical center with only a handful of doctors and students to a significant health resource with more than eighty clinics all over India, catering to over 600,000 patients per year (Kloos 2016).

It is therefore not surprising that MTK dealt with the prevalence of tuberculosis among exiles, which has been characterized as a humanitarian emergency by the head of the TB programme in Dharamshala. In addition to the focus on disease agents pertaining to the environment and the place of exile, Dharamshala settlers often commented upon the social context of public health problems like the prevalence of diseases such as TB and malaria. This runs close parallel to the establishment of first Ayurveda College in India, where the effort for organized training and capacity building was initiated in the context of horrendous outbreak of infectious diseases like cholera in the Thiruvananthapuram region (Madhavan 2008).

Unlike the other systems of medicines, Sowa Rigpa had to confront the pharmaceutical regulations at an early stage of institutionalization and capital formation in India. Given the fact that, most of the indigenous medicine documents and regulations in India largely carry an assumption of facilitating industrial development (Banerjee 2009), an early stage medical system may face varied struggles and negotiations. The structure of industrial development in both

Ladakh and Dharamshala is at a stage of petty production even now, besides a few exceptional units produce reasonably large scale (MTK in Dharamshala and Ladakhi Amchi sabha in Ladakh). Although the situation is changing fast, the majority of the practitioners in the present day still employ simple manual technology in order to produce small amounts of between 30 and 100 kinds of medicine, which they prescribe to local patients. Home production remains, for now, the primary source of Sowa Rigpa medicines in Ladakh, particularly (but not exclusively) in rural areas (Blaikie and Madhavan 2015). Hence Sowa Rigpa is not only uniquely placed in addressing the local aetiologies, but sustained mostly with local markets in many parts of India. This recalls the relevance of 'local' approach in the public action, along with the negotiation at national and international levels for protecting the larger interests of knowledge protection and share in the herbal market.

A 'Local Public Good' Approach in Contrast to Global?

The national policy articulations on the integration and mainstreaming systems like Sowa Rigpa are not effectively translated into the state context. The local and regional institutions need serious attention in the integration and mainstreaming process and for sustainable protection of interests of Sowa Rigpa within the state health system.

This takes us to an alternate concept of local public goods, which are enjoyed collectively within a geographical location or as part of a community and are characterized by being beneficial to those who have access to them, as well as being collectively protected and sustained. This description— especially at the non-global level—is purely descriptive. Local public goods can be of common pool resources type or replenishable type. Sowa Rigpa can be considered as a medical knowledge that can be degradable and replenishable. The rate of degradation can be increased or decreased by frequency of harmful action, in which individuals use a public good in a way that reduces its availability to others (Sheely 2013). In contrast, a mix of harm prevention and repeated provision can maintain replenishable local public goods. Not only an increasing intergenerational mobility of Sowa Rigpa knowledge, but also the raw material availability for the Sowa Rigpa emerges as an important question.

In this context, probably two adaptable examples may be relevant for Sowa Rigpa. One is the people's biodiversity register, which codifies the locational knowledge and forms a local and decentralized management/monitoring of resources through a body called biodiversity management committee, incorporates the local knowledge holders, the local administrators and members from the state biodiversity boards. This committee not only protects the knowledge, but also initiates innovative attempts to sustainably cultivate the required resources through many innovative ways. This can solve the issues of degradation/ extinction of knowledge and resources in Sowa Rigpa. Second example is a public-private consortium (for e.g. Care Keralam in Kerala) of small manufactures with the help of shared funding from the government and private manufacturers. As part of cluster development, there are many such PPP initiatives in various

states in Ayurveda, offering organized arrangement of raw materials, ensuring the quality mechanisms, centralized GMP units for production, and patent and proprietary advice to the producers. Hence it works as a facilitator for small-scale industries to compete in the market. With a large number of small home based/ petty manufacturers, Sowa Rigpa may gain from the local collaborative approach.

While along with making use of exemptions and gain more through negotiations in the present regime, what might be feasible is to focus on 'Local' in the public good approach - where the community and the government work together to strategize what is important for the system within a particular geographical area - might be useful and ease the transformation process and protect the component of its folk element. Peoples' biodiversity register and public-private consortiums could be adaptable in a local public good approach of Sowa Rigpa. Being a medicine of migrant nature, the application for property rights also need to be either country specific or of a co-operative one, where different countries decides to follow sui-generis method.

Endnotes

1 Ministry of law and justice, 2010, The Indian Medicine Central Council (Amendment) Act,.

2 Please see for further details, AYUSH website: http://ayush.gov.in/tenders-vacancies-and-announcements/publications/essential-drugs-list-ayurveda-siddha-unani-and-homeopathy (retrieved on January 02, 2017) and MoI (2022)

3 Only very few drugs require industrial licensing from the central authority, however recently the number of drugs are reduced substantially with only those use the recombinant DNA technology, those involve use of nucleic acid as the active principles, and the formulations based on the use of specific tissue/ cell. They need to apply to the central authority as per the industrial and drug policy.

4 Section 3(a) and (h) and First Schedule of Drugs and Cosmetics Act, 1940

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Unani Medicine - An Overview of Indian Scenario and Prospects for Globalisation

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Introduction

Unani medicine is one of the recognised systems of traditional medicine in India. The system of medicine has a global presence and is practiced in several countries like Bangladesh, South Africa, Pakistan, Sri Lanka, UAE and China. Unani medicine has passed through many countries, getting enriched along the way, before being introduced in India around 8th century CE. Since its introduction, India's continuous contribution to the further development of Unani medicine has been globally recognized. In India the system has been systematically nurtured and integrated in India's healthcare delivery system with ample government support in terms of patronage and funds. With its wide network of quality educational institutions, comprehensive healthcare facilities, state-of-the-art research institutions and quality drug manufacturing industries, India has emerged as the global leader in Unani medicine. Quality of education has been enhanced with upgradation of educational institutions.

Globalisation of Indian traditional systems of medicine has been happening since many years, but has sped up enormously during the last decade after the establishment of separate Ministry for Ayush in 2014. Since globalisation is grounded in the theory of comparative advantage, India is well positioned to offer Unani Medicine knowledge, products and services to the global community.

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In this article we present the strengths of Unani medicine and its integration in mainstream healthcare highlighting the recent strides in education, research and development and quality control thereby providing strong foundation for its globalisation.

Strengths of Unani Medicine and its Integration in Mainstream Healthcare

The Unani medicine is a comprehensive medical system, which provides preventive, promotive, curative and rehabilitative health care. The basic framework of this system is based on the concept of four Humours, put forward by Hippocrates (460–370 BC), according to which any disturbance in the equilibrium of humours causes disease and therefore the treatment aims at restoring the humoral equilibrium.[1, 2] With increase in incidence and prevalence of chronic diseases, there has been a rising awareness among the people regarding the benefits of traditional medicine products.

Unani medicine gained momentum as an effective alternative to conventional medicine due to its systematic approach towards diagnosis and treatment of diseases, effective management of lifestyle disorders and primary focus on prevention of ailments. A holistic approach is adopted in managing diseases. Unani medicine provides a radical and safe cure for various chronic disorders, such as psychoneurotic disorders, hepatobiliary disorders, gastrointestinal disorders, and metabolic disorders. Unani Medicine believes that the real physician is the body's intrinsic power of healing which maintains its normal state of health (*Tabi'at*). Accordingly, a number of drugs are available which boost up the immunity of the body. The concept of using organ and system-specific tonics is a unique feature of the Unani Medicine and a number of drugs are prescribed to strengthen and tone up various vital organs of the body.[6]

Dietotherapy is an important part of treatment in Unani medicine. It is used for prophylactic purposes for the maintenance of health as well as for therapeutic purposes for the treatment of diseases since ancient times. Before

Strengths of Unani Medicine

- Unique concept of (Mizaj) Temperament
- Holistic approach to treatment
- Safe and radical cure of chronic ailments
- Focus on prevention of disease
- Ilaj Bil Ghiza (Dietotherapy)
- Ilaj Bil Tadbir (Regimenal therapies
- Strengthening of Immunity
- Use of Muqawwiyat(Tonics)
- Low cost

treatment with drugs, Unani physicians recommend treatment by modifications in diet according to age, daily routine, gender, season to remain healthy. (Razi, 1991 and Majusi, 2010)

Amidst the global concern related to chronic diseases and ageing, the low-cost, holistic and nature based Unani interventions have attracted the interest of several countries leading to their growing demand and acceptability.

Status in India

Since promotion of health is one of the priority areas for the Government of India, to improve the health status of people through traditional systems of medicine, the Government has taken many steps including strengthening of educational systems, facilitating the enforcement of quality control of Ayush drugs and sustainable availability of raw-materials. Increasing patronage and funds for multifaceted development has led Unani medicine to form an integral part of national healthcare delivery system.

Education and Practice

India has wide network of Ayush educational institutes and a solid framework of regulatory provisions to govern the education in Ayush systems of medicine including Unani medicine. The National Commission for Indian System of Medicine is the statutory body constituted under National Commission for Indian System of Medicine Act, 2020. The Act provides for a medical education system that improves access to quality and affordable medical education and ensures availability of adequate and high quality medical professionals of Indian System of Medicine in all parts of the country.[7, 8]

There has been a significant increase in AYUSH colleges/teaching institutions during the last decade. The central government has increased the financial support from Rs 09 crore to Rs 70 crore to ensure more Ayush colleges are opened across the country.[9] At present there are 57 colleges of Unani medicine in India with a total intake capacity of 3312 undergraduate seats and 319 post graduate seats. The number of Institutionally Qualified (IQ) registered practitioners has also increased during the last decade. There are around 43959 Registered Unani Practitioners in India and Unani medical care services are being provided through 252 Unani hospitals and 1688 dispensaries.[10]

Unani Medical Centres are also co-located in major Government Allopathic Hospitals like Dr. Ram Manohar Lohia (RML) Hospital, New Delhi[11], Deen Dayal Upadhyay (DDU) Hospital, New Delhi[12] and Safdarjung Hospital, New Delhi[13]. The centres provide GOPD facilities and specialized Unani treatment for some selected disorders like Vitiligo, Eczema,

Table 1 : Infrastructure for Unani Medicine in India

No. of Colleges	No. of UG Seats	No. of PG seats	No. of Registered practitioners	No. of Hospitals	No. of Dispensaries
57	3312	319	43959	232	1688

Source: Ayush in India, 2019 , Report , Ministry of Ayush

Psoriasis, Rheumatoid Arthritis, Bronchial Asthma, Sinusitis, Infective Hepatitis, Diabetes Mellitus, etc.

The National Ayush Morbidity and Standardized Terminologies Electronic Portal (NAMASTE - Portal) is exclusively dedicated to the centralized collection of morbidity statistics of all Ayush systems. Morbidity codes of Unani Medicine were developed and are now used all over India and in the peripheral Institutes of CCRUM via NAMASTE Portal.[15] The A-HMIS (Ayush Hospital Management Information System) has also been successfully implemented in peripheral institutes of CCRUM.[16]Ministry of Ayush has also brought out Telemedicine Practice Guidelines for Ayush systems of medicine to enable ASU practitioners to use the telemedicine tools.[17] Mobile apps on Single Unani Drugs, Unani treatment guidelines and know your temperament application, has been developed by CCRUM and launched on Unani Day 2022.[18]

Research and Development

The Central Council for Research in Unani Medicine (CCRUM) is the apex institution in India entrusted with research and development of Unani Medicine. During more than four decades of its existence, CCRUM has made significant strides in clinical research, drug standardization, survey and cultivation of medicinal plants, and literary research. The Council under its Clinical Research Programme has conducted studies on a number of investigational drugs besides validating several pharmacopeial formulations in different disease conditions at its research centres and in collaboration with other scientific institutions. Based on the outcome of research conducted by the Council, 17 patents have been granted by the Indian Patent Office (IPO) and seven patent applications are under consideration at the IPO. Researches carried out by the Council are published in the Journals of International / National repute.[19]

Research on Unani medicine is also being undertaken in academic Institutions of Unani Medicine like National Institute of Unani Medicine (NIUM), Bengaluru, School of Unani Medical Education and research, Jamia Hamdard, Ajmal Khan Tibbiya College, Aligarh Muslim University Aligarh and other institutes of repute. An interdisciplinary approach making use of the advanced scientific tools is being adopted in conducting research and innovation on Unani medicine. The AYURGYAN Scheme (Erstwhile Extra Mural Research Scheme) of the Ministry of Ayush provides support for Education, Research and Innovation in Ayush.[20] Consequently a number of reputed Government as well as private academic and research Institutions are engaged in establishing the evidence-base of Unani medicines which include Council for Scientific and Industrial Research (CSIR), All India Institute of Medical Science (AIIMS), New Delhi, Jamia Hamdard, New Delhi, Vellore Institute of Technology, Vellore, Vallabhbhai Patel Chest Institute (VPCI) University of Delhi, Delhi, University College of Medical Sciences (UCMS) and Guru Teg Bahadur (GTB) Hospital, Delhi, National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad, Jamia Millia Islamia, New Delhi and many more. Some of the areas / diseases where important research and innovation studies on Unani drugs are being carried out include dengue, cancer,

neurodegenerative diseases like dementia, diabetes, lifestyle disorders, Immuno-modulation etc.[21]

Quality Control and Development of Standardized Unani Formulations

Since the worldwide demand for alternative medicine resulted in growth of natural product markets therefore, the need for developing international standards for Ayush products also became imperative. In India, several legislative and administrative measures are in place to control the manufacturing and sale of Ayurveda, Siddha and Unani medicine. Chapter IVA in the Drugs and Cosmetics Act, 1940 describes the provisions for regulation of manufacturing, packaging, labelling and sale of ASU drugs. The Government of India has established the Pharmacopoiea Commission of Indian Medicine and Homoeopathy with the primary mandate of publishing Pharmacopoeias and Formularies for drugs/formulations used in Ayurveda, Siddha, Unani and Homoeopathy (ASUandH) systems of Medicine. The Commission serves as an umbrella organization for Ayurvedic, Siddha, Unani and Homoeopathy Pharmacopoeia Committees. The Phytochemical Reference Standard (PRS) is maintained by Commission to support the ASUandH manufactures for the Quality Control of ASUandH Medicines.[23]

The Unani Pharmacopeia of India for single drugs and compound drugs and National Formulary of Unani Medicine have been published to assure Quality and standards of Unani medicine. So far 298 single drugs and 200 compound formulations have been standardised in accordance with the format approved by Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIMandH) and Unani Pharmacopeia Committee. Besides, the National Formulary of Unani Medicine, in six volumes, contains 1,229 formulations. These formularies and pharmacopoeias serve as official compendia of standards under the Drugs and Cosmetics Act, 1940 pertinent to quality standards of the Unani Medicine. As a result Quality standards for Unani drugs have developed significantly over the years to maintain identity, purity, efficacy and quality of the drugs. An interdisciplinary approach making use of the advanced tools and modern scientific methods is being adopted to develop globally acceptable and universally applicable Unani drugs and formulations.

At industry level, there is a coherent approach where Unani manufacturers have come together on a common platform with the name Unani Drugs Manufacturers Association (UDMA).. Currently, over 70 Unani manufacturers from across the country are its members, which comprise of more than 95% of the overall Unani industry in India, both in terms of volume and value of business.–UDMA is actively engaged in taking part in various initiatives of Ministry of Ayush.[27]

Ayush Systems during COVID-19 Pandemic

The approach of Ayush systems for strengthening host defence has proven to be useful as an effective, safer, accessible, and affordable prophylaxis in management of COVID-19. The Ministry of Ayush issued various guidelines and advisories to improve immunity and advised simple home remedies easily accessible to the general public. It also recommended a

set of self-care guidelines for preventive health measures, with special reference to respiratory health and enhancing immunity. (Kotecha, 2021).

CCRUM carried out an Add-on study in hospitalized SARS-CoV2 tested positive asymptomatic /mild to moderate symptomatic COVID-19 cases, managed as per Government. of India COVID-19 management guidelines, at a COVID-19 management facility at A and U Tibbiya College, New Delhi. Another study to assess the safety and efficacy of add-on Unani regimen in preventing the progression of the severity of the disease in mild to moderate symptomatic COVID-19 RT-PCR Positive cases has been conducted in collaboration with Safdarjung Hospital, New Delhi. In-silico studies on four Unani formulations namely Triyaq-e-Wabai, Triyaq-e-Arba, Arq-e-Ajeeb and Novel Unani drug have shown the efficacy of Unani formulations against SARS-COV-19 virus which has been carried out at Sri Rama Chandra Institute of Higher Education and Research, Chennai. These studies are aimed to provide evidence-based data in the support of Unani Intervention for the prophylaxis against Covid 19 and pave new horizons in understanding the preventive potential of Unani Medicine.[28]

Global Practice and Institutionalisation of Unani Medicine: India's Outreach

Unani system is presently practised in India, Bangladesh, Pakistan, Sri Lanka, China, Iran, Iraq, Malaysia, Indonesia, Central Asian and Middle Eastern countries, some African and European countries, etc. Unani system is popular in different parts of the world with different names. In India, Bangladesh, Sri Lanka and South Africa it is known as Unani Medicine or Unani Tibb as it originated from Greece. In Iran, it is called as Persian Medicine, in Pakistan as Eastern Medicine, and in China as Uyghur Medicine.

Unani Medicine has institutional framework in Bangladesh, Sri Lanka and Pakistan. In South Africa, the School of Natural Medicine, Faculty of Community and Health Sciences, University of Western Cape offers a four-year degree course in Unani Tibb. In Iran, Unani Medicine is practiced as Traditional Medical System, and the Government is keenly interested in its revival and development and has initiated a number of programmes for this purpose. There is Traditional Medicine and Materia Medica Research Center established at Shaheed Beheshti Medical University, Tehran. In Malaysia, Unani Medicine is recognized and practiced under Traditional Indian Medicine. In Kuwait, Unani Medicine is practiced as Islamic Medicine and an Islamic Medicine Center is also established.[29]

The popularity of Unani Medicine is more in the South Asian countries due to cultural, historical and geographical commonalities. The countries in the region have vast resources of medicinal plants, and have extensive systems of Traditional medicine within existing health services. The role of Unani medicine and its practitioners have been recognized by the governments in this region.

The concerted efforts taken by the Government of India domestically towards the growth and development of Ayush systems of medicine by way of improving the quality of educational institutions, establishing comprehensive healthcare facilities and state-of-the-art research

institutions and developing quality drug manufacturing industries, have boosted the confidence in the Ayush systems of medicine globally. With a large network of Unani educational Institutions providing quality education, scientific validation of Unani practices through clinical researches, application of stringent quality control measures in the manufacturing of Unani drugs, India has emerged as the global leader in Unani System of Medicine and is well positioned to offer Unani Medicine knowledge, products and services to the global community.

The interest in Unani medicine and its acceptance in the global community was evident during the International Conferences organized by CCRUM during 2018, 2020 and 2022, where a number of delegates from Bahrain, Bangladesh, China, Hungary, Israel, Portugal, Slovenia, South Africa, Sri Lanka, UAE, UK, USA, Iran, Malaysia, South Africa and Sri Lanka had participated. [30, 31,32] Today the globalization process of the Unani medicine has reached many nations, due to the efforts of the Ministry of Ayush and Central Council for Research in Unani medicine. At International level, CCRUM has engaged in fruitful dialogue with countries like South Africa, Iran, China, USA, UK, Israel, Greece, Bangladesh, Sri Lanka and few other countries. An MoU between CCRUM and Tajik State Medical University named after Avicenna for cooperation in the field of Traditional Medicine was signed in the presence of Hon'ble former President of India, Shri Ram Nath Kovind and Hon'ble President of Tajikistan Emomali Rehmon in Dushanbe, Tajikistan.[33] An MoM was signed with Ministry of Health in Iran for cooperation in the field of traditional medicine.

A major initiative taken by the Ministry of Ayush is establishment of Ayush academic chairs in foreign Universities.[34] An academic Chair was set up at School of Natural Medicine, University of Western Cape, South Africa where a Professor was deputed for three years to help in promoting and propagating Unani medicine. An MoU with Hamdard University, Bangladesh to set up an academic Chair was also signed by CCRUM. An expert has recently joined the University as chair.

Resurgence of Ayush at international level also resulted in growing demand from foreign students to study in Indian institutions. The Government of India supports foreign nationals under Ayush scholarship programme for undertaking Ayush courses at premier institutions in India.[35] A number of students from the foreign countries have received training in Unani medicine at reputed institutes in India under the scheme. These scholars who take admission in Ayush courses in India take the knowledge to their home country for the practice of this system of medicine there. In a way they become the Ambassadors of Ayush system in their country.

There is futuristic work going on for Unani medicine in World Health Organization under an MoU signed between WHO and Ministry of Ayush. As a result, Benchmarks for training and practice in Unani medicine has been published. The WHO benchmarks for the training and practice of Unani medicine defines the minimum requirement/criteria for providing training and establishing practice in Unani medicine in WHO Member States. This document provides WHO Member States with general and minimum technical requirements for

quality assurance and regulation of Unani medicine practice. [36]

Work is also in progress for inclusion of Unani morbidity terms/codes along with Ayurveda and Siddha in ICD TM 2 ASU module.[38] The positive outcomes of Ayurveda, Unani and Siddha getting integrated into the ICD will not be restricted to India, but will be available to all WHO member states (in practice all countries were ICD is adopted), and will be notably felt in nearly 50 countries where these systems or their closely related forms are practiced. ICD will facilitate the counting of health services and encounters of these systems, further enabling the measurement of their parameters like form, frequency, effectiveness, safety and quality.(Ranjit Kumar, 2022)

Future Strategies for Globalisation

As is evident from above, Government of India has provided ample support at national and international level for the development of Unani medicine along with other Ayush systems. At global level, the acceptance of our various Indian systems including Unani Medicine would depend on sound scientific explanations of the basic theories and specific strengths of these systems. Adhering to the quality standards for the products and services is important for the growth of the traditional medicinal products market. Availability of trained competent workforce for providing services as required by international standards is also equally important.

The Government of India's 'Heal by India' initiative is meant to generate job opportunities abroad for India's trained Health professionals. Strengthening the country's educational institutions in the health sector and upgrading education is an important task being undertaken to produce professionals who are competent to work anywhere in the world.[39] To establish a successful practice of Unani medicine in foreign countries it is important to be aware of the cultural background of that country including social etiquettes, social behaviour, food, language, culture etc. Developing good communication skills will also be essential in dealing with patients. The practitioner should develop proficiency in treatment with single drugs which are locally available, and advising life style modifications in accordance with the fundamentals of Unani medicine. .

Knowledge about the legal status pertaining to the practice of traditional and complementary medicine is also very important in establishing overseas practice of Ayush. Several countries have provisions for practice of Unani and other Ayush systems of medicine. These include UAE, Malaysia. Countries like US, Canada and Australia have varying degrees of legal permissibility. These may be explored for greater penetration of Unani in other countries.

Conclusion

Modern therapies have limitations to completely cure chronic and lifestyle conditions. There is also a shift in the global consumer trend towards herbal, organic, natural, and wholesome health solutions. The treatment modalities of Unani medicine include diet, lifestyle modifications, products and therapies. This holistic approach of Unani medicine in the management of diseases makes it not just a curative system of medicine but also a preventive and promotive healthcare

system. This has led to a paradigm shift in adoption of Unani medicine into the mainstream healthcare. The focussed attention of the Government of India towards research and development of this system has resulted in its exponential growth and acceptance globally. With a strong thrust on promotion of Ayush systems of medicine by the government and an increased and prioritised focus on the products and services of traditional medicine, there has been a rapid rise in the industry's market potential. Industry needs to be more proactive in terms of expanding the horizons and making use of various initiatives of Government. of India. There is a need to continue the initiatives to improve the level of awareness about Ayush systems of medicine and their strengths among the public, and particularly among the younger generation for the future growth of the system at national and international level. There are enabling provisions in many countries which can be explored by Unani professionals to establish themselves and seek job opportunities at global level. WHO benchmarks for training and practice can be the guiding principles for further promotion and propagation of the system.

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Quality Assurance in Ayush: Relevance of Voluntary Certifications and Accreditations

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Introduction

As one of the biggest and fastest growing economies, India rightly aspires for considerable presence and leadership for its goods and services in the global market. However, global market access is often dependent on subscription to global standards. India's traditional medicine (TM) sector is no exception. Given that it has health implications, Ayush products and services are liable to regulation as enunciated in the WTO Agreements on Technical Barriers to Trade (TBT) for goods and General Agreement on Trade in Services (GATS)[1]. The wide diversity of goods and services produced by the Ayush sector, often allied with other industries such as food, cosmetics and nutraceuticals, and evolving global norms specific to traditional medicines, creates adoption of globally accepted standards a challenge. While subscription of essential regulatory requirements are the first steps towards safety and quality assurance, conformity assessment which is often a mix of manufacturers' self declaration, government approval and third party certification vary as per the specification of the buyer in a given market. This article looks at the relevance of voluntary standards and certifications in fulfilling these conformity assessment requirements to gain access to global markets.

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Quality and Safety Assessments for Marketing Goods and Services: Norms in Traditional Medicine Sector

Traditional medicine is subject to varied regulations globally. In countries of origin such as India and China, these systems have strong institutional integration in the healthcare delivery systems and drugs are a part of the pharmaceutical industry with distinct legislations addressing the quality and safety of manufactured goods. In several countries, these systems are yet to be recognised as systems of medicine. At the same time, the regulatory norms are in the process of evolution in many others. This includes the EU's European Directive on Traditional Herbal Medicinal Products (THMPD) and Canada's Natural Health Product Regulation, which allow traditional medicines to be registered for market authorisations subject to conditions. The regulations globally have some common requirements – Good Manufacturing Practice (GMP) subscriptions which are atleast at par with WHO GMP[2] guidelines. It is necessary to meet these requirements even if simpler regulations to provide access to traditional medicines have been promulgated by some countries.

Typically, compliance norms include two components. The first includes legislation driven product (or service) requirements sometimes accompanied by production- related practices e.g. GMP in Ayush or modern medicine sector in addition to product requirements prescribed in the respective Pharmacopoeia. The second is the method of demonstrating compliance, called 'Conformity Assessment' (CA), which also has to be internationally acceptable. The global acceptance of Ayush is increasingly dependent on CA which is discussed further in later sections. The same components are part of any voluntary certification/accreditation programme.

Regulatory Requirements for Ayush Goods in India

As an industry that impacts the health and safety of citizens, Ayush is subject to strict regulatory norms in India. This includes licensing requirements and renewal thereafter. Quality control through exclusive provisions in the Drugs and Cosmetics Act, 1940 and Rules 1945 is mandated for the licensing, manufacturing, laboratory, shelf-life and testing of Ayush drugs along with Pharmacopoeial standards for both single herb drugs and formulations.

GMP Compliance under Drugs and Cosmetics Act, 1940

Under the Drugs & Cosmetics Rules, 1945, Schedule T (Rule 157) specifies the requirements of factory premises and hygienic conditions with the aim of introducing a uniform standard of hygiene for the manufacturers. Compliance with GMP as per the Rules is mandatory for all the manufacturers of Ayurveda, Siddha and Unani drugs. Table 1 highlights the GMP compliance units. As shown in the table subscription to these standards has grown across systems in the last decade. Among others, this demonstrates the growing modernisation of the industry and readiness for global markets. However, GMP requirements as per the Drugs and Cosmetics Rules 1945 are not at par with the WHO GMP guidelines.

Pharmacopoeial Standards

Pharmacopoeial standards are also mandatory requirement for the implementation of the drug testing provisions under the Drugs and Cosmetics Act, 1940 and the Rules thereunder. These standards are essential to check samples of drugs available laboratories in the market for their safety and efficacy. Pharmacopoeial standards through Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H) are official Formularies. Pharmacopoeias of Ayurveda, Siddha, Unani and Homoeopathy drugs define uniform standards for the preparation of drugs and to prescribe working standards for single drugs as well as formulations in the respective system. Standards-setting exercise till date comprises of publication of the Ayurvedic Formulary of India (Part I-III) consisting of 985 Formulations, Siddha Formulary of India (Part I-II) consisting of 399 Formulations and the National Formulary of Unani Medicine (Vol. I-VI) consisting of 1229 Formulations.[3] Further pharmacopoeial monographs on 645 Single drugs (Vol. I-IX) and 202 Formulations (Vol. I-IV) of Ayurveda, 139 Single drugs of Siddha (Vol. I-II), 298 Single drugs (Vol. I-VI) and 200 Formulations (Vol. I-IV) of Unani and 1117 drugs (Vol. I-X) of Homoeopathy have been published[4]. Uniformity and safety are ensured through the pharmacopoeias, although mutual recognition of pharmacopoeias between countries are often a challenge, specially with respect to traditional herbal medicines such as Ayush. While Ayush pharmaceuticals may subscribe to the respective pharmacopoeias in India, these may not be adequate for market authorisation in countries such as US or EU which do not accord formal recognition to Ayush pharmacopoeias. In this context conformity assessment becomes relevant.

Conformity Assessments (CA)

The International Standard Organisation (ISO) independent, non-governmental international organization with a membership of 167 national standards

Table 1 : Year-wise/System-wise number of GMP Licensed enterprises

Year	Ayurveda	Unani	Siddha	Homoeopathy	Total
2010	4841	185	83	199	**5308**
2011	5465	206	88	181	**5940**
2012	6182	225	88	192	**6687**
2013	6455	212	85	207	**6959**
2014	6937	232	103	230	**7502**
2015	7100	212	103	238	**7653**
2016	6808	273	181	226	**7488**
2017	6834	277	93	229	**7433**
2018	7142	383	211	229	**7965**
2019	6984	375	147	200	**7706**

Source: Ministry of AYUSH, Ayush in India 2019 Report

bodies, defines CA as the process that demonstrates whether a product, service, process, claim, system or person meets the relevant requirements. Such requirements are stated in standards, regulations, contracts, programmes, or other normative documents[5] . The European Commission defines CA as 'procedures required to demonstrate that a product, before it is placed into the market, conforms to these essential requirements of the directive that apply to it' [6] . A comprehensive definition of CA procedure is provided by WTO which describes it at 'any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled. CA procedures include, inter alia, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations'[7]. It is thus no longer enough to merely comply with mandatory domestic regulatory requirements. There are a variety of conformity assessment routes that are being adopted. The least stringent is the self declaration of conformity (SDoC), used extensively by the European Commission in its regulations for Conformitè Europëenne (CE) Mark[8] to the intensive third party assessment of the kind Bureau of India Standards (BIS) uses for example in compulsory certification of bottled water or cement[9]. Non subscription to CA has become a major cause for trade barriers. A study by WTO in 2016 on 'specific trade concerns' raised in its TBT Committee indicated that while 30 per cent issues were based on product or related standards, 70 per cent issues were due to CA [10]. This is because there can be one common standard for the products, but depending on the risk, the method of demonstrating compliance can vary from self-declaration of conformity to independent testing to independent testing and certification. An example of the way conformity assessment can affect global acceptance of Indian goods is the case of gold jewellery in India, where despite the purity being at par with global requirements and being certified as Hallmarked[11], gold may still face challenges in acceptance abroad because the assaying centres in India are not accredited to ISO 17025[12], an international non-governmental organisation certified voluntary standard. CA of goods manufactured, is thus dependent on subscription to both technical regulations prescribed and the globally accepted standards recognised in the export destinations. For example, good laboratory practices (GLP) is often a requirement for traditional medicine products export. Laboratories that are accredited to the international standard, ISO 17025[13] may gain greater confidence with the buyer in the export destination. Voluntary standards, both public and private, are an essential means to CA.

Development of Voluntary Standards and Certifications for Ayush Goods

Even as India's domestic regulations for Ayush are evolving, the question that remains to be answered is that pending adoption of globally accepted standards, how does Ayush industry demonstrate compliance with global standards and CA? Voluntary standards and certifications (for manufacturing) and accreditations (for services) become relevant in this context. While regulations mean standards enforced by law compulsorily for everyone, as has been enumerated above, voluntary standards/certifications/accreditations,

Table 2: Comparative level of aflatoxins permitted under Standard Mark and Premium Mark

Aflatoxins	AYUSH Premium Mark (permissible limit)	AYUSH Standard Mark (permissible limit)
B1	0.5 ppm	0.5 ppm
B1+ G1 + B2 + G2 sum of	10 ppb	1.2 ppm

Source: Quality Council of India.

as the name implies, are adopted by the industry of their own free will. Globally voluntary certifications and accreditations are prevalent even in regulated sectors like food or medical devices and are even a prerequisite to operate in global markets as these are primarily demanded by buyers. The food sector has such certifications as ISO 22000[14] for food safety management systems and private certifications like FSSC 22000[15] or BRCGS[16] all focussed on food safety systems. In medical devices, ISO 13485[17] for quality management systems specifically focussed on the medical device industry is widely popular and now even being referenced in some regulations. At present, Ayush manufacturers who export their products as food supplements, are already facing demand for these voluntary or private certifications from their buyers in addition to adherence to regulations of importing countries' regulations.

Some of the important initiatives undertaken by India towards voluntary standards/certifications for Ayush include the following:

WHO –GMP Certification of Pharmaceutical Product (CoPP)

The CoPP is issued under the WHO-GMP Certification Scheme for the purpose of international commerce. Issued by the Central Drugs Standard Control Organization (CDSCO), till date, 47 enterprises have obtained this certificate[18]. The CoPP is mandatory in many countries that require WHO accreditation for pharmaceutical products being imported. It may be noted, however, that the adherence to global standards can be demonstrated through the system of WHO GMP and CoPP certificates although these are not acceptable in many developed economies such as the EU, USA, UK, Canada, Australia etc who have laid down their own regulations for herbal or traditional medicines.

Ayush Mark Scheme

One of the first attempts at voluntary standards for Ayush goods has been the development of voluntary Ayush certification scheme comprising of the *Ayush Standard Mark* and *Ayush Premium Mark*[19] by the Quality Council of India (QCI) in 2009. *Ayush Standard Mark* is based on compliance with the domestic regulatory requirements; *Ayush Premium Mark* is based on either or both of the following options; Option A: Compliance with GMP Requirements based on WHO Guidelines and Levels of contaminants as given in the Certification Criteria document. Option B: Compliance with the regulatory requirements of any importing country provided they are more stringent than Option A above. Given that it is designed for international markets with stricter standards, *Ayush Premium Mark* imposes a higher level of restrictions on

permissible limits of contaminants for some parameters (as shown in Table 2 below). It has often been argued that a *Premium Mark* should also be encouraged in the domestic market.

International Organization for Standardization (ISO)

As the world's largest developer of voluntary international standards for products, services and good practices, ISO has also ventured into traditional medicine by setting up a technical committee, ISO TC 249, for Traditional Chinese Medicine (TCM) although specific standards on these systems of medicine are in nascent stages. Traditional medicine as food/ dietary supplements and ANI at present resort to several ISO standards on quality and safety for exports, In India, the Bureau of Indian Standards (BIS), the national standards body and member of ISO, has also set up a technical committee on Ayurveda at the behest of the Ministry of Ayush and has taken the initiative to formulate ISO standards on Ayurveda with ISO. A Working Group (WG–10) on 'Traditional Medicine' has been created in the ISO/TC-215 'Health Informatics'. Under development is the ISO/CD TR 4421 (Introduction to Ayurveda) [20]. Once formulated, certification to ISO standards can be a useful tool to add credibility to ayurvedic products.

Regulatory compliance for Ayush Services

The services, especially hospitals, are within the ambit of the Clinical Establishment (Registration and Regulation) Act, 2010[21]. Health being state subject, the provisions of the Act is subject to adoption by state governments. Only eleven states have adopted it, and hardly any have implemented the minimum standards prescribed under it[22]. Some states like Delhi even have a regulation in place for Ayush paramedical personnel in the form of the Examining Body for Para-medical Training for Bharatiya Chikitsa[23], although it is yet to notify any regulations. India also has a system of regulating Ayush education under the National Commission for Indian Systems of Medicine Act, 2020[24] and Homeopathy education under the National Commission for Homeopathy. Similarly, in hospitals, regulations are yet to take effect.

Development of Voluntary Standards in Ayush Education and Healthcare

The launch of Ayush hospital accreditation programme by the National Accreditation Board for Hospitals (NABH), a wing of QCI, in 2009 was one of the first steps towards voluntary compliance in Ayush health services to global standards. More than 100 hospitals have been accredited till date[25] assisting in promoting medical tourism in India.

NABH itself is accredited by the International Society for Quality in Healthcare (ISQA)[26] for showcasing facilities with global standards. Hence accreditation should be undertaken for ensuring quality assurance at par with the standards prescribed. However, there has been undue focus on accreditation at the expense of regulations in healthcare services. The experience of the Insurance Regulatory and Development Authority of India (IRDA) with empanelled hospitals is to be noted in this regard.[27] The IRDA started by prescribing NABH accreditation for empanelled hospitals, then got an entry-

level certification standard introduced to increase coverage of hospitals under quality standards. However, in July, 2022, it abandoned both since the progress among empanelled hospitals in meeting these standards was quite slow and instead placed the onus on the insurance providers to prescribe criteria for empanelment of hospitals. It was realised that this may lead to a multiplicity of standards with hospitals having to meet varying criteria which is not a desirable situation. It would be desirable to focus on minimum standards laid down under Clinical Establishment Act 2010 when mass healthcare is to be catered to since accreditation standards were intended to showcase world- class facilities in India and which has enabled growth of medical tourism.

Since the formation of the Ministry of Ayush in 2014, more steps on voluntary standards for Ayush services have been taken which include promoting Yoga professionals and training by setting up a certification framework with the help of QCI in 2015, a dedicated Yoga Certification Board in 2018 and the Ayurveda Training Accreditation Board in 2021 for promoting Ayurveda professionals and training[28] to meet the requirements of the global market. The Rashtriya Ayurveda Vidyapeeth, an autonomous institution under the Ministry of Ayush, has been notified as the Accrediting agency for various Ayurveda professional courses being run in the country and abroad and for certification of Ayurveda professionals, including therapists /counselors etc., not covered under IMCC Act, 1970 or any other regulations. While these programmes have initiated accreditation based on indigenous standards, it is expected that international standards like ISO 29993 for Learning Service Providers could be customized and adapted for training services under above mentioned Boards in future to gain greater international acceptance.

Recommendations and Way Forward

While it is argued that voluntary certifications/accreditations can help India gain international acceptance even as the regulations are upgraded in a defined time frame to adopt global standards, it is pertinent to know if there is any example of acceptance of India's certification systems by overseas regulators. The good news is that there are several examples/case studies:

In 1997, the EU banned seafood exports from India on grounds of these being unsafe. In order to lift the ban, India could demonstrate through the Export Inspection Council (EIC) that it had an agency dedicated to regulate and certify exports to importing countries' requirements. The European Commission, after an assessment, accepted the EIC system and designated it as the 'competent authority' which is still operating. EU accepts any seafood plant certified by EIC to its regulations and seafood has easier access to the EU market.

There are other food products where EIC has been able to secure acceptance of its certification systems, like basmati rice, poultry meat, chilli etc, from various countries like Japan, Bhutan, Thailand [29]etc.

In the mid- 2000s, the Agricultural and Processed Food Products Export Promotion Authority (APEDA) installed a system of organic certification, the National Programme for Organic Production (NPOP), based on global standards and

successfully secured its acceptance by the USA, EU and other countries to facilitate the export of organic products from India which is still operating

These examples demonstrate that institutional systems can be implemented and accepted overseas.

In building the quality regime in Ayush sector, it would be prudent to refer to the Indian National Strategy for Standardization (INSS) released by the Department of Commerce in June, 2018,[30] which articulates sound, internationally acceptable principles on which India should base its quality ecosystem. Its recommendations on the separation of roles of regulation and voluntary accreditation/certification and the recognition of the constraints under which regulations are framed in India and the need to promote Brand India through voluntary certification (accreditation in services) programmes are especially pertinent.

Based on the above narration, some recommendations can be made for the promotion of Ayush sector globally:

India needs to adopt global standards in its regulations for Ayush products and services in a defined time frame in the long run. The regulators should be advised to evolve a road map for adopting globally acceptable standards in their regulations – be it Ayush medicines or hospitals, or education.

In the immediate term, the government should focus on evolving minimum standards which can be applied across the entire sector through regulations.

The recognition of laboratories under the Drugs & Cosmetics Rules, 1945 should prescribe accreditation to ISO 17025 to enhance the acceptability of the test reports globally.

Voluntary certifications (in manufacturing) and accreditations (in services) to world- class standards should be promoted as a strategy to gain global acceptance and these systems should be presented to overseas regulators for acceptance.

Regulations and voluntary certifications/accreditations should be housed separately as a good practice. It would be desirable to follow the principles set out in the Indian National Strategy for Standardization[31] in building the quality ecosystem for Ayush sector.

For policy makers and industry alike it is imperative to recognize that voluntary certifications for goods or accreditations in services are the way to demonstrate world- class products and services until such time that India can implement robust regulatory regimes in Ayush sector based on global standards. This includes amending the GMP requirements in Drugs and Cosmetics Act, 1940 (Schedule T) at par with WHO Guidelines. Given the health implications of the sector, the primary focus of the government needs to be on comprehensive regulation of Ayush products and services to assure quality and safety to the domestic consumers at par with international markets.

Endnotes

1 Devin McDaniels and Marianna Karttunen, *Trade, Testing And Toasters: Conformity Assessment Procedures And The Tbt Committee*, WTO Working Paper ERSD-2016-09

2 WHO, 2007, Guidelines for Good Manufacturing Practices for herbal medicines https://apps.who.int/iris/bitstream/handle/10665/43672/9789241547161_eng.pdf?sequence=1

[3] Press Information Bureau, government of India , 7th December 2021 https://pib.gov.in/PressReleseDetailm.aspx?PRID=1778871

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[23] http://web.delhi.gov.in/wps/wcm/connect/doit_ebpmtbc/EBPMTBC/Home/Affiliation+of+Institutes/

[24] https://egazette.nic.in/WriteReadData/2020/221863.pdf

[25] https://www.nabh.co/frmViewAccreditedAyushHosp.aspx

[27] Empanelled Hospital means any private institution established for inpatient medical care with sufficient facilities for the disease treatment and surgeries and empanelled under the Scheme by the Insurer as per the Empanelment Guidelines

[28] http://ravdelhi.nic.in/en/Ayurveda-Training-Accreditation-Board-ATAB

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[30] https://commerce.gov.in/wp-content/uploads/2020/02/MOC_636655449469105249_INSS_Booklet_2018.pdf

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Conservation through Sustainable Use: Lessons from India

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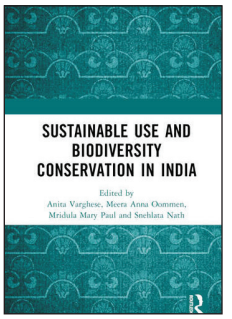

Krishna Ravi Srinivas*

Krishna Ravi Srinivas

Sustainable Use has been identified as one of the cross-cutting issues in Convention on Biodiversity (CBD) and Decision VII/14 adopted the Addis Ababa Principles and Guidelines for the Sustainable Use of Biodiversity. While the idea of sustainable use may not be controversial, there has been scepticism on this as a practice as some conservationists are of the view that sustainable use by communities is not feasible and will, in fact, adversely impact conservation. But many others think that conservation and sustainable use can be complementary and mutually supportive. This is considered as an inclusive model of conservation and much work has been done in India on this model. The inclusive model is not insensitive to the tensions and contradictions in making conservation and sustainable use as mutually supportive and complementary. It recognizes the rights of the various stakeholders, traditional resource rights and the equity and justice aspects of conservation instead of linking conservation with species and ecosystems only. The Forest Rights Act of 2006, aka Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006 recognizes the rights of ' forest dwelling tribal communities and other traditional forest dwellers' to forest resources and one of the objectives of the Act is to develop positive linkage among conservation, sustainable

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use, rights of the stakeholders under the Act and conservation of biodiversity. This volume addresses this issue through case studies from India and identifies the lessons from the case studies.

The editors in the introductory chapter contextualize the issues in sustainable use and under the complexity of sustainable use as a theory and practice. They point out that one way of classifying sustainable use would be to categorize sustainable use as consumptive use and non-consumptive use and provide examples for this and the stakeholders involved. By introducing the case studies and identifying the issues, they address, they have more or less summarized the contents in the introductory chapters. The case studies are listed under four sections categorized as Governance, Enterprises, Community Knowledge, and Intangible benefits. While some of them are related to case studies involving tribal communities, some pertain to stakeholder engagement and commercialization. I have found that the sheer diversity in case studies is amazing and very relevant because while issues may seem to be common or similar, the contexts are different and so are the lessons/implications from case studies. Obviously, they also point out the emerging conflicts among stakeholders, the wide variance in values and norms and the dynamics of change in sustainable use. They illustrate the many narratives of the idea and practice of sustainable use and cover different categories of sustainable use. Obviously, the power dynamics between those who use it sustainably and those who control it play out, although often the former has little or no control over resources. Similarly, some values and practices related to sacred groves may be inducing the right behaviour related to conservation. But in some contexts, the value and norm conflicts between traditional communities, outsiders and newly settled groups result in conflict over use and claims on use. The diversity in the case studies makes it obvious that potential and real conflicts among various stakeholders have to be addressed if sustainable use is to be sustained. The editors provide suggestions and way forward, based on inter alia- the case studies. I see merit in them, although some of the emerging challenges are either understated or ignored. For example, sustainable use or, for that matter, biodiversity itself is facing a threat from climate change, not to speak of other threats like deforestation, and impacts of large scale development projects. I do agree with the editors that 'interdisciplinary approach in research and practice' is required, but larger policy changes may also be needed. How to bring in those changes is really a challenge but identifying them is also necessary.

To sum up, this volume, through case studies and reflections based on them, provides an enriching account on the issues and dilemmas related to sustainable use in the Indian context. Its merit lies in linking the idea/theory with ground reality through case studies and in providing suggestions and a way forward. This is a must- read for anyone interested in biodiversity, particularly sustainable use of biodiversity and conservation.

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Use's' in '-ise' '-isation' words; e.g., 'civilise', 'organisation'. Use British spellings rather than American spellings. Thus, 'labour' not 'labor'. Use figures (rather than word) for quantities and exact measurements including percentages (2 per cent, 3 km, 36 years old, etc.). In general descriptions, numbers below 10 should be spelt out in words. Use fuller forms for numbers and dates — for example 1980-88, pp. 200-202 and pp. 178-84. Specific dates should be cited in the form June 2, 2004. Decades and centuries may be spelt out, for example 'the eighties', 'the twentieth century', etc.

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