Executive Summary

Focus of the Report

This Report has six chapters and an Epilogue. The genesis of each chapter and important features that stand out are summarised below. The Report describes the status of Ayurveda, Siddha and Unani (ASU) systems of medicine with reference to areas that impact directly on the public. Consequently, aspects of work that go on elsewhere in the traditional medicine sector but do not directly touch peoples' lives have not been included here. Since the thrust is on the Indian public, the globalisation aspects of ASU are also not included except briefly in the Epilogue.

Chapter 1: Historical Perspective

The historical developments that have impacted on this sector have been described in the first chapter and also in the introduction to the chapters on Education and Drugs. This has been done because the history of Indian medicine is generally available to policy makers in the form of summaries. These do not give an idea of events and policies that have influenced the world of ASU. Most generalist administrators assume office as Secretaries and Directors of Indian Systems of Medicine (ISM) in the Ministry of Health or in the States, without an exposure to the historical evolution of policy. This often leads to understanding priorities as presented by one or more protagonist groups in which the consideration of public benefit often takes second place.

The whole debate between purists and modernists in fact started in the 19th century but the issues are alive even today and remain unresolved. That dichotomy has been carried through and is reflected in the structure of the college curricula, medical practice, the manufacture of drugs, their packaging and marketing. All this even as the formulation of drugs by hand and traditional practice of medicine continues side by side. Given this background it is only by reading the critiques published by those who had no stake in the power-play of knowledge or commerce is it possible to understand factors that have driven and continue to influence the sector.

The first Chapter describes the history from 1912 onwards and the responses of the Vaidyas and Hakims to the advent of Western medicine and their efforts to re-position traditional medicine. After independence there was growing support for Indian medicine but almost every Committee set up by the Government recommended that the systems re-prove themselves by meeting the benchmarks for scientific research as prescribed for modern medicine. The move to integrate the systems with modern medicine through the vehicle of education resulted in a backlash. Although the integrated course was discontinued, subsequent developments caused by market developments and the aspirations of the ASU practitioners who sought parity with the modern medicine sector has led to the re-introduction of a heavy component of modern medicine in the curricula of ASU professional colleges.

Political support for ASU has not been lacking either at the Centre or many states. The history of the creation of an independent Department, the change in the name of the Department from ISM to AYUSH, and efforts to spread awareness about the systems in other countries have been described which were the result of the protagonists of traditional medicine devoid of vestiges of modern medicine.

Chapter 2: Research

From the '60s onwards, investments have been made in pursuing traditional medicine research. In the government sector this was initially done by the Indian Council of Medical Research (ICMR) and somewhat later by the Council of Scientific and Industrial Research (CSIR), the Department of

Biotechnology (DBT) and the Department of Science and Technology (DST). In the 70s, autonomous research councils were established for pursuing research in ASU medicine. The chapter attempts to collate at one place specific outcomes of research that directly benefit the public.

In summary, some of the work of CSIR related to a few drugs that have reached the market, the superb execution of the traditional knowledge digital library and efforts made towards drug standardisation stand out.

In the case of ICMR, despite a promising start, proven research findings published by the Council have not been translated into products even when all the rigours of biomedical research have been adhered to, as in the case of *Vijaysar* for diabetes.

The outcomes reported by DBT give hope for the future, when seen as initiatives that can protect, preserve and conserve specific medicinal plants; but the dimension of the impact has to be seen against the extent of shortage of medicinal plants and the gaps that biotechnological interventions can hope to fill.

An enumeration of numerous projects awarded by DST exhibit the thrust areas of those who have been pursuing research with funding support. All the projects continue to be in progress, in some cases, for several years. According to DST it is too early to talk of outcomes. On another plane, the advice of Secretary, DST on how future clinical research should be undertaken provides a simple roadmap for the future that carries conviction. The approach has been corroborated by several experts engaged in traditional medicine research and has been described fully.

On the basis of responses received from the Central Councils engaged in conducting research into Ayurveda, Siddha and Unani medicine, two facts stand out: first that in-house clinical research undertaken by the councils has not yielded positive outcomes either by way of published work or by way of grant of patents. Despite that, thousands of people are reported to have benefited from the utilisation of formulations prepared by the two councils and the demand for treatment offered at various centres is extensive. A change of track has been recommended in the report along with a new mantle to be donned by the research councils, so that the work done for more than three decades can at least now benefit a wider public.

The chapter on research also gives a bird's-eye view of the canvas on which academic research in the ASU sector is undertaken in universities and colleges along with the impact factor of research undertaken by such bodies.

Chapter 3: Education

In this chapter after recounting the broad status of how college education for the traditional systems of medicine was first introduced in the early 19th century, the current status has been described with special reference to the curriculum and syllabus prescribed for undergraduate and postgraduate medical education courses. The chapter is based upon the outcome of extensive consultations held with the faculties of universities and leading ASU colleges and written responses received to detailed questionnaires sent online and through post. The findings indicate a host of shortcomings that exist from the point of view of the majority of stakeholders. Based upon their opinions and suggestions, recommendations have been made on various aspects of the curriculum and syllabus.

More importantly, the case has been made to view professional education in the traditional medicine sector as a means to build competences and skills in the practitioner which would be beneficial for the delivery of health services but more specifically to treat patients seeking authentic ASU treatment. The debate between inclusion and exclusion of modern medicine has been addressed presenting the views expressed by the Courts, the ground realities and well-known arguments on both sides. The recommendations made are based upon the views of state governments and individual faculty members that had contributed in a series of discussions and in response to the questionnaires.

In particular, the orientation of the curriculum, the need for involvement of professional bodies in curriculum design, a discussion on bed strength and availability of inpatient load, the sequencing of the training, the need for paramedical and non-teaching staff, suggestions relating to the teaching of Sanskrit and Urdu, improvement in the availability of text books and journals, teachers' qualifications and aptitude have been reflected, based on comments received. Other aspects like the need for early exposure to good clinical practice to satisfy the students' curiosity, improving computer literacy, the need to encourage intra-ASU system interaction and the possibility of introducing a bridge course for modern medicine doctors have also been discussed.

The chapter discusses the need for using information technology to be able to teach the practical component of the curriculum by establishing a Virtual Resource Centre and by providing downloadable modules so that students regardless of their institution receive the opportunity for meaningful self-study.

Chapter 4: Practice

This chapter is descriptive of actual practice as conducted in the government set-up and in private establishments. Different levels at which clinical care is offered, whether through a single practitioner or through multi-speciality hospitals, has been described. This is intended to be a quick cross-sectional view to give an idea of the kind of cases that are being treated, the clientele that seems to be accessing services and the general atmosphere in which patient care services are provided. There is minimal written description and the effort is to present a series of photographs which speak for themselves. The need for public edification has been discussed particularly as few people know of the existence of such practice. Also the need for agreed standards on Panchakarma procedures which are increasingly being presented only as relaxation massage. Several unique practices go on in a highly localised context but they have seem to have potential for addressing not only chronic diseases but also for alleviating pain and discomfort caused by modern-day lifestyles. The illustrated chapter presents a pictures of the reality of ASU practice. The picture is uneven but the outreach is substantial.

Several recommendations have been made for building greater awareness about the availability of specific treatment and on creating more avenues to access reputed ASU treatment.

Chapter 5: Medicinal Plants

This chapter has three sub-chapters dealing with:

- The Uniqueness of Traditional and Folk Medicine
- The Raw drug trade - Interaction with dealers
- Demand and supply of raw drugs

The first sub-chapter is an attempt at exploring whether the usage of certain medicinal plants used by tribal and folk practitioners reported in the monographs prepared by the Research Councils (and which do not find place in the codified ASU texts) are unique as compared to their reported usage in published scientific literature. The findings cannot form the basis for any assumption but it does show that the use of medicinal plants by tribal and folk healers is unique, at least in the few cases taken up for study in this Report. This points to the need to go beyond mere documentation to foster further enquiry into the findings.

The second sub chapter-deals with the main conduit through which medicinal plants are procured and purchased by the raw drug dealers. The traders are important because they have a virtual monopoly on the supply of medicinal plants to industry but little has been done to upgrade their practices either through training, incentives for modernisation or through regulation. This is one of the most important links in the chain of drug processing and manufacture and determines the quality of inputs that go into the making of ASU drugs. Therefore it was important to understand what the traders had to say.

The chapter shows that they are willing to move to better practices but equally, as invariably happens whenever there is a move to change the status quo, there is a tendency to shift the responsibility on to the government. The chapter gives an understanding of how far it might be possible to reorient the collection and supply of medicinal plants.

The third sub-chapter deals with the demand and supply of medicinal plants and tries to show the enormous opportunity that lies ahead for India to become a strong and sustainable supplier of raw and processed drugs after meeting its own needs. The measures that would have to be adopted based upon the advice of botanists, those who regulate drug manufacture in the government, professionals in charge of quality control and regulatory affairs in the ASU drug industry have been recounted. A roadmap for temporarily utilising existing structures and eventually setting up new organisations has been described.

In the long term, there is a suggestion to set up a professional institute for managing trade in medicinal plants with a division for tribal and folk medicine and using extensive surveys undertaken by 22 centres under the ASU research councils. The suggestion is to set up a consortium of similar institutions that are all working in this area to run professional courses which would develop regulatory and marketing competencies needed to manage the many facets of the medicinal plant sector to run productively. Also to use the result of pain staking work done on tribal and folk medicine imaginatively so that the oral tradition remains alive.

On improving the availability of medicinal plants, after describing the supply chain, there is a suggestion to set up a Federation which can work through a cooperative network to encourage the collection, grading and certification of medicinal plants by using lateral linkages which are already available. The role of the National Medicinal Plants Board has also been dwelt upon, not to recount what is already well-known but to indicate a wider role that NMPB should be encouraged to play.

Chapter 6: Drugs

In this chapter the history of ASU drug manufacture and the move to mechanisation and regulation have been described going back to the colonial period and the enactment of specific laws governing this sector in 1960s and '70s. The introduction is followed by three sub-chapters:

- Manufacture of ASU drugs and quality assurance.
- Dipstick Survey of Consumer preference for ASU products.
- Dipstick Survey of industries manufacturing ASU products.

In the first sub-chapter relating to quality assurance, the current status, the legal provisions and the way in which ASU drugs are presently marketed have been described. The need for insistence on Good Manufacturing Practices (GMP) juxtaposed with the fact that two-fifths of the manufacturing units do not possess this mandatory requirement has been discussed; the continuance of the traditional manufacturing processes and the need for also sustaining them as a part of tradition and history but not through organised retail trade have been debated on the basis of ground realities. A roadmap for dealing with this situation by setting up a new category of traditional processors that can supply their products to practitioners but cannot market the produce in retail has been deliberated upon, elaborating the risks of maintaining the status quo.

The need for quality control and certification to ensure consumer safety has been highlighted, describing ways to move to more sophisticated ways of conducting tests to guard against substitution and adulteration; also to allay public apprehensions about the addition of non-permissible substances or the presence of heavy metals beyond permissible limits. Specific scientific tests which can build confidence have been referred to with the suggestion that there should be a focus on wholesale upgradation of testing requirements for both impurities and metal based preparations in the 12th Five Year Plan.

Contentious issues like the branding of classical medicine which is presently disallowed, systematising the licensing procedure, introducing simpler quality-control certification for consumer guidance, incentivising the use of cultivated raw material and upgrading pharmacopoeia standards to international levels has been discussed and several suggestions made.

The need for laying standards for new categories of ASU drugs such as beauty products so that the consumer knows the proportion of essential ingredients used by reading the label, has been discussed. Similarly a new category called ASU knowledge-based drugs have been suggested to be introduced on the lines of what is being done in some other countries which would enhance the credibility of the systems and garner investment for R&D.

The need for addressing claims which are made on the labels of ASU products which are legally not permissible and also for ending the display of advertisements which are misleading and are disallowed has been highlighted, indicating how this should be taken in hand in a decentralised way.

Finally, the need for widening the scope of the Traditional Knowledge Digital Library (TKDL) to be used not only to guard against patents but also for wider public use has been touched upon. The potential of this knowledge base is enormous and putting it to a positive use while safeguarding against exploitation need to be balanced. The recommendation is for holding wider policy consultation instead of freezing TKDL only as a means to ward off patents. Imaginative and innovative uses can be made of this database while currently there appears to be little thought beyond maintaining the status quo.

In the second sub-chapter, the result of a dipstick (a rapid survey) on consumer preferences of ASU drugs and the conditions to which they are being accessed has been given. Although it is just a ready reckoner of consumer preferences the similarity of responses from different cities shows that the findings on consumer knowledge and preferences are fairly reliable.

In the third sub-chapter the responses to a questionnaire sent to a large group of manufacturers and the views expressed by many of them have been captured. The conditions for which people access to drugs appear to tally on the whole with the responses received through the consumer survey.

Opinions and suggestions of manufacturers about the National Medicinal Plants Board, suggestions about improving quality control, and building awareness about the effectiveness and safety of ASU products have also been recounted.

Epilogue

The epilogue as the name suggests is an addition to the Report. It is first time that there is a futuristic vision of the impact that can be made through the propagation and globalisation of Ayurveda. The conclusions point towards the need for high level co-ordination as Indian medicine has spin-offs for a wide range of beneficiaries but Indian players have to work in unison to grasp those benefits. Comparisons with China's focus on gaining recognition for acupuncture and the need to position high quality *Panchakarma* to demonstrate its effectiveness abroad has been justified. The need for a paradigm shift from approaches which have been pursued and have yielded insignificant results so far, has been underscored. Since the 12th Five Year Plan is on the anvil the time to act it concludes is now.

Summary of Major Recommendations

Research

1. Re-orientation of clinical research

Clinical research needs to adopt a multidisciplinary approach leading to comparative Therapeutic Outcome Research (TOR) studies which would indicate the degree of effectiveness of selected ASU treatment compared to conventional treatment. Instead of making it a drug based approach which has been the focus for the last 40 years, the ASU physician should be left free to offer treatment in a holistic way with the patients' parameters checked by an independent multidisciplinary group. Patients should be enrolled on a voluntary basis from those accessing treatment in allopathic hospitals for diseases/afflictions and who opt for ASU treatment. A multidisciplinary monitoring body comprising of independent experts (including ASU experts) should finalise the inclusion and exclusion criteria and a Central Register should list the patients that opt for ASU treatment. The therapeutic outcomes of patients undergoing ASU treatment as well as allopathic treatment should be documented by research officers and statisticians who report their findings directly to the multidisciplinary group for evaluation. This would give the public an authentic idea of the degree of effectiveness of ASU treatment rendered in a holistic way.

2. New mechanism for approval of multi-disciplinary clinical research

To conduct comparative studies on therapeutic outcomes, there is a need for co-ordination with the Department of Health, the DGHS, the ICMR, the medical superintendents and clinical heads of allopathic hospitals dealing with the identified diseases/ conditions where ASU has strength. This can only be done if the funding for such extramural clinical research projects is approved by a Secretary level officer. In the initial stages it is recommended that the Secretary AYUSH should chair this committee with advisers from ICMR and CSIR and medical superintendents and clinicians that run specialty clinics for diabetes, rheumatoid arthritis, bronchial asthma, liver disorders and skin problems in major allopathic hospitals. The DGs of CCRAS & CCRUM should be members of this committee and offer their advice on the award of such projects as well as the choice of ASU treatment centres and practitioners where holistic treatment can be provided. A budget would need to be earmarked for undertaking such research.

3. Recommendations to Enhance Collaborative Effort

Numerous projects related to traditional medicine are funded by different agencies. Often this results in a proliferation of small initiatives which do not yield outcomes of any substance from the public point of view. A review of research in progress in the traditional medicine sector (funded with public money) needs to be institutionalized. It would also discourage repetitive projects and ensure that the focus remains on outcomes of direct advantage to the public. Joint meetings of AYUSH, ICMR, CSIR, DBT and DST are already being held but a special meeting to conduct a stocktaking of clinical research projects is necessary to retain the focus.

Recommendations Relating to the Research Councils – CCRAS and CCRUM

1. The aims and objectives of the research councils should be revisited

It seems wasteful for the Research Councils to continue producing formulations in the name of research, to treat patients that access the research facility but fall outside the research programme. As far as research is concerned decades of work has not led to the grant of patents or publications. In house documentation of the treatment provided cannot be accepted as credible evidence of effectiveness of the treatment extended under the umbrella of research. The conclusions lose credibility as they are self-referential.

In addition to areas of comparative strength which are quite specific and well known, the areas of maternal and child health were found very useful for reducing anaemia, enhancing breast milk and reducing the occurrence of vaginal tears during child-births. It is necessary to confirm the efficacy of such treatment in hospital settings to be evaluated

by an independent multidisciplinary group. CCRAS and CCRUM research officers engaged in clinical practice can the included in providing treatment as they have been doing such work for several decades.

2. Establishment of Specialty Clinics

The two councils have treated thousands of patients all over the country covering several disease conditions. According to the Councils' own responses they have documentation which shows a clear strength in 6 to 8 identified areas which have been described in detail in the chapter on the clinical work done by the Councils. Therefore, instead of treating whoever happens to come to the research centres in a general and diffused kind of way, the work needs to be reorganised so that specialty centres are opened to provide treatment for areas of proven strength. Each centre should be operated by the councils' staff that have in any case been providing treatment for decades. Such specialty clinics need to be run on modern lines with both free and paid clinics. Treatment for only one speciality should be offered at each clinic to maintain the focus. In that way thousands of patients from the paying as well as non-paying category will be definitely be inclined to visit the speciality clinics for chronic problems, even coming from out-of station. (Specialty clinics have been suggested under the chapter of Research because the councils were primarily set up to conduct research.)

3. Production of Formulations for Special Treatment Centres

The formulations that are provided at the proposed special treatment centres should be sourced from good manufacturers in the government or private sector and thorough oversight of raw material and processes followed. The Councils' staff has knowledge of drug formulation but in order to maintain supplies, it would be better to outsource the preparation of the drugs. High standards of packaging and labeling should the insisted upon.

4. Awareness about Speciality Treatment Centres

Funds should be set aside for an awareness campaign on the establishment of the proposed speciality treatment centres; also for providing information on the website and through printed brochures about the identified condition, the average time needed for treatment, the typical range of remission achieved, together with the location of the facility, the doctor's qualifications and experience, and the centre's contact details. Panchakarma procedures can be outsourced to accredited private facilities and practitioners but the Speciality Centre should retain overall responsibility for providing treatment.

5. Media Plan to Build Awareness

A government campaign that promotes these speciality treatment centres and assures the public about the quality of drugs and the competency of the ASU doctors manning the treatment centres would evoke a huge response. Therefore a phased programme has to be planned so that the services can cope with the demand. Funds need to be set aside for the media plan as well as for the engagement of professional staff with degrees in hospital administration or business management to run the front office and back end management of the free and paid clinics. In the report, the places where such speciality centres can be established without constructing or hiring new facilities has been indicated. While it should be possible to run the centres using the Councils' clinical research staff, the engagement of part-time consultants from among private-sector ASU practitioners may be considered (in addition), to be remunerated from the fees collected from paying patients in due course.

6. Patent route needs complete rethinking

The process of acquiring patents appears to have no significance because no industry has shown interest in using the research findings of CCRAS and CCRUM. The continuation of in-house clinical research should be phased out as this is not justified in terms of outcomes over three decades.

7. Modify aims and objectives of the Councils

The Department of AYUSH should consider altering the aims and objectives of CCRAS and CCRUM to assign the Councils a specific role in providing treatment for 6-8 identified conditions and running Speciality clinics for public benefit. This would benefit patients enormously because a wider public would know where to access ASU treatment for identified chronic conditions and government backing would give confidence.

Education

Focus of recommendations

The recommendations concerning the Education sector focus on the curriculum and syllabus prescribed by CCIM for the ASU colleges and matters related thereto. As explained in the introductory chapter on Education,issues related to provision of infrastructure and teaching faculty have not been commented upon as this is being directly monitored by Department of AYUSH.

Currently there are two sets of curricula in force for ASU's students. CCIM's website displays the new curriculum for UG, PG and postgraduate diploma courses 2010–11. The discussion is related to both the new and the "pre-existing" curricula (as it is referred to by CCIM.) The following recommendations have been made:

1. Orientation of the curricula

The curricula needs to set out explicitly what the student would learn in terms of theoretical knowledge and practical skills. The curricula also needs to state the precise role expected to be played by the ASU graduate in hospital settings, in the public health arena and in general practice. This would provide a context and a purpose for teaching individual subjects.

2. Learning objectives of curricula need to be clearly stated

A summary of how each subject integrates with earlier subjects already covered needs to be apparent from the syllabus. The teaching and learning methodology to be followed in the theory and practical classes, the method of internal assessment, and marks given for each segment of each paper needs to be spelt out in the curricula. The curriculum needs to clearly indicate the skills that would be taught. A perusal of the present curricula does not indicate this explicitly.

3. Need to build confidence in ASU practice through the curricula

A substantial section of students opt for the ASU courses as a fall-back not having gained admission into the MBBS course. Instead of leaving the students to find their own feet, it would be better to expose them in the very first year to the work of good practitioners so that they understand how the public is accessing ASU medicine and for what conditions. This would stimulate an interest in the subject. It would be useful to send the students to visit reputed ASU teaching institutions and private clinics so that they observe actual treatment in progress. It is necessary in the case of ASU to build curiosity about the systems. The ASU faculty has pointed out that didactic teaching from the ancient texts frustrates the students who come with a science background. It is also necessary to make the students understand that they are being prepared to become competent ASU practitioners, to pursue higher education in ASU and to support industry. Unless this is clarified at every step, the tendency to want to practice modern medicine at the cost of ASU will never reduce.

Discussion in brief about inclusion of modern medicine/allopathic practice

The arguments for and against the inclusion of modern medicine in the ASU syllabus have been given extensively in the report along with references to Court judgments and state government orders that have determined the current policy on this. The report recognizes that both under NRHM and by virtue of special orders issued by certain state governments, ASU practitioners are permitted to prescribe modern medicine; but no one has spelt out whether that includes prescription of all Scheduled drugs and other interventions. There is no negative list on what ASU practitioners must not prescribe. Likewise there is no clarity about whether the ASU graduate is permitted to conduct interventions and procedures which are used in the casualities of hospitals and in general practice. Such orders need to issue explicitly so that the teaching of allopathic subjects has a relationship to the extent to which government policy expects the ASU graduate to contribute to the provision of such services. Only then can the curriculum bear a relationship to the role that the ASU graduate would be expected to play.

4. Recommendations relating to teaching of modern medicine

Assuming that it is the intention of the concerned state governments that ASU practitioners also practice modern medicine, the allopathic clinical subjects included in the syllabus need to be taught by modern medicine teachers. This shortcoming

needs to be confronted as the element of modern medicine in the ASU curriculum has increased with time.

Unless the students have adequate clinical exposure (patient-load) they cannot gain sufficient proficiency. In the present CCIM syllabus there are long lists of allopathic subjects. It is not clear which part of the syllabus is only for providing background knowledge and information to enable the practitioner to function alongside modern medicine practitioners, to understand modern diagnostics and to be able to discuss cases with treating physicians; alternately how much of the syllabus is for the ASU practitioner to actually practice modern medicine. This needs to be spelt out clearly to avoid the present situation when practitioners are making individual claims about what they can do. If government policy supports practice of modern medicine by ASU graduates, including selected interventions and procedures, these need to be listed and then the standard of teaching should not differ between allopathic and ASU Colleges in so far as these subjects are concerned.

5. Involvement of professional bodies in curriculum design by establishing a super arching body

Despite a large component of modern medicine subjects, CCIM does not appear to have taken inputs from professional organizations that are statutorily responsible for designing the curricula for modern medicine. This is a specialized area and special committees of Medical Council of India, the National Board of Examinations and the All India Institute of Medical Sciences (which prepares its own curricula under authority of an Act of Parliament,) debate at length about what should be included in the syllabus. From time to time the Department of Health have drawn the attention of the Medical Council of India to current priorities relating to public health, reproductive health and impending threats of pandemics to include those aspects in the curriculum. If the ASU graduate has to play a complementary and supplementary role in the provision of health services by additionally conducting modern practice, the responsibility for curriculum design should be entrusted to the proposed National Council for Human Resources in Health (NCHRH) or a similar body should be established for the AYUSH systems. This new entity should possess competency to design and regulate the modern part of AYUSH medical education in addition to the ASU content. CCIM was never established to prepare a syllabus for modern medicine. Simply listing conditions and procedures treated through modern medicine raises false expectations among ASU graduates and practitioners. With additional responsibilities entrusted to ASU practitioners by State Government a different approach to health manpower planning and curriculum design is needed, keeping court orders in view.

6. Sequencing of training and clarity about teaching methodologies

At present the curriculum content seems to be a mixture of methodologies with unnecessary repetition of subject content. The Ayurvedic and modern medicine contents have to be separated and the faculties of ASU and modern medicine should teach the subjects independent of one another but with proper sequencing. There is an acute shortage of allopathic teachers for certain subjects even in modern medicine colleges and therefore steps need to be taken by the medical education departments of the state governments that have permitted modern medicine practice to ASU practitioners to provide for classes to be taken by allopathic teachers. This has to be preceded by a statement of policy from the Department of AYUSH as medical education is on the concurrent list of the constitution

7. Bed strength and paucity of patients in ASU hospitals

The bed strength of ASU hospitals has been increased over the years but in several hospitals visited it was evident that the beds were underutilized. Most indoor patients were admitted for Panchakarma procedures related to musculoskeletal and neurological conditions for the most part. In surgery the admissions were mostly relating to the eye, ENT, and for conducting ano-rectal procedures – many of which are also OPD procedures. Most patients were examined by students in the OPD and not as hospitalized patients. The need for increasing so many beds in ASU hospitals needs to be re-examined with reference to whether the patients actually need admission, as government funds are used to run the public sector facilities. Bed strength has to be related to medical, surgical work that the ASU graduate is expected to perform and if the cross-

section of patients does not provide that exposure, increasing beds as an end in itself is not justified.

The National Institute of Ayurveda provides facilities for medical emergencies. It was not clear whether this was being provided because some patients may suddenly need emergency care or because NIA is willing to accept emergency cases from outside 24x7. There was also a chair for dentistry and a regular dentist was providing treatment. A view has to be taken on whether ASU colleges should start providing such interventions, presumably to attract patients and increase their own relevance. There is a need for a stated policy on this as supervision becomes very important once such facilities are opened up.

8. Sanskrit and Urdu

A policy decision needs to be taken about the present manner of inclusion of Sanskrit and Urdu. While knowledge of both the languages is definitely an asset, but this can also become a deterrent that prevents many aspirants who would like to join the AU courses from ever doing so. This kind of exclusion promotes insular thinking. The AU colleges would benefit immensely if students from the SAARC countries as well as other foreign students join these courses. A spirit of enquiry, a quest for knowledge and personal development would be the spin-offs of allowing students with different backgrounds to join the AU colleges. Therefore prior knowledge of Sanskrit and Urdu should not become an insurmountable hurdle. Special textbooks need to encapsulate all the verses and phrases which are of relevance to the student's professional understanding of the treatises and these should be taught by language teachers. Also special courses can be run for those who have no background, to bridge the gap.

9. Special ASU diploma and degree courses for MBBS doctors and postgraduates

As a policy, modern medicine doctors on completion of MBBS should be permitted to undergo a post-graduate ASU diploma course and a graduate course of two years duration for postgraduates, to learn ASU medicine. Modern medicine doctors working in specialized areas would find this an asset as they would be able to use the beneficial aspects of ASU medicine in conjunction with allopathic treatment. Such modern medicine doctors would be in a position to network with good facilities and competent ASU practitioners, helping patients thereby. This would be particularly meaningful in areas where there is a possibility of reducing the intake of drugs in specialized areas like diabetes, Parkinson's disease, musculo-skeletal and neurological problems and mental health illnesses. It would reduce the hubris that surrounds ASU in the mindset of modern medicine doctors. Up to five seats in each college can be kept aside for foreign students and modern medicine doctors, in colleges that are considered of a relatively high standard. But a beginning needs to be made because ASU medical education would gain through this cross-fertilization of minds and patients would feel comfortable with practitioners who have been educated in both systems.GAU has built up some experience in running online courses and a portion of the syllabus for modern medicine graduates and postgraduates can be run online to save time.

10. New textbooks, computers, teaching aids

It is very important to encourage the writing of new textbooks with multidisciplinary authorship. A budget needs to be set aside to commission the writing of good textbooks.

Agencies/suppliers can be identified for supply of hardware and software and specifications given to the government colleges so that they can directly indent for such items.

A list of teaching aids should be prescribed as essential for all colleges because a substantial part of the teaching was reported to be following rudimentary methods. The creation and use of audiovisuals, you-tube and video lectures needs to be encouraged. The website of Department of AYUSH and subsequently the new All India Institute of Ayurveda and the National Institutions should display the management of most procedures step-by-step.

11. Establish a decentralised agency for fund release and oversight

The Department of AYUSH should consider providing assistance for college upgradation by persuading the Universities of Health Sciences or a Board on the lines of the University Grants Commission to work as a conduit. This would obviate the possibility of late fund release by State Governments and involve the Universities that affiliate the colleges. Alternately this can be done

by requesting the Planning Commission to make funds alloted for college upgradation as non-divertible.

12. Developing competencies to treat geriatric problems and contemporary illnesses/ disabilities

Modern lifestyles are leading to new kinds of illnesses as well as disabilities and handicaps related to excessive use of computers, including painful syndromes, eyestrain and back and shoulder pain. Employees in computer related jobs are laid off because recovery is very slow.ASU has several therapies, massages and treatments like steaming, oil massage and cupping which are very useful. ASU uses non-invasive and plant-based remedies for dealing with skin problems like leucoderma, acne, facial hair and obesity. The practitioners in Kerala have perfected the regimen for bone setting and fracture healing non-invasively. The varma therapy which is a part of Siddha medicine undertakes expert manipulation to relieve acute stiffness e.g. frozen joints. These and many more conditions are affecting an increasing number of people. These skills need to be imparted to the ASU graduate because numerous people would like to avail of these services but they are not being taught uniformly with standard operating procedures (SOPs). The syllabus needs to give a thought to doing this in a uniform manner.

13. Funding ASU colleges

High-quality professional education alone would ensure that the practitioner remains relevant to the needs of the public. However standards of many ASU colleges are deficient and even some of the best State government colleges lack funds to be able to invest in even routine maintenance, leave alone renovation and modernization. The Department of AYUSH should make a selection of at least 15 colleges every year in the government sector that would benefit through an infusion of funds for specific activities. However it was found that even where upgradation had been sanctioned and undertaken the quality of work was poor. The colleges do not seem to have the wherewithal to be able to extract high-quality construction and maintenance work. Therefore as is done by the University of Delhi, a panel of architects should be empanelled centrally either by Department of AYUSH or by using the Hospital Services Consultancy Corporation. The colleges which are selected for receiving grants should be asked to get the work done through the identified architects. Consultants should be engaged for extending oversight over quality of work and timely completion as the use of government funds needs to be monitored. The selection of colleges in the government sector should start with those where the patient-load is relatively high so that investments are made where the public is likely to benefit, besides the students.

14. Paramedical and supporting staff in ASU hospitals

The practice of ASU necessarily requires the assistance of ASU pharmacists, Panchakarma and Ksharasutra technicians, laboratory technicians and assistants to manage the anatomy and physiology departments and herbariums. Nursing staff, ward boys and librarians are also needed. These are basic requirements for the efficient functioning of ASU colleges. The need for supporting staff should be recognized and normative standards need to be prescribed. At the time of inspection this aspect should receive due attention.

15. Certificate level courses

These need to be organised for supporting staff particularly panchakarma masseurs. Such courses are being run by some organisations but there is a need for trained people to be employed uniformly by all ASU colleges.

16. Recommendations regarding encouragement of ASU in Central universities

There should be a dialogue with the Central universities to create ASU departments particularly with a view to supporting interdisciplinary research. Only the Department of AYUSH is in a position to take this up as it is unlikely that individual colleges and departments would be able to do so. Without multidisciplinary involvement held in a collaborative manner, ASU will not be able to create a wider interest or generate respect for what the systems can offer. Today only a handful of social scientists are engaged in ASU research and they have little access to study the ongoing ASU work. There would be greater interest were Departments of ASU in Central universities to be established which study the social science and anthropological aspects of this sector.

17. Recommendations regarding ASU Degree eligibility for different courses and new openings

The ASU curriculum needs to be designed in a way that the products of an ASU education can also move laterally to join courses in different areas of agriculture, veterinary science, human behaviour and allied sciences, nutrition and dietetics, botany, ethnobotany, ecology and environmental sciences to name only a few. This would need to be planned well in advance in collaboration with university departments and possible employers. This is not something that CCIM is equipped to do. A centrally appointed committee with representation from ASU's non-clinical departments together with the relevant departments of Jawaharlal Nehru University, Benares Hindu University, Aligarh Muslim University, Jamia Hamdard and Environment, Agriculture and Veterinary Science universities and colleges need to come together to discuss how the outreach of ASU can be widened. The focus should not be the career interests of ASU students and practitioners but on how cross fertilisation can being the strengths of ASU to benefit several sectors.

General recommendation on funding ASU colleges

- During the 12th plan the Department of AYUSH could consider persuading Ministry of HRD to set up a UGC like body or get the Universities of Health Sciences to agree to cater to ASU colleges. All funds could be routed through a newly formed AYUSH division of UGC or the State Health Science Universities so that there is uniformity as well as a check on proper utilization of funds. A beginning can be made with the Universities of Health Sciences in the states of Maharashtra and Karnataka which have the maximum colleges. While it is not the responsibility of the Central government to be funding government colleges in the States, looking at the neglect of even some of the best government colleges, an infusion of funds would be needed if they are to be brought to an acceptable professional standard.
- Funds should be set aside for the establishment of an educational portal or a Virtual Resource Centre including its updation and maintenance. This portal should cover the practical aspects of the ASU curriculum particularly where procedures have to be observed step-by-step. This can be given as a turnkey job either to C-DAC, NIC, EDUSTAT or IGNOU as they have adequate server space. A University of Health Sciences which sets up an independent division for AYUSH can be entrusted with the preparation of software. An advisory committee could oversee content clarity with educationalists, researchers and practitioners from leading institutions/universities like IPGT&RA, GAU, Benares Hindu University, NIA, Jaipur and AVS Kottaikal. It should not become the preserve of educationists from a single university or institution.
- In the 12th plan multiple contributing authors need to be persuaded to take up the design and publication of new textbooks in regional languages which should be funded. It should be compulsory for ASU colleges to purchase new books which are published. Department of AYUSH should make a plan provision to encourage the writing as well as support the purchase of textbooks by ASU colleges. An Agency like National Council of Education Research and Training (NCERT), National Book Trust (NBT) or the Raja Ram Mohan Roy Library, which regularly deal with publishers could be given a consultancy to commission textbooks based upon the advice of experts but written by people who know how textbooks should be organised. The Department could also give an annual grant to Government colleges to purchase new textbooks and also make all text books available on-line.

Practice

Recommendations regarding model for best clinical practice

The All India Institute of Ayurveda, New Delhi is patterened on the All India Institute of Medical Sciences. The focus of the Institute has to be steered from inception. The Institute should primarily be the focal point from where protocols for multidisciplinary therapeutic outcome studies are drawn up and examples of the best clinical practices carried out. It should have a strong full time Chief Executive Officer at this stage to oversee the infrastructural development and also to network with other institutes in the field of Ayurveda as well as other disciplines. At this point it would be better to position a non-practitioner as there is a huge need for attending to lateral linkages with several

agencies. The All India Institute of Medical Sciences and Indian Council of Medical Research both have full time Deputy Directors of Administration, who are IAS officers of Joint Secretary level. That is vitally needed here at this juncture to ensure that administration and co-ordination aspects are handled with resourcefulness.

Hospitals providing Panchakarma and allied procedures: The carrying capacity of the areas where patiets wait or undergo Panchakarma procedures in government hospitals need to be managed in a hygienic way. There is overcrowding in these areas which requires staggering of patient load. The housekeeping and hygiene standards need enormous upgradation. The Government facilities should be the first to try and get NABH accreditation. Funds should be earmarked for this so that State Government hospitals can be renovated and modernized starting with 10 hospitals in the first year. Instead of giving funds to the Hospital, the Dept of AYUSH should ask the Hospital Services Consultancy Organisation HSCC to work out turn-key contracts which can be funded through the Corporation once an MOU for handing over space is entered into.

Government Dispensaries: A comprehensive set of guidelines on what a government dispensary should essentially provide are needed. At least one model dispensary for either Ayurveda/Siddha or Unani should be there in one district in each state for others to visit and emulate. The local purchase of drugs needs to be facilitated so that there is no let-up in treatment which brings a bad name to the system and turns people away.

Recommendations regarding Creation of Directories of Practitioners and Panchakarma Clinics

People who would like to try ASU treatment do not have an idea of the names of registered practitioners, their addresses or telephone numbers or other details – whether institutionally qualified or otherwise. It would therefore serve a public purpose if the AYUSH/ISM officials at the state level are given funding to have a city and district-wise Directory created and updated every year. The work can be outsourced or got done departmentally but such a Directory would give an idea of the range of practice and also give credibility to the work that is going on. There could be a disclaimer with the following wording:

Disclaimer: *"This Directory has been compiled to give information about ASU practitioners and clinics. The entry of any practitioner's or clinic's name does not reflect any government endorsement."*

Recommendation regarding Protecting the Name of Ayurveda

It should be made mandatory for private clinics and indoor facilities to display (like a menu card) the therapies which would be provided, their duration and the oils and medication to be used from sealed bottles. In the absence of that a lot of gimmicks are being marketed in the name of Ayurveda. This needs collaborative action on the part of both the Ministry of Tourism and the Department of AYUSH. However the possibility of harassment has to be avoided by engaging an agency at the State level which is asked to provide guidance but maintain oversight. Guidelines need to issue on minimum standards for each procedure offered (time required and materials used). Kerala Government's green leaf scheme can be expanded.

Recommendations regarding speciality clinics

Efforts should be made to include good centres for providing speciality treatment under the CGHS because that would give recognition and legitimacy to the work that is going on. To give an example if speciality clinics were approved both in the government and the private sector for skin diseases, asthma, liver problems and arthritis (Rheumatoid arthritis and Osteo arthritis) and the cost of the treatment is borne by CGHS, there would be several patients who would be interested. Although availing of Panchakarma treatment at recognised places has been approved, it would be better to include it as recognised treatment for post trauma/after stroke rehabilitation, chronic back pain, computer shoulder and carpal tunnel syndrome, eye problems and mental problems. These are growing challenges and there is a lot that ASU can do for these kinds of patients.

Recommendations regarding employment opportunities for ASU practitioners

There were suggestions that ASU treatment should be introduced in Railway hospitals, in hospitals run for public sector enterprises, and in the dispensaries of IITs, IIMs, and other large Government institutions. Likewise in the medical facilities set up

by Central and State Universities. The Department of AYUSH should ask the State AYUSH Departments to draw up a panel of practitioners prepared on a city-wide basis after having the qualifications and competencies evaluated by a Board. The names could be given to large institutions starting with the Government sector, desirous of setting up a facility for ASU consultation.

Recommendations regarding insurance cover for ASU treatment

The advice of the Insurance Regulatory Development Authority (IRDA) and medical Insurance Companies in the public and private sector should be taken about bringing specific ASU treatment under insurance cover. This should not be confined only to hospitalization; outpatient treatment for specific diseases based on a consumer preference survey may be included. To start with young people working in Call centres and jobs requiring constant computer work could be insured for syndromes that result in being laid off work. Similarly insurance cover may be extended on optional basis for diseases like Chikanguniya, chronic muskulo-skeletal problems and neurological conditions for which modern medicine has limited treatment. The modalities would require hospitals and practitioners to be recognized but the Government can act as a facilitator to start a dialogue between the facilities and insurance companies.

Medicinal Plants

Recommendations relating to 'Traditional and Folk Medicine'

Institute for Trade in Medicinal Plants: The Department of AYUSH should consider setting up an Institute for Trade in Medicinal Plants on the lines of Indian Institute for Foreign Trade (IIFT) to offer postgraduate diplomas and MBA qualifications for ASU graduates as well as those with backgrounds in agricultural sciences, botany and allied disciplines. The Institute should provide knowledge and skills required for managing trade and commerce in medicinal plants, including the sustainable export of cultivated produce. The objective would be to equip students to become proficient in the management of medicinal plant trade. The institute can also run certificate courses which provide competencies for sorting, grading, labelling and certification of medicinal plants.

The Governing Board of the proposed Institute can run like a Consortium where institutions like FRLHT and others that have excellent connections with local collectors of medicinal plants can contribute in a practical way. Such institutions can also see that aspects relating to protection of bio-diversity and sustainability are given due importance in the curriculum. Knowledge about identification of plants banned from export or which are becoming extinct should also be imparted, so that products of these institutions can offer consultancies or join customs' offices and ASU drug regulatory and quality control positions both in the public and private sector. The Institute should build capacity for operating the proposed medicinal plants database with unique product codes for both classical and proprietary drugs. Students should be given professional know-how on administering and implementing bar coding requirements and for handling import and export of raw drugs at customs.

The Institute can have a tie-up with industry for creating competencies for trading in processed medicinal plants for internal use as well as for export. The students can also be trained to undertake demand supply analysis of medicinal plants and forecast international trends for consumption of raw and processed drugs.

Division of Tribal & Folk Medicine: There should be a division for Tribal & Folk medicine in the proposed Institute.CCRAS and CCRUM should not stop with the publication of monographs and storage of survey data and herbarium sheets. These should be made accessible to students from various disciplines attending courses in the proposed Institute. In particular, students of botany and allied subjects should be given access to the specimens that have been stored in survey units at 22 places in the country. A protocol should be designed and University Departments of Botany, Agriculture, Anthropology, etc. should be encouraged to organize visits of college students to selected units. During the 12th plan, efforts could be made to upgrade at least five such units and to make them capable of imparting practical knowledge. These units can in due course become satellite centres of the proposed Institute.

Recommendation relating to 'Raw Drug Trade'

Management of Raw drugs Trade: In the 12th Plan, looking at the general conditions in the market, there would need to be a complete overhaul of the

management of raw drugs because that is fundamental and critical to the quality of medicine. Although suggestions made by the raw drug dealers are correct in their own place, simply upgrading one part of the supply chain will not yield much result. While registration of the traders should be undertaken, certain non-negotiable requirements should be made mandatory for industry to follow when they purchase the raw drugs. In the ultimate analysis the supply chain itself would have to be examined link by link to introduce checks that ensure that there is minimal scope for substitution, impurities and loss of quality in transit and storage.

Recommendations relating to 'Demand and Supply of Raw Drugs'

- **All crude drugs need to be given unique identification (ID) codes:** It should be made mandatory for suppliers and manufacturers to label a particular raw material by its assigned codes. This would also ensure that quality raw materials and supplied to physicians and industry.
- **Adopt successful systems/processes of other countries:** There is a need to learn from countries like China, Thailand, Korea and Japan, who manage their raw material collection, drying, storage and packaging in ways that ensure that the raw material is free from microbial and fungal contamination when supplied to the end users. China exports quality assured raw material all over the world. Best practices in post-harvesting technology, low temperature moisture free godowns, including installation of processors for hygienic packaging should be introduced with the assistance of expert institutions that have been using such devices for grading, packaging and storing other commodities.
- **Bar coding:** In due course this database can be used for linking manufactured products to bar codes which should be made mandatory.
- **Need to establish a Federation to support collection/ transportation and grading of medicinal plants:** Most State Medicinal Plants Boards do not have the clout or wherewithal to coordinate this work. It would be better to initially outsource this work to established organisations like the Horticulture Board, Spices Board or to any organisations that has set up a supply chain. In the long term NMPB should set up a Federation which can organise this work on a continuous basis.
- **General Recommendation:** Unless the approach for collection, grading and storage of raw material is handled professionally India will lose the opportunity to sell high quality products or to export raw drugs in a planned and sustainable manner. Therefore this needs to be given high priority in the 12th plan but it is important to leverage the strength of existing organisations, instead of waiting until NMPB is able to upgrade itself incrementally.

Drugs

I. Recommendations Relating to Manufacture of ASU Drugs and Quality Assurance

Quality of raw material

Steps should be taken to develop up-to-date quality specifications for plant material and minerals and to introduce bar-coding/ pharmacognostic image analysis for the identification of raw and processed ingredients. These are broader globally accepted quality parameters and they need to be adopted to cover all the 960 items of plant material that are traded and used by the ASU industry. It is expected that this work would be done by the autonomous ASU pharmacopoeia commission which has been approved to be established.

Recommendations to review current needs of the GMP compliance

It may not be possible to ensure that all the manufacturers get GMP compliance because they have not done it for the last nine years. Forty percent of the manufacturing units appear to be operating without GMP and producing drugs for sale to the public. These drugs can be harmful as they may contain raw material containing impurities, strong chemicals and non-permissible substances. The drugs containing metals and minerals can cause long-lasting harm when used indiscriminately. The public interest demands that such items are not allowed in retail sale in the name of medicine unless tested.

Recommendations regarding new category of traditional processors

A new category of Traditional Processors/Bheshaja

Kalpana producers who can only produce drugs to be supplied to practitioners or their own clientele but not for sale in retail outlets should be created. The responsibilities of the practitioner are recognized under the D& C Act and he is allowed to formulate ASU medicine. Today hardly any practitioner does this by hand himself. The work is outsourced to people who process the drugs as demanded by the practitioners.The recommendation is, therefore, to give recognition and legitimacy to this activity which is already permitted under law but to distinguish it from 'manufacture'.

Traditional processor can run OPD/IPD for his patients

If the traditional processor runs his own OPD or engages a physician to diagnose and treat patients and to prescribe medicines made in his pharmacy, there is no harm. Therefore there is no need to close down such small units which in their own way are the only vestiges left of tradition. No processor who is selling small quantities for use by practitioners would be interested in deliberately adulterating raw material or selling spurious drugs because sooner or later the clientele would stop using the drugs. In the chapter on practice, there is a description of several ASU practitioners who are dispensing medicine made by their own pharmacies. This should not be discouraged but the responsibility for quality would remain that of the practitioner supplying the drugs.

Recommendation on retail sale

Only GMP compliant units should be allowed to sell in retail in ASU shops or in regular chemists' shops. Special registration should be given for shops that stock GMP licenced ASU medicine. A small fee should be collected for such registration and the public encouraged to look for the GMP mark/number. That is the only way of protecting the consumer who has no way of knowing how to distinguish quality products which adhere to GMP and pharmacopoeia standards and those which do not.

Recommendation on enforcement of GMP

For manufacturers who wish to sell their products in the retail market or act as stockists of ASU medicine, a GMP certification number should form a part of the label as a legal requirement. If even a few cases of non-compliance are prosecuted each year in each state, the manufacturers will become conscious of the need to comply. Moreover, if only GMP compliant manufacturers' products are allowed to be sold in retail, they would be obliged to obtain GMP. This should be projected as a means to protect the public and not as a means to rein in manufacturers.

Disposal of court cases

It has been the experience of some state FDA's like Maharashtra that cases relating to spurious/ unlicenced/adulterated drugs take even more than 15 years to be decided and therefore there is no fear of the law. A review of the number of cases charged in courts and their progress needs to be made by every state AYUSH Department. Long term pendency of cases need to be taken up with the Registrars of the High Courts by the State Secretaries in charge of AYUSH and monitored centrally to keep up the pressure in public interest.

Recommendations on harmonized licensing system

Presently there is no uniformity in the way applications are entertained for grant of license for the production of P & P or classical medicine. The following recommendations are made:

- There should be a uniform licensing system for adoption across the States based on technical data submission which can be called a dossier approach. A dossier was suggested by one of the drug manufacturers' associations and the copy is at Annexure-II.
- In respect of classical medicine, the system followed by other countries of having a pre-market notification would be far more efficient. In that case if the manufacturer already has a license for the production of a particular dosage form (Asava, Arishta, Ghrita,) he needs to only notify the licensing authority when he adds one more item. This is because there is no mind application involved in accepting the license application in respect of classical products as the recipe given in the classical text has to be followed invariably.

Recommendations to expand or alter the QCI Scheme

Presently according to Manufacturers' Association, the QCI Scheme does not seem to have taken off

as consumers are unaware of what it denotes. Manufacturers complain that the certification is given product wise and since numerous products are made by each company, it is not cost-effective to seek QCI certification for each product. However consumers of ASU medicine need to be assured of the following:-

(i) That the drugs do not contain contaminants and impurities beyond permissible levels.

(ii) That the metallic and mineral content does not exceed permissible limits

(iii) That there is no addition of chemicals on non-permissible substances (like corticosteroids or synthetic anti-inflammatory agents).

Items (i) and (iii) above can be tested through HPLC/ HPTLC testing which can test the presence and absence of impurities and additives. Any manufacturer who obtains a certificate showing that the drug is free from contaminants, microbial presence specified adulterants and chemicals, can obtain an AYUSH mark from QCI approved third party certification agencies. Testing charges should be settled annually by D/o AYUSH at the Centre and the label of such ASU products which meet all these test requirements could have a specified logo "AYUSH mark": "Quality Certified".

Recommendations on heavy metal testing

An Inductively Coupled Plasma Analyzer (ICPA) is capable of testing the presence of all the Heavy metals like arsenic, mercury, lead, cadmium, zinc, copper etc. in one sample, with only one injection. This equipment should be provided to at least 10 laboratories to start with at a cost of approximately Rs 80 lakh per laboratory. Obtaining certification should be made mandatory for all herbo-mineral and metal based ASU products. For Bhasmas, Rasa Aushadis (Metals/ Herbo-metal/Mineral preparations) the label should say "This product contains Metals & Minerals used in ASU medicine upto permissible levels". Such products containing minerals and metals should not be allowed to be sold in retail without certification.

Recommendations to permit branding of classical medicines

Branding of classical products should be allowed as this will promote more research and development on the efficacy of the original textual recipes. This would be in consumer interest.

Recommendations on new categories of ASU drugs

While it is a welcome step that new categories have been introduced for supplements, cosmetics etc. there is a need to review the accompanying regulations. The Regulations should help the consumer understand the proportion of plant based/herbal material used in the product.

Recommendations to create a new category of ASU modern drugs based upon scientific data

When the use of modern technology of extraction/ concentration/fractionation is used to present new dosage forms using the knowledge contained in ASU, a new category called **modern ASU drugs** can be introduced. Far from taking away from the strength of Ayurveda, it will enhance the reputation of the systems.

Recommendations to provide incentives to promote use of cultivated raw materials

150% Income Tax exemption on the purchase value of cultivated raw materials and 100% exemption from CST (Central Sales Tax, 4%) may be given on purchase of plant-based raw materials from cultivated sources. MODVAT credit of 40% should be given on the cost of purchase of cultivated raw materials. This will need to be argued at the time of Budget formulation with Ministry of Finance.

II. Recommendations Relating to Consumer Preference for ASU Products

Consumer information

It is apparent that people largely access ASU medicine for specific diseases and conditions. Much more information should be made available about the different modes of administration of drugs for such conditions, the reason why drugs are prescribed choosing so many different dosage forms and how they work not only on the disease but also on addressing the root cause of imbalance. The Department of AYUSH website should provide basic information about the conditions for which the public is predominantly buying the drugs. The prototype of the information needs to be placed on the websites of the State AYUSH Departments. There should be a section called Consumer Information as well as Frequently Asked Questions (FAQs) which can focus upon the identified conditions – system wise, where the using public has shown almost universal interest.

Capacity building through District ASU officers

In view of the fact that drugs seem to be sold mainly on the repeated prescription data handled by the shopkeepers, it is very necessary to build up the capacity of both practitioners and shop owners. The State and District ASU officers need to be given standard material which they can share through workshops and training programmes with practitioners, shop owners and stockists so that at least for the most popular areas where public relies on ASU medicine, confidence levels are built up and there is uniformity in approach. This is necessary because people get turned off by an absence of knowledge. In the Dipstick survey of common preference, shopkeepers had asked for this know how to be given to them.

Essential drug list

Since most of the drugs are accessed on prescription, it is very necessary that the practitioners are made aware at the city and district level about the quality, safety and efficacy aspects of the drugs. They should be given the list of essential classical drugs which are considered appropriate for given conditions – not in the nature of the drug regimen but so that they receive general guidance.

Labeling requirement

Since consumers are concerned about quality and safety issues, they need to be guided through television programmes, brochures and leaflets about how to look for good quality. This aspect has to be centralized. The need for proper labeling has been dealt with under the drugs chapter where specific suggestions have been made.

Commoditization of ASU drugs and products

The restriction on branding of classical drugs, classical medicine has reduced the sale of classical drugs to hardly 10% of the market. An awareness campaign has to be built up so that the public is aware of the difference between classical and propriety products and the difference between different modes of administration and how each works. In addition, the fact that ASU medication works only if a good practitioner has diagnosed the problem and prescribed *Prakriti / Mizaj* appropriate drugs has to be highlighted. Whereas it will not be possible for the government to stop aggressive marketing of company names, what to look for when buying products is something that should be promoted through a central campaign.

III. Recommendation Relating to Dipstick Survey of Industries Manufacturing ASU Products

Recommendations on making the licensing procedure transparent and uniform

- The website of the State Government should indicate the number of licensed manufacturers and number of products licensed in respect of each manufacturer.
- The number of survey/statutory samples obtained and the number of licenses cancelled/ suspended and prosecutions launched should be updated on the website of the state ISM departments and the office of the State Drugs controller. Regular news items should be given to Pharmabiz and similar publications. At present neither industry, shopkeepers or consumers have any faith that even rudimentary surveillance is being maintained.
- Failure to update information on new licences issued and cancelled should be monitored and an official engaged on contract and positioned under Pharmacopoeial Laboratory for Indiam Medicine (PLIM) with exclusive charge for follow-up with individual states. Exception reports of non furnishing of data should be sent to Department of AYUSH which in turn can alert the Directors of ISM / AYUSH in the States that information has not been updated in time. This would ensure that survey and statutory samples are collected regularly and updated which will keep up the pressure on the State licnencing/drugs control authorities.

Recommendations on implementation of pharmacopoeial standards

Pharmacopeial standards are mandatory but during discussion with representatives of industry there was an admission that pharmacopoeial standards remained on paper and in the absence of enforcement it was optional whether to follow the standards prescribed. Therefore, the lifting of a prescribed number of survey / statutory samples should be strictly followed by the drug inspectors.

- **Raw materials stacked by the manufacturers.** Plant material loses efficacy over time. Therefore new regulations need to be

introduced under the Drugs and Cosmetics Act asking for packaged, source certified raw materials to be used with a best before date.

- Every invoice should be accompanied by test reports and source of origin of raw material. This practice is very common in pharmaceutical industry and should not result in any harassment.
- Quality tested raw material with Certificate of Analysis as per API should be the medium-term aim. State Forest Corporations may also be encouraged to provide certified quality raw material as per API.
- A Scheme for registration of vendors (raw material traders) supplying ingredients to ASU drug manufacturers should be introduced and manufacturers asked to maintain vendor data.
- The QCI certificate is very expensive and very few manufacturers are likely to opt for getting the certification. It would be better to start a simpler scheme for certification, for products which have been subjected to tests in recognized laboratories and which conform to packaging and labelling requirements as laid down.
- The quality mark should be publicized and consumers advised to look for the mark as was done in the case of the ISI mark in its formative years. Manufacturers could be given a limited window of two years to get the mark before the awareness campaign for consumers is put into action. A formal tie up with Department of Consumer Affairs would help.
- **Publication of advertisements about magical cures and misleading claims:** This needs to be taken up with the Press Council of India and publishers of newspapers and magazines. State governments should be asked to engage college interns who can go through English and vernacular newspapers and prepare monthly lists of newspapers which break the law. The State Health/ ISM secretaries should be encouraged to take this up officially with the publishers in the case of regional newspapers and magazines. This should be received frequently at a central level as it is one of the major factors affecting the reputation of ASU practice and drugs.
- **Consumer Forum:** A consumer Forum should be set up State-wise in co-ordination with Department of Consumer Affairs so that issues like medical service by practitioners, quality of drugs (fulfilment of pre-testing and labeling requirements) are given prominence. The awareness compaign for ASU treatment and drugs can be a part of the common awareness compaigns already undertaken by Department of Consumer Affairs on television.
- **Whom to Contact:** A "Whom to Contact" in case suspicious products have to be reported should be prominently available on the AYUSH and State ISM websites along with a helpline numbers accessible at district level, Toll Free. No such facility is presently available.

Epilogue

The recommendations in the epilogue are in the nature of a futuristic vision. They fall outside the main Report and are summarised here as follows:

- Consider the establishment of an over-arching commission to pursue the propagation and globalisation of Ayurveda with a standing secretariat.
- Abandon the college education route to popularise Ayurveda abroad; instead focus on demonstrating the effectiveness of *Panchakarma* for specific conditions; as a precursor to seeking recognition on the lines of Chinese acupuncture.
- Make efforts to corner research funding from US bodies as China has done, in the areas of current medical concern, not drug research.
- Invest in opening Indian medicine PhD's in modern medicine to create allies and collaborators who can bolster clinical research.