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Drugs

Drugs

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Quality Assurance of Drugs

I. Manufacture of ASU Drugs and Quality Assurance

History of ASU Drug Manufacture

It is important to go a little back in history and consider how the drug industry evolved. Up to the first half of the 19th century ready-made Ayurvedic and Unani medicines were never considered as commodities to be marketed for money. MS Hiralal in his article 'Commercializing traditional medicine'[1] has described how the production of medicine was concentrated in and around the physician who worked within a given locality and offered his services to the public.

In the mid-19th century the response of the community of Vaidyas and Hakims to the spread of epidemics was the first movement towards shifting household production to bulk production of drugs. However, the real initiative into large scale production started in Bengal and in Kerala. The evidence shows that Ayurveda, Unani practitioners formed associations of Hakims and Vaidyas. Recognizing the negative attitudes of colonial powers towards them and after their efforts to be recognised as physicians with state backing failed, then a new way of establishing hegemony had to be found. The market was a promising option.

The late 19th century saw Bombay (Shree Dhootpapeshwar, 1888), Kottakal (Arya Vaidya Sala, 1901), Coimbatore (Arya Vaidya Pharmacy, 1902) and Calcutta (Kalapataru Ayurvedic Works, 1884) as the pioneers that transformed Ayurveda into a new world of large scale production. While using mechanized production systems, the traditional procedures for making the medicines were preserved. Thereby the six main forms, in which Ayurvedic medicines were made - Bhasmas, Churnas, Lehas, Arishtas, Asavas and tablets - were retained, but modern machinery enabled bulk production and modern dosage forms.[2]

Regulation

Today modern factories manufacturing Ayurvedic medicines are completely mechanized. The industrial scene has been described as having an "oligopolistic structure" with a few big firms dominating the market. Nonetheless thousands of small firms also operate which have small production capacity but enjoy a wider social base. After Independence and particularly after the 1970s a host of new formulations called Patent and Proprietary (P&P) products came into the market, running in parallel to the marketing of classical products. Branding and advertising became the new way of promoting Ayurvedic products, which introduced a spirit of commerce for the first time.

By the later part of the last century branded products increasingly replaced classical medicine. Practicing Ayurvedic physicians, particularly those running large clinics and hospitals preferred to buy medicines from professional manufacturers. Pharmaceutical companies also started using agents to talk to chemists and stockists of Ayurvedic and Unani medicines much as is done in the case of allopathic drugs. Marteen Bode[3] has referred to the phenomenon as the, commoditization of Ayurvedic and Unani medicine which according to him *"eroded the position of the traditional physician, abandoning and ignoring the efficacy*

1. Hiralal, MS. "Ayurvedic Manufacturing in Kerala." *Economic and Political Weekly,* April 18, 2009, Vol. XLIV, No.16.
2. Banerjee, Madhulika. *Power, Knowledge, Medicine: Ayurvedic Pharmaceuticals at Home and in the World.* Hyderabad: Orient Blackswan, 2009.
3. Bode, Maarten. *Taking Traditional Knowledge to the Market: The Modern Image of the Ayurvedic and Unani Industry, 1980-2000.* Hyderabad: Orient Longman, 2008.

of humoral diagnostic methods and therapies." While that is correct, once manufacturing took root, the medicines were no longer hand-made and hand-distributed. The dynamics of the market and the introduction of state regulation required laboratory testing and employment of scientific methods for identification and formulation of drugs. To protect consumer safety, quality became fundamental. Regulating the manufacture and sale of ASU medicines was no longer an option but a necessity.

Current Status of ASU Drug Manufacture and Quality Control

The ensuing report is based on interaction among others with the Drug Controller General (India) discussions with the Director and professional staff of the Pharmaceutical Laboratory for Indian Medicine (PLIM), the FDA officials of Maharashtra, Gujarat, Delhi and Kerala. Among others, members of the Ayurvedic Drug Manufacturers' Association (ADMA), and several pharmacy experts as well as the heads of ASU manufacturing units in the Government and private sector were also consulted. The Chapter focuses on the existing legal set-up and the measures that can be introduced to overcome concerns about raw material quality, standardization issues, metallic content of ASU drugs, and the present absence of uniformity in providing oversight within and across the States.

Legal Status of ASU Drug Manufacture

The Drugs and Cosmetics Act (DCAR), 1940 was amended in 1964 and Chapter-IV A was introduced with regulations defining the manufacture and sale of ASU products. The Rules and Regulations have undergone numerous revisions with the aim of protecting the consumer and keeping abreast with technological advancement and innovation.

Regulations were put in place to ensure safety and quality of ASU products but the basic model was derived from the Food, Pharmaceutical or Cosmetic industry. Ensuring the use of the right medicinal plants of proper quality became a mandatory requirement; to achieve that the formularies and pharmacopoeias were declared as legal benchmarks for determining the quality of the ingredients and the processing methodology used in ASU drugs manufacture.

Good Manufacturing Practice (GMP) for ASU drugs was introduced in the DCAR under Schedule T and under Schedule T-1 for Rasaushadhis (metal based preparations). GMP was first notified in June 2000 when it became a mandatory requirement for new ASU drug manufacturing units. For existing units a two-year grace period was given to obtain GMP certification. But notifying a standard was not enough. Its adoption by manufacturers required constant monitoring, an aspect that obviously did not receive much attention in the States that were responsible for enforcement under the law.

Today the ground situation is undulating. In the interest of consumer protection it is better to have a realistic view of what is possible and what affects public safety the most. Quality of raw material is critical for producing high-quality medicine. Unless the ingredients are authentic and the processes follow the mandatory measures prescribed, the products can prove to be ineffective. The quality of ASU medicines is being questioned across the country and mostly by potential users who feel unsure of the contents and safety of the products although they would like to try the traditional systems for a variety of reasons.

Marketing of ASU Drugs

The products are marketed in the following ways:

1. Classical Ayurvedic/Unani products sold through Vaidyas and Hakims and also purchased by consumers from shops selling ASU medicines. These are often sold with rudimentary packing and labeling or packaged as capsules and tablets in blister packs, along with syrups and oils. These are also sold through clinics and franchises of manufacturers.
2. Proprietary ASU medicines which are branded and sold through ASU retail outlets or through licensed chemist shops and groceries. For such products sales are promoted through advertisements and through pharmaceutical agents engaged by manufacturers. These proprietary medicines are prescribed by ASU practitioners and sometimes even by modern doctors (A large number of ASU products now have modern sounding names). (See page 251.)

3. Proprietary or classical preparations using one or more metals including heavy metals (Rasa preparations, Bhasmas, etc.) prescribed by practitioners and supposed to be taken under their supervision. These products are freely available in "Desi Dawai" outlets and sold across the counter by ASU shopkeepers. (No pharmacists or ASU practitioners are generally present).
4. Proprietary ASU toileteries and cosmetics which are marketed as medicine. These products are primarily for the skin, hair or dental care. They do not have serious drug like activity, although they do have medicinal properties.
5. Though very small in value and volume some Ayurvedic products are also sold through therapy centers and spas as well as beauty salons.

The Department of AYUSH (DoA) has issued a Gazette Notification in 2010 introducing a new Category under 3(h) of DCAR, as "Soundaryavardhak" – which refers to cosmetics.

Formulation of ASU Drugs

The Ayurvedic Formulary of India (AFI), Part I, First edition was published in the year 1978 and was the first official document of its kind on Ayurvedic medicine. This document enjoined the manufactures to follow the prescription and processes laid out. By introducing it in the First Schedule of the Drugs and Cosmetics Act, 1940 it gave legal status to the compendium. Since then AFI Part II has been published together covering 635 formulations in all.

Implementation of Regulatory Requirements

In the last decade a slew of measures have been taken to provide a legal and qualitative framework for making quality products available to the consumer. However, in practice the manner in which the Rules are enforced leaves a lot to be desired. During interactions with at least seven licensing authorities from the States having large number of manufacturing units, it was apparent that the concerned officers do not possess the wherewithal (technically qualified human resources) to ensure that the manufacturing units fulfill their obligations. Approval is granted on the basis of claims made by the manufacturer. A very large number of items are approved for manufacture at a time when manufacture has not commenced. After it commences, there is very little done by way of inspections, sampling and independent authentication of raw material used by the manufacturer.

There is a vast difference between the top players and the standards they adhere to at times above the expectations of GMP and those followed by the small manufacturers particularly those who are making a handful of items. The licensing authorities seem to lack the authority or willingness to refuse grant of license or suspend or cancel the licenses when it is apparent that the raw material has not been stored properly or the process specified in the pharmacopoeias has not been followed.

In terms of the range of items, many of the small and tiny producers are like cottage industries. The approach of the Government schemes has been to try and bring all players under the GMP umbrella through persuasion and financial support. But that is not motivating those that are way below the benchmark because there is in their view no advantage from getting GMP and no disadvantage either as there is no penalty attached.

Enforcement is notoriously weak and attributed to shortage of manpower. If the rules, regulations and pharmacopoeial standards are to be enforced it would be necessary to have a high degree of surveillance not just over GMP but over the quality of raw drugs and processes used. Many of the inspectors who work in the ASU sector are often people who have had no exposure to how botanical identification is done; it is vitally important that that capacity is developed and the possibility of sub-standard raw drugs entering the manufacturing process is minimized. The state-wise variation and high percentage of GMP non-compliant manufacturers is a cause for serious concern

Status of GMP Compliance

A little good news is that things appear to have improved over two years. Whereas the total percentage of ASU GMP compliant units in India was 53% in 2008 (http://indianmedicine.nic.in/writereaddata/linkimages/0203216722-Section-5.pdf) it is now reported to have increased to 62% in 2010 (http://indianmedicine.nic.in/writereaddata/linkimages/8789837245-Licenced%20Pharmacies%20Part-II.pdf).

Almost all states have shown an improvement in the percentage of GMP units from 2008 to 2010.

Gujarat however showed 100% GMP compliance in 2008 which has inexplicably plummeted to 16% GMP compliance in 2 years.The chart below captures the differences and calls for much more stringent monitoring. The mechanical approach to data collection at the state level challenges its veracity.

Manufacturing units showing more than 50% non-compliance of GMP

Manufacturers of the following states are apparently not following GMP to a very large extent. Those with more than 50% non-compliance are Madhya Pradesh (91%), Gujarat (84%), Tamil Nadu (78%), Assam (64%), Maharashtra (59%), Bihar (58%) and Uttarakhand (57%).

Priority to Consumer Safety

Looking at this picture, it is difficult to say whether the sector is ever going to improve as nine years have elapsed since the GMP requirement became mandatory. On the one hand if certain states can achieve cent percent GMP compliance, it is not an unattainable standard. On the other hand if almost half the units are refusing to become GMP compliant which is a mandatory legal requirement, and they continue to operate in violation of the law, shelter cannot be taken for all times on the grounds that they cannot afford to meet GMP requirements.

Factory-based Manufacture vs. Traditional Manufacture

In the ASU sector, thousands of units fall in the small and tiny category and they are nothing more than cottage units making hardly a score of items being supplied to limited outlets. These people have limited financial resources and they are unlikely to ever upgrade their manufacturing processes, or undertake stage by stage testing in the foreseeable future.

Requirement for factory based manufacture

QCI Marking

The PI was told by members of the Drug Manufacturers, Association that the Quality Control of India (QCI) mark strategy is meeting with apathy as the costs are prohibitive and the mark is being offered for individual items and not for the manufacturer's unit as a whole. As such very few manufacturers seem to aspire for QCI certification which will hold back a well-intentioned scheme.

Products Containing Metals and Minerals

The mineral and metallic content of ASU drugs has been highlighted in the press from time to time. The Department of AYUSH issued a press note on 2nd September 2005 notifying mandatory testing of heavy metals for Ayurveda, Siddha and Unani being exported from India w.e.f. 1.1.2006. Furthermore, toxicological testing of eight Rasa Aushadhis (Herbo-metallic formulations) was carried out at CSIR laboratories by selecting a reputed manufacturer to supply the products which were taken up for physico-chemical characterization and toxicity studies. On the basis of 28 days toxicity studies, all the eight Rasa Aushadhis were found to be non-toxic. But this is by no means a universal or permanent indication of absence of toxicity.

Heavy Metals in Medicinal Plants

Samples of 600 Indian medicinal plants collected from the wild as well as different medicinal plant gardens in India were sent to a cross-section of CSIR and other reputed laboratories which reported that lead, mercury and arsenic were not been found above the permissible limits laid down by WHO (10 ppm for lead, 1ppm for mercury and 3 ppm for arsenic). This study seems to show that Indian medicinal plants collected from the wild or cultivated sources, were been found to be free from lead, mercury and arsenic contamination. However adverse reports continue to be published in India and abroad.

Herbo-metallic compound formulations are not being exported. But even for the Indian market a check on herbo-mineral and metallic products must be mounted continuously and the outcomes publicised regularly to allay misgivings.

Supplementary Guidelines

The Department of AYUSH published "Supplementary guidelines for manufacturing Rasaushadhis or Rasamarunthukal and Kushtajat (Herbo-mineral-metallic compounds) of Ayurveda, Siddha and Unani medicines in March, 2009.

This is a welcome step but it is necessary to publicize such measures in the lay press as very few people are aware of the measures initiated to protect consumer safety. The public is unaware about these measures.

The Risk to the Consumer

Products made by some units whose GMP has been cancelled are reportedly still sold in the open market. Obviously the state licensing authorities are not in a position to ensure that such products do not come into retail sale. Drug inspectors expressed helplessness due to shortage of staff and time.

To be realistic, it appears difficult to expect total compliance because a large number of units have nothing to gain or lose by not getting GMP. As long as the products sell and there is a captive clientele, manufacturers know that the punishment which is prescribed in the law will not be enforced. Even if the Central government provides the manpower to run the State Drug Testing Laboratories (a scheme that was referred to as being under consideration), unless there is a willingness to enforce the law on the part of State governments, quality control may take years to become a reality.

The present system of stacking raw drugs outside the manufacturing area is quite haphazard at places. Washing and drying is hardly being done before powdering many raw drugs. As a result chances of impurities and contaminants lingering in the powders remain.

The consumer should not be exposed to buy medicinal products which do not meet the prescribed standards. The Principal Investigator discussed this matter with a wide cross-section of experts. It was felt that the time has come to look at the issue from the consumers' end. Prolonged and indiscriminate use of products for enhancing sexual potency were reported to be rampant. Industry associations would like to see every manufacturer becoming GMP compliant because that give credibility to the entire industry. Further the benefit of sales should legitimately accrue to those who follow the law and not to those who disregard it. Hence they push for GMP but the manufactures who do not have GMP are least bothered.

Differentiating Between "Manufacture" and "Preparation" of ASU Drugs

There is a need to look at the picture differently. The law permits the Vaidya/ Hakim/ Siddha to manufacture his own medicine using the ingredients in the classical texts but according to his own genius. As long as the medicines are formulated for the use of his patients and administered by him, he is not expected to follow GMP. Therefore smaller manufacturers that are supplying the Vaidyas and who process or repack or blend bulk raw drugs cannot be called "manufacturer". This category needs to be defined afresh. It is also debatable whether such suppliers who are following the traditional way of making ASU drugs should be closed down for want of GMP.

On inspection if such units do not come under the category of "manufacture" they should not be allowed to enter their products in the normal trade channel distribution/C&F agents/retail outlets, etc. But in all fairness they should be permitted to continue to supply practitioners employed by them or practicing independently.

It is time to introduce a system where household and tiny units are not permitted to sell products in the distributive system; but they should be allowed to supply relatively small quantities to practitioners.

Stacking of Raw Drugs just outside production area of a factory


View of the Dhanwantari Pharmacy manufacturing Ayurvedic drugs and metallic products


View of furnace and preparation of Bhasma at Dhanwantari Pharmacy



Preparation of Rasausadhis and other formulations

IPD at Dhanwantari Pharmacy

Some Ayurvedic outlets like the Dhanwantri Ayurvedic sale outlet in Jaipur shown in the pictures above follow age-old traditional methods of making drugs including preparations containing metals and minerals. The pharmacy is dispensing those drugs in an OPD and a ten-bed hospital running inside the premises. The only difference is that today the Dhanwantri Ayurvedic shop which operates from the main Jaipur market, can sell all its products to anyone from the public. If the suggestion being made by the PI is accepted, the shop would not be allowed to sell the products in retail but could continue to administer the drugs to the outpatients and in-patients and to also supply the same to other practitioners. This is covered by the existing law. Only an embargo on retail sale of such ASU products should be in place and practitioners made responsible for the drugs they provide.

Need to Uphold Traditional Production of ASU Drugs Used by Practitioners

A separate set of provisions regulating such small producers of ASU medicines need to be introduced

and guidelines issued so that requirements of hygiene are observed. It would be a retrograde step to close such units down. They represent the last vestiges of traditional preparation of drugs. Just like the country invests so much to preserve its heritage including the skills of its weavers, artisans and their arts and crafts, this too represents a part of tradition which should not be shut down with the single aim of ensuring that only those who have GMP are allowed to make ASU medicine.

A new licensing category defining such firms as either "Traditional processer license/ or ASU "Bheshaja Kalpana license" need to be added under the DCA Rules. Alongside clear regulatory provisions should also be introduced to protect the consumer:-

i) Such products made by the traditional processors should be limited for supply to practitioners (Vaidyas, Siddhars and Hakims) and the subsequent responsibility for prescribing this medicine or selling it to individual patients would be of the practitioner. At all times the linkage with a practising Vaidya would need to be established by any traditional processor.

ii) The practitioner would be responsible to ensure that such drug processors use quality raw material, undertake all processing in a hygienic manner and maintain records of the processing and sale of products to the practitioner.

iii) A specific provision should be made disallowing the issue of manufacturing licenses to such establishments. The produce of such units should be allowed for distribution to practitioners within the state because interstate commerce poses several problems. FDA Maharashtra Officers showed the PI samples of spurious drugs for sexual potency sold in Maharashtra and manufactured in Punjab. These small producers without GMP should not be permitted to sell their medicines in retail to Ayurvedic shops or to chemists and sale to ASU practitioners should be restricted to the State boundaries.

Excluding such units that supply only to practitioners, the remaining units which manufacture ASU products for distributive trade and interstate commerce need to be made fully GMP compliant. The current levels of GMP also need to be upgraded in keeping with international best practices.

Registration of ASU Sale Outlets

Side by side all retail outlets stocking/selling ASU medicines should be asked to get registration for sale of ASU drugs. This is in consumer interest because at present the shops are selling several formulations, classical and proprietary, purely plant-based or herbo-mineral as well as products containing metals. The simple claim that all processes given in the classical texts have been followed is insufficient for consumer protection.

Consumers purchase drugs and use them for extended periods which could be harmful. Loyalty to the system should not overlook consumer rights and safety. The Drug Controller of Kerala suggested that shop registration should be introduced at a nominal cost of Rs.2000 per year. The State has 25,000 sale outlets and it is not possible to oversee what each outlet is stocking and selling. The funds collected from annual registration could be put into a revolving pool, which could pay for fulfilling consumer related activities. An undertaking to stock and sell only GMP compliant companies' drugs should be obtained and should be checked through random visits.

Pharmacopoeial Standards

Present status of publication

The progress has been commendable.

- Ayurvedic Pharmacopoeia Part I with 540 single drugs has been published.
- Ayurvedic Pharmacopoeia Part II with 101 monographs on formulations has been published.
- The Unani and Siddha formularies contain 1091 and 248 formulations respectively. Source: http://indianmedicine.nic.in/writereaddata/linkimages/9084167477-apc%20web%20july%2010.pdf (accessed on 1.8.2011)
- The Unani pharmacopoeias contain 298 single drugs and 100 formulations. Source: http://www.ccrum.net/research/upc/ (accessed on 1.8.2011)
- The Siddha pharmacopoeia contains 73 single drugs. Source: http://crisiddha.tn.nic.in/committee.html (accessed on 1.8.2011)

The ASU pharmacopoeias (API, UPI, etc.) specify the morphology and microscopic tests for checking the botanical authenticity of plants used in the

manufacture of ASU drugs. The technology being used for confirming botanical identity has remained somewhat static. Meanwhile fears about substitution and adulteration of raw drugs are on the rise. Qualified and experienced botanists and taxonomists are not easily available as the career is not considered rewarding. The current trend of using pre-powdered plants further necessitates that identity testing and confirmation is done on powdered substrates also.

The Pharmacopoeia Committees have not opted for new technologies like "bar coding" based on an analysis of the specific portions of the DNA of the plants. During discussion with experts it was indicated that nowadays the identification process can be fine-tuned to cover even the powdered form. Some of these are indicated in the foot note.[4]

While a test TLC (Thin layer chromatography) profile which gives a specific and unique pattern of spots has been suggested this test is not mandatory for acceptance or rejection of a consignment.

International Best Practices and Standards

According to experts consulted by the PI, the pharmacopoeial tests prescribed are insufficient and need to be upgraded. Far higher standards are demanded in international commerce. The Books of Standards (Pharmacopoeias) of countries like the United States, the U.K., Republic of China and Europe, all demand quantitative estimation of the chemical composition of the parts of plants/ whole plants and extracts.

Indian and ASU Pharmacopoeia Commissions

The Indian Pharmacopoeia (IP) published by the Indian Pharmacopoeia Commission has 89 monographs relating to plants and plant extracts that meet this standard. If the plant sample under examination does not show the presence of prescribed percentages of the ingredients or does not meet the assay requirements, such samples simply fail. Keeping this in mind, it is time that the Ayurvedic Pharmacopoeia Commission of India (APCI) becomes functional so that the same rigor can be exercised in respect of Ayurvedic drugs.

It is understood that in the latest volume of the API (Volume 8) specifications have been developed on the lines of IP 2010/BP and USP. This is a welcome trend. Wherever the international standards are at par, Department of AYUSH also needs to initiate steps to have reciprocity/bilateral acceptance of the specifications laid down in various volumes of the pharmacopoeias and formularies.

Incentives to Promote Use of Cultivated Raw Material

The subject of medicinal plants has been dealt with at length in a separate chapter of this report. In order to encourage industry to buy raw material from cultivated sources and also to provide an incentive to cultivators to diversify into medicinal plant cultivation the following proposals were made by industry. They deserve consideration because it would give an impetus to the production of quality products:-

- 150% Income Tax exemption on the purchase value of cultivated raw materials: In the pharmaceutical industry, in order to promote R&D, Government of India had reportedly introduced a provision of 150% Income Tax exemption on the amount spent on clinical trials as a part of R&D. A similar provision can be extended to AYUSH Industry which will automatically lead to an increase in the demand for high quality cultivated plant material.
- 100% exemption from CST (Central Sales Tax, 4%) may be given on purchase of herbal raw material from cultivated sources. Allowing MODVAT credit of 40% on the cost of purchase of cultivated raw material will work in two ways: Industry will be willing to buy the raw material at a higher cost because it will be able to claim it back by way of MODVAT. At the same time the cultivation of medicinal plants can become a sustainable business, coupled with ancillary

4. There are a number of parameters that can be used in the identification process such as starch grains and their structures, lignified parenchyma, cork and their structures, calcium oxalate crystals, stomata and differences in stomatal index, vessels and tracheids, stone cells, type and varieties of fibers pollen grains, which can be seen, even if the herbs are supplied in "powder form". Scientific studies using a microscope with image analysis tools, coupled with IT tools are available and this would be an easier and much more authentic test, if developed with a data base on the most commonly used ASU plants and their substitutes and adulterants. Source: Anantha Narayana DB, Guest Editor, Pharmacog Magzine, Vol.6 Issue 23, July-Sept. 2010, p.145-146)

schemes that promote grading, testing, certification, packaging and sale of raw drugs through district co-operatives.

Systematizing Licensing of ASU Drugs

Currently licenses for manufactured ASU medicines whether classical or P&P preparations are granted by the State Licensing Authorities where the manufacturing units are situated. There is no standard format for application for the grant of these licenses leading to enormous variation in the information and data required to be attached to the application while seeking a license. The process followed for grant of licenses is also not uniform which leads to delays and unnecessary paper work.

Examination of the application is minimal while granting licenses for classical preparations since manufacturers are bound to adopt the formulation as given in the official texts recognized in first schedule of Drugs & Cosmetics Act and also adopt the process as given in those books.

Once the premises have been inspected and the capacity to make certain forms of medicine is accepted, it should suffice if the manufacturer notifies that he has started producing additional items in the same classical category. A letter informing the licensing authority about adding more items in the same type of category (Asava, Arishta, Ghrihta etc.) should be taken as adequate. Such premarket notification systems (as opposed to post-market licensing systems) are reported to be in vogue in other parts of the world including ASEAN countries. This step will reduce red tape, and improve efficiency while the Regulatory authorities would always have information on the number and type of classical medicines being produced by each manufacturer. This should be put on a website and updated constantly. Industry groups and competitors will be quick to point out deficiencies in case incorrect claims are made.

Licensing of P&P Medicine

As regards P&P medicine licenses there is an urgent need to review the current system and to notify a standard format for application for additional product licenses. Along with such standard formats a uniform approval system should be laid down to bring efficiency and objectivity. An ASU Industry Association, ADMA had suggested that a "Dossier approach" should be adopted. The suggested dossier is given at **(Annexure-I)** which could be sent to the States for uniform adoption. It would prevent haphazard proliferation of license applications and make it incumbent on the licensing authority to take a view within a prescribed period.

Incomplete application forms need not even be accepted. The dossier would hold the manufacturer responsible for what he has claimed. The products would be licensed for the claims made and the insistence on product inserts would be in consumer interest.

Quality Control Certification for Consumer Safety

At present QCI has been appointed to give quality certification and QCI in turn has identified and appointed third-party certifying agencies. The scheme does not seem to be attracting too many manufacturers because according to members of ADMA, the certification is not manufacturer-based but product-based which turns out to be extremely costly. Besides, there is no chance that sales will increase by obtaining the certificate because there is no matching publicity about what the QCI certificate stands for.

Instead of finding ways to distinguish between manufacturers producing high quality products and others, it would be beneficial to look at things from the consumer's point of view. The most important concerns that the public would like addressed cover five areas. If ASU treatment and drugs are going to be accepted by a wider public, there is a need to insist on specified of testing without which the sale of medicines in retail should not be permitted. This is to protect the public and is not aimed at helping or harming the manufacturers. The main concerns voiced by the public invariably refer to:

1. Anxiety about the presence of heavy metals and minerals exceeding permissible levels.
2. Substitution and adulteration of plant based ingredients.
3. Presence of impurities and contamination.
4. Addition of non-permissible substances like corticosteroids and pain-killers.

5. Labelling and advertisement claims about curing diseases like cancer, cardiac problems, diabetes, reproductive health infections, epilepsy etc. which is expressly forbidden by law.

After discussions with a number of experts, the following course of action appears to be in urgent need of adoption to protect public safety and to give the public the way of knowing whether it is safe to use ASU drugs. Testing for heavy metals ought to be mandatory. For substitutes of medicinal plants, contaminants, impurities and added chemicals, the tests can be outsourced by QCI and consumers encouraged to look for the quality certificate. The technical description of the tests follows:

Heavy Metal Testing

There is a need for Government to fund setting up of laboratories with sophisticated equipment required to test heavy metal contamination levels. An Inductively Coupled Plasma Analyzer (ICPA) is capable of testing for the presence of all heavy metals like arsenic, mercury, lead, cadmium, zinc, copper, etc. in one sample, with only one injection unlike the Atomic Absorption Spectrophotmetry (AAS) which is widely recommended. AAS needs each metal/mineral to be tested separately and individually. ICPA has detection levels in "parts per billion (ppb)" while AAS can normally test only to "parts per million (ppm) level". The cost of the equipment is reported to be around Rs 80 lakh per laboratory and at least 10 such laboratories would be needed. A large number of private test houses approved by State Drug Controllers are already approved for testing ASU products. Some of these laboratories should be advanced full funding for setting up ICPA facilities on agreed testing rates and a proportion of earnings can be set off against the loan. Five private laboratories (called Public Test Houses) can be funded and the rest can be established by Government at PLIM and the Homoeopathic Pharmacopoeial Laboratory (HPL) among others.

Obtaining certification should be made mandatory for all herbo-mineral and metal-based ASU products. The label should state *"This product contains Metals & Minerals used in ASU medicine within permissible limits."*

Substitution/Adulteration/Addition of Non-Permissible Substances

In order to confront concerns which are voiced about the presence of impurities, contaminants and the addition of non-permissible substances like cortico-steroids, anti-inflammatory agents and even drugs like Sidenifil (Generic for Viagra) HPLC/ HPTLC testing should be encouraged. This can test the presence and absence of all such impurities and additives. Any manufacturer who obtains a certificate showing that the drug is free from contaminants, microbial presence and specified adulterants and chemicals can obtain an AYUSH mark from the QCI approved third-party certification agencies. Testing charges should be settled annually by Department of AYUSH and the label of such ASU products which meet all the test requirements could have a specified "AYUSH mark" which should simply read: *"Quality Certified."*

The Department of AYUSH should launch a massive TV programme to encourage consumers to buy products that carry the *"Quality Certified"* mark on the lines of the ISI mark.

Manpower to Run Heavy Metal Testing Laboratories

To overcome the need for positioning specialized manpower many Government laboratories have started appointing Young Scientists - like M.Sc./ M. Pharm, B. Pharma as Research Associates on a consolidated payment basis for two-year tenure. These scientists get a learning opportunity and provide valuable professional capability. Such temporary Research positions can be factored into the scheme which should be treated as high priority because it involves public safety.

Labeling of ASU Products

All manufactures of Ayurveda, Siddha and Unani medicines have to adhere to the requirements of Rule-161 (Part-XVII) of Drugs and Cosmetics Act, 1940, viz. the list of ingredients, pharmacopoeial standards, date of manufacture, batch number, manufacturing license number, the complete address of the manufacturer have to appear on the label. Generally, it is observed that most of the companies write only the name of the State or the PIN code, which does not meet the requirements of law.

The term Ayurvedic Medicine, Siddha Medicine or Unani Medicine should also be printed on the label along with the reference of authoritative book included in First Schedule of the Act. ASU manufacturers do not adhere to this requirement.[5]

Labeling provisions are extremely important and the public has to be educated through consumer campaigns to look for the fulfillment of various requirements on the label. Every stockist or a chemist/shopkeeper engaged in retail sale of ASU products needs to be registered and made responsible for stocking ASU products that fulfill the quality certification requirements for herbo-mineral and metal-based products as prescribed, and abide strictly to labelling requirements. Consumers need to be made aware of these requirements and to look for them.

Enforcement of Law on Product Claims and Advertisements

Although the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 prohibit claims to treat and cure disorders or conditions specified in Schedule I of the Act, several such diseases are routinely mentioned on the labels of ASU medicine.

It is also surprising that when practically all medicines manufactured by some lesser known units routinely claim to treat and cure diabetes, epilepsy, heart diseases, female diseases, paralysis, rheumatism, and blood pressure, *which are expressly prohibited under the Act,* the State authorities have taken no visible action despite this practice being rampant.

The sale of products that make such claims over the counter presents great risk to the public. The law applies to everyone and there cannot be a separate dispensation for ASU drugs.

It is incumbent on the State Governments to appoint an officer who can scrutinize the labels of ASU medicine and act upon what is found. Contravention of the Act leads to imprisonment or fine or both and offences by companies are also covered.

The Department of AYUSH should commission a survey to ascertain the extent of this practice and also ask the State governments to ensure that labeling claims keep within the ambit of the law. This should always be presented as a public safety issue and not merely as a means of getting after manufacturers.

Branding Classical (Grantha) Products

Classical ASU products are not allowed to be "branded." By executive orders issued during the last few years further restrictions have been placed on putting any "prefix or suffix" for the purpose of branding. Only the name of the company manufacturing such classical preparations is allowed. However branding has many advantages.

A brand name is a created word around which the manufacturer builds trust, acceptability, or "positioning" in the minds of consumers. The prohibition against branding of classical products has led to a situation where the production and sale of classical medicines is on the wane. Pharmacy experts told the PI that proprietary ASU products are nothing but classical preparations which have been "tinkered" with by omitting a few ingredients or adding some. Most such products are neither great innovations nor new ASU drugs. Modern sounding names are intended to get modern medicine practitioners interested in prescribing them.[6] See table below:

Modern Sounding Names Introduced by Top Ayurveda Manufacturers

Dabur	• Dabur Chywanaprash (Immunomodulator, for general well-being, promotes lung function, reduces chances of falling sick, family tonic), • New Liv Fit (Treats Hepatitis B & E infections, Anti-viral, improves liver functions, Non-alcoholic hepatic steatitis, improves appetite), • Greneem (Adjuvant to oral anti-diabetic, skin health/ infections, acne reducer),

5. International Journal of Ayurveda Research, October – December 2010 written by Supriya Bhalerao *et.al.* from the Department of Clinical Pharmacology, TNMC and the BYL Nair Hospital, Mumbai, has been brought out that Ayurvedic drug container labels were not compliant with most of the requirements specified in the D&C Act.
6. Source: "Reverse Pharmacology-Translational Impact", Talk delivered at Training Programme on Reverse Pharmacology at Kasturba Health Society, Mumbai, DBA Narayana, April 6th, 2011).

	• Osteofit (Treats osteoporosis and osteopeniea), • Honitus (Cough and cold remedy), • Pudin Hara (For stomach pain, griping pain, colic, gas and carminative), • Vatika (Anit-dandruff and hair fall reducer hair oil), • Ashokristha (For women problems, menstrual disorders), treats Dysfunctional Uterine Bleeding (DUB), • Restora (Promotes blood circulation), • Stresscom (Anti-stress, treats insomnia, tranquilizer).
Himalaya	• Bonnisan (Carminative, griping pain, gas remover) Bonnispaz (Anti-spasmodic, treats colic pain), • Bresol (Improves lung function, asthma treatment), • Liv-52 (Treats Hepatitis B & E infections, Anti-viral, improves liver functions, Non-alcoholic hepatic steatites, improves appetite), • Mentat (Mental performance improver, memory enhancer) Septilin (Immunity builder, natural antibiotic), • Clarina (Anti-acne), Evecare (Uterine care), • Menosan (Treats pre-menopause and post-menopause syndromes) V-Gel (Treats vaginal infections), • Reosto (For Bone health, osteoporosis treatment),· Styplon (Natural styptic for uterus), • Himolin (For sexual health of men), • Himplasia (Prostrate problems treatment), • Speman (Oozspermia and spermatorrhoeia), • Tentex Forte (Non-hormonal sexual stimulant for men), • Abana (Cardiotonic),

	• Geriforte (Anti-stress and adoptogenic for aged), • Pilex (Treats piles), • Systone (Treats urinary stones, helps dissolve urinary stones in- situ), • Rumalaya (Osteo- and rheumatic pain/inflammation treatment), • Diabicom (Treats diabetes), • Serpina (Treats BP).
Charak	• Alsarex (For acid peptic disorders/ulcers), • Optizooom (Mental performance enhancer), • Arjunin (Coronary vasodialator, cardiotonic), • Arthrella (Anti-arthritic and remission inducer), • M-2-Tone (For DUB, menstrual problems), • Livomyn (Hepatoprotecive, cholagouge), • Hiponidd (Anti-diabetic and hypolipidemic), • Addyzoa (Spermatogenic, improves male infertility).
Bafco	• Acibac (For pepetic disorders), • B-Slim (Anti-obesity), • Diabac (Anti-diabetic), • Rectacare (Treats piles), • Respicare (Improves lung function, cough & cold), • Strex (Anti-stress), • Herbo Iron (Natural haemotonic, treats anemia).
Zandu	• Kesarijeevan (Immuno-modulator, for general well being, promotes lung function, reduces chances of falling sick, family tonic). • Zandu Balm (For local pain, muscular pain, headache, clear nostrils, cold), • Brento (Brain tonic), • Satavarex (Promotes mother's milk secretion), • Rhumayog (For treating rheumatic and arthritic pain and inflamation),

	• Zandopa (Natural treatment for Parkinson's disease), • Chandraprabhavati (Effective treatment for urinary tract infections), Sudershan (Quick treatment for many types of fevers), • Trishun (Effective treatment of cold, recurrent cold/cough), • K-4 Tablets (for benign prostrate hypertrophy).
Emami	Sona Chandi Chywanprash (Immunomodulator, for general well being, promotes lung function, reduces chances of falling sick, family tonic, and also mental performance enhancer).
Dhoot-papeswar	Many Bhasmas (For treatment of acid peptic disorders, migraine, psoriasis, supportive with cancer treatment).
Baidyanath	• Rheumartho Gold (for treating rheumatic and arthritic pain and inflamation), • Kesari Kalp (Immunomodulator, for general well being, promotes lung function, reduces chances of falling sick, family tonic).
HUL	• Fair & Lovely Ayurveda (Natural skin care with skin lightening benefit), • Brooke Bond Red Label Natural care (Tea with herbal flavors/ extracts for immunity). • Lever Ayush Range of Products (For treating cough/cold, rasayana, pain, infections of skin, antidandruff, etc.)
Vasu Health Care	• Ural (For treatment of urinary stones), • Ural BPH (For benign prostrate hypertrophy).

Industry has not invested in any form of technological research or quality improvement or even improvement in product delivery and packaging as far as classical medicines are concerned. This is because adequate returns are not likely to accrue. It is natural for manufacturers to invest in R&D and product up-gradation when branding is permitted. It should be recognized that classical preparations have a long documented history of safe use. The opportunity of conveying this to the public is lost because there is no "build-up" for these classical products. The result is that the classical drug sales are down to 10% of the total sales and will further reduce if there is no investment in up-gradation of classical products.

One strategy can be to encourage the building up of a chain of franchisees where companies sell their own drugs and where there is a consulting physician to diagnose and offer treatment (Arya Vaidyashala, Kottakal approach). The physician will act as a bridge and the outlets can display logos that keep the public informed of the chain. (Kairali does this for Ayurvedic wellness treatment and massage also).

The second strategy could allow branding of ASU drugs on the lines of consumer essentials like water, wheat flour and sugar and also allopathic generic drugs. Over the years this will bring lot of value to the system and products.

Some examples of how generics are presented are given in the pictures below:

Drinking Water

Differentiation of bottled drinking water by:

- Ozonization
- Naturally Mineralized/added minerals
- Micro-filtration
- Low Sodium
- High Potassium
- Low Hardness
- Tasty

Wheat Flour

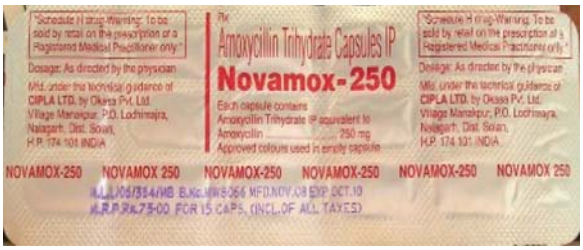
Differentiation of flour (Atta), rice and salt by:

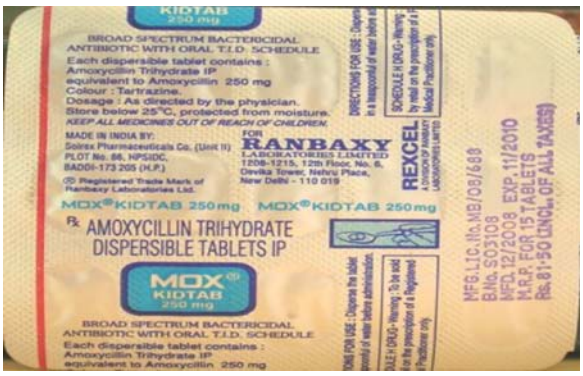
- Brand building
- Quality
- Performance
- Purity

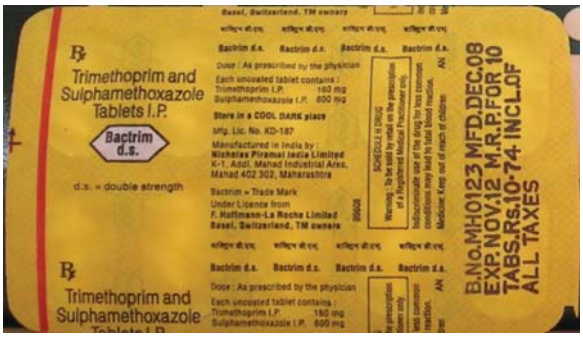
Generic Drugs

Differentiation of pharmacopoeial medicine by:

- Micronization
- Fast dissolution







Ayurvedic Grantha/Classical Medicines have no Branding and Look Alike

New Categories of ASU Drugs

Last year a gazette notification was issued introducing new categories like Poshaka/ Balya (supplements category), Soundaryavardhaka (Cosmetics category). The same notification also added another category called "Satvas/Extracts". This is a welcome development but unless it is accompanied by regulations which convey expected standards and what the labeling requirements should state for each category, the consumer will not benefit. This notification needs to be reviewed and standards need to be introduced which tell the consumer e.g. the proportion by percentage of plant-based material compared to the quantity of excipients contained in the product. Only mentioning Tulsi, sandal, aloe-vera is not sufficient.

New ASU Knowledge-based Drugs

China has provisions to allow new TCM (Traditional Chinese Medicine) drugs using the knowledge based in Chinese medicine after a scientific evaluation of safety, quality and efficacy of such drugs has been done. Only after that marketing authorization is given for such drugs. Therefore when the use of modern technology of extraction/ concentration/fractionation is used to present new dosage forms using the knowledge contained in ASU, this new category of drugs can be introduced. Far from taking away from the strength of Ayurveda it will enhance the reputation of the systems.

New Ways of Using the Traditional Knowledge Digital Library

Undoubtedly TKDL was established to safeguard against patents and claims being registered by the international patents offices using knowledge which emanate from ASU classics. (Recall the fight against patents given to Haldi, Karela and Jamun when patents were claimed for the medicinal properties of these items which had been used for their medicinal properties for millennia). The argument used by India was that this was not a discovery and the basis for the claim was in the public domain, namely the classical texts of ASU for centuries. TKDL has done a splendid job in preventing the grant of patents but time has come when it has to be seen whether the purpose of all this knowledge should simply rest with one single, limited objective.

There is a need to consider taking the matter back for policy modification by arguing that mankind should benefit from the information which is now available in different languages, in a digitized fashion. Therefore, a policy needs to be drawn up about how this information can be accessed, by whom and for what purpose and under what conditions.

The use of such knowledge would enhance the availability of new ASU drugs that have their basis in ASU knowledge. Already this knowledge is available in published form in public domain in Sanskrit, Tamil and Arabic/Persian/Urdu. Permanent restrictions on the use of TKDL for all times would be self-defeating.

Of course there would be huge worldwide interest if TKDL were to be opened up. Therefore, the risks and benefits of doing so have to be evaluated objectively. Whether there should be a fee for the use of this knowledge has also to be determined as well as which formulations should be made accessible. During discussions it was indicated that because of an embargo placed by a cabinet decision the possibility of using TKDL for any purpose other than for rebutting the grant of patents, has been precluded. This would therefore need intervention at a policy level, guided by whether the outcome would be in the larger public interest. Issues like the use of intellectual property and to whom it belongs will also come up whenever commercial interests are involved and a multidisciplinary group can be asked to go into this. To withold this repository form further use forever will not be a forward-looking way of dealing with the goldmine of data which is in a retrievable form.

II. Consumer Preference for ASU Products

Overview of Public Perception About ASU Drugs

Drugs and therapies in Ayurvedic, Siddha and Unani (ASU) systems of medicine are increasingly creating an interest both within the country and abroad. Consumers are broadly aware of the benefits of relying on the ASU treatment regimen and medication. But asked about the range of products that are easily accessible and are in comparatively higher demand, few people can give any response other than referring to a handful of products like Chyawanprash, Triphala, Ashwagandha, Shilajit, Liv-52, Cinkara, Safi, Joshina and the like.

Except for a few well known names like Himalaya, Dabur, Baidyanath, Hamdard, Zandu, etc. hardly any person is aware that the range of products runs into an inventory of anything from 200 to 1000 products produced by over 4000 manufacturers. Owing to iatrogenic problems and also reactions to continued use of certain medication, a new clientele would like to use ASU products but they have little or no information about how to access a good practitioner or understand the applications of the drugs. Some people tend to ask the shopkeepers for remedies for everyday problems, aches and pains. They accept the product offered over the counter provided it carries an indication that it is ASU medicine. Few users ask for product literature or what effect the ingredients can have.

Likewise very few users know the difference between branded products and classical products. They also do not know that certain manufacturers have indeed conducted studies on toxicology, that they have undertaken animal studies to determine safety and efficacy and that their products are comparatively of a higher standard. The present cross-section of consumers is not in the habit of looking at the label or asking for product information. Claims to treat "cancer, diabetes, cardiac ailments" are made routinely on the labels of products sold in the market. Since obtaining a license for manufacturing ASU products is a relatively simple process with little or no requirement for clinical validation of safety and efficacy, there is nothing to distinguish products which are made following a sound manufacturing process, that abide by the Ayurvedic, Unani and Siddha pharmacopoeias and formularies and those that ignore mandatory requirements and simply make claims. In such a situation the public either ignores the ASU products altogether or whenever they opt for them, they rely on big names, family tradition, advertising and word-of–mouth. While they do access products on the advice of practitioners they are also guided by shopkeepers. In the case of allopathic drugs the pharmacist knows what the drug contains and is able to distinguish the salts while suggesting an alternative to the prescribed product. Shopkeepers do not have similar knowledge about ASU drugs. Herbo-mineral preparations should not be taken indefinitely but particularly in the case of sexual dysfunction drugs, it is common knowledge that people buy the products, quite casually from the shops and use them over extended periods.

A section of people access ASU products regularly but what motivates them to use these products, the conditions, signs and symptoms for which they dominantly seek ASU medication is not known except anecdotally. Such studies are available for allopathic drugs but hardly any information is forthcoming in respect of the ASU sector, except for a few scholarly articles and books which normally stop with examples of large manufacturers with large turnovers.

Rapid Dipstick Survey

A "dipstick" survey was conducted as a part of the product over a six month period, starting September 2010. The aim was to gauge where consumer interest and preference lay. Interviewing consumers would have required a huge sample and may not necessarily have yielded reliable responses. Therefore it was felt that a common questionnaire could be issued to shops dealing with sale of ASU medicines to get a sense of what the shop owners had to say with reference to consumer attitudes and preference.

Several efforts were initially made by contacting research organizations. The PI tried to locate an organization already working in the pharmaceutical field by working through the Department of Pharmaceuticals. Although the senior officers of the

Department including the Secretary were very helpful, after exchanging several e-mails with the contacts given, it was clear that no one was interested in undertaking a survey of this kind. The idea of off loading the survey to a consultant was not inspiring; in the process the questionnaires might be filled by employees of manufacturers to save time. It was apparent that no one was willing to actually visit the stockists and shops of ASU medicines.

Still, the consumers preference needed to be examined in the most practical way as it has direct relevance to benefits accruing to him. In order to conduct such a study in the least possible time but ensuring that the responses were actually filled up in the shops and not by manufactures or practitioners, the PI selected several cities which she felt would give a representative picture about consumer preferences. She contacted the Drugs Controller General of India (DCGI) Dr. Surinder Singh and he readily undertook to direct the zonal inspectors working in different zones in the country to visit a cross-section of shops, city-wise to get the questionnaires filled up. Questionnaires were framed separately for Ayurveda, Unani and Siddha range of products (prepared by Research Officers of the three Research Councils) to ascertain consumer preference. The cities were selected in a way that all the regions and systems got representation. The responses received through the inspectors of the DCGI were then tabulated to arrive at a general picture about consumer preference.

In some places like Maharashtra and Gujarat, the Food and Drug Authority (FDA) was asked by the Health Secretary of the State to help collect this information by sending officials to the shops. This was also done in the case of Rajasthan State and Delhi where the Health Secretary entrusted the work to the local drugs inspector. The faculty and students of National Institute of Ayurveda, Jaipur were also engaged for one day to cover the main shops. In the case of Unani drugs, a Research Officer was sent to Meerut, Moradabad, Anantnag, Srinagar, Pulwama and Jammu city where the use of Unani medicines was comparatively more popular.

Contents of Questionnaire

a) The fastest moving ASU medicines with reference to different diseases;

b) Consumer's preference on various kinds of ASU products e.g Vati, Avaleha, Kwatha, Ghrita, Taila etc. in case of Ayurvedic drugs (which would indicate prescribing habits also);

c) Consumer's source of knowledge about ASU products and their applications;

d) Difference between the popularity/use of ASU products in different regions of the country;

e) Extent of consumer's concern about efficacy/ safety/quality of the products;

f) Knowledge of the shopkeepers/dispensers of medicines (working in the chemist shops) and of the consumers themselves relating to ASU products;

g) Consumer's concern and perceptions about the ad-mixture of allopathic substances with ASU products.

A copy of the questionnaires is at **Annexure-II(a), II(b), and II(c)** for Ayurveda, Siddha and Unani, respectively. The city-wise findings are at **Annexure-III.**

1. Findings on diseases/conditions for which Ayurvedic drugs are preferred

The diseases and conditions for which the Ayurvedic drugs were being purchased were almost similar throughout the country, and these areas were joint disorders, liver disorders, skin ailments, asthma and irritable bowel syndrome. Next to these conditions, the drugs were being purchased for diabetes, obesity, sexual dysfunction, nervous disorders and infertility in a relatively high proportion.

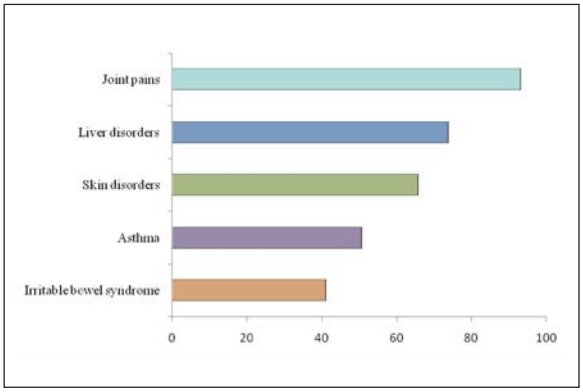


Figure-1. Diseases/Clinical conditions for which the Ayurvedic drugs are preferred.

2. Findings on the basis on which above responses were given

The basis for giving the information was repeated prescription handled by the shopkeepers followed by the discussion with a cross–section of practitioners.

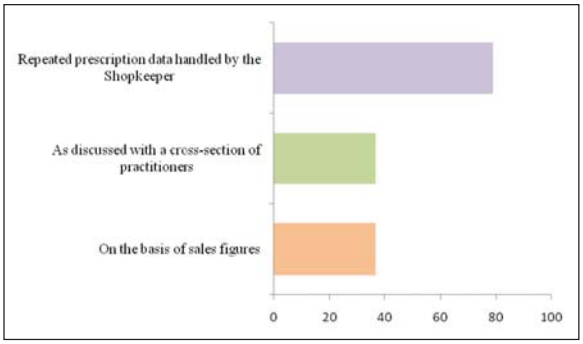


Figure-2. Basis for providing information on consumer preference.

3. Findings on the methodology by which majority of consumers access the medication

Most consumers came to the shops seeking the medicine on the basis of prescription, followed by what they had learnt through advertisements and then by word-of-mouth. The recommendations of the shopkeeper/shop assistant/ pharmacist working in the shop also mattered.

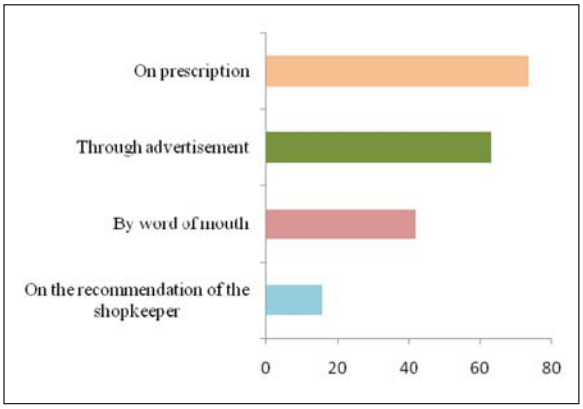


Figure-3. Methods by which majority of consumers access the medication.

4. Findings on consumer concern about the quality, safety & efficacy of Ayurvedic products

The consumers showed concern about quality and safety. Questions about efficacy were not asked to the same extent. This indicates that the consumers might be treating efficacy as a matter of individual reaction to the treatment; perhaps the medicine was being used as an alternative to be given a try and not as the first or only mode of treatment.

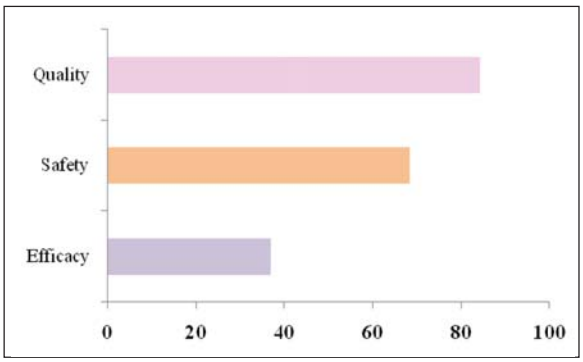


Figure-4. Consumer's concern about products.

5. Findings on whether consumers sought products stating the name of the company

The consumers overwhelmingly sought drugs on the basis of a company name and the pharmaceutical representatives had a big role to play in providing information to the shopkeepers working in the shop.

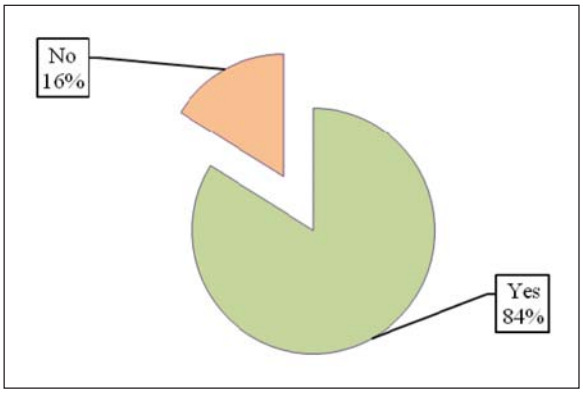


Figure-5. Consumers seeking products stating the name of the company.

6. Findings on whether consumers know the difference between the different presentation (decoction/tablet/powder used in Ayurvedic medicine and how they act

In some places like Pune, Indore and the Southern States there was knowledge about the difference between Asava/Arista/Ghrita/Churna but in cities like Delhi and Ghaziabad consumers had no knowledge about different presentation of administration of Ayurvedic drugs.

7. Findings on the awareness of the ahopkeepers/pharmacists about the difference between various categories of Ayurvedic drugs and their actions

Owners, shop level staff and pharmacists working in the shops had information about the difference between various categories of Ayurvedic drugs and their application. Pharmaceutical agents also provided them information about this.

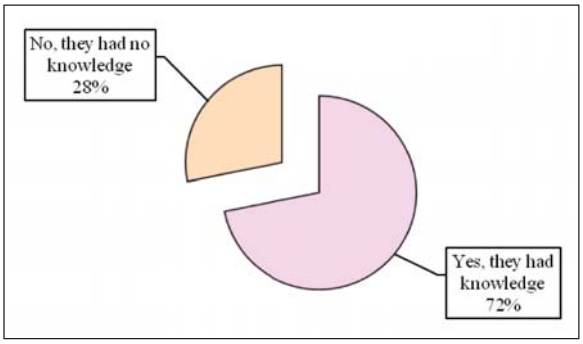


Figure-6. Shopkeeper's awareness about the difference between various categories of Ayurvedic drugs and how they act.

8. Findings on consumers' concern about the admixture of allopathic/non-permissible substances in the product

Admixture of allopathic/ non-permissible substances in the Ayurvedic drugs was not a major concern when consumers asked for the medicine. This statement is completely at variance with the huge concern that is expressed by *potential* users of Ayurveda who would like to use Ayurvedic treatment but are acutely concerned about the admixture of non-permissible substances. The response can be attributed to the bias of the shopkeepers.

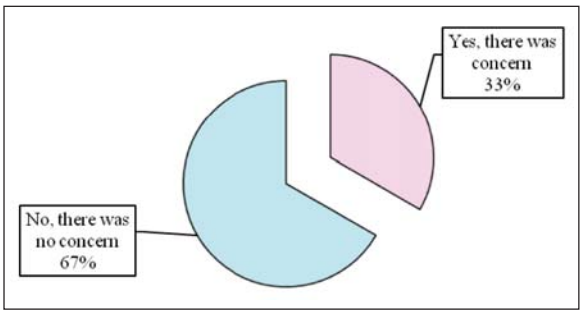


Figure-7. Consumer's concern about the admixture of allopathic or non-permissible substances.

II. Appraisal of Consumer Preference of Siddha Drugs

The information obtained on various queries on Siddha medicines can be summarized as follows:

1. Findings on diseases/conditions for which Siddha drugs are preferred

The diseases and conditions for which the Siddha drugs were being purchased were almost similar throughout the state of Tamil Nadu, and these areas are asthma, liver disorders, joint disorders, skin ailments, gynaecological problems, paediatric diseases and life style disorders. Next to these conditions, the drugs were being purchased for sexual dysfunction, nervous disorders and infertility in a relatively high proportion.

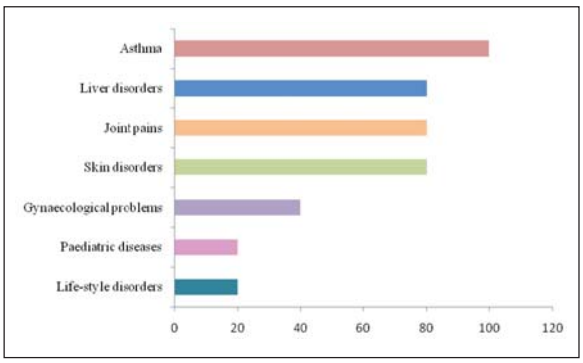


Figure-1. Diseases/Clinical conditions for which the Siddha drugs were preferred.

2. Findings on the basis on which data was generated for aforesaid issue

The basis for giving the information was repeated prescription handled by the shopkeepers followed by a discussion with a cross-section of practitioners and finally on the sales figures.

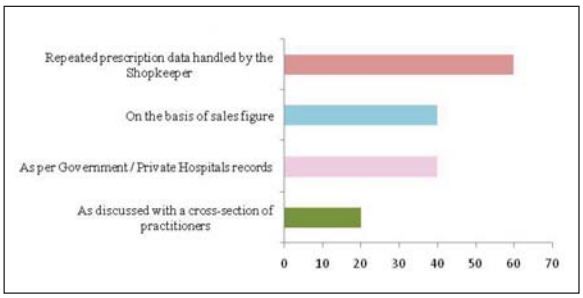


Figure-2. Basis for providing information on consumer preference.

3. Findings on the methodology by which majority of consumers accessed the medication

Most of the consumers came to the shops seeking the medicine on the basis of prescription, followed by what they had learnt through advertisements and then by word-of-mouth. The recommendations of the person who dispensed the medicine were relatively less important.

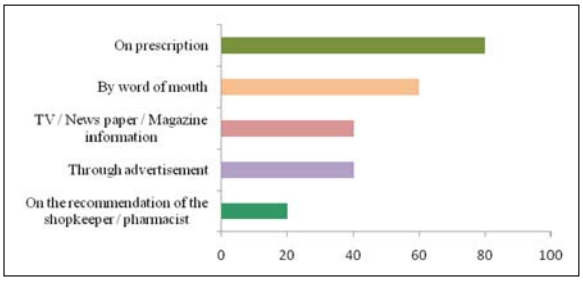
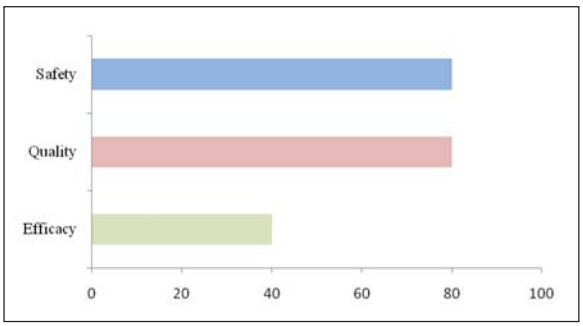


Figure-3. Methods by which majority of consumers accessed the medication.

4. Findings on consumers' concern about the quality, safety and efficacy of Siddha products

The consumers showed concern for quality and safety. Questions about efficacy were not asked as much indicating that the consumers were using the drugs on prescription and treated efficacy as a matter of individual reaction. It could also be on account of bias of the shopkeepers who responded.



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The consumers overwhelmingly sought drugs on the basis of a company's name and the pharmaceutical representatives had a big role to play in providing information to the shopkeeper/ pharmacists working in the shop.

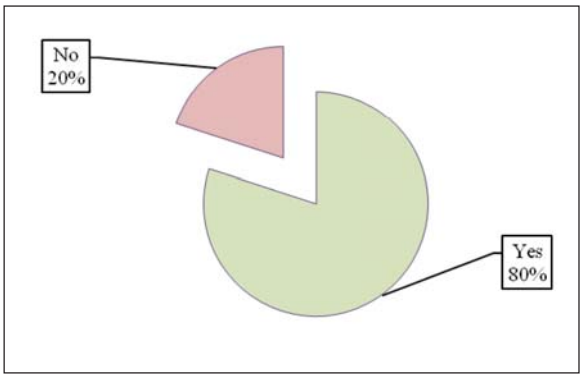

Figure-5. Consumers seeking the products stating the name of the company.

6. Findings on whether consumers know the difference between the various categories of Siddha medicines and how they act

The consumers had personal knowledge about the different presentations of administration of Siddha drugs.

7. Findings on the awareness of the shopkeepers/pharmacists about the difference between various categories of Siddha drugs and their actions

Owners, shop level staff and pharmacists working in the shops had information about the difference between various categories of Siddha drugs and their application.

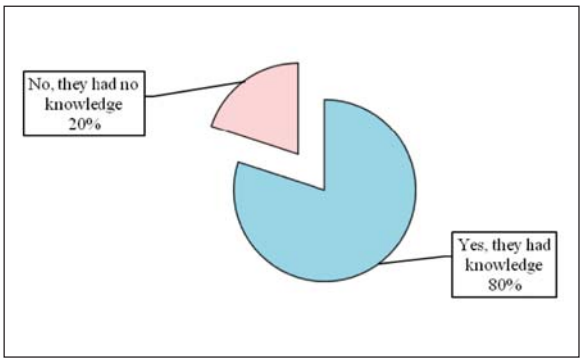

Figure-6. Shopkeeper's awareness about the difference between various categories of Siddha drugs and how they act.

8. Findings on consumers' concern about the admixture of allopathic/non-permissible substances in the products

Admixture of allopathic/non-permissible substances in the Siddha drugs was not an issue when consumers asked for the medicine.

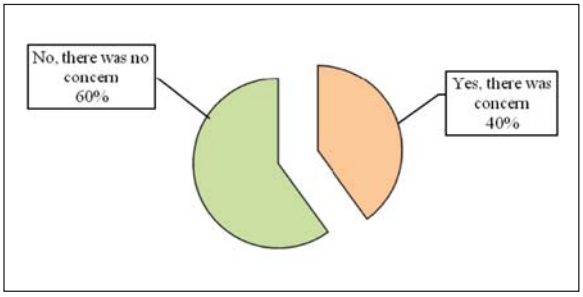

Figure-7. Consumer's concern about the admixture of allopathic or non-permissible substances.

III. Appraisal of Consumer Preference of Unani Drugs

1. Findings on diseases/conditions for which Unani drugs are preferred

The diseases and conditions for which the Unani drugs were being purchased were almost similar throughout the country, and these areas are liver disorders, skin ailments, joint pain, irritable bowel syndrome, respiratory diseases, asthma and cardiac problems. Next to these conditions, the drugs were being purchased for diabetes, sexual dysfunction and infertility in a relatively high proportion.

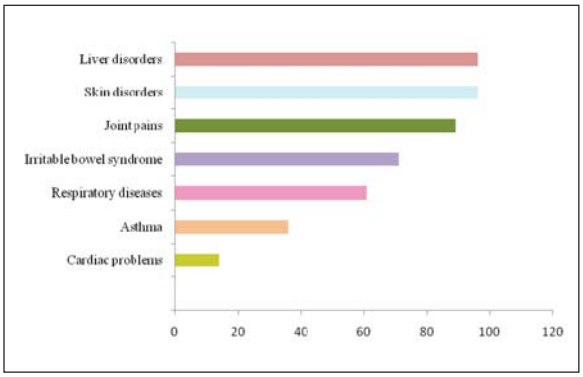

Figure-1. Diseases/Clinical conditions for which the Unani Drugs are preferred.

2. Findings on the basis on which data was generated for aforesaid issue

The basis for giving the information was repeated prescription handled by the shopkeepers followed by the discussion with a cross-section of practitioners and finally on the sales figures.

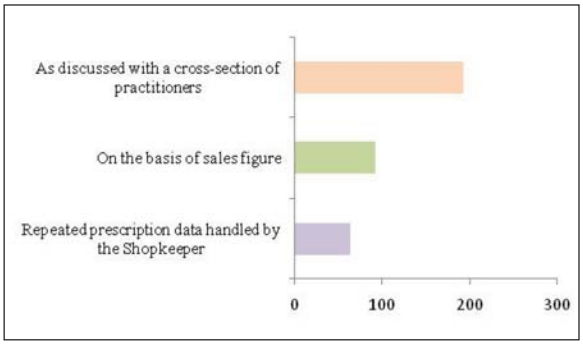

Figure-2. Basis for providing information on consumer preference.

3. Findings on which category of Unani medicine appears to be most popular

Raughaniyat (medicated oils), Ma'ajeen (semi solid formulations), Khamirajat (stickly semi-solid formulations) and Haboob (tablets) were the most popular form of drugs among the consumers.

4. Findings on methods by which majority of consumers accessed medication

Most consumers came to the shops seeking medicine on the basis of prescription, followed by what they had learnt through advertisements and then by word-of-mouth. The recommendations of the person working in the shop mattered but it was relatively less important.

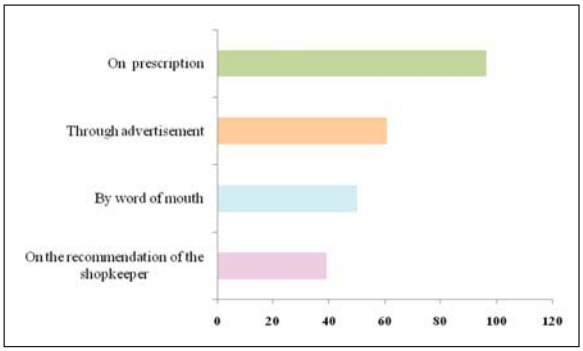

Figure-3. Methods by which majority of consumers accessed the medication.

5. Findings on consumer concern about the quality, safety and efficacy of Unani products

The consumers showed concern for quality and efficacy. The safety of the Unani products was of lesser importance.

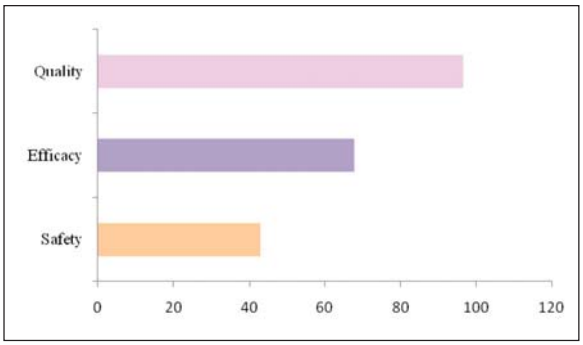

Figure-4. Consumer's concern about products.

6. Findings on whether consumers sought products stating the name of the company

The consumers overwhelmingly sought drugs on the basis of a company's name and the pharmaceutical representatives had a big role to play in providing information to the shopkeeper/ pharmacists working in the shop.

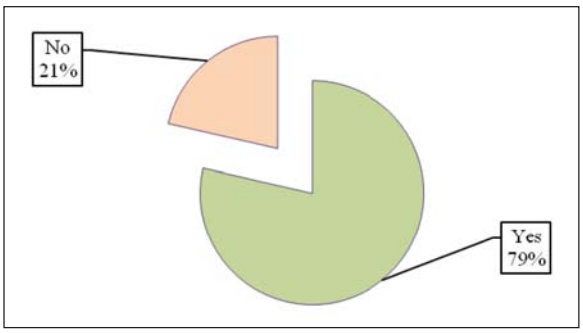

Figure-5. Consumers seeking product stating the name of the company.

7. Findings on the awareness of the shopkeepers/pharmacists about the difference between various categories of Unani drugs and their actions

Owners, shop level staff and pharmacists working in the chemist's shops had information about the difference between various categories of Unani drugs. Pharmaceutical agents also provided information on this.

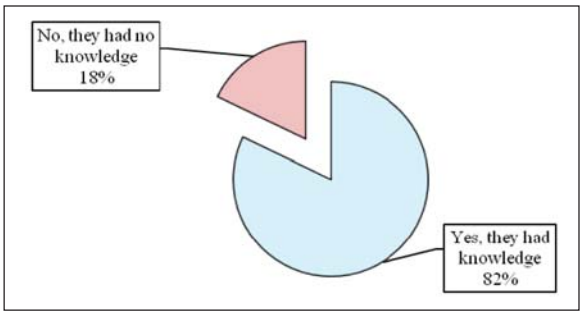

Figure-6. Shopkeeper's awareness about the difference between various categories of Unani drugs and and how they act.

8. Findings on consumers' concern about the admixture of allopathic/non-permissible substances in the Unani products

The consumers were concerned about the admixture of allopathic/ non-permissible substances in the Unani drugs.

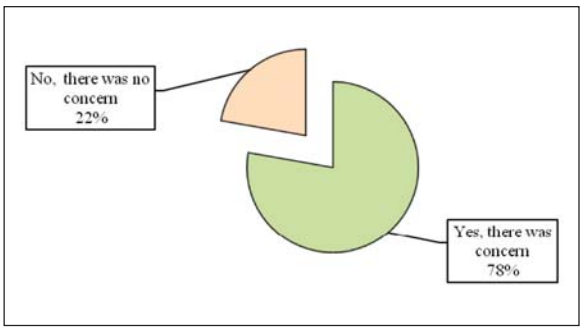

Figure-7. Consumer's concern about the admixture of allopathic or non-permissible substances.

III. Dipstick Survey of Industries Manufacturing ASU Products

Although the Pharmacopoeia Committees for ASU have laid down standards for single/compound formulations which include determinants of identity, purity and strength of the drugs, due to a variety of factors, including short supply of raw material and the absence of rigorous enforcement, several drugs are being substituted /adulterated with cheaper versions, thereby reducing the quality of the products and bringing the entire system into disrepute.

The principal users of the raw material are the ASU manufactures and it was important to ascertain their point of view relating to legal and enforcement issues primarily. A questionnaire was developed to understand the manufacturing sector's views and experience in responding to quality control and marketing issues; also their interface with suppliers of medicinal plants and the Drug Control/ licensing authorities in the states.

An effort was made to obtain the list of all manufacturers through the Department of AYUSH but since the addresses were incomplete and there was no certainty that the responses would be forthcoming, to save time it was decided to use one of the representative manufacturers' associations. A Questionnaire was sent to respondents identified by the Ayurvedic Drug Manufacturer Association (ADMA) with the instructions that responses should be sent online or by post to the PI directly. The questionnaire is at **Annexure-IV**. The list of manufacturers to whom the questionnaire was sent can be seen at **Annexure-V**.

Responses were received from a cross-section of industries and some of the responses were more detailed than others. Arya Vaidyashala, Kottakal, Shree Dhootpapeswar Pvt. Ltd., Mumbai; Immense Health Care Pvt. Ltd., Natural Remedies, Bangalore; Dabur India Ltd., Sahibabad; Ayu Lab. Private Ltd., Rajkot; Ayur Chem Products, UAP Pharma Pvt.Ltd., Ahemedabad; Charak Pharmaceuticals, Shree Dhanwantari Herbal, Amritsar, S.G. Phytopharma Pvt. Ltd., Kolhapur; Prashant Marico Ltd. Mumbai and Sanjay HERBAL PRODUCTS, New Delhi provided responses which were comparatively detailed.

On 19th November, 2010; ADMA organized a one-day meeting where the PI who was able to interact face-to-face with the representatives of industry that attended the meeting. Detailed meetings were also held with the manufacturers whose premises were visited, both in the government and private sector. In-depth interviews were conducted with, among others, S/Shri Ranjit Puranik, the then Secretary of the ADMA Association, Nimesh Shroff who is on the executive body after the elections, Dr Murali of Aryavaidyashala Kottakal, the Directors of Vaidyaratnam Kerala, Dr.Ram Manohar of Ayurveda Trust Coimbatore and Shri Chadershekhar, Managing Director of Tamcol, Chennai. Independent of this, Dr.D.B.A. Narayana, Dr. C.K. Katiyar and Dr.Baba - all three professionals who have worked or are still working with Dabur, Hindustan Lever, Ranbaxy all having the requisite technical background and years of industry experience were also consulted in-depth. The PI called on the Drug Controller General (India) Dr.Surinder Singh and held discussions with him and with Dr. Mitra his Deputy who deals with ASU matters. The responses received through the questionnaires and through discussion are summarized below:

Industry Responses

1. Drug formulation/quality control issues/ estimation of consumer preference of ASU products

From the responses it was seen that 89% of the manufacturers said that there was no representative survey available and nearly 11% of the industries did not respond to the question. Not a single manufacturer gave 'yes' as an answer which

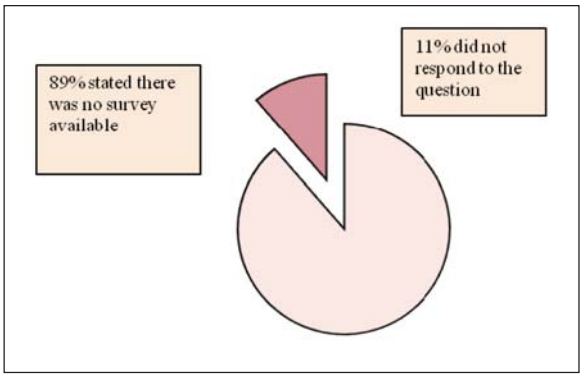

Figure-1. Responses received relating to availability of a representative survey about the fastest moving drugs.

indicates that a comprehensive survey was never conducted.

2. Manufacturers' willingness to share raw material utilization data

Findings

Majority of respondents (64%) did not respond enthusiastically. Only 36% said they could submit consumption of raw material data for all the licensed products that were manufactured with batch numbers specified. Data on consumption of raw material is an important requirement as it goes to the root of availability and quality control of ASU drugs. The non-committal response from a majority of industry respondents indicates an apparent unwillingness to treat this requirement seriously.

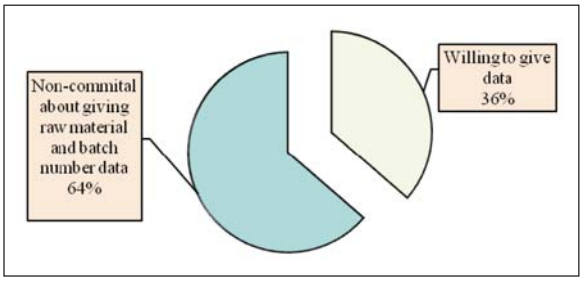

Figure-2. Responses about willingness to submit annual data on the consumption of raw material with batch numbers.

3. Important conditions for which ASU drugs have strength

Findings

The manufacturers confirmed that people predominantly accessed ASU medications for joint pains, skin disorders and gynaecological disorders. Other than these, ASU medications were also accessed for liver disorders, asthma and irritable bowel syndrome. In the 'others' category manufacturers included the following areas among fast moving drugs:-

Tonics and drugs for managing diabetes, obesity, sexual dysfunction, energy boosters, hypertension, hair loss, ageing, memory boosters and blood purifiers. The response of the shopkeepers selling ASU drugs and of the manufacturers was therefore similar. That provides an overall focus for the licensing authorities and drug inspectors to draw samples and exercise oversight. It also gives a focus for awareness campaigns which need to be launched for public benefit.

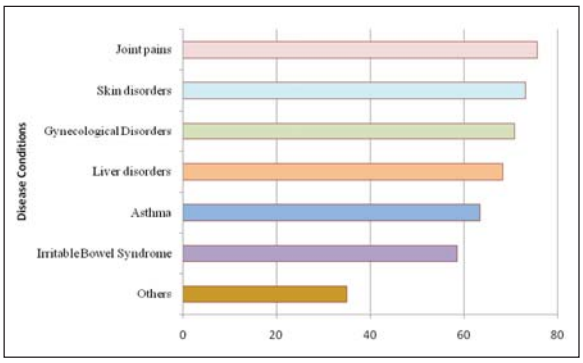

Figure-3. Manufacturers response about main disease conditions for which drugs were accessed.

4. Manufacturers' response to the introduction of food supplements and nutraceuticals categories under the food safety and standards act (FSSA), 2006

Findings

It was found that responses were divided and there was an absence of clarity on the issue. Some companies were aware of the notification but were confused about seeking product permission, especially for single ingredients used in making powders and syrups. Many of the herbs and spices are mentioned both in FSSA as well as Ayurvedic Pharmacopoeia of India. In the Ayurvedic system of medicine, food plays a vital role. For almost every ailment the Ayurvedic classics describe the importance of food regimen. Spices like ginger, black pepper, clove, cinnamon, cardamom, etc. are used in daily food preparation as well as in drugs. To avoid confusion as to whether a medicinal plant is a drug or food, it was recommended that the classification should depend upon the "Intention and claim of use" of the plant.

The respondents favoured a separate regulatory body for nutraceuticals, dietary supplements and food supplements.

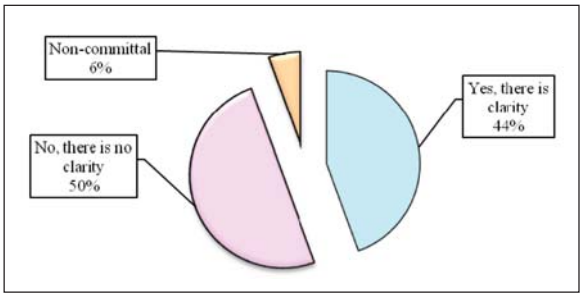

Figure-4. Clarity of manufacturers about registration under (Drugs & Cosmetics Act or Food Safety and Standards Act).

5. Regulation of nutraceuticals/dietary supplements/food supplements having a health claim but no therapeutic claim

Findings

A larger proportion of manufacturers responded as follows:-

- Nutraceuticals should be regulated by a different body.
- The efforts of government should be to form a different Commissionerate in order to regulate FSSA 2006.
- To sell a product effectively it is important to be able to tell the users the merits of the product for which it is used. The recent Gazette notification dated 10.8.10 needs to be expanded further to indicate the health claims which would be permitted.
- However, these products need to be treated separately from "P&P medicine".

6. Responsibility for quality control of ingredients and adherance to prescribed processes

Findings

There were mixed responses to the question whether the owner instead of the quality control manager should be held responsbile for following quality control and process requirements. 36% of the industries responded that the responsibility to have a check on the proper use of ingredients and the prescribed processess should be of 'both', i.e the quality control manager as also the owner of the manufacturing unit. 36% of them said the responsibility should rest only with the quality manager as he is a trained person. 21% said that the responsibility should not be of the Quality Control Manager which means it should be of the owner. 7% of the industries remained 'Non-Committal'.

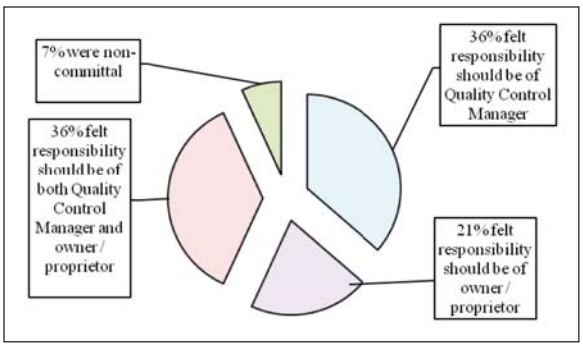

Figure-5. Responsibility/liability for use of proper ingredients and adherence to prescribed process.

7. Effectiveness of national medicinal plants board to improve availability and quality of raw materials

Findings

Nearly 68% of the manufacturers said that the functioning of the National Medicinal Plants Board had not improved the availability of quality raw material. 23% of the industries said that the NMPB had improved the availability. Another 9% from industry remained 'Non-Committal'.

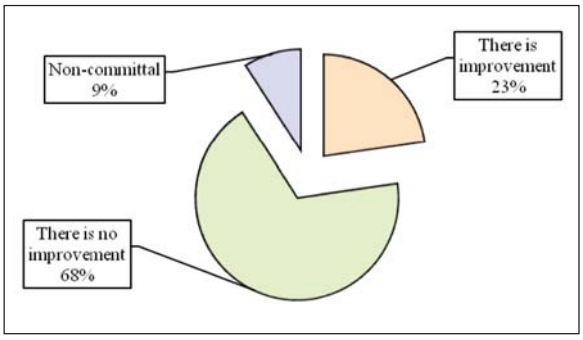

Figure-6. Effectiveness of National Medicinal Plants Board in enhancing quality of raw material.

8. Expectations of Industry from national medicinal plants board (NMPB)

Comments of Industry relating to Medicinal Plants availability/quality are summarized below:

a. There is poor awareness about NMPB. A nodal agency like NMPB and its state chapters should bring together all stake holders, industries and farmers. At present, there is no organized way of co-coordinating between the stakeholders.

b. All dealers dealing with raw materials should be registered with NMPB and the board should organize regular inspection of raw materials sold. Manufacturers should be obligated to purchase raw materials only from NMPB's registered dealers.

c. Raw materials should be tested, certified and made available in small packs- (pre-powdered and semi-processed, if possible.) Raw material

suppliers should possess a license to supply raw materials used for ASU drugs.

d. The NMPB generally asks for information from the Industry about the annual requirement of raw materials. It is not possible for many of the Small Scale Industry units to provide the yearly data as the product portfolio keeps changing and is mainly dependent on the future market demand.

9. Suggestions of industry relating to NMPB

NMPB should:

- Set up regional clusters to calculate cumulative requirements and inform all manufacturers on a periodic basis.
- Establish multiple crude Drug Repositories and encourage studies that focus on cultivation and conservation.
- Develop the capacity of State Medicinal Plants Boards and make them accountable. In addition, sufficient staff should be engaged.
- Set up an informative website with policies and data on specifications, standards and policies available online.
- Include representatives of small scale manufacturers and traders of medicinal herbs as members of the National Medical Plants Board.
- Develop herbal gardens on land owned by Government organizations in all major cities.
- Encourage State boards to promote herbal plantations as an income generating activity.
- Focus on Panchayats to enable them to access basic know-how on good agricultural practices (GAP) and help them to sell their produce through co-operative efforts.
- Conduct proper testing at collection stage which will improve the situation substantially.
- Insist that manufacturers purchase raw materials from registered dealers only.

10. Suggestions of industry relating to drug quality

- The State Quality Testing Laboratories should randomly test raw materials. Plant materials do not expire but they certainly lose their efficacy over time. Therefore, packaged and source certified raw materials should be insisted 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 Ayurvedic Pharmacopoeia of India would be very useful. State Forest Corporations may also be encouraged to provide certified quality raw material as per API, as an additional vending source.
- All traders of medicinal herbs should be registered and their storage conditions should be checked periodically. Drug Testing Laboratories should be established/ recognized by the Government where they can obtain test reports.

A special agency should be designated to procure/ supply/ liquidate the raw material produced by the farmers and to ensure release of immediate payment to them.

Legislative changes

a. There should be a uniformity mandated by law for grant of license to manufacturers of classical and proprietary medicines. (Today each State follows its own procedures).

b. State government should mandate that all units possess GMP certificate and regularly upload names of units whose licences have been cancelled. Public should be warned about this which will increase credibility.

c. Legally binding registration process for suppliers should be introduced through subordinate legislation. Government should facilitate use of high quality material by establishing on site Quality Control Laboratories for testing raw materials.

11. Suggestions to improve public confidence

1. Public confidence is at a low ebb because the composition given on the labels of the same generic product differs from manufacturer to manufacturer. This is because the composition given in Ayurvedic Formulary of India has not

specified the batch size for which the quantity shown is to be used. Hence, every manufacturer writes the composition as per the yield he gets. It is important to lay down parameters or standards by specifying the batch size of the product.

2. Before the State Drug Testing Laboratories become fully functional, the Government should advertise the names of private laboratories (registered) through electronic and print media etc. The endorsement given by Government to selected private laboratories would make a big difference.

3. The awareness campaign should highlight the safety aspects of Ayurvedic products. Mandatory statement should be there in every packet as in the case of "Cigarette smoking is injurious to health" on the lines of: "This product contains no added metals/minerals" or" This product has been tested for absence of non-permissible substances at .....Lab... vide test report ....."

4. Some ASU medicines (Rasa Aushadis and Bhasmas) contain metals and minerals. There should be a caption stating that "this product contains metals/minerals within permissible limits but should be taken only on prescription."

5. At present, there is no motivation for ASU manufacturers to invest in R&D to validate the safety and efficacy of their products. This is because therapeutic pluralism is not permitted. Allopathic doctors are not allowed to prescribe ASU medicines. The ASU practitioners have relatively small practice. Thus, the ASU manufacturers do not see any scope of return on their investments unless the regulatory framework changes in India. Therefore a list of drugs that allopathic doctors can prescribe should be drawn up as this would benefit the public.

12. Suggestions for awareness building

- Facilitate continuous interaction between industry associations and consumer associations.
- The best and the most effective way to improve public awareness about ASU products in an ethical manner include:

a. Organization of AYUSH Camps offering free medical checkup and treatment.

b. ASU exhibitions should be held by inviting companies to display their products, and information regarding the therapeutic and prophylactic use of their products should be conveyed through talks.

c. ASU treatment should be provided in all district hospitals with supply/sale of medicines on the premises.

Suggestions for creating/enhancing awareness about the effectiveness and safety of the products

- The website of the Department of AYUSH should feature comprehensive information about the disease conditions and the availability of medicines in classical forms. This should be linked to State ISM Department's websites.
- The website should give a description of specific medical conditions in layman's language and indicate which types of drugs ASU systems prescribe for these conditions along with whether the drugs contain minerals and metals and the basis for confirming the safety of the herbal ingredients on account of continued usage.

13. Suggestions regarding quality certification

a. Advertise and popularize AYUSH standard and AYUSH premium mark to such an extent that majority of consumers start demanding the marks from the ASU manufacturers.

b. The present Quality Council of India (QCI) system of product certifications needs improvement. Too much emphasis has been given on testing only instead of emphasizing steps to improve quality. Excessive testing makes the certification process unnecessarily expensive and out of reach for the majority of manufacturers.

c. Small Scale Industries (SSI) should be given periodic training (at least once in a quarter) with reference to qualitative/quantitative chemical test analysis with the use of minimum sophisticated lab instruments, so that the standard of input material is raised.

Recommendations

I. Recommendation Relating to Manufacture of Ayurveda, Siddha and Unani Drugs and Quality Assurance

❖ **Recommendations on 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 the ingredients. There are broader globally accepted quality parameters and these need to be adopted to cover all the 960 items of plant material that are traded and used by the ASU industry. This work can 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. Over 4000 of them appear to be having no licenses and are still producing drugs for sale to the public. These drugs can be harmful as they can contain raw material containing impurities, strong chemicals and non-permissible substances. The drugs containing metals and minerals can cause long-lasting harm. The public interest demands that such items are not allowed in retail sale in the name of medicine.

❖ **Recommendations regarding new category of Traditional Processors:** Create 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. 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 who have an interest in quality of material used. The recommendation is, therefore, to give recognition and legitimacy to this activity which is already permitted under law but never referred to.

- **Recommendation on only GMP compliant units to sell in retail:** Only those who have a GMP compliance certification should be permitted to sell products in retail whether in ASU shops or in regular chemists shops. Special registration of such shops that stock only ASU medicine should be introduced and a small fee collected for such registration. That is the only way of satisfying the need for providing protection to 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.

- **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. There is no gainsaying that 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 their own medicine.]

- **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. The selection of manufacturers and products that have to be taken up for in-depth scrutiny should be done through a computerized programme so that there is secrecy and objectivity in selecting the items. Even if 25 cases are taken to their logical conclusion every 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 the industry or harass the 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 takes 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 ISM Departments and an officer in Department of AYUSH should collect this information. Long term pendency of cases need to be taken up with the Registrars of the High Courts by the State Secretaries in charge of ISM.

❖ **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. Dossier had been suggested by one of the drug manufacturers' associations and the copy is at Annexure-II.

- For 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,) all that he needs to do is to notify the licensing authority that he has added one more product. 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 is simply to be followed.

- **Recommendations to expand or alter the QCI scheme:** At the moment according to ADMA sources, the QCI Scheme does not seem to have taken off and 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 all 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" which should simply read: "QUALITY CERTIFIED."

- **Recommendations on heavy metal testing:** An Inductively Coupled Plasma Analyzer (ICP) is capable of testing for the presence of all the Heavy metals like arsenic, mercury, lead, cadmium, zinc, copper etc. in one sample, with only one injection. This should be provided to at best to 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. The label should say that "the products are within limits for any metal contaminants". 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. This has been dealt with earlier while recommending the *registration of shops selling ASU medicine to the general public*.

- **Recommendations to permit branding of classical medicines:** Branding of classical products should be allowed as this will promote more research and development on 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 regulations. These should help the consumer decide the extent of plant based/herbal material used in the product. The present omnibus provision, will not help. The Regulations may need a change of law for each category which is worth undertaking in consumer interest.
- **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

❖ **Common Information:** It is apparent that people access ASU medicines for specific diseases and conditions. Much more information should be made available about the different modes of administration of drugs for these 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. In layman's language, both in English and Hindi. Without going into too much detail, the Department of AYUSH website should provide basic information about the conditions for which the public is buying the drugs. The prototype of the information needs to be placed on the website of the State ISM 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 public has already 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 some uniformity in approach. This is necessary because people get turned off by an absence of knowledge and concern. 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 it works. In addition, the fact that ASU medication works only if a good practitioner has diagnosed the problem and prescribed the 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.
- ❖ **Building Public knowledge:** Awareness about the way different drugs work and their mode of administration is very poor. In the case of western medicine it does not matter because medicine is generally purchased in tablet/ capsule form and sometimes as bottled syrups. In the case of the ASU drugs, there is a lot of difference between different forms of medication and therefore it is important that the public understands this in a simple way which would help to remove the hubris that surrounds ASU medication – mainly among those who have never used it.

III. Recommendation Relating to Dipstick of Industries Manufacturing ASU Products

(Explanatory Note: the recommendations made by the Industry Association and the responses received from individual manufacturers have been tabulated along with their suggestions in the relevant sub-chapter on industry responses. The recommendations that follow represent a small selection from those recommendations which the PI felt deserved priority.)

- ❖ **Recommendations for comprehensive survey:** It is time to commission a representative survey through a professional agency so that the licensing authorities and drug suppliers are aware of the fastest moving drugs and focus on those products while sending samples to the drug testing laboratories. The target should be initially on the range of products that fall in the high demand category and affect the largest share of consumers of ASU products.
- ❖ **Recommendations on enforcement:** Drug Inspectors should enforce compliance by checking at least a given percentage of manufacturing units by operating a computer generated programmme for selection of the manufacturers to be investigated. This would alert manufacturer to maintain the data and make it available. A budget should be included for this activity which should become an essential requirement. The state governments can be funded to use research fellows and pool officers to assist the regular staff which can become a part of an educational scheme.
- ❖ **Recommendations on making the licensing procedure transparent and uniform :**
  - **Uniformity of licensing procedure:** A uniform process for receiving, time taken for examination and grant of licences for both classical as well and P & P drugs should be described by way of guidelines and the State ISM Departments should be asked to have this adopted by the licensing authorities.
  - 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. Only then would public faith that a quality control mechanism exists get strengthened. 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 to be 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 regularly collected and updated which will keep up the pressure on the State licnencing/drugs control authorities.

- Since the licensing authority has the final say and there is no watch dog to oversee that the work performed by the licensing authority has been done diligently, it is very necessary for senior officers in the state government to monitor the work and performance of the licensing authorities. Such officers could be asked to collect quarterly reports from licensing authorities on licenses renewed, and new licenses granted to check progress. The PI found that licensing authorities were taking a very routine interest in licensing work and were not aware of basic data concerning this their own area of work although it was their direct responsibility. Combining the functions of the Director ISM and licencing authority should be stopped.

❖ **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. Shortage of manpower for lifting samples and for obtaining test reports from the State drug testing laboratories needs to be addressed urgently. (As suggested earlier to use of pool officers and research staff is not prohibited and that could be managed as a part of a research study.

❖ **Recommendations on giving primacy to quality control** – The awareness campaign should highlight the safety aspects of Ayurvedic products. A mandatory statement should be there on the label of ASU products being sold as medicine on the lines of:: "This product contains no metals/minerals" in the case of purely herbal medicine or "This product has been tested for absence of non-permissible substances at …..Lab… vide test report number …. dated……". This is very necessary in the case of products/drugs being used for conditions like diabetes where maximum suspicion about the admixture of steroids and chemicals has caused anxiety in the public.

- **Labeling requirements:** Labeling requirements for ASU drugs have been specified but research has shown that these provisions are flouted. The states should prosecute a few offenders each year and the registered chemists should be made responsible for stocking products that follow labeling requirements including to sell products carrying a GMP certificate only. Public should be asked to look for GMP number.

- **Owner of the company/Directors to be made responsible for adherence to quality control standards:** The Quality Control Manager is only an employee and is generally not assertive. In some industries visited by the PI, the stacking of raw material and the general condition of hygiene was very poor. If the Directors of the company are made at least partially responsible, they would take greater interest in this aspect.

- **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 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.
- QCI certificate and Simpler Alternatives: 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 tie up with Department of Consumer Affairs would help.

❖ Recommendation on optional course or a Diploma in Ayurveda at the postgraduate level in allopathic medical colleges: This suggestion of industry should be pursued through discussion with the Department of Health, Ministry of Health & Family Welfare and Medical Council of India. Initially the purpose of this course should be to provide exposure to the allopathic postgraduates to witness the application of panchakarma and other therapeutic treatment regimens. Theory can be taught on the lines of courses run by GAU. In that way, allopathic doctors would be more inclined to partner with ASU doctors particularly in handing difficult and chronic cases of rheumatology, infertility, neurological and musculoskeletal conditions, immobility including recovery after stroke and cerebral palsy cases. The examples of Medanta and Moolchand Hospital in Delhi should be explained to the Department of Health/ MCI.

❖ Recommendation on enforcing law on 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 the newspapers and prepare monthly lists of English as well as vernacular newspaper advertisements 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 practitioners and drugs.

❖ Recommendation on setting up a consumer forum on ASU drugs: 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 to be fulfilled) 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.

❖ Recommendation on Toll Free facility for ASU products: 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. This is different from the Adverse Drug Reaction Registry which is being maintained by IPGT&RA, GAU.

Annexure-I

Suggested Dossier for Application of License for P&P Medicine

#	Generally Required Data
1	Certificate - GMP
2	Certificate - License Issued by Local Food and Drugs Authority
3	Certificate - Free sale
4	Composition
5	Rationale
6	Therapeutic Indications
7	Dosage and Administration
8	Herbal Raw Material Profile Family Latin Name Common Names Parts Used Habitat Botanical Description Pharmacognosy Phytochemistry Properties Indications Therapeutic Area References
9	Manufacturing Data (SOP)
10	Raw Material Specifications
11	Packaging Material Specifications
12	Work in-process Specifications
13	Finished Product Specifications
14	Analytical and Stability Data
15	Certificate of Analysis
16	Method of Analysis
17	Specimen - Printed Package Insert
18	Sample of the Preparation in its offered Packing
19	Specimen - Printed Label
20	Specimen - Printed Carton
21	Safety Studies
22	Clinical Trial Report

Annexure-II(a)

Questionnaire on Consumer Preference of Ayurveda Products

Relates to: Drugs and ASU products widely used by public for obtaining treatment / mitigation of disease or reducing debilitating conditions under Ayurveda, Siddha and Unani (ASU) systems of medicine:

Introduction

1) Ayurvedic, Siddha and Unani medicine have been increasingly creating an interest within the country and abroad. Consumers are broadly aware of the benefits of relying on the ASU treatment regimens, medications and applications. But asked about the range of products that are easily accessible and are in comparatively higher demand, few people can give any response other than referring to a handful of products like Chawanprash, Liv 52 or Triphala and similar names.

2) Except for a handful of industries (eg Himalaya, Dabur, Baidyanath, Hamdard and Zandu) even the names of the manufacturers are not identifiable to most people. The safety and efficacy of the medicines is little known as many products do not match the level of scrutiny that is increasingly demanded for medicine to be accepted as efficacious, having minimal side effects which too are known and declared.

3) Some manufacturers do conduct studies on toxicology, undertake animal studies, publish monographs and their products have been in the market for several years. But since licensing of new ASU products (which all use formulations in the codified texts) is a relatively simple process with no requirement for clinical validation of safety and efficacy, there is nothing to distinguish products which are made following a sound manufacturing process, that abide by the Ayurvedic pharmacopoeia and formularies and those that simply make claims. In such a situation the public either ignores the ASU products altogether or whenever they use an ASU product, they rely on big names, family tradition, and word-of–mouth recommendations or access the products over-the-counter on the advice of practitioners or pharmacists employed by chemists. Practitioners either dispense medicine from their own pharmacies or give prescriptions-which forms a temporary basis for the selection of drugs .

4) Given this background, it is very difficult for an uninformed person to understand the range of hundreds of ASU products whether classical products or patent proprietary items. A majority of people remain ignorant about what is available, by what name the products can be accessed or how one product differs from the other. On the other hand, a section of people continue to access ASU products either over-the-counter or on the prescription of practitioners but what motivates them and the conditions, signs and symptoms for which they dominantly seek ASU medication is not known except anecdotally. Similar studies are available for allopathic drugs but hardly any information is forthcoming in respect of the ASU sector, except for a few scholarly articles and books which normally stop at examples of large manufacturers with a turnover of Rs 50 crore or more.

5) As far as the consumer is concerned, apart from knowledge and access issues, concerns about quality control are increasingly deterring even the most committed and determined users who on principle would like to avoid allopathic medicine because of fear of chemicals and harsh side-effects. But the absence of standardization, poor enforcement, units functioning without GMP and issue of licences in a perfunctory manner is the depiction that consumers read about. In actual fact, these realities continue despite several legal requirements having been imposed and measures to improve standardization and quality control having been mandated.

Questionnaire

1. What are the disease/clinical conditions for which people access the ASU drugs — is it possible to say with any degree of authenticity that (for example) the fastest moving drugs are purchased for

Skin disorders (1)	☐	Joint pains (2)	☐
Irritable bowel syndrome (3)	☐	Liver disorders (4)	☐
Asthma (5)	☐		

Any other _____

2. The basis for giving this information may be provided either

On the basis of sales figures (1)	☐
Or repeated prescription data handled by the pharmacist (2)	☐
Or as discussed with a cross-section of practitioners. (3)	☐

3. Which category of Ayurvedic/Unani medicine appears to be most popular and for what treatment is that used? [Add Boxes for the following:

Vati (1)	☐	Avaleha (2)	☐
Churna (3)	☐	Syrup (4)	☐
Kwatha (5)	☐	Parpati (6)	☐
Ghrita (7)	☐	Taila (8)	☐
Asava/ Arishta (9)	☐	Rasayoga (10)	☐
Gugullu (11)	☐	Loha (12)	☐

Others _____

Note

Asava and Arista: Asavas and aristas are medicinal preparations made by soaking the drugs, either in power form or in the form of decoction (kasaya), in a solution of sugar or jiggery, as the case may be, for a specified period of time, during which it undergoes a process of fermentation generating alcohol, thus facilitating the extraction of the active principles contained in the drugs. The alcohol, so generated also serves as a preservative.

Arka: Arka is a liquid preparation obtained by distillation of certain liquids or of drugs soaked in water using the Arkayantra or any convenient modern distillation apparatus.

Kvatha Curna: Certain drugs or combination of drugs are made into coarse power (Javkut) and kept for preparation of kasaya. Such powers are called kvatha curna.

Guggulu: Guggulu is an exudates (niryasa) obtained from the plant *Commiphora mukul*. Preparations having the exudates as main effective ingredient are known as Guggulu.

Ghrta (Snehakalpa): Ghrtas are preparations in which ghee is boiled with prescribed kasayas (decoctions) and kalkas of drugs according to the formula. This process ensures absorption of the active therapeutic principles of the ingredients used.

Curna: Curna is a fine power of drug or drugs.

Taila: Tailas are preparations in which taila is boiled with prescribed kasayas (decoction) and kalkas of drugs according to the formula. This process ensures absorption of the active therapeutic properties of the ingredients used.

Lepa: Medicines in the form of a paste used for external application are called lepas.

Vati and Gutika: Medicine prepared in the form of tablet or pills are known as Vati and Gutika. These are made of one or more drugs of plant, animal or mineral origin.

Vartti, Netrabindu and Anjana: Medicines used externally for the eye come under category of Vartti, Netrabindu and Anjana Netrabindu is prepared by dissolving the specified drugs in water or kasaya and used as eye drop.

Rasayoga: Preparations containing mineral drugs as main ingredients are called Rasa Yogas. They may be in pill form. They are mixed and triturated together.

Lauha: Lauha kalpas are preparations of Lauha Bhasma as main ingredient added to other drugs.

If the respondent is an Association like ADMA or Chemist's Associations, the percentage share of the market occupied by 25 to 30 fast moving drugs and medicaments under each ASU system covering a range of 5-10 clinical conditions may be given. The reply may be divided into classical products and patent proprietary products as far as the fastest moving drugs are concerned. [Replies received from representative number of A, B and C category chemists in selected cities and areas within the city serving different strata of society may be given for which boxes have to be created].

Classical formulation with dosage form and indications

1. Ashwagandha Churna (Churna)/General debility/Health promoter ☐
2. Triphala Churna (Churna)/Constipation/Eye diseases ☐
3. Sitopaladi Churna (Churna)/ Cough, Cold & Asthma ☐
4. Lavana Bhaskar Churna/ Indigestion, colic pain ☐
7. Ashokarista/ Menstrual problems ☐
8. Dasamularista/ Backache, after delivery, nervine tonic ☐
9. Draksharista/ General debility, asthm. ☐
10. Arjunaristha/ Heart disease ☐
11. Saubhagya shunthi khanda/After delivery ☐
12. Kutaja Ghanavati/ Dysentery, Diarrhoea ☐
13. Chitrakadi Vati/ Indigestion, Loss of appetite ☐
14. Arogyavardhini vati/Skin diseases, Liver disease ☐
15. Haridrakhanda/Allergic Conditions ☐
16. Triphalaghrita/ Eye diseases ☐
17. Phalaghrita/ Infertility ☐

18. Yogaraj Guggulu/ Neurological diseases, Osteoarthritis ☐
19. Kanchanara Guggulu/ Goitre, tumor ☐
20. Mahanasayan Taila /Osteoarthritis, Neurological disorders ☐
21. Jatyadi taila/ Wounds, ulcers ☐
22. Saptamrita Lauha /Eye diseases ☐
23. Chyavanprash(Avaleha)/ Immunity Promoter ☐
24. Vyaghri Haritaki(Avaleha)/ Bronchitis, Bronchial Asthma ☐
25. Avipattikara churna/ Hyperacidity ☐
26. Hingvashtaka churna/ Indigestion, Flatulence ☐
27. Mahamanjishthadi Kvatha/ Skin diseases, Gout ☐
28. Chandraprabha Vati /Diabetes, Urogenital diseases ☐

Proprietary medicine with Dosage form and indication

1. M-Vasaka (Syrup)/ Cough & Cold ☐
2. M-Liv (Syrup/Tab.)/ Liver disorders ☐
3. Live-52(Syrup/Tab.) Liver disorders ☐
4. M2 Tone (Syrup)/ Excessive uterine bleeding ☐
5. Posex (Tab.) ☐
6. Shatavarex (Granules)-Lactation ☐
7. Shankhapushpi(Syrup)/Memory enhancer ☐
8. Septilin (Syrup)/Respiratory tract infection, Immune promotor ☐
9. Rhumalaya (Tab.) / Arthrits ☐
10. Reosto (Tab.)/Osteoporosis, osteopenia ☐
11. Step (Syrup/tab.) RTI/UTI ☐
12. Zulcer gel (Suspension)/Hyper acidity ☐
13. Pilex (Tab./ointment)/Piles, fissures. ☐
14. V-gel (Gel)/Vaginitis ☐
15. Abana (Tab.)/Cardiac disorders ☐
16. Serpina(Tab.)/Hypertension ☐
17. Cystone(Tab.)/Urinary stone ☐

18. Livomin(Syrup)/Liver disorders ☐

19. Rumasyl (Oil)/Arthritis ☐

20. Shilajit (Capsule)/Aphrodisiac ☐

21. Spemen forte (Tab.)/ Oligospermia ☐

22. Vomitab (tab. & syrup)/Vomiting during pregnancy ☐

23. Neeri (Syrup)/Urinany tract infection ☐

24. Koflet (Syrup)/cough ☐

25. Crux (Syrup)/cough ☐

4. A vast number of the medicaments available under the ASU systems can be purchased over the counter: (OTC.) Please indicate how the majority of consumers access the medication –

It is on prescription (1) ☐

By word of mouth (2) ☐

Through advertisement (3) ☐

On the recommendation of the chemist (4) ☐

5. There is considerable difference between the reliance placed upon the ASU products in

South India (1) ☐

Please specify the difference _____

North India (2) ☐

Please specify the difference _____

West India (3) ☐

Please specify the difference _____

Note: *Please specify the differences that are apparent between the three regions*

6. Do consumers seek product information on

Quality (1) ☐

Efficacy (2) ☐

Safety (3) ☐

If so up to what extent? _____

7. Do consumers ask for products stating the name of the company?

Yes (1) ☐ No (0) ☐

Do consumers know the difference between the different categories of ASU medicine and how it acts?

Yes (1) ☐ No (0) ☐

8. Are the pharmacists working in the chemist shops aware of the difference between different categories of ASU drugs and how they act?

Yes (1) ☐ No (0) ☐

If yes, please specify _____

Do the company representatives speak about this aspect?

Yes (1) ☐ No (0) ☐

9. Do consumers show concern about the admixture of allopathic or non-permissible substances?

Yes (1) ☐ No (0) ☐

10. What suggestions can be made to improve public awareness about ASU products? What steps can be taken both by the government and by industry to enhance public awareness on how to distinguish between products? QCI is a voluntary scheme. Can any other approach be suggested?

_____

Annexure-II(b)

Questionnaire on Consumer Preference of Siddha Products

Relates to: Drugs and ASU products widely used by public for obtaining treatment / mitigation of disease or reducing debilitating conditions under Ayurveda, Siddha and Unani (ASU) systems of medicine:

Introduction

1) Ayurvedic, Siddha and Unani medicine have been increasingly creating an interest within the country and abroad. Consumers are broadly aware of the benefits of relying on the ASU treatment regimens, medications and applications. But asked about the range of products that are easily accessible and are in comparatively higher demand, few people can give any response other than referring to a handful of products like Chawanprash, Liv 52 or Triphala and similar names.

2) Except for a handful of industries (eg Himalaya, Dabur, Baidyanath, Hamdard and Zandu) even the names of the manufacturers are not identifiable to most people. The safety and efficacy of the medicines is little known as many products do not match the level of scrutiny that is increasingly demanded for medicine to be accepted as efficacious, having minimal side effects which too are known and declared.

3) Some manufacturers do conduct studies on toxicology, undertake animal studies, publish monographs and their products have been in the market for several years. But since licensing of new ASU products (which all use formulations in the codified texts) is a relatively simple process with no requirement for clinical validation of safety and efficacy, there is nothing to distinguish products which are made following a sound manufacturing process, that abide by the Ayurvedic pharmacopoeia and formularies and those that simply make claims. In such a situation the public either ignores the ASU products altogether or whenever they use an ASU product, they rely on big names, family tradition, and word-of–mouth recommendations or access the products over-the -counter on the advice of practitioners or pharmacists employed by chemists. Practitioners either dispense medicine from their own pharmacies or give prescriptions-which forms a temporary basis for the selection of drugs.

4) Given this background, it is very difficult for an uninformed person to understand the range of hundreds of ASU products whether classical products or patent proprietary items. A majority of people remain ignorant about what is available, by what name the products can be accessed or how one product differs from the other. On the other hand, a section of people continue to access ASU products either over-the-counter or on the prescription of practitioners but what motivates them and the conditions, signs and symptoms for which they dominantly seek ASU medication is not known except anecdotally. Similar studies are available for allopathic drugs but hardly any information is forthcoming in respect of the ASU sector, except for a few scholarly articles and books which normally stop at examples of large manufacturers with a turnover of Rs 50 crore or more.

5) As far as the consumer is concerned, apart from knowledge and access issues, concerns about quality control are increasingly deterring even the most committed and determined users who on principle would like to avoid allopathic medicine because of fear of chemicals and harsh side-effects. But the absence of standardization, poor enforcement, units functioning without GMP and issue of licences in a perfunctory manner is the depiction that consumers read about. In actual fact, these realities continue despite several legal requirements having been imposed and measures to improve standardization and quality control having been mandate.

Questionnaire

1. What are the disease/clinical conditions for which people access the Siddha drugs — is it possible to say with any degree of authenticity that (for example) the fastest moving drugs are purchased for

Skin disorders (1)	☐	Joint pains (2)	☐
Gynaecological problems (3)	☐	Liver disorders (4)	☐
Asthma (5)	☐	Life-style disorders (6)	☐
Paediatric diseases (7)	☐		

Any other _____

2. The basis for giving this information may be provided either

On the basis of sales figures (1)	☐
Or repeated prescription data handled by the pharmacist (2)	☐
Or as discussed with a cross-section of practitioners. (3)	☐
Or as per Govt. Hospitals / Private Hospital records (4)	☐

3. Which category of Siddha medicine appears to be most popular and for what treatment is that used?

Mathiri (Tablets) (1)	☐	Senthooram (2)	☐
Churnam (3)	☐	Kudineer (Decoction) (4)	☐
Parpam (5)	☐	Kalimbu(Ointment) (6)	☐
Lehiyam (7)	☐	Thailam (8)	☐
Manappagu (Syrup) (9)	☐	Otradam (Fomentation) (10)	☐
Vethu (Steam Bath) (11)	☐	Thokkanam (Massage Techniques) (12)	☐
Varmam (Therapeutic pressure points) (13)	☐		
Patru (Paste for external applications) (14)	☐		

If the respondent is an Association like SDMA (Siddha drugs Manufacturing Association) or Chemist's Associations, the percentage share of the market occupied by 25 to 30 fast moving drugs and medicaments under Siddha system covering a range of 5-10 clinical conditions may be given. The reply may be divided into classical products and patent proprietary products as far as the fastest moving drugs are concerned. [Replies received from representative number of A, B and C category chemists in selected cities and areas within the city serving different strata of society may be given for which boxes have to be created].

4. A vast number of the medicaments available under the Siddha systems can be purchased over the counter: (OTC.) Please indicate how the majority of consumers access the medication –

It is on prescription (1)	☐

by word of mouth (2) ☐

through advertisement (3) ☐

on the recommendation of the chemist (4) ☐

TV / News paper / Magazine information (5) ☐

5. There is considerable difference between the reliance placed upon the Siddha products in

South India (1) ☐

Please specify the difference _____

North India (2) ☐

Please specify the difference _____

West India (3) ☐

Please specify the difference _____

Note : Please specify the differences that are apparent between the three regions

6. Do consumers seek product information on

Quality (1) ☐

Efficacy (2) ☐

Safety (3) ☐

Cheap (4) ☐

Availability (5) ☐

If so up to what extent? _____

7. Do consumers ask for products stating the name of the company?

Yes (1) ☐ No (0) ☐

Do consumers know the difference between the different categories of Siddha medicine and how it acts?

Yes (1) ☐ No (0) ☐

8. Are the pharmacists working in the chemist shops aware of the difference between different categories of Siddha drugs and how they act?

Yes (1) ☐ No (0) ☐

If yes, please specify _____

Do the company representatives speak about this aspect?

Yes (1) ☐ No (0) ☐

9. Do consumers show concern about the admixture of allopathic or non-permissible substances?

Yes (1) ☐ No (0) ☐

10. What suggestions can be made to improve public awareness about Siddha products? What steps can be taken both by the government and by industry to enhance public awareness on how to distinguish between products? QCI is a voluntary scheme. Can any other approach be suggested?

_____

11. Prescription given by (with degree of authenticity)

Educational Qualified Doctors (1) ☐

Registered Traditional practitioner not educationally qualified (2) ☐

Quacks (3) ☐

Modern (allopathy) doctors (4) ☐

Self (5) ☐

Annexure-II(c)

Questionnaire on Consumer Preference of Unani Products

Relates to: Drugs and ASU products widely used by public for obtaining treatment / mitigation of disease or reducing debilitating conditions under Ayurveda, Siddha and Unani (ASU) systems of medicine:

Introduction

1. Ayurvedic, Siddha and Unani medicine have been increasingly creating an interest within the country and abroad. Consumers are broadly aware of the benefits of relying on the ASU treatment regimens, medications and applications. But asked about the range of products that are easily accessible and are in comparatively higher demand, few people can give any response other than referring to a handful of products like Chawanprash, Liv 52 or Triphala and similar names.

2. Except for a handful of industries (eg Himalaya, Dabur, Baidyanath, Hamdard and Zandu) even the names of the manufacturers are not identifiable to most people. The safety and efficacy of the medicines is little known as many products do not match the level of scrutiny that is increasingly demanded for medicine to be accepted as efficacious, having minimal side effects which too are known and declared.

3. Some manufacturers do conduct studies on toxicology, undertake animal studies, publish monographs and their products have been in the market for several years. But since licensing of new ASU products (which all use formulations in the codified texts) is a relatively simple process with no requirement for clinical validation of safety and efficacy, there is nothing to distinguish products which are made following a sound manufacturing process, that abide by the Ayurvedic pharmacopoeia and formularies and those that simply make claims. In such a situation the public either ignores the ASU products altogether or whenever they use an ASU product, they rely on big names, family tradition, and word-of–mouth recommendations or access the products over-the -counter on the advice of practitioners or pharmacists employed by chemists. Practitioners either dispense medicine from their own pharmacies or give prescriptions-which forms a temporary basis for the selection of drugs.

4. Given this background, it is very difficult for an uninformed person to understand the range of hundreds of ASU products whether classical products or patent proprietary items. A majority of people remain ignorant about what is available, by what name the products can be accessed or how one product differs from the other. On the other hand, a section of people continue to access ASU products either over-the-counter or on the prescription of practitioners but what motivates them and the conditions, signs and symptoms for which they dominantly seek ASU medication is not known except anecdotally. Similar studies are available for allopathic drugs but hardly any information is forthcoming in respect of the ASU sector, except for a few scholarly articles and books which normally stop at examples of large manufacturers with a turnover of Rs 50 crore or more.

5. As far as the consumer is concerned, apart from knowledge and access issues, concerns about quality control are increasingly deterring even the most committed and determined users who on principle would like to avoid allopathic medicine because of fear of chemicals and harsh side-effects. But the absence of standardization, poor enforcement, units functioning without GMP and issue of licences in a perfunctory manner is the depiction that consumers read about. In actual fact, these realities continue despite several legal requirements having been imposed and measures to improve standardization and quality control having been mandated.

Questionnaire

1. What are the disease/clinical conditions for which people access the ASU drugs — is it possible to say with any degree of authenticity that (for example) the fastest moving drugs are purchased for

Skin disorders (1)	☐	Joint pains (2)	☐
Irritable bowel syndrome (3)	☐	Liver disorders (4)	☐
Asthma (5)	☐	cardiac problem (6)	☐
Amraz-e-Riya (Respiratory diseases) (7)	☐		

Any other _____

2. The basis for giving this information may be provided either

On the basis of sales figures (1)	☐
Or repeated prescription data handled by the pharmacist (2)	☐
Or as discussed with a cross-section of practitioners. (3)	☐

3. Which category of Unani medicine appears to be most popular and for what treatment is that used?

Arks (1)	☐	Kushta (2)	☐
Raughan (3)	☐	Majoon (4)	☐
Khamira (5)	☐	Sharbat (6)	☐
Qurs (7)	☐	Haboob (8)	☐
Jawarish (9)	☐	Joshanda (10)	☐

Any other _____

Classical		Patent Drugs	
Jawarish Kamooni		**Dimagheen**	
Jawarish kamooni is a semisolid preparation It is for Loss of Appetite Stomach Ache Flatulence etc.	☐	Dimagheen is a semisolid prepeartion where Brain tonic, loss of memory, etc.	☐
Khameera Gaozaban		**Hazoomi**	
Khameera is a semi-solid preparation Cardiac tonic, palpitation, improve vision	☐	It is in the form of haboob Indigestion, stomach ache	☐

Dawaul Misk Maotadil

It is a semi-solid medicinal preparation ☐

Liver disorder, jaundice, and cardiac disorders

Arq Kasni

It is a liquid preparation, ☐

Anti inflammatory (reduces the inflammation in jaundice)

Sharbat Deenar

It is in the from of syrup ☐

Inflammation of liver, pain in stomach, Constipation etc.

Sharbat Nazla

It is in the from of syrup ☐

For cold and cough and seasonal flu constipation

Habb-e-Shifa

It is in form of Habb (pills) ☐

Cold & cough, headache, chronic fever

Khameera Khaskhas

It is semi solid preparation ☐

Nazla due to heat, and coolant property ☐

Itrifal Ustokhuddoos

It is a semisolid preparation ☐

Chronic sinusitis, and other brain disease.

Qurs Jiryaan

It is in form of Qurs. ☐

Premature ejaculation and other male Sexual disability

Sadri

It is in the form of syrup ☐

Branchial Asthma, and other respiratory disorders

Safi

It is in the from of syrup ☐

Purifies blood in case of pimples and other skin disorders

Tihali

It is in the from of syrup ☐

Malaria, seasonal fever, kala-azar and anaemia.

Roghan Badam Shirin

Oil is obtained from the drugs ☐

for skin and hair care, memory enhancer, etc.

Aujai

it is in the form of tablet ☐

Rheumatisms and Gout

Lipotab

It is in form of tablet or Qurs ☐

Control cholesterol, heart disease due to hypercholesteremia

Pachnool

It is in the form of Qurs

It is digestive

Masturin

It is in the form of syrup ☐

Uterine tonic, ensure pain free periods

4. A vast number of the medicaments available under the ASU systems can be purchased over the counter (OTC). Please indicate how the majority of consumers access the medication –

It is on prescription (1) ☐

by word of mouth (2) ☐

Through advertisement (3) ☐

on the recommendation of the chemist (4) ☐

5. There is considerable difference between the reliance placed upon the ASU products in

North India (1) ☐

Please specify the difference _____

East India (2) ☐

Please specify the difference _____

South India (3) ☐

Please specify the difference _____

West India (4) ☐

Please specify the difference _____

Note : Please specify the differences that are apparent between the three regions

6. Do consumers seek product information on

Quality (1) ☐

Efficacy (2) ☐

Safety (3) ☐

If so up to what extent? _____

7. Do consumers ask for products stating the name of the company?

Yes (1) ☐ No (0) ☐

Do consumers know the difference between the different categories of ASU medicine and how it acts?

Yes (1) ☐ No (0) ☐

8. Are the pharmacists working in the chemist shops aware of the difference between different categories of ASU drugs and how they act?

Yes (1) ☐ No (0) ☐

If yes, please specify _____

Do the company representatives speak about this aspect?

Yes (1) ☐ No (0) ☐

9. Do consumers show concern about the admixture of allopathic or non-permissible substances?

Yes (1) ☐ No (0) ☐

10. What suggestions can be made to improve public awareness about ASU products? What steps can be taken both by the government and by industry to enhance public awareness on how to distinguish between products? QCI is a voluntary scheme. Can any other approach be suggested?

_____

Annexure-III

City-wise Findings on Public Perception of Ayurveda, Siddha and Unani Products

City-wise Findings on Public Perception of Ayurveda Products

Navi Mumbai

- The fastest moving drugs or those in high demand were accessed for Liver disorders and Asthma followed by Skin disorders, Joints pains and Irritable Bowel Syndrome. Ayurvedic products were also purchased for certain diseases like kidney stone etc. The information is based on the average sales turnover of such drugs at the chemist's end.
- Churna and Syrup were the most popular modes of drug administration followed by Vatis and Syrup. Majority of consumers were influenced by word-of- mouth publicity followed by other modes of advertisement and prescription.
- There was a belief that ASU products manufactured in South India were more reliable and also more popular in south region.
- Most of the consumers were concerned about quality and efficacy of the drug.
- However, the consumers demanded the products stating the name of the company. They were aware of the difference between the different categories of ASU medicines and their applications. Pharmacists working in the chemist's shops too were aware about the difference between different categories of ASU drugs.
- The consumers were not concerned very much about the admixture of allopathic or non-permissible substances in ASU products.

Pune

According to the responses received, the drugs in high demand were mainly used for Joint pains and Skin disorders followed by liver disorders, Irritable Bowel Syndrome and Asthma. Besides, the drugs were purchased for treatment of Diabetes mellitus.

Both the sales figures and the repeated prescriptions handled by the pharmacist formed the basis for giving this information. Though the consumers have been using all the categories of products, Avaleha was the most popular dosage form.

Majority of the consumers accessed the medication mainly through word-of mouth publicity, advertisement and on the advice and recommendation of the chemists. They sought information on the quality and safety of the products.

The response showed that almost all the consumers sought products giving the name of the company. They were aware about the difference between the different categories of Ayurvedic medicines and their related applications. Pharmacists working in the chemist shops too were aware about ASU drug applications. The company representatives did not give information to them about these aspects.

The consumers however did not show concern about the admixture of allopathic or non-permissible substances in ASU products.

Delhi

In response to the questionnaire, it was observed that Delhi people prefer using Ayurvedic products for liver disorders which is the number one area for which Ayurvedic medicine is accessed, followed by joint disorders, skin disorders and coughs and colds. Besides these, Ayurvedic products were popular for treating sexual disorders and as general health enhancers. The average sales turnover of drugs was the main source for providing the information.

Majority of the people used Ayurvedic medicines in the form of Vatis and Capsules followed by syrups, powders and Avalehas. It was also observed that classical drugs are not popular as compared to proprietary products.

Majority of the consumers in Delhi accessed medications mainly guided by advertisements followed by physician's prescriptions and by word-of–mouth. The least number of consumers accessed drugs on the recommendation of stockists/sellers of medicine.

The practice of Ayurveda was far less in the Northern region as compared to other regions of the country for the following reasons:

i) Presence of Vaidyas and Hakims actually practicing the system was less in Northern India;

ii) Promotion of Ayurvedic products has not been taken by State Governments in North India as compared to promotional activities in South India.

The consumers did not ask for good products; instead they stated the name of the company. They were unaware about the difference between different categories and various forms of ingesting ASU medicines. They were not aware of their applications in relation to different medical conditions. The pharmacists working in the chemist shops also were not aware about the drug applications. However, they received some information from medical representatives.

Delhi consumers were not concerned about the admixture of allopathic or non-permissible substances in Ayurvedic medicines.

Nagpur

The fastest moving consumer drugs (FMCD) were purchased for Joint pains and liver disorders followed by irritable bowel syndrome, gastric symptoms and acidity. The average sales figure of various products was the basis for giving this information. Repeated prescriptions for specific disease conditions or afflictions was the basis for giving the information. Although the consumers were using all categories of medicines, Churna and Syrups were the most popular forms.

The majority of the consumers accessed medication mainly through word-of-mouth publicity followed by advertisements and lastly on the recommendation and advice of shop owners/ chemists. They asked for the products by stating the name of the manufacturer but were not aware about the difference between the different categories of Ayurvedic medicines and their applications.

Pharmacists working in the chemists shops had little knowledge about different categories of Ayurvedic drugs. However they did receive this knowledge from the medical representatives.

The consumers did not evince concern about the admixture of allopathic and/or non-permissible substances with the Ayurvedic products.

Indore

Based on consumer response, it was observed that fastest moving consumer drugs (FMCD) were purchased for joint pains followed by skin disorders, liver disorders, asthma and diabetes mellitus. The information is also based on the average sales turnover of products. The use of Vati was the most popular dosage form in comparison to other medicinal modes of administration.

Majority of the consumers accessed the products through word-of-mouth publicity. Most of the consumers indicated that ASU products of South and West India were more reliable because of their excellent quality. Information on the quality aspects was sought but less so relating to efficacy and safety of the products.

It was observed that almost all consumers asked for the products by stating the name of the manufacturing company. They were aware of the difference between the different categories of Ayurvedic medicines and their related applications.

Mixed responses have been received from pharmacists and employees working in different chemist shops. When asked whether they were aware about the difference between different categories of Ayurvedic drugs, it was observed that medical representatives had provided product information.

Consumers did not show concern about the admixture of allopathic or non-permissible substances in Ayurvedic products.

Ghaziabad

From consumer responses it was apparent that the fastest moving Ayurvedic drugs were purchased for diseases like joint pains followed by skin disorders, irritable bowel syndrome and asthma. Ayurvedic medicines were also used for diseases like acidity, peptic ulcer, diabetes, hair fall, gastro-intestinal disorders, general debility, sexual disorders, leucorrhoea and constipation. The sales figures of drugs formed the most prominent basis for giving the information.

Among various categories of Ayurvedic medicines used by consumers, Vati, Churna, Taila, Asava/

Arishta, Syrup and Kwatha were the most popular forms of drugs followed by Rasayoga, Gugullu and Loha.

Majority of the consumers accessed the medication mainly through medical practitioner's prescriptions and advertisements followed by word-of-mouth publicity and on the recommendation of the chemist.

Most of the people relied on the Ayurvedic products manufactured in North India followed by products from South India. Consumers basically sought product information about quality and safety aspects rather on product efficacy.

It was observed that almost all the consumers directly asked for the products stating the name of the manufacturing company and majority of them were aware about the difference between the different categories of Ayurvedic medicines and their related applications.

Pharmacists/shop staffs working in the chemist shops were aware of the difference between different categories of Ayurvedic drugs. The medical representatives seldom spoke to them about these aspects.

The consumers did not show concern about admixture of allopathic drugs or the presence of non-permissible substances in Ayurvedic products.

Ahmedabad

It was observed from the public response on the fastest moving consumer drugs (FMCD) related to medication for joint pains followed by skin disorders, irritable bowel syndrome, and asthma. The basis of giving this response was the repeated data handled by the pharmacist followed by average sales figures and discussions among a cross section of practitioners.

Among various categories of Ayurvedic medicines, use of Vati, Avaleha, Churna, Syrup and Kwatha were the most popular forms of drugs.

Majority of the consumers accessed the medication mainly based on media publicity and on the prescription of registered practitioners followed by word–of-mouth publicity.

Most of the people relied on Ayurvedic products procured from manufacturing companies located in South India. Consumers basically sought product information on product quality rather than product safety.

It was observed that almost all consumers directly asked for products stating the name of the manufacturing company. They were not aware about the difference between the different categories of Ayurvedic medicines and their applications.

It was observed that the pharmacists working in the chemist shops were aware of the difference between different categories of Ayurvedic drugs. The medical representatives did speak to pharmacists/ shop staff also.

The consumers did not show concern about the admixture of allopathic or presence of non-permissible substances in Ayurvedic products.

Raipur

It was observed that the fastest moving consumer drugs (FMCD) are purchased by consumers for joint pains and liver disorders. It was observed that the sales figure formed the most prominent basis for giving the information.

Among the various categories of Ayurvedic medicines, Churna and Syrups were most popular forms of drug followed by Vati, Taila, Asava/Arishta, and Kwatha. The majority of consumers accessed the medication mainly through word-of-mouth publicity and other modes of advertisement.

People relied upon Ayurvedic products procured from South India because they thought the manufacturers in South region produced quality products. Most of the consumers basically sought product information on quality.

The consumers directly asked for the products stating the name of the company but they were not aware of the difference between the different categories of Ayurvedic medicines and their applications in different disease conditions.

Pharmacists/shop staff working in the chemist shops were not aware of the difference between different categories of Ayurvedic drugs. However, the medical representatives did speak to them about this aspect.

The consumers did not show concern about the admixture of allopathic or non-permissible substances in Ayurvedic products.

Udaipur

It was observed from the responses that the fastest moving drugs were purchased for liver disorders and irritable bowel syndrome followed by joint pains, skin disorders and asthma. Despite these disease conditions, Ayurvedic products are also purchased for diabetes, ulcer and mental disorders. The sales figures formed the most prominent basis for giving this information.

Among various categories of Ayurvedic medicines Vati is most popular form of drug followed by Churna, Taila, Syrup and Asava / Arishta. Moreover, majority of the consumers accessed the medication mainly through advertisement and on prescription followed by the recommendation of the chemist and the least by word-of-mouth publicity. Most of the consumers were concerned about quality and drug efficacy.

Majority of the consumers demanded products stating the name of the company. They were aware of the difference between the different categories of Ayurvedic medicines and their applications. Pharmacists/ shop staff working in the chemist shops too were aware about the difference between different categories of Ayurvedic drugs.

The consumers were not anxious about the admixture of allopathic or non-permissible substances in Ayurvedic products.

Hyderabad

It was observed from the responses that the fastest moving drugs were purchased for skin disorders, joint pains and liver disorders followed by irritable bowel syndrome and asthma. Despite these disease conditions, Ayurvedic products were also purchased for infertility, menstrual disorders, hemorrhoids, sciatica, hair loss and paralysis. The repeated data handled by the pharmacist and sales figures were the most prominent basis for giving this information followed by discussion with a section of practitioners

Among the various categories of Ayurvedic medicines, Churna & Syrup are most popular form of drug followed by Vati, Avaleha, Kwatha, Asava / Arishta, Guggulu, Ghrita and Taila.

Majority of the consumers access the medication mainly on the prescription and through advertisement and least assess it by mouth publicity and on the recommendation of the chemist.

Most of the people specified that the Ayurvedic products in South India are more reliable. Consumers basically seek product information on quality and safety followed by efficacy.

It was observed that the consumers asked directly for the products stating the name of the company, and majority of them were also aware of the difference between the different categories of Ayurvedic medicines and how they act.

Pharmacists working in the chemist shops were aware of the difference between different categories of Ayurvedic drugs. However, the company representatives also speak to them about this aspect.

Moreover, the consumers were least concerned about the admixture of allopathic/ non-permissible substances.

Trivandrum

The fastest moving drugs were accessed for joint pains followed by skin disorders, liver disorders and asthma. Ayurvedic products were also purchased for Diabetes mellitus. The information is based on repeated prescription handled by the pharmacist.

Churna, Kwatha, Taila and Asava / Arishta were the most popular form of drugs. Majority of consumers were influenced by the advertisement for the use of Ayurvedic products.

The consumers were basically concerned about the quality of the drug. They demanded the products stating the name of the company, and were aware of the difference between the different categories of Ayurvedic products and their applications. Pharmacists working in the chemist shops were aware of the difference between different categories of Ayurvedic drugs.

The consumers showed concern about the admixture of allopathic/ non-permissible substances.

Ernaculum

The fastest moving drugs were accessed for joint pains followed by skin disorders, liver disorders and asthma. Ayurvedic products were also purchased for Diabetes mellitus. The information is based on repeated prescription handled by the pharmacist.

Churna, Kwatha, Taila and Asava / Arishta were the most popular form of drugs. Majority of consumers were influenced by the advertisement for the use of Ayurvedic products.

The consumers were basically concerned about the quality of the drug, and demanded the products stating the name of the company. They were aware of the difference between the different categories of Ayurvedic products and their applications. Pharmacists working in the chemist shops were aware of the difference between different categories of Ayurvedic drugs.

The consumers showed concern about the admixture of allopathic/ non-permissible substances.

City-wise Findings on Public Perception of Sidha Products

Chennai

The fastest moving drugs were purchased for asthma, liver disorders, skin disorders and joint pains followed by gynecological disorders, lifestyle disorders and pediatric diseases. Products were also purchased for other diseases like nervous disorders and impotency.

Basis for giving this information was repeated data handled by the pharmacist followed by sales figure and the records of the Government and private hospitals.

Mathiri (Tablets), Churnam, Lehiyam, Thailam were the most popular forms of drugs.

Majority of the consumers accessed the medication on the prescription followed by word of mouth and different modes of advertisement. They sought product information on quality and safety, and asked the products stating the name of the company. Mixed responses were observed on the awareness about different categories of Siddha medicines and their action.

Owners, shop level staff and the pharmacists working in the chemist shops were also aware about different categories of Siddha drugs as the company representatives speak to them about this aspect.

The consumers did not show their concern about the admixture of allopathic/ non-permissible substances.

Puducherry

The fastest moving drugs were purchased for skin disorders, joint pains and asthma followed by lifestyle disorders. The products were also purchased for infertility and impotency. The sales figure was the basis for giving this information followed by repeated data handled by the pharmacist.

Mathiri (Tablets), Churnam, Lehiyam, Thailam were most popular forms of drugs followed by Kudineer, Parpam, and kalimbu.

Majority of the consumers were accessed the medication mainly on prescription followed by word-of-mouth.

The consumers basically sought product information on quality followed by efficacy and safety. They asked for the products directly stating the name of the company and they were also aware about the different categories of Siddha medicines and their application.

Owners, shop level staff and pharmacists working in the chemist shops were aware about the different categories of Siddha drugs as the company representatives spoke to them about this aspect.

The consumers did not show their concern about the admixture of allopathic/ non-permissible substances.

City-wise Findings on the Public Perception of Unani Products

Srinagar, Anantanag, Pulwama, Jammu (Jammu & Kashmir)

The fastest moving Unani drugs were purchased for joint pains followed by liver disorders, skin disorders and irritable bowel syndrome. The products were also purchased for sexual dysfunction, renal stones, sinusitis, gynaecological disorders, chronic constipation, piles etc. The prescription handled by the pharmacists followed by discussion with a cross section of practitioners formed the basis for giving this information.

Khamira, Jawarish, Majoon, Qurs , Sharbat, Haboob, Raughan etc. were most popular forms of Unani. Mufradat (Single drugs, dry herb) Hamool, Siyaf were also the popular form of drugs.

Majority of the consumers access the medication

through prescription, followed by advertisement and the least number of consumers access it on the recommendation of the chemist.

A large number of Unani practitioners of North India were practising Unani System of Medicine and people are very much aware to the system of medicine.

The consumers were basically seeking product information on quality followed by efficacy. They were less concerned about safety. Majority of the consumers do not ask directly for the products stating the name of the company. They were somewhat aware about the different categories of Unani medicines and their action.

Pharmacists working in the chemist shops were aware about different categories of Unani drugs as they were registered with ISM Board. However, the company representatives also speak to them about this aspect. The consumers showed concern about the admixture of allopathic/ non-permissible substances to some extent.

Meerut, Moradabad

The fastest moving Unani drugs were purchased for joint pains followed by liver disorders, skin disorders and irritable bowel syndrome. The products were also purchased for diseases like sexual dysfunction, renal stones, insomnia, diabetes, prostate and gastric problems like chronic constipation, piles etc

The basis for giving this information was cross-section discussion with practitioners followed by repeated data handled by the pharmacists / shopkeepers.

Khamira and Jawarish were most popular forms of drugs followed by Majoon, Qurs, Sharbat, Haboob, Raughan etc.

The consumers did not ask directly for the products stating the name of the company and there was little awareness about the different categories of Unani medicines and their application. The consumers accessed the medication mainly through the prescription followed by word-of-mouth and other modes of advertisement

The consumers basically sought product information on efficacy followed by quality. They were less concerned about safety due to minimal toxic effects as per their knowledge.

The pharmacists working in the chemist shops were aware about the difference between different categories of Unani drugs and the company representatives also spoke to them about this aspect.

Certain consumers showed concern about the admixture of allopathic/ non-permissible substances.

Delhi

The fastest moving Unani drugs were purchased for liver disorders followed by skin disorders and asthma etc. The products were also purchased for disease like sexual dysfunction also.

The prominent basis for giving this information was sales figures followed by discussion with a cross-section of practitioners.

Sharbat and Jawarish were most popular forms of drugs followed by powder. Majority of the consumers accessed medication mainly through the advertisement followed by mouth publicity and prescription.

The consumers basically sought product information on efficacy followed by quality.

They sought the products stating the name of the company but they were not aware about the different categories of Unani medicines and their application.

Owners, shop level staff and pharmacists working in the chemist shops were aware about different categories of Unani drugs. However, the company representatives were also spoke to them in this aspect.

The consumers showed concern about the admixture of allopathic/ non-permissible substances in the products.

Kolkota

The fastest moving Unani drugs were purchased for skin disorders followed by liver disorders, irritable bowel syndrome and asthma. The sales figures and discussion with a cross-section of practitioners were the basis for giving this information

Khamira and Majoon were the most popular forms of drugs followed by other dosage forms.

Majority of the consumers were accessed the medication mainly through the prescription, followed by word-of-mouth and different modes of advertisement. They sought product information on quality followed by safety. The issue on efficacy was least important.

Most of the consumers asked the products directly stating the name of the company. They were not aware about the different categories of Unani medicines and their application.

The pharmacists working in the chemist shops were aware about different categories of Unani drugs. The company representatives too spoke to them about this aspect.

The consumers showed their concern about the admixture of allopathic/ non-permissible substances in the drugs.

Patna

The fastest moving Unani drugs were purchased for skin disorders followed by liver disorders, IBS and asthma. The sales figures and discussion with a cross-section of practitioners were the basis for giving this information

Khamira and Majoon were the most popular forms of drugs followed by other dosage forms.

Majority of the consumers were accessed the medication mainly through the prescription, followed by word of mouth and different modes of advertisement. They sought product information on quality followed by safety. The issue on efficacy was least important.

Most of the consumers asked the products directly stating the name of the company. They were not aware about the different categories of Unani medicines and their application.

The pharmacists working in the chemist shops were aware about different categories of Unani drugs. The company representatives too spoke to them about this aspect.

The consumers showed their concern about the admixture of allopathic/non-permissible substances in the drugs.

Following suggestions were made to improve public awareness

a) Government should create awareness about Unani medicines through different modes of advertisements.

b) Unani practitioners should be registered and Government should stop the practices run by the quacks.

Annexure-IV

List of Questions sent to Manufacturers relating to Drugs and ASU Products widely used for Treatment /Mitigation of Disease or debilitating Conditions

Introduction

The purpose of this exercise is to reflect upon present patient/beneficiary preferences which are a partial indication of where consumer needs and interest lies. Questions are often asked about what drugs/ medicaments under the Indian systems are most widely used. Either the responses are too diverse or too cryptic.

Until now, the effort in the government system has been to validate what is available in the classical texts, to prepare drugs/medication/applications in tune with what the systems refer to and test efficacy on limited groups of patients. Also to facilitate the standardisation of drugs and enhance quality control.

Manufacturers of ASU products in the private sector have been conducting their own research, preparing monographs and marketing classical as well as proprietary preparations. This questionnaire is aimed at seeking information about such drugs/ medications/applications to try and understand consumer preferences, the possible areas of growth reflected by sales, challenges faced by industry, quality control and marketing issues as experienced by Industry.

The questionnaire seeks to understand the size of the market, the size of each segment, subdivided on a regional basis if possible. The information given would be treated as confidential and would not be quoted or entered into the report without permission. However it is expected that the data given would be authentic and based upon reliable sources.

The questionnaire may be responded to as applicable but in case it does not apply advice may be given on better sources.

Part I: Drug Formulation/Quality Control Issues/Consumer Preference of ASU Products.

1. Is there any representative survey available about the fastest moving drugs/applications used in the Ayurvedic/Unani/Siddha systems?

   Yes (1) ☐ No (0) ☐

   If yes, please indicate where it can be accessed and provide a summary of the findings.

   Which drugs and other medicaments under the Ayurveda / Unani / Siddha system are the most widely used on a regional basis? Please reply as applicable. Mention the products and the signs and symptoms they are used for. Please give numerical marking (1,2,3,4,etc next to each dosage form for top 5 categories of products)

System	Dosage Form	Name of the product		Region	Sign & Symptoms (as per labelling)
		Classical	Proprietary		
Ayurveda	Vati (e.g Rank I)				
	Avaleha (e.g Rank 4)				
	Churna				
	Syrup				
	Kwatha				
	Parpati				
	Ghrita				

System	Dosage Form	Name of the product		Region	Sign & Symptoms (as per labelling)
		Classical	Proprietary		
	Taila				
	Asava/ Arishta				
	Others				
Siddha	Mathiri (Tablets)				
	Senthooram				
	Churnam				
	Kudineer (Decoction)				
	Parpam				
	Kalimbu (Ointment)				
	Lehiyam				
	Thailam				
	Manappagu (Syrup)				
	Any other				
Unani	Arks				
	Kushta				
	Raughan				
	Majoon				
	Khamira				
	Sharbat				
	Qurs				
	Haboob				
	Jawarish				
	Joshanda				
	Any other				

2. What are the diseases/clinical conditions for which people access the ASU drugs? A suggested list is given below with numerical marking (purely indicative). Please put the correct number in the box as per experience of your industry and add more boxes and names if needed.

Skin disorders (1) ☐ Joint pains (2) ☐

Irritable bowel syndrome (3) ☐ Liver disorders (4) ☐

Asthma (5) ☐ Gynaecological Disorders (6) ☐

Others _____

_____

3. Apart from drugs as therapeutics what other products based on ASU ingredients are top sellers manufactured by your company? (Put a tick (") on the appropriate region)

Products	Give Rank I,2,3,4 5 as applicable on Regional basis and name fastest moving item.	North	South	East	West
Toileteries					
Cosmetics					
Body enhancers					
Nutraceuticals					
Any other (Name product)					

4. What are the sales figures for the fastest moving non therapeutic items (ex: Toileteries, Cosmetics, etc as mentioned above) sold as ASU medicine on a regional basis over a period of 3 years? Give data from published document or mention any other source. No reply should be shown as "Reply not given".

Region	Non therapeutic items	Sales figure	Source
North			
South			
East			
West			

5. A vast number of the medicaments available under the ASU systems can be purchased over the counter: (OTC.) Please indicate how the majority of consumers access the medication –

It is on prescription (1) ☐

By word of mouth (2) ☐

Through advertisement (3) ☐

On the recommendation of the chemist (4) ☐

Research

1. Pharmacopoeias and formularies have been prepared for ASU drugs and considerable headway has been made in bringing out the publications, training the State Drug testing lab officials, pharmacies licencing authorities and drug inspectors. The First criticism however is that the States do not have anywhere near the manpower needed.

   Yes (1) ☐ No (0) ☐

2. The Second criticism is that pharmacies and manufacturers do not adhere to what has been recommended in the mandatory documents which have to be followed on the plea that the raw material is not of standard quality.

   Yes (1) ☐ No (0) ☐

3. The Third criticism is that there is no oversight and enforcement from the Drugs Controller/ licencing Authority in the States and licences are given without reference to whether the agency has the capability to follow the pharmacopoeia and formulary prescribed.

   Do you agree or disagree with this argument?

   Agree (1) ☐ Disagree (2) ☐

4. The Fourth criticism is that hardly any statutory or even survey samples are collected to give any confidence on the state of quality control.

   Are sufficient statutory or survey samples collected?

   Yes (1) ☐ No (0) ☐

5. The ultimate aim of the standardization work is to improve the quality of products made available to the public. What according to you are the ESSENTIAL, NON-NEGOTIABLE requirements that all manufacturers have to fulfill and what is the best way this can be enforced? Please write at least three major suggestions below and serial number them.

   Suggestions: -

   a. _____

   b. _____

   c. _____

   d. _____

   e. _____

6. Should the responsibility / liability for use of proper ingredients and following the process prescribed be placed on the owner/proprietor as opposed to the QC Manager who is only an employee?

   _____

Part-II: Policy Issues

1. There is a growing interest in identifying and using drugs and other products which do not have a high dependence on chemicals and are essentially plant-based. The government has taken several measures to improve the availability of quality products like improving access to quality raw material, issuing pharmacopoeias and formularies, issuing GMP, cancelling the licences of non-GMP compliant

manufacturers, upgrading the State Quality Testing Laboratories and imparting training. Even so it is well known that there is considerable variation in manufacturing standards and quality of products.

Keeping in mind that health is a state subject under the Constitution, what policy initiatives can be recommended that augment knowledge about the ASU products and their benefits.

---

2. Has the functioning of the National Medicinal Plant Board improved availability of quality raw material?

   Yes (1) ☐ No (0) ☐

   If yes, then approximately to what percent?

   10% (1) ☐ 25% (2) ☐ 50% (3) ☐

   Not at all (4) ☐

   Give suggestions to improve the functionality of the National Medicinal Plant Board.

---

3. Raw material quality and sustained supply is a major issue . What steps do you suggest for certifying the quality of raw material used? What legal instrument can be used without causing harassment? Please give suggestions.

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4. What suggestions can be made to improve public awareness about products in an ethical manner which inspires confidence? (For ex: through advertisements on television, in local buses, in trains, metro, etc)What can be said which builds confidence in a sustained manner but does not make wrong advertising claims?

---

5. It appears batch samples are not being insisted upon with the result that the presence of non-permissible substances and adulterants cannot be stopped by withdrawing the entire batch.

   Would the batch by batch inspection and withdrawing the entire batch help to reduce the problem?

   Yes (1) ☐ No (0) ☐

6. What essential steps can be taken to inspire public confidence **before** the aim of making the State Drug testing Laboratories fully functional is realized? Are there any legal changes that can make a big difference?

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7. Any other suggestions which can enhance the safety, efficacy and credibility of ASU products within the country?

Annexure-V

List of Manufacturers to whom Survey Questionnaires were sent through ADMA

S.No.	Member Company	Town	State
1	Dabur India Limited	Ghaziabad	Uttar Pradesh
2	Himalaya Herbal Healthcare	Bangalore	Karnataka
3	Charak Pharma (P) Ltd.	Mumbai	Maharashtra
4	Natural Remedies Pvt. Ltd.	Bangalore	Karnataka
5	The Zandu Pharmaceuticals Works Ltd	Dadar	Maharashtra
6	Chemiloids	Vijayawada	Andhra Pradesh
7	Shree Baidyanath Ayurved Bhawan Pvt. Ltd	Patna	Bihar
8	Shree Dhootpapeshwar Ltd	Mumbai	Maharashtra
9	Sandu Brothers P. Ltd.	Mumbai	Maharashtra
10	Hindustan Unilever Ltd.	Bangalore	Karnataka
11	Emami Limited	Anandapur	West Bengal
12	Kerala Ayurveda Ltd	Ernakulam	Kerala
13	Vicco Laboratories	Mumbai	Maharashtra
14	Uma Ayurvedics Pvt. Ltd	Mumbai	Maharashtra
15	Ayurchem Products	Thane	Maharashtra
16	Hi-Tech Bio Sciences India Limited	Kothrud	Maharashtra
17	Vasu HealthcarePvt.Ltd.,	Vadodara	Gujarat
18	Arya Vaidya Sala	Kottakkal	Kerala
19	Mehta Unani Pharmacy & Co. Pvt. Ltd	Rajkot	Gujarat
20	Ayurveda Rasashala	Pune	Maharashtra
21	Ban Labs Ltd.	Rajkot	Gujarat
22	Konark Herbals & Health Care	Mumbai	Maharashtra
23	Shree Dhanwantri Herbals	Amritsar.	Punjab
24	Dey's Medical Stores (Mfg) Ltd	Kolkata	West Bengal
25	Abhisheik Pharmaceuticals	Ludhiana	Punjab
26	Ansar Industries	Surat	Gujarat
27	Anju Pharmeuciticals	Indore	Madhya Pradesh
28	AYURPRIYA	Mumbai	Maharashtra
29	Ayusiddh Health Care P. Ltd	Ahmedabad	Gujarat
30	Amrita Drugs	Hyderabad	Andhra Pradesh
31	Ayurved Rasaushadhalaya	Pune	Maharashtra

S.No.	Member Company	Town	State
32	Amit Biotech (P) Ltd	Kolkata	West Bengal
33	Anuja Pharmaceuticals P. Ltd	Mumbai	Maharashtra
34	Akshay Pharma Remedies	Mumbai	Maharashtra
35	Alarsin	Mumbai	Maharashtra
36	Arogya Pharmacy	Mumbai	Maharashtra
37	Ayurved Pratisthan	Nashik	Maharashtra
38	Aayurmed Biotech Pvt. Ltd	Mumbai	Maharashtra
39	Aum Herbovedic and Cosmetics	Pune	Maharashtra
40	Arya Vaidya Nilayam Ltd.	Madurai	Tamil Nadu
41	Alathur Pharmaceutical Manufacturers' Association	Alathur	Tamil Nadu
42	Arvind Remedies Ltd.	Chennai	Tamil Nadu
43	Ayulabs Pvt. Ltd.	Rajkot	Gujarat
44	Ayushakti Ayurved Pvt.Ltd	Thane	Maharashtra
45	Ayurved Incorporation	Manavdar	Gujarat
46	Ayurveda Rasayani,	Pune	Maharashtra
47	Ayurvet Ltd.	Solan	Himachal Pradesh
48	Akshaya Remedies Pvt.Ltd	Pune	Maharashtra
49	Ashwin Fine Chemicals and Pharmaceuticals	Thane	Maharashtra
50	Atmasantulana Therapy Centre	Karla	Maharashtra
51	Aushadhi Bhavan	Nashik	Maharashtra
52	Ayurveda Herbals	Ahmedabad	Gujarat
53	Atlantic Pharmaceuticals	Mumbai	Maharashtra
54	Ashtavaidyan Thaikkattu Mooss	Thrissur	Kerala
55	Abhinav Healthcare Products Pvt. Ltd.	Mumbai	Maharashtra
56	Avitech Animal Health Pvt. Ltd	Gurgaon	Haryana
57	Amrut Pharmaceuticals	Mumbai	Maharashtra
58	Apcos Naturals	Mohali	Punjab
59	Atharv Ayurved Pharmaceuticals	Mumbai	Maharashtra
60	Ayurved Sumshodhanalaya (Pune) Pvt. Ltd	Pune	Maharashtra
61	Arya Aushadhi Pharmaceutical Works	Mumbai	Maharashtra
62	Amar Remedies Ltd.,	Mumbai	Maharashtra
63	Aravali Chemicals P. Ltd	Mumbai	Maharashtra
64	Ayuherb Healthcare	Satara	Maharashtra
65	Ayurved India	Lucknow	Uttar Pradesh
66	Bipha Drug Laboratories	Kottayam	Kerala

S.No.	Member Company	Town	State
67	B.G. Pharmaceuticals	Bhubaneswar	Orissa
68	Bio Ved Pharmaceuticals Pvt. Ltd	Pune	Maharashtra
69	Bellan Pharmaceuticals	Vadodara	Guharat
70	BAPS Herbal Care	Ahmedabad	Gujarat
71	BACFO Pharmaceuticals (India) Limited	Delhi	New Delhi
72	Biocare Remedies Pvt. Ltd.	Gandhinagar	Gujarat
73	Bharat B Doshi & Mukesh D. Gathani	Baroda	Gujarat
74	Cholayil Pvt Ltd.	Chennai	Tamil Nadu
75	Chadda Trader	Kangra	Himachal Pradesh
76	Cosvedic Drugs P. Ltd	Nashik	Maharashtra
77	Clinfound Clinical Research Services Pvt. Ltd	Cochin	Kerala
78	CTIL Pharma Pvt Ltd	Mumbai	Maharashtra
79	Chawla Ayurvedic Pharmacy	Amritsar.	Punjab
80	Chandan Drug Pharma	Amritsar.	Punjab
81	Chawla Drug Pharma	Amritsar.	Punjab
82	CRIA Care Pvt. Ltd	Mumbai	Maharashtra
83	Chaitanya Pharmaceuticals P Ltd	Nashik	Maharashtra
84	Datu Manji Padamji Surmawala	Mumbai	Maharashtra
85	Dr. Jain's Forest Herbals P. Ltd.	Mumbai	Maharashtra
86	Dave Pharmaceuticals	Panvel	Maharashtra
87	Dr. Palep's Medical Research Foundation	Mumbai	Maharashtra
88	Deer Products	Mumbai	Maharashtra
89	Dhathri Ayurveda Pvt Ltd	Ernakulam	Kerala
90	Divya Pharmacy	Haridwar	Uttarakhand
91	Dhanshree Pharmacy	Vadodara	Gujarat
92	Dawn & Company Pvt. Ltd.	Mumbai	Maharashtra
93	Dr. Asma Herbals	Amritsar.	Punjab
94	Essar Pharma	Mumbai	Maharashtra
95	EURAFRIC Pharma Pvt Ltd	Ambarnath	Maharashtra
96	Epic Pharmeuciticals	Satara	Maharashtra
97	Growel Pharmaceuticals	Ghaziabad	Uttar pradesh
98	Fidalgo Healthcare	Ludhiana	Punjab
99	Glaxo Smithkline Asia Pvt.Ltd	Gurgaon	Haryana
100	Goswami Drugs	Ratangarh	Rajasthan
101	Goka Company	Nashik	Maharashtra

S.No.	Member Company	Town	State
102	GoodBee Honey & Spices Company	Bengaluru	Karnataka
103	Gurusiddhi Marketing & Exporters	Mumbai	Maharashtra
104	Harinarayan Pharmacy	Ahmedabad	Gujarat
105	Hasham Manji Padamshi Surmawalla	Mumbai	Maharashtra
106	Hesh Pharma	Mumbai	Maharashtra
107	Herbs N Drugs	Kolkata	West Bengal
108	Hindustan Biosynth Ltd.	Baroda	Gujarat
109	Healthcare Pharmaceuticals	Mumbai	Maharashtra
110	HPR Medicines Pvt. Ltd	Dombivli	Maharashtra
111	Hakeem ChiChi Pharmacy	Surat	Gujarat
112	Hemma Herbs P. Ltd	Kolkata	West Bengal
113	Harkab Chemicals Pvt. Ltd	Mumbai	Maharashtra
114	Herbotech India	Ludhiana	Punjab
115	Herb N Health	Mumbai	Maharashtra
116	Herbotech Pharmaceuticals	Amritsar.	Punjab
117	Hari Parasuram Aushadhalaya	Pune	Maharashtra
118	Isha Agro Developers P. Ltd	Mumbai	Maharashtra
119	Indian Herbs Research & Supply Co. Ltd	Saharanpur	Uttar Pradesh
120	Ivycomm Systems	Faridabad	Haryana
121	Ixoreal Boimed Pvt. Ltd.	Hyderabad	Andhra Pradesh
122	Immense Healthcare Pvt. Ltd.	Mumbai	Maharashtra
123	Jark Pharma Pvt. Ltd	Jamnagar	Gujarat
124	Jai-Son Herbals Pvt. Ltd.	Nashik	Maharashtra
125	Jiwadaya Netraprabha Pharmaceuticals	Mumbai	Maharashtra
126	Jenburkt Pharmaceuticals Ltd	Mumbai	Maharashtra
127	Jainson Pharmaceuticals Pvt. Ltd	Mumbai	Maharashtra
128	Jhawar Chemicals Pvt. Ltd	Harda	Madhya Pradesh
129	Jairamdass Khushiram	Mumbai	Maharashtra
130	Koral Pharma	Nashik	Maharashtra
131	Kanda Pharmacy	Ludhiana	Punjab
132	Kokban Ayurvedic Pharmaceuticals Pvt. Ltd	Mumbai	Maharashtra
133	Keva Industries	Ludhiana	Punjab
134	Kalyani Chemicals	Baghalpur	Bihar
135	Kumar Pharmaceuticals (India)	Jalandhar	Punjab
136	LVG Healthcare Pvt. Ltd.	Ahmedabad	Gujarat

S.No.	Member Company	Town	State
137	Mamata Herbals	Mumbai	Maharashtra
138	Mona Lab	Mazgaon	Maharashtra
139	Meridian Enterprises P.Ltd.	Mumbai	Maharashtra
140	M.H. Javerian & Sons	Mumbai	Maharashtra
141	Miracle Formulations India Pvt. Ltd.	Hyderabad,	Andhra Pradesh
142	Mission Vivacare Limited	Mumbai	Maharashtra
143	Manil Ayurved Pharma Pvt. Ltd.	Pune	Maharashtra
144	Manphar Ayurvedic Drugs	Hyderabad,	Andhra Pradesh
145	Millennium Herbal Care Ltd.	Mumbai	Maharashtra
146	Megha Herbal Healthcare Pvt. Ltd	Mumbai	Maharashtra
147	Maharishi Ayurveda Products Pvt. Ltd	Delhi	New Delhi
148	Minor Forest Produce Processing & Research Centre	Bhopal	Madhya Pradesh
149	Madaan Pharmaceuticals	Jalandhar	Punjab
150	Maa Sarada Agrotech & Dairy Pvt. Ltd.	Kolkata	West Bengal
151	Marico Limited	Mumbai	Maharashtra
152	Navin Ayurveda Pvt. Ltd.,	Mumbai	Maharashtra
153	Nagarjun Pharmaceuticals (P) Ltd.	Ahmedabad	Gujarat
154	Numero – Uno Natural Herbs	Delhi	New Delhi
155	NASR Pharmaceuticals Pvt. Ltd	Mumbai	Maharashtra
156	Nanal Softwares & Herbals	Pune	Maharashtra
157	Navbharat Ayurvedic Pharmacy	Amritsar	Punjab
158	Nandan Pharma	Kundaim	Goa
159	Nandan BioMatrix Limited	Hyderabad,	Andhra Pradesh
160	NCL Agro Foods	Rajkot	Gujarat
161	Nagarjun	Nashik	Maharashtra
162	Omni Potent S Pharmaceuticals	Hissar	Haryana
163	Orient Ayurvedic Pharmacy	Chandisar	Gujarat
164	Oriental Medicines Pvt. Ltd	Alappuzha	Kerala
165	Om Ayurvedic	Mumbai	Maharashtra
166	Punarnava Ayurveda Pvt. Ltd	Coimbatore	Tamil Nadu
167	Paras Pharmaceuticals Ltd	Ahmedabad	Gujarat
168	Progen Research Lab	Belgaum	Karnataka
169	Punayur (India) Pharmaceuticals	Ludhiana	Punjab
170	Pacecon Technosys Pvt. Ltd	Mumbai	Maharashtra
171	Premji Laxman Ravarya	Mumbai	Maharashtra

S.No.	Member Company	Town	State
172	Pentavox Herbals P. Ltd.	Ludhiana	Punjab
173	Pharma Packaging	Mumbai	Maharashtra
174	Proctor & Gamble Hygine & Healthcare Ltd.	Mumbai	Maharashtra
175	Prophyla Biologicals Pvt. Ltd.	Mumbai	Maharashtra
176	Pitambari Products Pvt. Ltd.	Thane	Maharashtra
177	Pushpam Health Care Products	Pune	Maharashtra
178	Prakash Pharmaceuticals	Shimoga	Karnataka
179	Prabhat Ayurvedic Pharmacy	Amritsar	Punjab
180	Prince Pharma	Ludhiana	Punjab
181	Prashant Pharmaceuticals	Rajpipla	Gujarat
182	PAT Pharmaceuticals	Panvel	Maharashtra
183	Prakash Trading Co.	Mumbai	Maharashtra
184	Pure Botanicals	Mumbai	Maharashtra
185	Ratan Ayurvedic Sansthan Pvt. Ltd.	Indore	Madhya Pradesh
186	Rakesh Pharmaceuticals	Gandhinagar	Gujarat
187	RYM Exports	Mumbai	Maharashtra
188	Retort Pharmaceuticals Pvt. Ltd.,	Chennai	Tamil Nadu
189	Rawal Medherb Consultants Pvt. Ltd.,	Delhi	New Delhi
190	Rajasthan Herbal International	Mumbai	Maharashtra
191	Rajni Healthcare Products	Pune	Maharashtra
192	Rajan Pharmaceuticals	Pune	Maharashtra
193	Rajasva Pharma Enterprises	Nashik	Maharashtra
194	Rakesh Sandal Industries	Kanpur	Uttar pradesh
195	Rashsala Aushadhasram (Gondal) P.Ltd	Gurgaon	Haryana
196	Saini Hair Products (P) Ltd	Delhi	New Delhi
197	Swaarnim Naturscience Limited	Indore	Madhya Pradesh
198	Swarna Herbals Pvt. Ltd	Etah	Uttar Pradesh
199	Shivayu Ayurved Ltd.	Nagpur	Maharashtra
200	S. K. Oil Industries	Jalgaon	Maharashtra
201	Shree Dhanvantari Pharmaceuticals	Pune	Maharashtra
202	S. N. Pandit & Sons	Mysore	Karnataka
203	Shri Ayurved Seva Sadan	Firozabad	Uttar Pradesh
204	S G Phyto-Pharma Pvt. Ltd	Kolhapur	Maharashtra
205	Shree Akshar Pharmaceuticals P. Ltd.	Sabarkhanta	Gujarat
206	Shree Shanker Ayurvedic Pharmacy	Ahmedabad	Gujarat

S.No.	Member Company	Town	State
207	Sunrise Remedies Pvt. Ltd.	Gandhinagar	Gujarat
208	Simandhar Herbal Pvt. Ltd.	Mumbai	Maharashtra
209	Siddhagiri Pharma	Ratnagiri	Maharashtra
210	Shriji Herbal Products	Mumbai	Maharashtra
211	Swadeshi Pharmaceuticals	Udipi	Karnataka
212	Sri Padmamba Rasoushadha Karyalaya	Shimoga	Karnataka
213	Sahajanand Bio-Tech Pvt. Ltd.	Surat	Gujarat
214	Shree Swami Atmanand Saraswati Ayurvedic Co-op. Pharmacy Ltd.,	Surat	Gujarat
215	SOS Pharma	Ludhiana	Punjab
216	SKM Siddha and Ayurvedic Medicines India Pvt. Ltd	Erode	Tamil Nadu
217	S.K Herbal & Bio Extracts	Mumbai	Maharashtra
218	Sheetal Medi-Care Products Pvt. Ltd.	Mumbai	Maharashtra
219	Shri Vardhman Udyog	Indore	Madhya Pradesh
220	Sanjeevani Pharma	Thane	Maharashtra
221	Shree Kamal Products	Panvel	Maharashtra
222	Sharangdhar Pharmaceuticals Pvt. Ltd.	Pune	Maharashtra
223	Safe Life Herbals Pvt.Ltd.,	Mumbai	Maharashtra
224	Stiriti Ayur Therapies Pvt Ltd	Hyderabad,	Andhra Pradesh
225	Sahul India Limited	Kolkata	West Bengal
226	Trio Healhcare Pvt. Ltd,	Ahmedabad	Gujarat
227	The Ayurvedeeya Arkashala Ltd	Satara	Maharashtra
228	The Varma Pharmacy P. Ltd.	Pune	Maharashtra
229	Tulsi Amrit Pvt. Ltd.	Indore	Madhya Pradesh
230	Tulip Lab Pvt. Ltd.	Mumbai	Maharashtra
231	The Tamil Nadu Ayurvedic, Siddhaand Unani Drug Mfgs. Association	Chennai	Tamil Nadu
232	Tulison Pharma	Delhi	New Delhi
233	Total Herb solutions Pvt. Ltd.	Mumbai	Maharashtra
234	The Arya Vaidya Pharmacy (Coimbatore)Ltd.	Coimbatore	Tamil Nadu
235	UAP Pharma Pvt.Ltd	Ahmedabad	Gujarat
236	Unjha Ayurvedic Pharmacy	Unjha	Gujarat
237	Umalaxmi Organics Pvt. Ltd	Vadodara	Gujarat
238	Vedic Life Sciences Pvt. Ltd.	Mumbai	Maharashtra
239	Vital Care Private Ltd	Vadodara	Gujarat
240	V. K. Swamy Agency	Madurai,	Tamilnadu

S.No.	Member Company	Town	State
241	Vaishnavi Organic Farm	Mumbai	Maharashtra
242	Vatsal Ayurvedic Products (P) Ltd.	Nashik	Maharashtra
243	Vaidya Khadiwale Vaidyak Sanshodhan Sanstha	Pune	Maharashtra
244	Vitromed Healthcare	Jaipur	Rajasthan
245	Vetmed Pvt. Ltd.	Kolkata	W.B
246	Vikrant Brothers	Jabalpur	M.P
247	Valley Pharma,	Mumbai	Maharashtra
248	Welex Laboratories Pvt. Ltd	Mumbai	Maharashtra
249	Warrier's Hospital & Panchkarma Centre.	Alappuza,	Kerala
250	Wintrust Pharmaceutical Ltd	Ludhiana	Punjab
251	Western India Chemical Co	Mumbai	Maharashtra
252	Wilson Drugs & Pharmaceuticals Pvt.Ltd.	Jalandhar	Punjab
253	Wagbhat Aushdhalay	Sangli	Maharashtra
254	Yogi Ayurvedic Products Private Limited	Nashik	Maharashtra
255	Yogini Products	Thane	Maharashtra
256	Yogiraj Pharmacy	Mumbai	Maharashtra
257	Birla Lifesciences Pvt. Ltd	Mumbai	Maharashtra
	ASU ASSOCIATIONS		
1	AMAM	Delhi	New Delhi
2	AMMOI		Kerala
3	Federation of Indian Herbal Industry		
4	5 HADSA		Maharashtra
5	FRLHT		Karnataaka
6	KIMMA		Karnataka
7	Konkan Seva sangh		Maharashta
8	Maharashtra Ayurvedeeya Aushadhi Utpadak Sangh		Maharashtra
9	MP Association		M.P.
10	Nashik Division Ayurvedic Drugs Manufacturers' Association		Maharashtra
11	Vidarbha Drug Manufacturers Association		Maharashtra
12	Punjab Ayurvedic Drugs Mfrs Assn		Punjab