The challenges ahead of the Ayurvedic Industry and the Association ADMA is far from being addressed meaningfully, by the Government of India. We, as responsible stakeholders’ forum, have had a meeting with the Secretary, Shri Anil Kumar, IAS, Department of AYUSH, along with his full team. Though our Hon. Secretary made a presentation highlighting the plight and status of the Industry and its future prospects, nothing meaningful has happened.

The levy of Excise duty, the bringing of Ayurvedic Industry under the scope of the Sales Promotion Employees Act are burning issues and we from the ADMA have given representations on such issues to the Department of AYUSH.

Unfortunately, the meetings which we have been seeking with senior officials who are responsible to take the issue forward have not responded meaningfully. This has been our biggest failure and let me as the Captain of the Ship assure you that we are not going to give up so easily and continue to pursue the various issues which plague our Industry.

As a matter of principle we need to stand united and optimize our resources so that the growth of the Ayurvedic sector is not compromised.

While, it will be our endeavour to strive to do our best, we also must realize that our responsibility and commitment to Society and conduct our affairs with all fairness and dignity.

I am sure you will be by the side of ADMA to live up to the challenges ahead.

JAI HIND

Subharthee Dey
President-ADMA
I am happy to inform all the Members that we are on follow up with the Department of AYUSH and Ministry of Environment on some of the issues of ASU Industry which are detailed below along with the other activities.

1. Our submission to Department of AYUSH on 20th April 2011 with regard to the additional points not covered in the Minutes of the Meeting dated 24th January 2011 was made.

2. ADMA had sent submission on 29th April 2011 to Department of AYUSH with regard to issue of Licence for New Products in Gujarat.

3. Our 3rd Managing Committee Meeting was held on 1st May 2011 in Ludhiana.

4. Workshop on Marketing Concept in Ayurveda at Amritsar on 2nd May 2011 organised by Herbal Health Research Consortium Pvt. Ltd. was attended by some of our Managing Committee members.

5. Our submission dated 7th May 2011 to the Secretary MoEF giving detailed comments on Office Memorandum with regards India’s hosting of CoP -11 to the Convention on Biological Diversity was made. Our Representative Dr. Badari Narayan, Dabur has attended the high level meeting organized by Ministry of environment and Forests on 23rd May 2011.

6. Our submission was made on 9th May 2011 to Shri Anilkumar requesting for obtaining the Observership Status for Government of India and Indian AYUSH Industry to understand and meet the European Quality methods.

7. Our representative had visited CDSCO office Delhi and met Mr. Arvind Kukrety, ADC (I) and Mr. M. Mitra, ADC regarding the Import Registration Certificate Procedure. It was mentioned to our representative that the proposed guidelines is not applicable for ASU medicines.

8. Our submission to Dy. Secretary Government of India, Ministry of Health & Family welfare requesting to consider the 12 Fairs for AYUSH Sector for funding under Market Access Initiative Scheme was made on 7th May 2011. We are awaiting response.

9. Policy Meet in Chhattisgarh for strengthening of AYUSH Herbal resource Management on 30th and 31st May 2011 wherein our Treasurer Shri Shashank Sandu represented ADMA.

10. International Conference on TCM Pharmaceutical Analysis scheduled on July 1-3, 2011 in Chengdu wherein some of the Members have already sent their Delegate Registration.

11. Our Meeting with the local Associations of Hyderabad, and Chennai took place on 26th May 2011, wherein myself and Mr. Nimish interacted with the Members of local Associations.

12. Submission was made to Jt Secretary, Department of AYUSH with a request not to make implementation of bar coding mandatory.

13. Members were requested to inform the Secretariat of ADMA with regard to Non-receipt of Subsidy by the members against their participation in AROGYA and other department of AYUSH supported fairs. ADMA has received the information only from few members. It is once again requested the members, who have not yet informed, to inform immediately to as to compile and make the submission to Department of AYUSH.

14. We are on follow up with the Department of AYUSH for excluding ASU Industry from the Notified list of the Labour Ministry for inclusion in the purview of Sales Promotion Employees Act.

Members who may require the copy of our submission may kindly inform the Secretariat of ADMA. Members, who are yet to renew their membership, are urged to renew their membership at the earliest.

Members are also requested to inform any change in their email id, address for prompt communication.
Ashwagandha - Classification

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<tr>
<th>Kingdom</th>
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<tr>
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<td>W. somnifera</td>
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<td>Zoological name</td>
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Other Species:
Withania coagulens and Withania simonii are the other related species of the Ashwagandha.

Location:
Ashwagandha is grown in all the parts of India. It is grown in India as the crop and can also be grown in the Kitchen garden. One can find this medicinal plant in the Sariska Tiger Reserve, Ranthambore National Park and Eravikulam National Park in India. It is also found in various Botanical gardens in India. It is found in the woodland garden, cultivated beds and dappled shade.

Cultivation methods:
Ripe red fruits of the plant are dried in the warm and well ventilated space. After some days the berries are separated, washed and dried up properly. Its seed can be shown in the early spring, they get germinated within two weeks, prefers light sandy, medium loamy and well drained soil. It grows more in the sunlight than in the shade.

Medicinal uses:
Ashwagandha is a very useful herb. It reduces stress; strengthen the immunity and nervous system. It helps in enhancing the mental functioning. It is useful in sexual and general weakness. It gives vitality and vigour and helps in building greater endurance. It is used to cure diseases like rheumatism, leprosy and arthritis. The leaves and the root bark of the pant are abortifacient, adaptogen, antibiotic, aphrodisiac, diuretic, narcotic and tonic. It is also used to tone the uterus after the miscarriage. The fruit and seeds are diuretic. All the parts of the plant are used in the herbal medicines. According to the Ayurveda studies Ashwagandha increases health and longevity. It is also sometimes used to treat the memory loss. In cases of cancer Ashwagandha acts as the adjuvant.

Other uses:
Ashwagandha is used as the substitute of the soaps. The leaves are an insect repellent. Ashwagandha mixed with the almond oil and rose water is used as the facial toner. Ashwagandha is taken with the milk, with sugar or honey as it promotes deep sleep.

Other Names:
Indian Ginseng, Ajagandha, Clustered Wintercherry, Kanaje, Orovale, Samm Al Ferakh, Strychnos, Withania are the other names used for the Ashwagandha. It has derived its name from the Sanskrit work meaning 'Horse smell.'

Description:
Ashwagandha is an evergreen shrub that grows up to the height of 0.5 m to 1.5 m. It is covered by the leaves all round the year. The flowers are hermaphrodite (they have both the male and the female organs) and are greenish yellow in colour. Its fruit and berries are orange-red in colour. Its roots are whitish brown in colour. Ashwagandha is a small woody shrub and flowers all the year round.
It is official now. Whole herbs are here to stay, no matter what their individual ingredients may point to. Susan G. Wynn and Barbara J. Fougère in their hard hitting article titled "Why Use Herbs?" have emphatically averred that herbs are not simply "unrefined drugs". In fact they are complex drugs with complex actions that go beyond the sum total of their ingredient parts. Here are some interesting and thought-provoking observations of these erudite scholar scientists:

- Why use an herb when we have available to us established, effective treatments for so many medical conditions? Most herbalists would answer this way: When conventional treatments are both safe and effective, they should be used. Unfortunately, that isn't the case for many serious chronic medical conditions: chronicity is virtually defined by the fact that medicine isn't working. Herbs represent an additional tool for the toolbox. Herbs also represent a different approach to the practice of medicine, that is, using the complex formulas “developed” by plants over millennia in relationship with the rest of the beings on the planet.

- Plants contain many dozens of chemical constituents. Some of these have pharmacologically unique and powerful activity and have been tapped by the drug industry to develop new pharmaceuticals. However, the other ingredients in plants may have important activity as well. Consider, for example, the vitamins, minerals, flavonoids, carotenoids, sugars, and amino acids contained in a plant. Do these assist effector cells in mounting the physiologic response initiated by the “drug”? And do constituents with lesser pharmaceutical activity than the one “recognized” active constituent play any role? These complex drugs offer the sick patient a greater range of effects. Because there are many conditions for which the etiopathogenesis is unknown, providing the patient with a choice of biochemical solutions makes sense.

- When asked which is the single active ingredient of any herb, the drum beat of the herbalist will always be: The Plant Is The Active Constituent!

- Synergy: The chemical compounds in plant medicines have additive, antagonistic, or synergistic effects. For instance, foxglove is less toxic than its active ingredient digoxin because the digoxin is diluted out by other plant constituents, some of which may antagonize its action. Additive effects are fairly easily quantified when the individual chemicals are well defined. Synergistic effects are more difficult to quantify and are the subject of some investigation into the effects of plants.

- Synergy between plant components may take pharmacodynamic forms or pharmacokinetic forms. In pharmacokinetic synergy, one component may enhance intestinal absorption or utilization of another component. Pharmacodynamic synergy occurs when two compounds interact with a single target or system. Not all of these interactions fit the strictest physicochemical definition of synergy, and experts have suggested that these should be called polyvalent actions of plant medicines. For instance, barberry (Berberis aquifolium) contains berberine, an alkaloid with documented antigiardial, antiviral, and antifungal properties. It is also an anti-inflammatory and has been shown to modulate prostaglandin levels in renal and cardiovascular disease. Herbalists have long used berberine-containing plants (which also include Goldthread [Coptis spp] and Goldenseal) for treating patients with infection. Use of the single drug berberine may lead to antibacterial resistance, although herbalists appear to use the whole plants repeatedly with no ill effects.

- Other examples of purported synergism may be seen in plant medicines. Wormwood (Artemisia annua) is the source of the antimalarial compound, artemisinin. The flavonoids contained in the plant apparently enhance the antimalarial activity of this compound in vitro. Similar types of activity have been determined for compounds found in kava, valerian, dragon’s blood (Croton draconoides), and licorice.

In short, whole herbs have stood the test of time over millennia. They offer solid enough reasons for their use in preference to isolated active constituents:

- The whole herb or whole extract is already understood from history and clinical trials.
- The herb’s constituents have complex actions that benefit the patient through additive, antagonistic, or synergistic effects.
- Some constituents are not stable when isolated.
- Most active constituents may be unknown.
At the outset we wish to thank you for having notified the above captioned rules under the Legal Metrology Act 2009. This will help proper implementation of the Act in the interest of the consumer.

You are aware that ours is a progressive association of Ayurvedic Drug Manufacturers always ready to cooperate in adopting progressive measures in the interest of consumers.

Recently, The Legal Metrology (Packaged Commodities) Rules were revised and the revised rules are effective from 1-4-11.

We would like to bring it to your kind notice the following facts in this connection.

1. Ayurvedic, Siddha and Unani drugs/medicines (ASU drugs) are covered under The Drugs & Cosmetics Act 1940 (D&C Act) & Rules thereunder. Rule 161 under the act prescribes the information to be declared on the label and every wrapper of a pack. This information is the same as that required under rule 6 of the Legal Metrology rules 2011 (LM Rules) except for declaration of maximum retail price.

In view of this our Association had made several representations to you and to the Dept of AYUSH to exempt ASU drugs from the purview of LM Rules. Our letter no. 0411/ADMA/91 dated 20th April 2011 copy of which is attached as annexure II refers and puts the matter under proper perspective. You will observe that Dept of AYUSH also supports our case, as can be seen from the letter dated 19th Oct 2007 addressed to Shri Matherbootham, Dir. Legal Metrology by Shri Chadha, Dept of AYUSH. The said letter is attached as annexure III. Subsequently the then Hon. Gen. Secretary, Mr. Ranjit Puranik discussed the matter in a personal meeting on 26th December 2007.

We therefore request you to amend Rule 26 and insert sub rule (e) as “it is an Ayurvedic, Siddha, or Unani drug or medicine covered under the D&C Act and exempt ASU drugs from the application of the Legal Metrology Rules 2011.

However, till such time the amendment is made, we request you to kindly provide following relief to us without prejudice to our request in para 1.

2. The revised rules are effective from 1-4-11. It is not clear whether the provisions apply to the stock-in-trade, and stock of finished and WIP stocks in manufacturers’ premises. We may mention here that such stocks would run in several crores of rupees. It is impossible to recall and re-label all these stocks to make them compliant.

We request you to issue clarification regarding the stocks to the effect that the rules are not applicable to stock in trade and stocks at the manufacturers’ premises and make the rule applicable to new production with suitable prospective date taking our entire submission into account.

3. Compliance to the revised rules with effect from 1-4-11 may put the industry to extreme hardship and entail huge expenditure which the industry can ill afford.

There would be significant stocks of printed material like labels, cartons, inserts etc which would bear the maximum retail price (MRP) in fraction of rupee without being rounded off. If rounding off is to be effective from 1-4-11 the stocks will be redundant and will have to be destroyed. This will not only be a huge loss to the industry but also a national loss which can be prevented.

Moreover getting new material printed will require lot of time and significantly affect the production. This loss will be tremendous and affect the economy of the nation significantly.

We request you to permit the use of the printed material till the stocks last. In the meanwhile the invoicing can be done on the basis of rounded off MRP and the retailer would charge the round MRP as provided. The invoicing with round MRP should be made effective from 1-1-12 to establish proper systems and to enable proper information to be sent to the retailers and wholesalers.

4. There is no provision for rounding off MRP containing fraction of rupee from 96 to 99 paisa.

Clarification may be issued to round off the same to the next rupee by inserting words “fraction between 96 and 99 paisa to be rounded to the next rupee” at the end of rule 2 (l).

5. Rule 6 states that provisions of Drugs and Cosmetics Act 1940 shall apply to cosmetics. As stated under para 1 ASU drugs also come under the purview of the D&C Act and they also provide information required under sub rules (1) a) to (1) d) of rule 6 of LM Rules under rule 161 of the D&C Act.

In view of this we request you to add words “and Ayurvedic, Siddha and Unani drugs/medicines” after the words “cosmetic products” in the proviso under sub rule (1) d) of rule 6 and exempt ASU drugs from the purview of rule 6.

6. Sub rule (4) of rule 7 prescribes that sub rules (1) to (3) of rule 7 are not applicable to commodities which are required to provide the information under any other law for the time being in force.

As stated earlier, we have to furnish the information covered under the sub rules stated above viz. net quantity under the D&C Act.

Hence we request you to confirm that sub rule (4) also applies to ASU drugs and they are not covered under the purview of sub rules (1) to (3) of rule 7.

7. As per rule 161 of the D&C Act, information on quantity in terms of net content, ingredients- names and quantity per unit dose, manufacturing lic no. batch no. date of expiry, name and address of the manufacturer etc has to be declared on all packs of ASU drugs irrespective of the size of the pack or of label. All this information has to be clear and legible. Many of the labels are 22 mm x 68 mm in size. It is not possible to leave the space as proposed under rule 8 on all the labels.

We request you to exempt ASU drugs from the provisions of rule 8 by adding suitable proviso under the rule.

8. Sub rule (5) (ii) of Rule 13 prescribes use of letters U or N for commodities packed in numbers. We may mention that tablets and capsules of ASU drugs are packed and sold in numbers. However there is an unwritten convention that the number is followed by letter T or C meaning tablet or capsule as the case may be. The consumers also have come to understand this conventional notation. ADMA had made a submission on the subject under ref no 0208/ADMA/496 dated 6-2-2008 which is attached as annexure VI to allow the practice to continue without change. Under circular letter dated 12-1-2007, the Dir. Legal Metrology issued a clarification that if the commodity is mentioned after the number it would be considered as compliance to the rule.

We request you to issue fresh clarification to allow the use of letter T or C instead of U or N.

We request you to consider the above submission and as short term relief issue clarification/amendment as appropriate and most important make the application wef 1-1-13 to prevent avoidable loss and hardship to the Industry. As a long term and permanent relief we request you to amend Rule 26 suitably so as to exempt Ayurvedic, Unani and Siddha medicines from the scope of The Legal Metrology (Packaged Commodities) Rules, 2011.

Copy of the same is also endorsed to Mr. Anilkumar, Secretary, Department of AYUSH.
It is a fact that more and more consumers want to go back to nature and the preference to buy products which are natural or organic is increasing. The term natural is not very clearly defined as on date in any guideline or regulations. In Asian countries, consumers are more aware of the term herbs or herbals which are a subset of naturals. While all naturals may not be herbals, all herbals will be natural. The dictionary meaning of natural would be “made up of, derived from, and originating from, anything that is available in nature”. However, the need for clarity on this term when used with products more so with cosmetic product has gained wide attention. A common complaint on this area a decade back used to be that information on herbals/naturals are scanty, not easy to find, many of which even if available are not fully scientific and reliable. However, the last decade has seen a lot of progress and developments in making more credible and scientific information available. This has been made possible by efforts of Government, National Laboratories, Academicians, and Industrial Research Organizations.

In 2010, International Organization for Standardization (ISO) took up a new project and constituted a working group namely ISO/ TC 217/ WG4. This Working Group is preparing an International Standard for “Definition, Terminologies, and Criteria for Natural and Organic Cosmetics”. This working group has so far met four times, the last of the meeting was held at Paris on 18th March 2011. This working group is preparing two documents:

2. A base document (Benchmark document or Technical Report) documenting available information on the above subject from various countries, listing and reviewing any guideline, provisions, agreements etc. whether mandatory or non-mandatory, whether prepared by any Government or Semi-Government or even Industry Bodies or Scientific Associations. This document/technical report will serve as a basis on which the main International Standard on the subject will be drafted apart from keeping in mind the current scientific, technological and understanding of the area.

The author of this article is a nominee of India through Bureau of Indian Standards (BIS) on this working group and has been attending face-to-face all the meetings of the working group and contributing to the development of the International Standard. The initial working document prepared by the European Cosmetic Association (COLIPA) was circulated by the author to members of ISTMA (Indian Soap & Toiletry Manufacturer’s Association) and also to the members of the Cosmetics Sectional Committee, PCD-19 of Bureau of Indian Standards (BIS). Based on inputs obtained from them and the author’s own inputs due to the expertise on herbals area, have been submitted to ISO/ TC 217/ WG4, and in the formats provided by ISO.

In addition to the above, various other developments have taken place in the last one decade related to herbals/naturals. Some of them are listed below:

1. Another working group of ISO is developing a technical report for essential and aromatic oils.
3. A new Work Introduction process has begun and is in the Voting stage for preparing an ISO standard on “Testing for Heavy Metals in Cosmetics”. Indian Standards have already covered the method for determination of heavy metals.
5. BIS has already published a standard, IS 15735:2006, “General Guidelines on Herbal Cosmetics”.
6. A number of organizations have undertaken highly scientific work to develop quality specifications for herbs, processed herbs and herbal products. This development is very noteworthy as they provide a reference point providing technical descriptions, tests, methods to perform the test and the acceptable tolerance limits. This has reduced conflict between buyer and seller, provided quality specifications when naturals are used either for preparing a supplement, or a food product or a medicine or for use in cosmetics. A few of such publications where either extensive data based monographs are published or quality specifications are published, are given below:

a. Indian Pharmacopoeia Commission, which is entrusted with the objective of laying down standards for Drugs & Pharmaceuticals have a committee to develop quality monographs on herbals. 89 such monographs providing objectively available quality specifications for raw herbs, herbal extracts, processed herbs and few...
herbal products have been published in Indian Pharmacopoeia 2010.

b. United States Pharmacopoeia has introduced more than 160 quality monographs on herbals. Such monographs providing objectively available quality specifications for raw herbs, powdered herbs and extracts, processed herbs and few herbal products have been published in latest USP.

c. British Pharmacopoeia has introduced more than 50 quality monographs on herbals. Such monographs providing objectively available quality specifications for raw herbs, powdered herbs and extracts, processed herbs and few herbal products have been published in latest BP.

d. Indian Council of Medical Research (ICMR) has been sphere heading efforts in the same area and as on date have brought out 8 volumes of “Quality Standards & Monographs for Indian Medicinal Plants). This publication is highly valuable as it provides scientific information on many aspects of Indian Medicinal Plants including photographs, TLC profiles, chromatograms and structures of compound and testing method for each of the plant listed. These plants find use across the spectrum of food, supplements, medicines as well as cosmetics. More than 200 plants have been covered in these volumes.

e. Ayurvedic Pharmacopoeia of India has also brought out 8 volumes of API which provide quality specifications for more than 300 commonly used medicinal plants that find references in Ayurveda.

f. Many years ago Indian Drug manufacturers Association brought out “Indian Herbal Pharmacopoeia” containing 52 monographs raw herbs.

Concurrently, India is known to be a bio-diversity hot spot, large number of medicinal plants and botanicals are available in wild as well as from cultivated sources. The natural products industry that provides quality herbs and herbal extracts which are standardized has also grown and it is estimated that more than 1200 Crores worth of herbs and extracts are produced and exported in India. Similarly the aromatic and essential oil growing of plants, extraction of oils, fractionation of these oils, and production of pure compounds from the essential oils is also a leading industry. High quality aromatic oils and aromatic compounds, and oleoresins are produced in India and exported for use in Fragrance and Flavor industry. India has about 8 to 9 % of Global market in this area and about Rs 1500 Crores turn over. The cosmetic industry in India has a total turnover of Rs 22,307 Crores in 2009, out of which cosmetics making natural or herbal claims are increasing.

It is to be recognized that unlike BIS Technical Committees which operate on a consensus approach, ISO operates in a democratic way and puts to vote any issue which may have more than one opinion and no consensus. The decision based on majority vote would be taken forward.

It is important that technical representatives from India take adequate interest and provide timely technical inputs in the development of any standards/guidelines and work closely with and through BIS.

The author feels that as of today, representation and participation in these standards bodies and their work is rather low, and this may impact on acceptability, of Indian herbs/extracts/products, trade, commerce, as also possibility of sophisticated test methods being prescribed. It is also known that limits for contaminants like Heavy Metals are not uniform across geographies for Herbals/traditional medicines, and ISO can be a suitable place to try and get harmonized standards developed. Industries involved in herbals need to play a proactive role.
Forthcoming Events

International Conference on ‘Standardization and Globalization of Traditional Chinese Medicine (TCM)’ hosted by the Specialty Committee of TCM Pharmaceutical Analysis and the National Engineering Laboratory for TCM Standard Technology, organised by Agilent Co. Ltd, Chengdu University of Traditional Chinese Medicine, and Sichuan Neautus TCM Co. Ltd. from July 1st - 3rd 2011 in Chengdu.


PHARMAC India 2011 organised by Orbitz Exhibitions Pvt. Ltd. and Indian Drug Manufacturers’ Association (Gujarat State Board) from September 17th-19th, 2011 at Gujarat University Exhibition Hall, Ahmedabad, Gujarat.

Middle East Natural & Organic Products Expo 2011 organised under the patronage of UAE Ministry of Health & Ministry of Environment & Water with the support of International Federation of Organic Agriculture Movement (IFOAM – Germany), International Vegetation Union (IVU-UK), Dubai Municipality from December 5th -7th, 2011 at Dubai World Trade Centre, Dubai.