Dear Members,

We are happy to inform all the Members that a Meeting with Representatives of ASU Industry Associations was held on 13th August 2013 under the Chairmanship of Shri Nilanjan Sanyal, Secretary, Department of AYUSH, wherein the following burning issues of the Industry were discussed.

i. Rule 161 for Labeling requirement – Implementation of GSR 844 (E) dated 26-11-2012

ii. Schemes as proposed in 12th Five Year Plan

iii. Matter relating to Normally Traded Commodities and Access Benefit Sharing

iv. Prefix and Suffix

v. Procurement Preference given to PSUs under NRHM Programmes

vi. Sale License for ASU Drugs

vii. Use of Mercury in Ayurvedic Formulations

viii. DMRA

ix. Drug Licensing of Herbal Extracts

x. Issue of Raw Drugs

xi. Requirement of Web Portal for NMPB as well as FDA of all States

xii. Participation in Arogya Events and as Foreign Delegates

xiii. Central Excise matter

We have also received the Minutes of the said Meeting from the Department of AYUSH, and the same is published in Page. No. of this issue.

We are thankful to the Secretary, Department of AYUSH for giving us an opportunity to appraise the hardship faced by the Industry and the guidance that has been provided to us during the interactive meeting.

I am happy to note that following new members were enrolled as an Annual member of our Association from 1st July 2013 to 30th September 2013.

1. M/s Navjeevan Ayurvedic Pharmacy, Mumbai
2. M/s. NJP Healthcare Pvt. Ltd., Gujrat
3. M/s Veerhealth Care Ltd, Mumbai
4. M/s Ajmera Herbas Ltd., Indore
5. M/s Medfield, Karnataka
6. M/s Aryaansh Bio Naturals Pvt. Ltd., Indore
7. M/s. Dhanwanthri Herbal Products, Kerala

I warmly welcome all of them and look forward to their active participation in the association's activities.

I am happy to announce that a Kerala State Chapter has been launched during the Seminar held at Cochin on 22nd September 2013 and such Chapters in all States would strengthen ADMA in its activities.

Dr. P.M. Varier
President - ADMA
Dear Members,

A gist of activities and updates are given below for your information.

ADMA sent its Comments to Department of AYUSH and WHO on draft Guidelines for Good Pharmacopoeial Practices floated by WHO, vide letter ref. no. 0713/ADMA/231 dated 3-7-2013.

As requested by Dr. Manoj Nesari, Joint Advisor (Ayu), Department of AYUSH to provide details of annual requirement, quantity available etc. of the plant ‘Caesalpinia sappan’. ADMA sent reply on 19-7-2013 informing that majority of the members are not using the plant ‘Caesalpinia sappan’ and we understand from some of the local dealers that the consumption of the said plant is less than 300 Kgs that too also is unpredictable and hence we are unable to submit the correct consumption data.

Member Secretary & DGFT (EFC), Mumbai had requested to forward the problems of Members relating to DGFT and Customs Authorities pertaining to export facilitation for consideration in the Meeting of EFC held on 16th July 2013. Mr. Milan Mehta attended this meeting on behalf of ADMA.

According to the 5th Amendment [under Rule 161 of D&C Act 1940], all the ASU Drugs and PP Medicines should declare the following on the label viz, Botanical Name, Part Used, Form Used etc. As Members had difficulties in finding the abbreviations for the item No.4 -Form used which are not mentioned in AFI/API, ADMA made submission vide letter ref. no. 0713/ADMA/258/AYUSH/Label dated 19th July 2013 requesting Department of AYUSH to extend the period for implementation of Notification F. No. K-11020/5/2011-DCC (AYUSH) dated 26th November 2012 [GSR 844 (E)] -Rule 161 & 5th Amendment to D&C Act 1940 by one year till December 2014.

Further submission was sent on 10-7-2013 to the Technical Officer, Department of AYUSH suggesting 50% subsidy from Department of AYUSH, 25% soft loan of 3% interest and 25% own for the development of appropriate technology and equipment for AYUSH processing / therapies under the Scheme for ASU Industry on 12th Five Year Plan.

We had received a request from the Sindhudurg district Abhiyan Samiti to nominate ADMA Representatives from the Sindhudurg district. We had nominated Shri Ashok Abhyankar, Proprietor, Shree Krishna Aushadalaya, Ratnagiri, as a representative of ADMA.

National Medicinal Plants Board had invited the Representatives of ADMA for the Meeting of the Standing Finance Committee for Central Sector Scheme for ‘Conservation, Development and Sustainable Management of Medicinal Plants’ on 11-9-2013 at New Delhi. Mr. Ranjit Puranik attended this meeting.

Dr. H.S. Kathait, Research Officer, Drug Control Cell, requested us to send a fresh proposal for suggestions from ADMA regarding the amendment in ITC (HS Code)2012. ADMA had sent the suggestions and requested them to finalise in co-ordination with Ministry of Commerce/ Director General of Foreign Trade.

MoEF invited the Representatives of ADMA for the Business and Biodiversity Workshop on 5th September 2013 at New Delhi. Dr. Badari Narayan Sarvepalli, Dy. Gen. Manager, Agro-biotech, Dabur Research & Development Centre represented ADMA in this meeting.

ADMA Representatives were invited for the Second Meeting of Ayurveda Sectional Committee, FAD 26 on 16th September 2013 at BIS, New Delhi. Dr. Amit represented ADMA in this meeting.

MoEF invited the Representatives of ADMA for the National Project Steering Committee Meeting scheduled on 17th September 2013 at New Delhi. Dr. N.B. Brindavanam attended this meeting.

Our Association organized a seminar on “Business Potential of Ayurveda in Domestic and International Market” at IMA House, Cochin -25 on Sunday, 22nd September, 2013 to provide a platform for the interactive discussion among policy makers, regulators and key players in Ayurveda Industry, and also give a fillip to the business potential of Ayurveda. There was also a Press Conference in Cochin. Proceeding of the Seminar is given in this AYURBIZ Page Nos.

Members interested for the copy of our submissions may kindly write to ADMA Secretariat for the same.

We are also requested to send their feedback as and when requested to enable us to make effective submission.

Chandrakant Bhanushali
Hon. General Secretary
**TURMERIC - Classification**

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Other names:
Kunyit, Haridra, Haldi, Halada, Manjal, Zirsood, terre merite, Holdi, Indian Saffron, curcuma, Pasapu, Arishina are the other related names used for the Turmeric Kunyit, Haridra, Haldi, Halada, Manjal, Zirsood, terre merite, Holdi, Indian Saffron, curcuma, Pasapu, Arishina are the other related names used for the Turmeric.

Description:
The plant of Turmeric is an herbaceous perennial, which is 60 -90 cm high. It has a short stem. It has large leaves oblong and up to one meter long. Flowers of the turmeric appear on a spike like the stalk. Its flowers are yellow white in colour. They are sterile and do not produce viable seed. The lamina is green above and pale green below, and is 30 -40 cm long and 8 -12 cm wide. Approximately 30 flowers are produced in a spike. Inflorescence is a central spike of 10 -15 cm in length. Its pant looks like the ginger pant.

Location:
It is the widely cultivated tropical plant of India, which is grown from sea level to 1200 meter MSL. It is widely grown in the Sanjay Gandhi National Park of India.

Cultivation methods:
Turmeric plant is planted in the month of September to October. It grows in light black, black clayey loams, and red soils in irrigated and rainfed conditions. The rhizomes are planted 5 7 cm deep. This crop is planted by the small rhizomes with one or two buds. It is harvested after 9 -10 months of planting. The lower leaves turn yellow and fall with age.

Medicinal uses:
It is taken as the blood purifier and is very useful in the common cold, leprosy, intermittent, affections of the liver, dropsy, inflammation and wound healing. The rhizome of the turmeric plant is highly aromatic and antiseptic. It is even used for contraception, swelling, insect stings, wounds, whooping cough, inflammation, internal injuries, pimples, injuries, as a skin tonic. Sweetened milk boiled with the turmeric is the popular remedy for cold and cough. It is given in liver ailments and jaundice.

Other uses:
The powered rhizome of this plant is used as a condiment and as a yellow dye. It is used to colour and flavour the foodstuff. It is used in the preparation of medicinal oils, ointments and poultice. It is even used in the cosmetics.

Cultural Importance:
For thousand of years it has been used in the Hindu religious ceremonies. It is the common belief among the the Hindus that Turmeric improves fertility. The dry turmeric root is considered as the symbol of purity and prosperity. It is used in Indian rites and rituals. Turmeric mixed in water is poured on the God and Goddesses. The dried turmeric roots in betel leaves are given to the women during the ceremonies as they are considered as fertile and bring good luck. Turmeric power is applied on the main entrance of the Indian Houses. The priests in the temples put tilak on the forehead with the turmeric power. Married women in India has to put Sindur a vermillion paste (mixture of turmeric with camphor).
Minutes received from the Department of AYUSH with regard to the Interactive meeting held on 13th August 2013 with AYUSH Drug Manufacturers’ Associations

A meeting with AYUSH Industry Associations was held on 13th August 2013 under the Chairmanship of Shri N.Sanyal, Secretary (AYUSH), Govt. of India. Secretary (AYUSH) welcomed the representatives of AYUSH industry associations and thereafter agenda-wise interaction progressed as under-

2. Difficulty in adopting amended labeling provisions for want of abbreviations for certain plant-ingredient forms: On account of multiple labeling provisions and non-availability of abbreviations for certain forms of plant materials in the pharmacopoeias, industry demanded grace period up to December 2014 for the adoption of Drugs & Cosmetics Rule 161 notified on 26th November 2013. JS (BP) clarified that lead period of one year for adoption of the said Rule is provided in the notification after due consultation with the industry and a Committee has been set up by the Department to recommend relevant abbreviations before the new Rule gets enforced w.e.f. November 2013. Department would issue the list of abbreviations at the earliest.

3. Reimbursement claims and suggestions of industry for schemes: Regarding the suggestions given by ADMA for the schemes under revision, Dr D.C.Katoch, Joint Adviser (Ay.) informed that in 12th Plan the Centrally Sponsored Scheme for Drugs Quality Control is proposed for merger into National AYUSH Mission with revised parameters and the scope of central scheme for providing incentive to ASU&H industry for various activities is likely to be expanded. It was clarified that the contours of these schemes will take final shape only after approval from the EFC and Cabinet respectively. ADMA representatives provided a list of pending cases of reimbursement claims under the central scheme and proposed for increasing the financial assistance for participation of ASU drug manufacturers in Arogya events and as foreign delegates in international fairs. JS (BP) informed that the funding pattern of the relevant scheme as well as the number of persons to be supported for industry participation in such events will be considered at the time of revision of scheme.

4. Issues of Normally Traded Commodities (NTC) and Access & Benefit Sharing (ABS) of natural resources: Industry suggested to make NTC list as wide as possible considering the consumption pattern of raw materials and to formulate separate guidelines for access & benefit sharing of natural resources in the interest of AYUSH industry. Listening to the divergent views of stakeholders on these very complex issues, the Chairman intervened to suggest that AYUSH industry associations should come together with one voice for discussion and bring up justified propositions for consideration of Ministry of Environment & Forests with regard to NTCs and amendment of Bio-diversity Act.

5. Impending global ban on the use of Mercury: Responding to the concern of ASU industry about the global ban on mercury, Joint Adviser (DCK) informed that the Department formally obtained the draft Minamata Convention and has written to MOEF to propose for including the ‘use of mercury in the traditional Indian Systems of Medicine’ in the exempted list of items. JS (BP) reminded the industry representatives about assurance given in 27th June 2013 meeting and reiterated to submit scientific inputs regarding the proof of safety & efficacy of use of mercury in ASU formulations. In this regard, Dr JLN Sastry was identified to coordinate and provide the relevant scientific inputs to the Department of AYUSH for onward transmission to MOEF with an appropriate note.

6. Banning the use of prefix and suffix with the names of ASU drugs: Industry representatives stated that they are not aware whether their concerns discussed in the meeting taken by JS (AKG) in January 2013 have been addressed while finalizing the notification. Joint Adviser (DCK) informed that all those points were further considered in the Department and the final notification is still under process.

7. Procurement preferences given to PSUs under NRHM: Industry representatives proposed for framing procurement guidelines and to allow private sector in ensuring regular supplies of medicines to the government health facilities. Secretary (AYUSH) informed that the guidelines regarding the procurement of drugs under NRHM come under the purview of Department of Health & Family Welfare and Department of AYUSH would like to formulate a viable broad-based procurement system for ASU&H medicines, for which a considered view could be taken to modify the procurement guidelines under the Centrally Sponsored Scheme but it is premature to say about the final outcome as the matter is under process.

8. Sale license provision for ASU drugs: Responding to the presentation on this agenda by Dr. Ramanathan, Dr D.C. Katoch, Joint Adviser stated that the ASUDTAB referred the matter to a Subcommittee. The report of the Sub-committee is to
be considered by ASUDTAB in its meeting scheduled in September 2013. Department of AYUSH would act in accordance with the recommendations of ASUDTAB.

9. **Provisions of Drugs and Magic Remedies Act vis-à-vis ASU drugs:** Considering the effectiveness of ASU drugs in treating certain disease-conditions which are not manageable with allopathic drugs, industry representatives questioned the application of DMRA to traditional medicines. Dr CK Katiyar & Dr JLN Sastry volunteered to provide specific inputs on this issue and suggested for framing positive guidelines of medicinal claims. Regarding review of the DMRA list of diseases it was felt to seek clarification as to whether DMRA provisions are equally applicable to ASU drugs and consider inclusion of relevant provisions in the proposed separate legislation for ASU&H drugs. Joint Adviser (Ay.) informed that in view of the serious concerns of the Parliamentary Committee over the rampant usage of misleading advertisements of ASU products in print and electronic media, an agenda item has been proposed for consideration of ASUDTAB regarding prior approval of contents of advertisement by the Licensing Authority.

10. **Regulatory confusion about licensing of herbal extracts as drugs:** Mr. Amit Agarwal raised that herbal extracts being used as intermediaries in herbal, cosmetic, food, medicinal and veterinary products cannot be licensed in the name of ASU drugs as some of the Licensing Authorities are insisting for. Clarification in this regard needs to be issued and if needed, relevant Rules may be amended in the light of the fact that as per Food Safety and Standards Act, no item licensed as drug is allowed in Food products. In order to address this issue JS (BP) stated that Department is considering for taking advice of Law Ministry before providing any clarification or direction.

11. **Consumption data of raw materials and web-portal facility:** In order to encourage industry for submission of consumption data of raw drugs and time-bound disposal of various applications under Drugs & Cosmetics Rules, Shri Ranjit Puranik expressed the need of preparing data base of medicinal raw materials used by the ASU drug Industry and web-portal facility for NMPB and Licensing Authorities. Secretary (AYUSH) pointed out it as a Herculean task to maintain real time data of raw ASU drugs used by industry due to weak infrastructure of State Licensing Authorities for ASU drugs. It was decided that the feasibility of online system of processing various applications under Drugs & Cosmetics Act may be considered by ASUDCC.

12. **Issues of Central Excise Duty and Shelf life of ASU drugs:** Dr. D. Ramanathan requested for special dispensation to ASU industry with exemption on Central Excise Duty for classical drugs. Secretary (AYUSH) clarified that Central Excise comes under the purview of Ministry of Finance, which cuts across the board and hence the matter may be taken up directly with them. Blanket coverage for tax exemption to ASU industry may not be possible but it can be argued, if adequate justification is given by the industry. Regarding the problem faced by Ayurveda drug industry in Kerala due to shelf life criteria of drugs imposed by the State Licensing Authority, ADMA was advised to provide specific information for the Department to take appropriate action.

13. **Concluding the meeting with a positive note** Secretary (AYUSH) stated to have frequent dialogue with the industry in the changing scenario of regulatory needs and developments. It was suggested to form an umbrella industry association than to interact with several small associations and come forward with one voice on the issues that need consensual interaction with the Department.

The meeting ended with a vote of thanks to the Chair.

**Conference Room**

**ADMA Conference Room is available for Meetings/ Workshops**

**For enquiry, kindly contact the Secretariat**
ADMA Activities - Positive scope for Ayurveda reinforced

The long cherished dream of Ayurveda drug manufacturers in Kerala got accomplished when the national outfit of the manufacturers’ association, ADMA launched its’ Kerala Chapter and conducted a one day long Seminar in Cochin.

The dream was for a strong voice for Ayurveda Drug Manufacturers in Kerala who were otherwise scattered, lacking a platform and strong voice to air their views and represent their proposals or suggestions to various authorities. These disconnect between the authorities and the manufacturers were seriously tampering the hopes of the entrepreneurs in this field.

Since the ADMA south zone became active and could launch the Kerala Chapter, the Ayurveda drugs Manufacturers have now new hope and avenue to address their issues.

The seminar on Business Potential of Ayurveda in Domestic and International Market was conducted by the Ayurveda Drug Manufactures Association (ADMA) on September 22, 2013 at IMA Hall Cochin.

The daylong seminar was inaugurated by Mr. Balaprasad, Joint Secretary Department of Ayush. Chief Guest of the function was Mr. Hibi Eden, Honorable MLA; Ernakulam. The function had a very good representation from the stalwarts of Ayurveda Industry, Government, regulatory officials and subject experts.

The seminar had two plenary sessions, leading to presentations and discussions on business potential of Ayurveda in domestic and international markets.

Mr. Balaprasad in his inaugural speech put forth many critical points where Ayurveda can concentrate like health coverage to all, sustainable industrial growth, since the tribal communities are ambassadors and main procurement source for raw materials, according to him support and livelihood of tradition and tribal community should be ensured.

He also stated that Ayush has significantly contributed in standard setting for Ayurveda, Unani, Siddha and Homeo and due to these initiatives, signed many international contracts which would benefit the acceptance of the science world over.

He said that undoubtedly there are tremendous growth prospects in Domestic and Export Market and recommended a three point growth strategy for the Ayurveda Industry. According to him Ayurveda entrepreneurs should aim to grow big and implement innovative marketing strategies like China. All the more they should take advantage of all the statutory schemes since statutory schemes & regulations are aimed at realistic growth.

Mr. Hibi Eden Hon’ble MLA of Cochin reiterated the importance of more herbal cultivation in Kerala. He stated that even if raw materials are procured from outside states, importance should be given to organic raw materials. He also told that the abuse and misrepresentation of Ayurveda in the media should be stopped.

Mr. Shashank Sandu Treasurer, ADMA, detailed the about objectives and achievements of ADMA.

Prof. Keyoor Purani Associate Professor, Marketing Management IIM, Calicut in his key note address presented the theme of Rejuvenation of Ayurveda. He said about the need for Ayurveda to have young and fresh look – quoted the success story of Zandu balm. Generating general and practical awareness of Ayurveda should be a constant endeavour. He told that aiming youth and executive community, making ayurvedic products and services available at relevant premises can make it acceptable in this era.

Mr. Ranjit Puranik, Vice President (West), ADMA presented the main models of ayurveda industry which can be adopted. Food & Nutrition are two areas of potential where Ayurveda has good scope. Projecting Ayurveda as a comprehensive and high performance health solution, Ayurveda business through online initiatives and through presence in modern trade chain stores were the other major business models he pointed out for the growth of Ayurveda. He also discussed about the emerging Branded Ayurveda Clinics.

Mr. Chandrakant Bhanusali, Hon. General Secretary, ADMA, touched upon the present state of regulatory affairs and statutory schemes. He said that the Regulatory affairs should have realistic approach and user friendly regulatory practices are required. He instilled confidence among the crowd by stating that ADMA can guide and lead regulatory practices for Ayurveda entrepreneurs.

Dr. JLN Sastry, Dabur India Ltd opined that the regulatory acts put in together are not that complicated. But more awareness and preparedness to adhere to rules is to be taken on a proactive basis by all companies and entrepreneurs. He stated that AYUSH Department should come out to help licensing formalities by providing adequate knowledge base for licensing and clinical trials.

Dr. Amit Agarwal, Natural Remedies Pvt Ltd, explained about the product possibilities in different countries and the regulations in various countries. In US, dietary ingredients have good scope. In Newzealand/Australia complementary & Alternative medicines have a scope. Positive and negative list of herbs are different in different countries, such information is not readily available,
and it will be beneficial if Pharmexcil is able to publish such a list. Explained the process of acceptability of their brahmi based product in US and the hurdles they faced in introducing there. He also stated that the scientific data publishing should be with care, since those can become references for acceptability and rejection. Regulations like TGA were touched upon.

Global scope of Ayurveda & Regulations was presented by Dr. Baidyanath Mishra, Katra group. He told about the need of traditional medicines to be formalized. Touched upon the current challenges faced by Ayurveda. The importance of process validation and why validation process is required where also presented.

WHO GMP requirement VS Schedule T Compliance was presented by Mr. Nimish Shroff, Joint secretary, ADMA. He explained the various requirements under various factors for both WHO GMP & Schedule T to be complied by a manufacturing unit. It was particularly mentioned that all these are available in ACTS and is extremely expensive to implement.

Dr. P.V. Appaji, Director General, Pharmexcil concluded the session by stating that Ayurveda is having only a small stake in the whole pharma business in the world. He also added that Pharmexcil will help in all possible ways to better Ayurveda exports scenario.

The seminar witnessed active participation of ADMA officials Dr. P.M. Varier, Kottackal, Dr. Anilkumar, KAPL & Dr. S. Sajikumar, Dhathri who are the office bearers of South India.

Thus eminent speakers and experts from the industry contributed to the seminar and the participants were highly benefitted since there were discussions after each presentation and offered a platform for clearing their doubts and concerns. Many assurances and helping hands were extended by the Ayush, Pharmaexcil etc which gives new hope for the manufacturers.

We hope that in the future also ADMA will be able to make quantum leaps in such initiatives to protect and uphold the cause of Ayurveda and the drug manufacturers.

Compiled by Dr. S. Sajikumar, Chairman, Dhathri Group & Regional Secretary (South), ADMA
### Forthcoming Events

<table>
<thead>
<tr>
<th>Event Name</th>
<th>Organiser</th>
<th>Dates</th>
<th>Location</th>
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<tr>
<td>Ayurveda World Summit &amp; Expo 2014</td>
<td>Organised by Octagon Communications Pvt Ltd</td>
<td>14th to 16th February 2014</td>
<td>Gandhinagar, Gujarat</td>
<td>14th to 16th February 2014 at Gandhinagar, Gujarat. <a href="http://www.octogoncom.in">www.octogoncom.in</a></td>
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<tr>
<td>Global Ayurveda Festival &amp; Arogya Expo (GAF)</td>
<td>Organised by the Centre for Innovation in Science &amp; Social Action (CISSA), jointly with the Government of Kerala and the Ayurveda Fraternity of Kerala</td>
<td>20th to 24th February 2014</td>
<td>Kochi, Kerala</td>
<td>20th to 24th February 2014 at Kochi, Kerala. <a href="http://www.gaf.co.in">www.gaf.co.in</a>.</td>
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<td>The India Show 2014</td>
<td>Organised by Confederation of Indian Industry CIIthe</td>
<td>26th to 30th March, 2014</td>
<td>Almaty, Kazakhstan</td>
<td>26th to 30th March, 2014 at Almaty, Kazakhstan. <a href="http://www.cii.in">www.cii.in</a></td>
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<td>Gulf Food</td>
<td>Organised by ITPO</td>
<td>23rd to 27th February 2014</td>
<td>Dubai (UAE)</td>
<td>23rd to 27th February 2014 at Dubai (UAE). <a href="http://www.gulfood.com/">http://www.gulfood.com/</a></td>
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<td>Lyon International Fair</td>
<td>Organised by ITPO</td>
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<td>21st to 31st March 2014 at Lyon (France). <a href="http://www.foiredelyon.com">www.foiredelyon.com</a></td>
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<td>SAARC Trade Fair 2013-14</td>
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<td>Almaty, Kazakhstan</td>
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