Minutes of the Third Meeting of Ayurveda, Siddha andUnani Drugs Consultative Committee (ASUDCC) held on 25th August 2015 at New Delhi.

Third meeting of the Ayurveda, Siddha and Unani Drugs Consultative Committee (ASUDCC)was held in the Ministry of AYUSH, New Delhi on 25.08.2015 at 11:00 AM under the chairmanship of ShriJitendra Sharma, Joint Secretary (AYUSH). **The list of participants isannexed.**

The meeting started with welcome remarks from the Member Secretary, Dr. D.C. Katochfollowed by introduction of the Chairman and participating members. Opening remarks of the Chairman emphasized the need for taking effective steps of quality control of Ayurveda, Siddha and Unani Drugs to achieve the overall objective of providing safe and effective medicines to the society. He called upon the state representatives to ensure proper monitoring of the quality of raw materials, finished products and implementation of regulatory provisions in letter and spirit.

With the permission of the Chair, Member Secretary presented the agenda items for discussion and recommendations as follows:-

Agenda Item No.1: Confirmation of the Minutes of last ASUDCC meeting held on 12.11.2014

Members discussed the comments of Punjab and Odisha regarding qualifications of the Inspectors and the Drugs Controlling Officers. The minutes of last ASUDCC meeting were confirmed with the recommendation based on the inputs& views from the representatives of Rajasthan, Punjab, Tamil Nadu and Andhra Pradesh that essentiality of postgraduate Ayurvedic qualification of Rasashastra/Dravyaguna and equivalent qualifications of Siddha and Unani systems may be considered in the eligibility criteria for the appointment of ASU Drugs Inspectors and Drugs Controllers.

Agenda Item No.2: Action Taken Report on the minutes of last ASUDCC meeting of 12.11.2014.

The Action Taken Report on the minutes of last ASUDCC meeting was discussed and following recommendations were made:-

a) In view of the fact that as a follow up to the 2nd ASUDCC meeting many of the states have not provided status information regarding GMP implementation, functionality of State Drugs Testing Laboratories and testing of ASU drug samples, regular reporting of such information to the Ministry of AYUSH is required from the states. Members suggested for introducing an online mechanism for submission of such information. **States were urged to submit the required information by 30th September 2015.**

b) Regarding the inclusion of the list of medicinal plants submitted by Delhi and Chhattisgarh in the First Schedule of the Drugs & Cosmetics Act, it was decided that **the matter may be referred to Pharmacopoeia Commission of Indian Medicine and Homoeopathy (PCIM&H) and their comments/views bebrought up in the forthcoming meeting of the ASUDTAB.**

c) On the issue raised by the representative of National Medicinal Plants Board regarding the statutory requirement of submission of consumption data of raw materials by the licensed ASU drugs manufacturers, it was noted that such information has not been received from States despite repeated requests. Chairman ASUDCC informed that there are approximately 10,000 licensed manufacturers of ASU drugs; however National Medicinal Plants Board(NMPB) andits agency named CERPA specifically engaged to document such data, have information of nearly 2000 manufacturers only. He emphasized the importance of collecting such information for policy and planning related to cultivation of medicinal plants and for the quality of finished products. **State Licensing Authorities wererequested to direct all manufacturers under their purview for providing the desired consumption data of raw materials to NMPB on the specified email id- info-nmpb@nic.in by 30th September, 2015. It was suggested that State Licensing Authorities may collect raw materials' annual consumption data from the manufacturers and send it collectively to NMPB and Ministry of AYUSH.**

d) For the development of common acceptable software for maintaining data bank of licensed ASU&H manufacturers, products, laboratories etc, it was informed that a letter was issued on 10-12-2014 to the Commissioner & Licensing Authority for AYUSH, Gujarat for providing template of the software used by them but no response has been received.The representative of Gujarat informed that they don't have any software for AYUSH instead the State FDA makes use of software for Allopathic drugs. **After discussion it was decided that the software on which FDA Maharashtra is working for AYUSH drugs and the software for allopathic drugs used in Gujarat State may be sent in hard copy as well as soft copy to the Ministry of AYUSH.**

Agenda Item No.3: New amendments made under the Drugs & Cosmetics Rules, 1945

Member Secretary explained the two recent notifications made by the Central Government for prohibiting the use of any prefix and suffix with the names of classical ASU medicines by the manufacturers and appointment of Central Inspectors for joint inspection of the laboratories seeking grant of license under Drugs & Cosmetics Rules. The state representatives from Delhi, Gujarat, Odisha and Madhya Pradesh raised certain queries related to the amendment provisions for naming of patent & proprietary drugs, which were thoroughly discussed and adequately addressed. **ASUDCC recommended that State Licensing Authorities may take necessary steps to enforce the new regulatory provisions for appropriate licensing of ASU medicines and ensure that the products in the**

market are checked for correctness of their names on the labels and action is taken against the defaulters. States were also sounded to facilitate the approval of private Drugs Testing Laboratories in accordance with the provisions of Rule 160 B of the Drugs & Cosmetics Rules and forward such applications complete in all aspects to Drugs Control Cell of the Ministry of AYUSH for consideration of joint inspection by the Central and State inspectors. State-wise list of ASU Drugs Testing Laboratories approved under Drugs & Cosmetics Rules may be widely publicized and put in Central and State websites.

Agenda Item No.4: Enforcement issues of ASU drugs raised by the States

State representatives had submitted in advance certain enforcement issues of ASU drugs and some were raised in the meeting. ASUDCC members discussed these issues in detail and made point wise recommendations as under-

State	Issue	Recommendations/Remarks
Tamil Nadu	i) Release of more volumes of Ayurvedic, Siddha and Unani pharmacopoeias on formulations, at least 50 monographs of compound drugs is required to be brought out per year.	Matter noted and may be taken upwith the PCIM & H.
	ii) Insertion of new Rule for appointing Controlling Authority of ASU drugs or amendment of Rule 162 A for its applicability to both SLA and Controlling Authority.	The point was noted for discussion during the forthcoming meeting of ASUDTAB.
	iii) Development of a standard protocol of clinical trial for generating proof of effectiveness as required under Rule 158-B in respect of guidelines for issue of license to Ayurveda, Siddha and Unani Drugs.	It was informed that the Ministry of AYUSH is in the process of publishing a document entitled "Requirements and Guidelines for approval to conduct clinical trials of Ayurvedic, Siddha and Unani (ASU) drugs" which will be a guiding tool to submit the application seeking permission to conduct clinical trials for generation of scientific data in respect of validation of ASU drugs. Ministry has already published the Guidelines for Good Clinical Practices (GCP) for conduct of clinical trials in ASU systems which the States may refer.

	iv) Supply of certified reference materials/markers by PLIM to all State Drug Testing Laboratories	The point was noted and it was informed that the matter will be taken up with PCIM & H.
	v) What is the progress on the observations & recommendations of ASUDCC on the draft Bill for New Act for ASU Drugs referred under the Agenda No. 7 in minutes of the 2nd meeting of ASUDCC held on 12.11.2014?	It was informed that the Ministry of AYUSH constituted an Expert Committee to prepare the draft Indian Medicine and Homoeopathy Bill. The exercise has been completed and in the meantime there is a new development by the Central Government for inclusion of AYUSH drugs related fresh provisions in the proposed amendment of the Drugs & Cosmetics Act.
	vi) Steps should be taken to make available certain banned animal parts and plant materials, which are required for the preparation of important classical Siddha drugs.	The point was noted and it was decided to take up the issue with the Ministry of Environment, Forests and Climate Change keeping in view the provisions contained in the National Biological Diversity Act / other laws. The States were advised to share as which species of Coral, Deer Horn, and other materials are required.
	vii) More authoritative books of ASU systems should be included in the First Schedule of Drugs and Cosmetics Act 1940 otherwise there could be a forced problem of licensing classical formulations as patent or proprietary drugs..	It was informed that the proposal of expanding the list of authoritative ASU books contained in the First Schedule has already been considered by the ASUDTAB and Ministry has initiated the process for amending the First schedule of the Drugs & Cosmetics Act.
Mizoram	(1) Standards of commonly sold extracts/juices of Amla, Aloe veraetc, which are also used in the preparation of ASU drugs, are required and a database of such preparations should be developed for adoption of a uniform system throughout the country.	The point was noted and house was informed that the uniform parameters for standardization of raw materials as well as finished products asdone in case of ASU drugs need to be followed by the States.

	(2) Manufacturing of drugs/medicines by the Local Traditional Practitioners should be in compliance to the licensing requirements for ASU drugs.	The point was noted for consideration and it was informed that the registered practitioners are exempted from the provisions of the Drugs and Cosmetics Act and Rules for preparation of medicines for their individual patients. It was advised that the State Governments in North Eastern Region need to appoint Licensing Authorities for ASU drugs to examine such cases and consider granting license to the establishments complying with the regulatory parameters.
	(3) Central Government may consider to support setting up a well-equipped Drug Testing Laboratory at Zonal or Regional level.	The point was noted and it was advised that the State Governments, where public drugs testing facilities do not exist, should appoint officers to pick up samples of ASU drugs from the market for the purpose of getting them tested from the NABL accredited laboratories or from the approved laboratories notified under the Drugs & Cosmetics Rules.
Delhi	i) Regulations for sale and stock of ASU raw materials are required.	The point was noted and it was agreed that there is indeed a need to evolve regulatory provisions for licensing or registration of sellers and stockistsofraw materials of ASU drugs. It was also felt that steps need to be taken for promoting selling of pre-tested / certified raw materials by the vendors.
	ii) Provisions of repackaging of ASU medicines for sale are needed in the Drugs &Cosmetics Act.	The point was noted and the State representatives were asked to suggest the provisions for regulating repackaging of ASU medicines.
	iii) Development of Software is required for listing of approved medicines as well as online submission and disposal of applications under the Drugs & Cosmetics Rules.	The point was noted and the State representatives were asked to suggest draft software to be discussed with the NIC Division in the Ministry of AYUSH.

	iv) Uniform Implementation of Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 and guidelines by all the states.	It was informed that States have been directed to appoint Gazetted Officers for monitoring inappropriate and misleading advertisements of ASU drugs and take necessary action against the defaulters. Central Government is also in the process of amending the Drugs & Cosmetics Rules, 1945 to control the menace of misleading advertisements. Members agreed that instead of granting approval or any certificate to the advertisement, the contents of the proposed advertisement may be 'noted' by the concerned State Licensing Authority and surveillance be done to penalize the cases of contravention.
	v) Uniform structure of State Regulatory framework is required for ASU & H Drugs.	The point was noted and it was informed that the matter has already been discussed in the 2nd meeting of ASUDCC and follow up action is being taken.
	vi) Amendment/Updationof First Schedule of the Drugs & Cosmetics Act may be undertaken to include certain herbal ingredients like Soyabeen, Tomato, Ginkgo biloba, Gurana, YasarGumba etc., which are commonly consumed but not included in the reference books of First Schedule.	The house was informed that the revision of list of authoritative books contained in the First Schedule of Drugs & Cosmetics Act, 1940 is under consideration and such regulatory amendment is initiated with the recommendation of ASUDTAB.
	vii) Amendment in Schedule 'T' for redesigning of categories /dosage forms of ASU medicines and regulations for sale and stocking of ASU products are required.	These points were noted for larger consultation to make a considered view.
Kerala	i) What is the position of the proposed separate Act for AYUSH drugs ?	Position as stated earlier in the meeting was explained.
	ii) Implementation of Sale Licence/Registration System for the ASU Drugs selling units andstockists.	The point was noted for further consideration.
	iii) Registration or Licensing System for	

	sale of raw drugs.	The point was noted and it was informed that standards of raw materials and of compound formulations as given in the ASU pharmacopoeias must be enforced across all the states to maintain quality control. Participating members appreciated the importance of keeping check over the sale of raw materials & manufactured drugs and proposed measures like the provision of sale license for schedule E-1 drugs, submission of proposals of voluntary licensing under National AYUSH Mission, third party assessment of ASU manufacturers by agencies like QCI to ensure use of certified raw-materials.
	iv) Required number of quality control personnel in the State?	It was advised that such requirement of appointing quality control personnel should be considered on case to case basis by the State Governments.
	v) Implementation of the provisions of Biodiversity Act and Wildlife Protection Act is hindering the supply and availability of certain important medicinal materials of ASU drugs, amendments are required.	The points were noted for taking up with the Ministry of Environment, Forests and Climate Change. The States were advised to promote the cultivation of medicinal plants for which support is provided under the National AYUSH Mission. It was advised that the State Licensing Authorities and the manufacturers under their purview should be sensitized about the guidelines of Access and Benefit Sharing (ABS) related with the use of Bio-resources under the Biological Diversity Act.
	vi) Development of Common Acceptable Software for regulatory purpose.	Maharashtra and Gujarat state representatives in the ASUDCC meeting were asked to send the hard and soft copies of the software used in their states to the Ministry of AYUSH.
	vii) Export of ASU products need to be controlled.	It was informed that export related provisions for ASU products do not exist in the Drugs and Cosmetics Act and Rules thereunder.

	viii) Implementation of Research Wing along with Enforcement Mechanism.	No discussion was held as this issue was not in the purview of ASUDCC.
	ix) Enhancement of punishment provisions under DMR(OA) Act 1954.	It was informed that Ministry of Health & Family Welfare constituted a Task Force including two Ayurveda Officers to look for required amendment of the Act for effective implementation and framing of specific provisions is in consideration of Ministry of AYUSH to regulate ASU drug advertisements under Drugs & Cosmetics Rules.
	x) Issuing of licence for Extracts and Balya/poshak/positive health promoter formulations.	It was informed that Rule 158-B of the Drugs & Cosmetics Rules, 1945 has the provisions for licensing requirements of various extracts and Balya/Poshak/Positive health promoter formulations.
	xi) Price Control Authority for ASU drugs	Price control of drugs is not in the mandate of Drugs & Cosmetics Act and Rules, hence not discussed.
Andhra Pradesh	i) Issues regarding submission of raw materials consumption data by the ASU drug industry, development of Common acceptable software for regulatory purpose, implementation of Drugs and Magic Remedies (Objectionable Advertisement) Act, 1945 and recent amendment of Drugs & Cosmetics Rules were raised.	Members were informed of the actions taken and being taken on these issues.
	ii) Strengthening of Quality Control System is required.	Provisions of the National AYUSH Mission Scheme for supporting states to take up quality controlinitiatives and strengthening of enforcement framework were explained. It was informed that in 2015-16, so far quality control related proposals of 18 states have been approved under National AYUSH Mission. State authorities need

		to work out proper proposals of quality control activities and include them in the State Annual Action Plans.
	iii) Single Window Clearance System is required in regulatory circles as adopted in Andhra Pradesh under the state initiative of APSWCS	The point was noted for further consideration.
Meghalaya	i) Training facilities to enforcement personnel are required.	It was informed that the training programs for regulatory and quality control staff members of the states are periodically conducted at Pharmacopoeial Laboratory of Indian Medicine (PLIM), Ghaziabad. States can depute officers for these training programs, boarding & lodging facilities are provided by PLIM.
	ii) Accreditation of laboratories is needed.	It was informed that Rule 160 A to J of the Drugs & Cosmetics Rules is meant for accreditation or approval of laboratories engaged in testing of ASU drugs.
	iii) Internet Facility to State Enforcement Agency is required.	It was informed that States can avail support for this purpose by projecting their requirement under the component of strengthening of drugs enforcement framework of the National AYUSH Mission scheme. However, the point was noted for further consideration.
Dadar& Nagar Haveli	i) Licensing for sale of Ayurvedic medicines may be introduced.	The point was noted for appropriate consideration.
	ii) Norms for clinical trials and scientific aspects of such trials of Ayurvedic drugs should be framed.	It was informed that the Ministry of AYUSH is in the process of publishing a document entitled "Requirements and Guidelines for approval to conduct clinical trials onAyurvedic, Siddha and Unani (ASU) drugs " which will be a guiding tool to submit the application for seeking permission to conduct clinical trials for generation of scientific data required for validation of ASU drugs.

	iii) Issues of misleading advertisements of Ayurvedic drugs and other herbal product need to be addressed.	It was informed that the proposal of amendment of Drugs & Cosmetics Rules for bringing specific regulatory provisions for advertisements of ASU drugs is under consideration of the Government.
Karnataka	i. Inclusion of Cosmetics under Drug & Magic Remedies (Objectionable Advertisements) Act 1954.	Task force set up by the Ministry of Health & Family Welfare is looking in to the required amendment of Drugs &Magic Remedies Act.
	ii. Formation of Committee to scrutinize the advertisement material & issue of 'No Objection Certificate.	It was informed that Drugs & Magic Remedies Act has a provision for appointing Gazetted Officers to supervise advertisementsand take necessary action. New provisions in Drugs & Cosmetics Rules for regulation of ASU drugs advertisements, which are under consideration of Government, will help addressing inappropriate advertisements.
	iii. Provisions for regulation of sale &stock of raw materials, appointment of Controlling Authority for ASU drugs and trainingof regulatory officers are required.	These issues have been discussed earlier with actions recommended for addressing them.
	iv. Need for price control of Ayurvedic, Siddha, Unani& Homoeopathic Drugs and provision of NOC for import of herbal raw materialsis required.	Points were noted for consideration.
Puducherry	i) Incorporation of sale licensing procedure similar to allopathic &homeopathic medicines may be done for Ayurvedic, Siddha &Unani Medicines (Rule No. 59 to 67H as per Drugs & Cosmetics Act 1940 & rules 1945.	The point was noted for further consideration.
	ii) AYUSH medical institutions with pharmacies should be registered under the Clinical Establishment Act to obtain sales license.	No discussion was held as this issue does not come under the purview of ASUDCC.

	iii) All ISM Pharmacies should have pharmacists as registered under the same discipline as done in the Puducherry Pharmacy Council.	It was informed that the Indian Medicine and Homoeopathy Pharmacy Central Council Bill is under consideration for the purpose of regulating pharmacy education and profession of Indian Medicine & Homoeopathy.
	iv) Good Laboratory Practices – under Schedule L with requirements of premises, equipmentetc should be applicable for testing of Ayurvedic, Siddha and Unani medicines.	It was informed that amendment of the Drugs & Cosmetics Rules for inclusion of GLP for ASU drugs testing laboratories isalready under consideration.
	v) To bring out the list of approved medicines as listed by DCGI in allopathic side.	It was informed that Ministry of AYUSH has published Essential Drug Lists of Ayurveda, Siddha, Unani and Homeopathy for facilitating supply of medicines to state dispensaries and hospitals.
	vi) Price control order may be issued for the ISM drugs which are sold at exorbitant prices.	Point was noted but no discussion was held since this issue does not come under the purview of ASUDCC.
Haryana	Modification in the list of diseases mentioned in Schedule-J of the Drugs &Cosmetics Act 1940 is required to accommodate ASU drugs.	It was informed that these concerns would be addressed with the proposed amendment in Drugs & Cosmetics Rules for controlling the contents of ASU drugs advertisements.
Chhattisgarh	Training for ASU Drug Inspectors	It was informed that the training facilitiesfor regulatory officers including Drug Inspectors are provided from PLIM, Ghaziabad. State may depute inspectors for training at PLIM.
Rajasthan	Control over ASU advertisements is needed, for which a Nodal Officer in every State may be appointed in each state to supervise the advertisements appearing in print and electronic media and report to the State Authority.	It wasinformed that necessary amendment in the Drugs &Cosmetics Rules recommended by ASUDTAB is under consideration.
Punjab	All the notifications made by Ministry of AYUSH should be made available on the website for easy access.	The suggestion was noted for taking necessary action.

Manipur	i) A Censor Board at the Central level be set up to monitor the contents of advertisements related to ASU drugs.	It was clarified that that licensing of ASU products being a State subject; it would not be feasible to have a central body for the purpose of controlling advertisements.However, the proposal of having a Nodal Officer in each state to monitor such advertisements is worth consideration.
	ii) For want of separate State Drug Licensing Authority for AYUSH in the State, the enforcement of regulatory provisions related to AYUSH drugs is vested with the Director of Health Services, who is an allopathic doctor. In this regard, Ministry of AYUSH may consider writing to the Manipur Government to create a separate State Drug Licensing Authority for AYUSH.	The state-specific issue was noted.
Uttar Pradesh	Need for Price Control and regulation of media contents related to ASU drugs from central level.	It was informed that licensing of ASU products being a state subject and multiple media channels operating in the states, it would not be feasible to have a central control system for the advertisements. However, the issue of price control of ASU drugsis worth consideration.
West Bengal	Submission of efficacy as well as safety data (where ever applicable) should be the pre-requisite for licensing of ASU drugs.	It was informed that Rule 158-B of the Drugs & Cosmetics Rules 1945 related to licensing guidelines provides for the necessity of submission of safety data and proof of effectiveness for various categories of ASU drugs.

Agenda Item No.5: Enforcement of the provisions of Drugs & Magic Remedies (Objectionable Advertisements) Act 1954 relating to ASU drugs.

The Chairman enquired from the participating State representatives their views about the provisions required for regulating advertisements of ASU drugs with the proposed amendment in the Drugs & Cosmetics Rules and the status of enforcement of the provisions of Drugs and Magic Remedies (Objectionable Advertisements) Act in relation to ASU drugs advertisements, particularly the number of officers authorized by the states under section 8 (1) of the Act. Member Secretary informed that in response of Ministry's repeated letters to the States, information regardingappointment of officers under DMR Act has been received from 23 states and some of the states have recently notified Nodal

Officers for monitoring of ASU drugs advertisements. Whereas, such information from remaining states is awaited, the states have not provided the details of the actions taken against the cases of violation of legal provisions. **It was recommended for the States to send therequired informationbythe endof September2015 including the actions taken during the last three years and the outcome of notices issued by the authorities to the defaulters under the provisions of Drugs & Magic Remedies Act.** ASUDCC members elaborately discussed the suggestion of the representatives ofRajasthan, Punjab, UP, Mizoram and Manipur for having the contents of the advertisementsvetted or approved by the concernedState Licensing Authority.Considering the possible implications of adopting such a procedure **all participants agreed with the intervention of Chairman that instead of granting any certificate or approval to the advertisement materials, it is advisable to keep the provision of noting or recording the contents of the intended advertisements and surveillance be done to find any deviation in the advertisements of ASU drugs so allowed.**

Agenda Item No.6: **Strengthening of Drugs Quality Control system in the States.**

Dr D.C. Katochpresented the details of providing financial support for quality control activities of the states under National AYUSH Mission. It was informed that the objective of Quality Control of ASU&H drugs can be achieved by availing grant-in-aid under National AYUSH Mission for the following purposes -

i) Establishment or strengthening of State Drugs Testing Laboratory
ii) Engagement of technical manpower in the existing Drug Testing Laboratory.
iii) Establishment or strengthening of ASU&H pharmacy
iv) Strengthening of regulatory/enforcement framework for ASU&H drugs
v) Documentation, publication and dissemination of quality control materials
vi) Testing of ASU&H drugs supplied to the health facilities and picked up from the market.
vii) Any innovative activity related to drugs quality control under flexible component

Dr Katoch told that during the financial year 2015-16 proposals of 22 States so far have been received and considered in the Ministry for providing financial support. Only 18 proposals had projected the requirement of funds for drugs quality control and that too in many cases were weak. **State representatives were advised to interact with the concerned officers in working out proper proposals for strengthening of regulatory and quality control system for ASU&H drugs and submit these proposals as well as supplementary proposals in time.**

With completion of agenda-wise discussions the Chairman made concluding remarks emphasizing the need for prompt and appropriate actions on the recommendations of ASUDCC. States were specifically urged to submit expeditiously the information related to enforcement of the provisions of Drugs & Magic Remedies Act, consumption data of raw materials from the individual ASU drugs manufacturers, status of Drug Testing Laboratories and list of licensed AYUSH drugs manufacturers.

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