



# Indian Systems of Medicine (Ayurveda, Siddha, Unani) and issues for regulating TM at International level

Verghese Samuel, Joint secretary

**Dr. Manoj Nesari, Deputy Adviser (Ayurveda)**

Dr. D.R.Lohar, Director (PLIM)

Department of AYUSH

Ministry of Health and Family Welfare

Government of India

# Regulatory and administrative setup

Govt. of India

Ministry of Health and Family welfare  
Department of AYUSH





# DEPARTMENT OF AYUSH

**A – AYURVEDA**

**Y – YOGA & Naturopathy**

**U - UNANI**

**S – SIDHA**

**H - HOMOEOPATHY**

# AYURVEDA



- Ancient system of Medicine
- Focus on the prevention of diseases as well as promotion of health
- Medicines mainly based on herbal formulations
  - Animal products, minerals and metals are also used in medicines.
- Time tested, Safe and efficacious
  - **Compendia of systematized health knowledge like *Charak Samhita and Sushrut Samhita* were written around 1000 years B.C.**
- “Sushruta” the father of plastic surgery

# Unani System of Medicine



- Originated in Greece and accepted in India since 13<sup>th</sup> century
- Similarity with Ayurveda
- Mainly Herbal formulations
- Time tested

# Siddha System of Medicine



- Practiced in southern parts of India
- Similarity with Ayurveda
- Herbo-mineral formulations
- Time tested.

# YOGA



- **Yoga has a very long history and is as old as civilization**
- **The first archaeological evidence of existence of Yoga is found in stone seals that had been excavated from the Indus Valley Civilizations (3000 B.C).**
- **The basic aim is not therapy but to promote Health, Harmony and Happiness**
- **Drug less therapy**

# POLICY FRAMEWORK

# Regulatory



- Ayurveda, Unani, and Siddha practices are the recognized systems of medicine by law.
- License to practice – by State (Provincial) Govt. Registration authority.
- Indian systems of medicine were looked after by the Ministry of Health after Independence.
- Establishment of **separate** Dept. for Indian system of Medicines – Dept. of AYUSH 1995
- Separate national policy on AYUSH - 2002

# Drug Development and Manufacturing



- **Drugs & Cosmetics Act, 1940 contains provision to regulate manufacture of Ayurveda, Siddha, Unani medicines.**
- **Pharmacopoeia Committees set up to lay down Pharmacopoeial standards.**
- **Implementation of GMP**
- **Setting up apex Pharmacopoeia Laboratories – 1970.**

# Research



- **Established National Research Councils for Ayurveda, siddha and Unani in the 1970's for Research in all streams of Indian TM.**
- **Encouragement for interdisciplinary research.**
- **Designing of Golden triangle Partnership Program – CCRAS + ICMR + CSIR**
- **Extramural research scheme.**
- **Promotion for Research in educational institutes**
- **Development of GCP guidelines for clinical Research in AYUSH sector.**

India



# **AREAS OF STRENGTH OF AYURVEDIC MEDICINE WHERE RECENT RESEARCH HAS YIELDED LEADS**

- **ANTISTRESS AND NEURO ACTIVE DRUGS**
- **IMMUNOMODULATORS AND ADAPTOGENS**
- **ANTIARTHRITIC DRUGS**
- **CARDIO PROTECTIVES AND HYPOLIPIDAEMICS**
- **ANTI DIABETICS**
- **PANCHAKARMA AND KSHARSUTRA TREATMENT**

# Education



- **Central Council of Indian Medicine (CCIM) the regulatory body for Ayurveda, Siddha & Unani systems established under Indian Medicine Central Council Act, 1970.**
- **Central Council of Homeopathy**
- **5 ½ Years Degree Course (BAMS, BSMS, BUMS). Uniform syllabus and institution Standard throughout India for quality education. Modern subjects incorporated in syllabus along with system specific subjects.**
- **Board of studies for each subject in Universities.**
- **3 Years Post Graduate Course (M.D.)**
- **Ph.D.**
- **All Courses conducted in University approved Colleges and recognized by Councils.**

# Institute of Post Graduate Teaching and Research in Ayurveda



Dr. Manoj Nesari (INDIA)  
drnesari@gmail.com

WHO Congress on TM Beijing,  
China. Nov. 7<sup>th</sup> 2008

# Institute of Post Graduate Teaching and Research in Ayurveda Jamnagar

- Only Institute exclusively for Post graduate studies and Research in Ayurveda
- Established in 1956
- Facility for full term post graduate courses for foreigners.
- National Center for Pharmacovigilance in Indian Systems of Medicine.

# NATIONAL INSTITUTE OF AYURVEDA Jaipur

The Institute imparts teaching and training for -

- Under-Graduate (BAMS) –
- Post-Graduate (MD- Ayurveda) –
- Ph.D. program.- –
- Foreigners Training program.

**Fully equipped teaching hospital**

## **OTHER FACILITIES**

- Classrooms well equipped with latest Audio Visual facilities
- Highly qualified and experienced faculty.
- Use of latest Information Technology for teaching & Research.
- Ayurvedic Drug Manufacturing Unit.



# Indian systems of medicines - Infrastructure

- **Teaching Institutions** **485**
- **Students Admission Capacity** **25,000**
- **No. of Institutionally qualified**
- **Regd. Practitioners.**  
**6,00,000**
- **Drug Manufacturing Units** **> 9,000**
- **Hospitals** **3,192**
- **Hospital beds** **60,237**
- **Dispensaries** **21,376**

# Medicinal Plants



- **The backbone of Indian systems of medicine.**
- **Forests as main source of Raw material**
- **Over use resulting in near extinction of some plant species.**
- **National Medicinal Plants Board**
- **30 State Medicinal Plant Boards**

# Activities of National Medicinal Plant Board

- to coordinate the activities of development of medicinal plants sector in a concerted manner.
- To streamline Conservation & Cultivation, Demand & Supply, Research & Development, Trade & Export, Quality Control & Standardization of medicinal plants & products.
- prioritized 32 medicinal plants for large-scale cultivation through organic farming and use of agro-technology.

# Some Important Medicinal Plants used in Ayurveda:

- **Brahmi (*Bacopa Monnieri*)** : regulates brain biogenic amines and enhances cognitive skills.
- **Ashwagandha (*Withania somnifera*)**: Relieves Stress and Anxiety.
- **Arjuna (*Terminalia arjuna*)**: Effective in management of CVD. Good cardio-protective
- **Guduchi (*Tinospora cardifolia*)**: Immunomodulator.
- **Vijay Saara (*Pterocarpus marsupium*)**: Anti diabetic
- Database on medicinal plants 1-7 Volumes published by CCRAS



# COMPONENTS OF AYURVEDA and Unani MEDICINES

- **Herbal** : **90-95 %**
- **Minerals** : **1-2 %**
- **Metals** : **1-2 %**
- **Animal Products** : **1-2 %**
- **Marine Products** : **1-2 %**

**These are used in single and multiple ingredients formulations**

# AYURVEDIC PHARMACOPOEIA OF INDIA [API]

❖ ABOUT 800 SINGLE DRUGS AND 1000 COMPOUND FORMULATIONS ARE COMMONLY USED IN INDIA.

❖ SIX VOLUMES OF API PUBLISHED.

- VOL -I 80 drugs
- VOL -II 78 drugs
- VOL- III 100 drugs
- VOL -IV 68 drugs
- VOL-V 92 drugs
- VOL-VI 101drugs
- Total single drugs 519
- Part II Vol. I 50
- Part II Vol II 51
- (compound formulations)

# TRADITIONAL KNOWLEDGE DIGITAL LIBRARY

- Collaborative work of Dept. of AYUSH and NISCAIR (CSIR)
- To protect the ancient and traditional knowledge of the country from misappropriation such as bio-piracy and wrong patents.
- Formulations from classical Ayurveda, Unani, Siddha and Yoga practices from classical texts have been digitized
- in five languages — English, German, French, Spanish and Japanese.

# Integration of Indian systems of medicine in Public health



Nov. 7<sup>th</sup> 2008 Beijing,  
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WHO Congress on TM

Dr. Manoj Nesari (INDIA)  
drnesari@gmail.com

# AYUSH in Public Health

- Health care needs of rural population in India is catered by ISM (**Indian system of Medicine**) practitioners.
- **6 lakhs institutionally qualified Ayurveda, Siddha, Unani practitioners** at sub centers/PHC after proper training in Public Health and National Health Programme such as disease control programmes, MCH immunization etc.
- Integrate and mainstream ISM in health care delivery system including the National Programmes. Co-locate ISM facilities with those of Modern Medicine hospital as to provide choice of treatment to the patient.

# Steps taken by Dept. of AYUSH to Integrate Indian systems of Medicine in Public Health Delivery

- Propagation Through IEC
  - Ayurvedic therapies like Ksharasutra, Panchkarma through IEC components
  - National campaigns–
    - Geriatric Care through Ayurveda and Siddha.
    - Mother & Child Health Care in Homoeopathy.
    - Ano-rectal diseases through Ksharasutra.

# Physical Integration and training

- All PHCs to have an Ayurveda /Siddha /Unani /Homoeopathy doctor.
- Qualified ASU&H practitioners appointed in Public health establishments
- Indian Public Health Standards (IPHS) finalized for CHCs/PHCs envisaging ASU&H facilities.

# Status of Integration



- Ayurveda/Siddha/Unani/Homoeopathy Units in 208 District Hospitals, 996 CHCs and 3842 PHCs.
- Appointment of ASU&H doctors in 2199 CHCs and 1683 PHCs.
- 27 States projected ASU&H components.
- Drug kit expanded to include Ayurveda, Siddha and Unani drugs having proven efficacy.

# Issues for Discussion

- WHO-COPP (Certificate of Pharmaceutical products) pharmaceutical guidelines read with supplementary guidelines for herbal medicines should be accepted for market authorization and International trade of herbal drugs.
- Harmonization of pharmacopoeia standards.
- Pharmacopoeia standards developed by India should be accepted for market authorization of ASU (TM) medicines.
- WHO permissible limits for heavy metals etc. in herbal medicines should be accepted for international trade.

# Issues ctd.



- Classical ASU (Ayurveda, Siddha, Unani) medicines to be excluded from the requirement of geno-toxicity data.
- Quality and Safety should be based on the holistic effect and not on the basis of any isolated chemical constituents. E.g. *Plumbago zylanica*.
- WHO in consultation with IRCH should evolve model formats and guidelines for use by all National drug regulation for market authorization of Traditional herbal Medicinal products.

# Issues Ctd.



- WHO guidelines (Under publication) on training and safety in Ayurveda, should be the basis for regulation of teaching and practice of traditional Medicine.
- National guidelines like guidelines on Basic training and safety in *Panchakarma* should be used by other countries.



**Thank you**