AYURVEDA IN EUROPE: HURDLES, CHALLENGES AND WAY-FORWARD

International conference-cum-exhibition on Ayurveda

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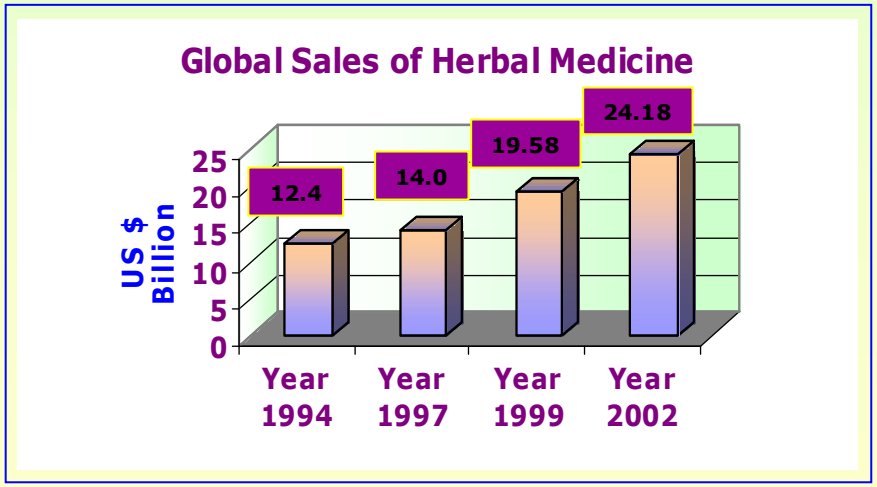
C K Katiyar
Director
Herbal Drug Research
Ranbaxy Research Laboratories
Gurgaon-122 001, India
chandra.katiyar@ranbaxy.com

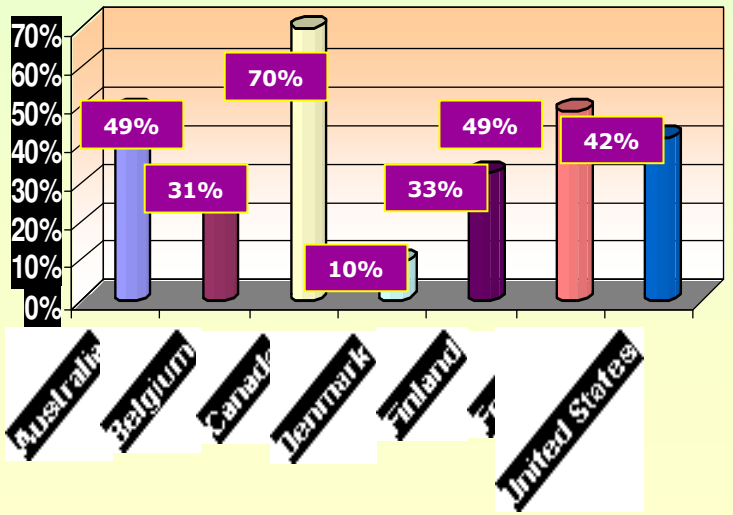
GLOBAL SCENARIO

GLOBAL HERBAL MARKET
INCL NUTRACEUTICALS
$ 70.4 BILLION

EXCLUSIVE
GLOBAL HERBAL MARKET
$ 24.2 BILLION



% Population using CAM in some Industrialized Countries

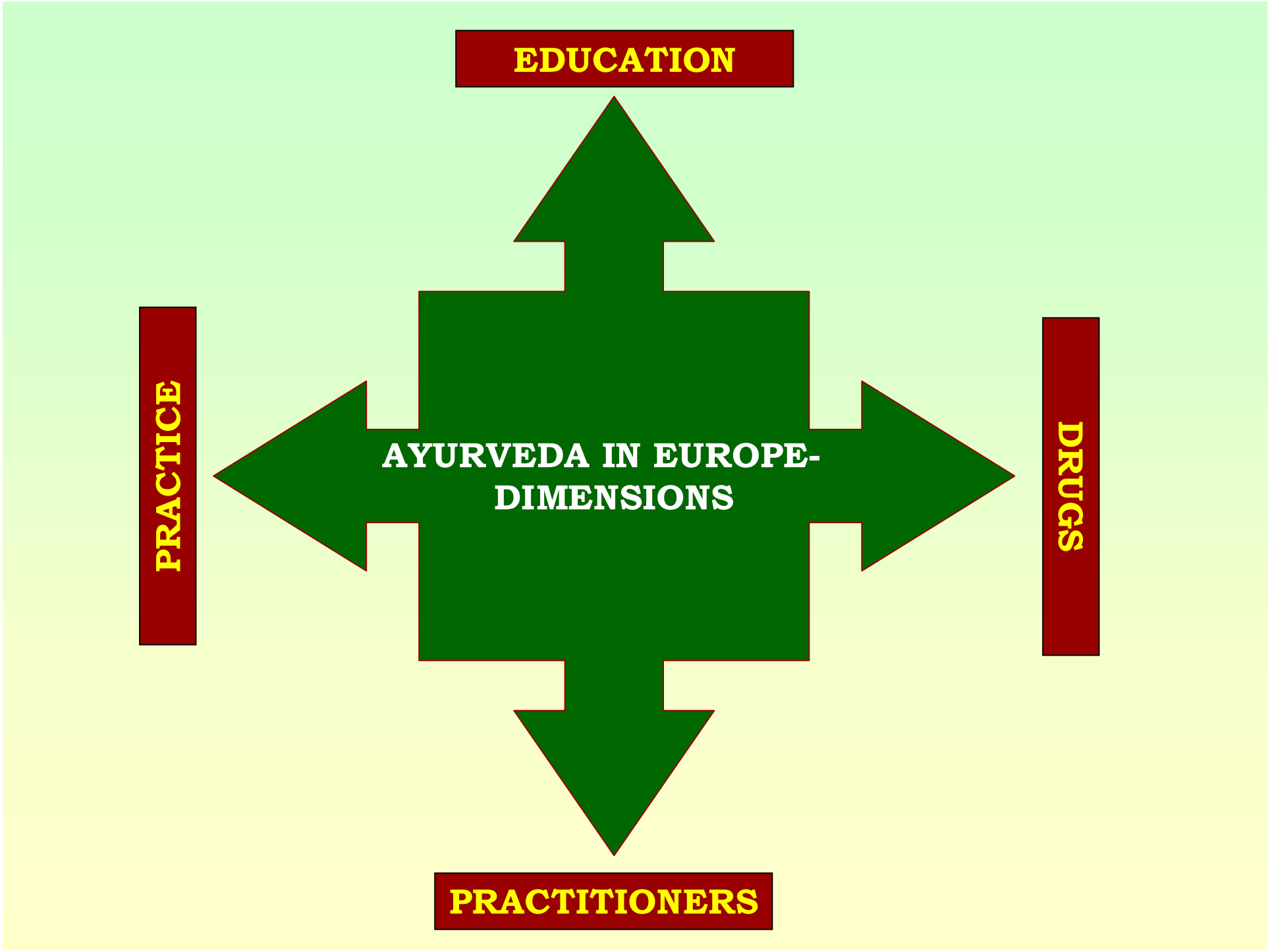


USE OF CAM IN THE UNITED KINGDOM

CAM	1999 (%)
Use of any CAM in past 12 months	20
Of which: *	
Herbal medicine	34
Aromatherapy	21
Homeopathy	17
Acupuncture / acupressure	14
Massage	6
Reflexology	6
Osteopathy	4
Chiropractic	3

**: Percentages of those who had used CAM. It must be noted that some individuals use more than one Therapy and thus the numbers above do not add up to 100.*

Ernst, E. & White, A. 'The BBC Survey of Complementary Medicine Use in the UK' in *Complementary Therapies in Medicine*, 8 (2000), 32-36.


EDUCATION
PRACTICE
AYURVEDA IN EUROPE-
DIMENSIONS
DRUGS
PRACTITIONERS

EDUCATION

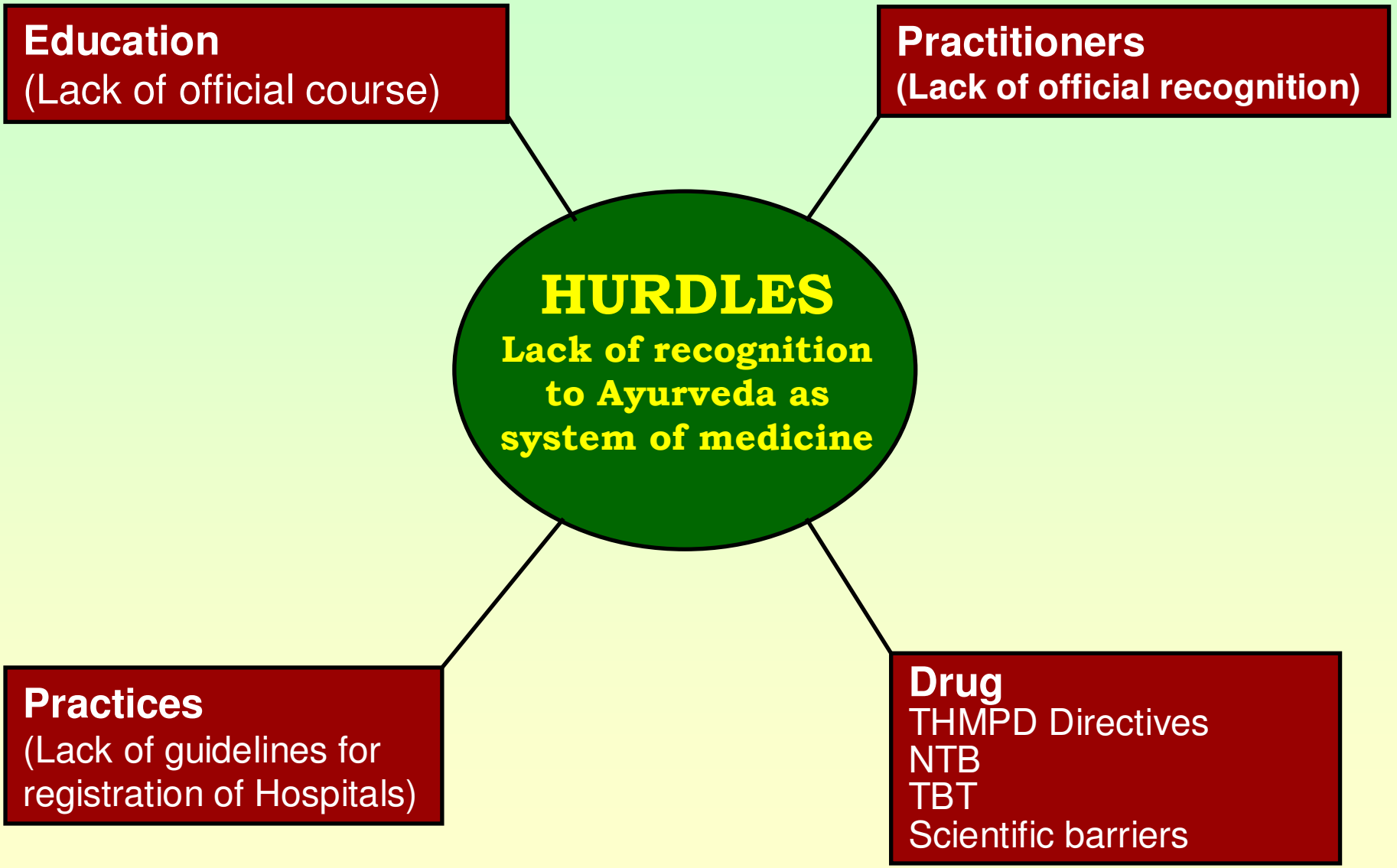
India	Europe
BAMS – - University Degree - 4.5 year course - 1year internship - Registration	Recognition of Course? Course content ? Duration of course ? 1-3 Yrs. Practical demonstration? Internship?

PRACTITIONERS

India	Europe
BAMS Degree - State/Central registration	Legal status ? Minimum eligibility criteria ?

PRACTICES

India	Europe
Ayurveda	Ayurveda
- *Pancha karma*	- *Pancha karma*
- *Shirodhara*	- *Shirodhara*
- *Ksharsutra*	- Massage
- Leach therapy	Yoga
- Massage	
Yoga	


Education
(Lack of official course)
Practitioners
(Lack of official recognition)
HURDLES
Lack of recognition to Ayurveda as system of medicine
Practices
(Lack of guidelines for registration of Hospitals)
Drug
THMPD Directives
NTB
TBT
Scientific barriers

What THMPD Offers?

- Provides conditional simplified registration to traditional medicines
- Amends article 16 of 2001/83/EC as regards traditional herbal medicinal products for oral or external use or inhalation fulfilling certain criteria
- Transition period till March 2011
- Used exclusively for traditional indications without medical supervision
- Traditional use data shows safety and efficacy in the proposed conditions of use
- Combinations with vitamins and minerals where their presence is ancillary to the herb

Hurdles- THMPD

NON TARIFF BARRIERS

- 15/30 Year use
- Positive list of plant monographs
- Cost of testing of multicomponent drugs
- Non equal treatment with Homeopathic medicine

Cost of Testing- Financial Barrier?

- Single herb stability study per packaging $ 20,000 per item
- A four herb combination tablet per packaging - $ 57,000
- QA and stability testing of a Herbal tea with 2 ingredients - $125,380

Ref: HerbalGram. 2006; 70: 62-66

Hurdles- THMPD

TECHNICAL BARRIERS TO TRADE

- Non availability of mutually acceptable guidelines on safety and efficacy
- Non-recognition of Ayurvedic Pharmacopoeia
- GMP requirements
- Genotox and Bio-assays
- Quality requirement of multicomponent drugs
- Heavy metal limit

HEAVY METAL PARAMETERS IN CRUDE HERBAL RAW MATERIALS

HEAVY METALS

Sr. No.	Pharmacopoeia	Heavy Metals	Limits (ppm)	Method	Ref. Source
01.	United State Pharmacopoeia(USP)	Total	NMT 20	Colorimetric	USP 2005
02.	European Pharmacopoeia (EP)	Pb Cd Hg As	NMT 5 NMT 0.3 NMT 0.1 NMT 2	Atomic Absorption Spectrometry	EP 2002
03.	British Pharmacopoeia (BP)	Pb Cd Hg As	NMT 5 NMT 0.3 NMT 0.1 NMT 2	Atomic Absorption Spectrometry	BP 2004
04	Indian Pharmacopoeia (IP)	Total	NMT 20	Colorimetric	IP 1996
05.	Indian Herbal Pharmacopoeia (IHP)	**Not Mentioned**			
06.	Ayurvedic Pharmacopoeia of India(API)	**Not Mentioned**			
07.	World Health Organization (WHO)	Pb Cd As	NMT 10 NMT0.3 NMT 10*	AAS** AAS Arsenic Apparatus	Quality Control Methods for Medicinal Plant Materials, WHO,2002
08.	German Ministry	Pb Cd Hg	NMT 5 NMT 0.2 NMT 0.1		German Ministry of Health Recommendations to Europe Union

- *Limit is not very clear, only standard dilution(10ppm) is mentioned
- **Atomic Absorption Spectrometry

Challenges

SCIENTIFIC BARRIERS

- Non availability of suitable scientific methods of evaluation of safety and efficacy

E.g.:
- *Amavata* - Carrageen model
- Limitation of double blind placebo controlled studies for treatment regime

Challenges

DIRECTIONS FOR SAFETY STUDIES

"Since the substance to be tested is already in use in Indian Systems of Medicine or has been described in their texts, the need for testing its toxicity in animals has been considerably reduced. If there are reports suggesting toxicity or when the herbal preparation is to be used for more than 3 months it would be necessary to undertake 4-6 weeks toxicity study in 2 species of animals".

Indian Council of Medical Research (2000). Ethical Guidelines for Biomedical Research on Human subjects, ICMR, New Delhi.

Way forward

PROPOSALS FOR TOXICITY STUDIES

Since the traditional medicines may contain ingredients of mineral/metal/and or animal origin in addition to herbal ingredients, the requirement of toxicity should depend on the composition besides the usage of the product.

Class of drug	Acute Tox	28 day Tox	90 day Tox	AMES test
1A. Traditional Herbal Medicine (same composition, formulation & use as in text or traditionally used)*	-	-	-	-
1B. Traditional Herbal Medicine (modified composition, formulation & use)	√	√	-	√
2. Herbo-mineral medicine	√	√	-	√
3. Herbo metallic medicine	√	-	√	√
4. Herbal Medicine containing known toxic herbs	√	-	√	√

** However, if reports are available suggesting toxicity or if the product is to be used for more than 3 months then 4-6 weeks toxicity studies should be conducted in 2 species.*

Challenges

DIRECTIONS FOR EFFICACY STUDIES

- Adopt a flexible approach to review the data with respect to efficacy.

- Randomized double blind placebo controlled studies may not be always suitable to evaluate the efficacy of Traditional Medicine products.

Challenges

EFFICACY ASPECTS OF TRADITIONAL MEDICINE

WHO recommends the following:

A. Evaluate traditional medicine in its own theoretical framework

B. Evaluate traditional medicine in the theoretical framework of conventional medicine

C. Compare the efficacy of traditional medicine with conventional medicine

D. Compare the efficacy of traditional medicine within the system of traditional medicine

World Health Organization (2000). Annexure IV. General guidelines for methodologies on research and evaluation of traditional medicine, WHO, Geneva.

Way forward

PARAMETERS FOR ASSESSING EFFICACY OF TRADITIONAL MEDICINE

1.	Traditional/Historical Usage
2.	Published/Bibliographical references (incl textbook refs)
3.	Uses mentioned in Pharmacopoeia & Monographs e.g. Ayurvedic Pharmacopoeia of India, WHO Monographs, German Commission E Monographs, British Herbal Pharmacopoeia, PDR for Herbals etc.
4.	Pharmacological Evidences using appropriate model a). In vitro b). In vivo
5.	Clinical Experience/Usage/Trial a). Single case design b). Ethnographic studies c). Consumer Usage Test d). Pragmatic trial design e). Observation Research f). Randomized double-blind placebo controlled design g). Post Marketing Surveillance

Way forward

Reproduced below is a model which was proposed to Govt. of India to regulate Ayurveda, Siddha and Unani (ASU) drug licensing.

Category	Ingredients	Indication	Clinical Trial	PMS
I. Classical medicines	As per text	As per text	NA	√
II. Proprietary medicines				
A. With ingredients mentioned in the ASU books & products for same indication already in the market for more than 5 years	As per text	As per Mktd products	NA	√
B. With ingredients mentioned in the ASU books & products for same indication in the market for less than 5 years	As per text	As per Mktd products	Claim Support Data to be provided	√
C. With ingredients mentioned in the ASU books but to be used for new indication	As per text	Any	√ (CT using suitable design)	√
III. Plant based medicines prepared from ingredients not mentioned in traditional medicine books				
A. Presence in the International Market for more than 5 years	-	Any	Bibliography data	√
B. Presence in the International market for les than 5 years	-	Any	√ (Bibliography data & CT on Indian population)	√
C. New Products (products not yet marketed)	-	Any	√ (CT on Indian population)	√

WAY FORWARD

- Recognize Ayurveda as independent system of medicine
- Delink from herbalism
- HMPC to extend the base and include experts from India for consultation
- Open dialogue with Traditional medicine rich countries like India and China
- Review of the provisions of THMPD

WAY FORWARD

- **EDUCATION**
  - Development of proper curriculum
  - Inclusion of Ayurveda under formal education program
- **PRACTITIONERS**
  - Provide legal status
  - Prescribe eligibility criteria
- **PRACTICES**
  - Establishment of Ayurvedic Hospitals
  - System of grading of services
- **DRUGS**
  - Resolve THMPD issues

WAY FORWARD

THMPD Issues

- Review 15/30 years use condition
- Defer implementation beyond 2011
- Continue dialogue
- Recognize API / ICMR monographs
- Rationalize registration requirement
- Rationalise registration fee

Fate of the drugs already registered as para medicine in Hungary ?

Let EU and India join hands for promoting health and providing longevity to their populations through AYURVEDA

THANKS