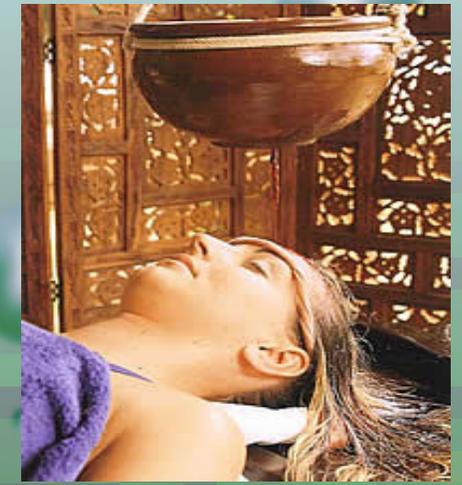


PHARMACOVIGILANCE OF DRUGS OF INDIAN SYSTEM OF MEDICINE

Do we need evidence for

- Efficacy
- Safety



Prof. K. C. Singhal

M.D., Ph.D. (Medicine), D.Sc., F.I.A.N., F.I.P.S., F.I.A.M.S.

Consultant WHO Center for International Drug Monitoring, Uppsala, Sweden

Vice – Chancellor,

NIMS University

Jaipur



*rns~o ;qDra HkS"kT;a ;n~kjksX;k; dYirsA l pSo
fHk"ktka Js"Bks jksxsH;ks ;% izeksp;sr~ AA*

C.A.1 Sutrasthana 1.134

To produce its characteristic effects a drug must be administered in proper dosage form by proper route and must be present in appropriate concentration at the site of action. many variables that effect transport across membranes influence absorption of drugs . Time of administration of drug i.e with relation to stomach being empty or otherwise, during day or at night and other factors may influence absorption. This is amply emphasized in Ayurveda that very medicine may be taken as properly administered which is capable to bring about disease free condition and that very physician as the best one who could relieve (the patient) of his disorder.

*;Fkk fo"ka;Fkk 'kL=ka ;Fkk·fuj'kfu;ZFkkA
rFkkS"k/kefoKkra foKkre`ra ;Fkk AA*

*vkS"k/a áufHkKkra uke:ixq.kSfL=kfHk%A foKkra pkfi
nq;qZDreuFkkZ;ksii/rs AA*

C.A.1 Sutrasthana 1. 124-125

A drug, if unknown, is (fatal) like poison, weapon, fire and thunderbolt while, if known is (vitaliser) like nector. A drug unknown by these - name, form and properties (including actions) - and badly administered even if known are responsible for complications. Drawing attention to causation of adverse reactions by drugs and their treatment, Charak states that in case there appear thirst, mental confusion, giddiness and fainting during digestion of the drug, pitta - alleviating, sweet and cold measures are recommended.

nw"khfo"ka rq

'kksf.krnq"V;k#%fdfVHkdksBfyaM~x pA

fo"kesdSda nks"ka lanw"; gjR;lwusoe~

AA

C.A.2 Chikitsasthanam .23.31

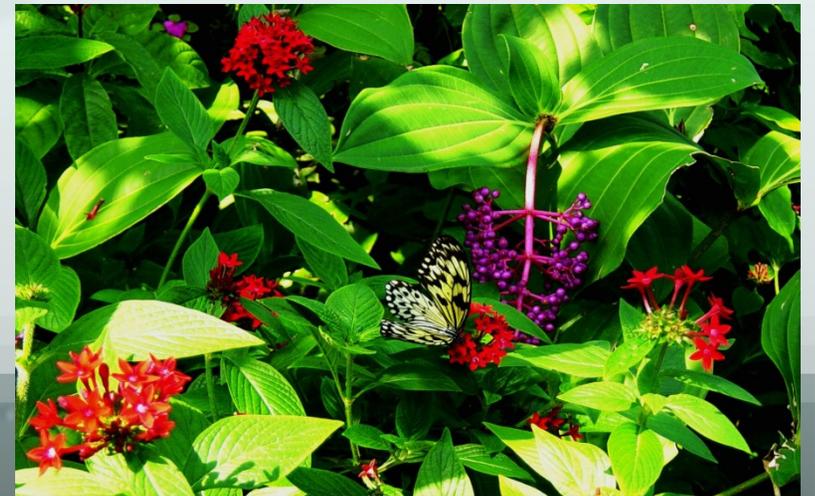
Dusivisa (latent poison) produces pustules, kitibha and urticarial rashes due to disorders of blood. Thus poison takes away



WHO

Traditional Medicine is the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in prevention, diagnosis, improvement or treatment of physical and mental illness.

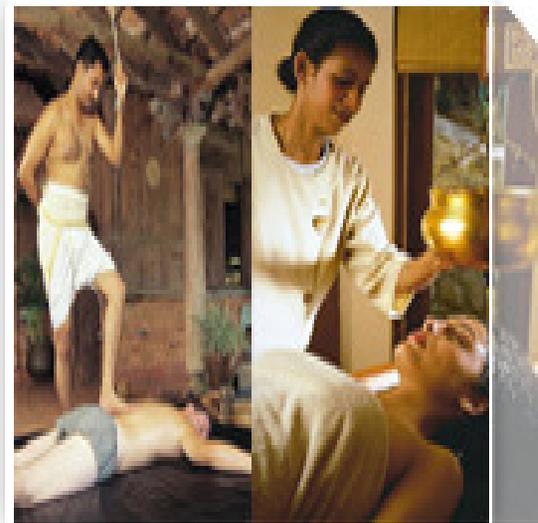
- ◆ **Medicinal Plants for Primary Care**
- ◆ **65 to 80% world population use traditional Medicine**
- ◆ **Use based on historical and anecdotal evidence**
- ◆ **Little data with regard to efficacy**



Pharmacovigilance in Traditional Medicine

Galen

"If you need a single drug of good quality which is not available, use a drug of lesser quality, for it would be less harmful than if you want to prepare a compound drug of which one single drug is unavailable, use the lesser quality drug double the weight of the original drug. Thus the efficacy of the drug would remain unchanged."



Maqala Fi Abdal Al-Adwiya Al Mustamala Fi

Al-Tib wa Al-Ilaj (Kitab Al-Abdal)

" All the drugs required for the treatment are not available everywhere. So, if the physician is unaware of substitutes which may be used in place of the original drug, the objectivity and benefaction of this medical profession would cease".

Examples of compound drugs along with substitutes

Drug

Substitute

Dawa al-Qust

Dawa ul-Kurkum

Dawa al-Luk

Roghan-e-hina Roghan-e-Marzanjosh

Roghan-e-gul

Roghan-e-Banafsha

Principles of substitutions

Avicenna - Substitute should only be used when original drug meant to be used is not available.

Avicenna - No drug can be a complete substitute for another drug in all respects.

Rhazes - Drug should be substituted for original drug for specific activity

- Different drugs may be substituted for different action

- Substituted drug should match the original in mijaz (Temperament)

Pharmacovigilance !

यथाविषं यथाशस्त्रं यथाऽग्निरशनिर्यथा ।
तथौषधमविज्ञातं विज्ञातममृतं यथा ॥

C. S., Su.- 1:124

**All drugs are dangerous some may
also be useful**

N Moore, BMJ, 2005, 330,

539-40

What is Pharmacovigilance !



यथाविषं यथाशस्त्रं यथाऽग्निरशनिर्यथा।
तथौषधमविज्ञातं विज्ञातममृतं यथा॥

C. S., Su.- 1:124

"No drug which is pharmacologically effective is entirely without hazard. The hazard may be insignificant or may be acceptable in relation to the drug's therapeutic action. Furthermore, not all hazards can be known before a drug is marketed... "A report by EU experts"

All drugs are dangerous some may also be useful

Wednesday, 12
November 2014

Moore, BMJ, 2005, 330, 539-40



No medicinal product is entirely or absolutely safe for all people, in all places, at all times. We must always live with some measure of uncertainty.

Be vigilant.....

मुहुर्मुहुश्च रोगाणामवस्थामातुरस्य च ।

अवेक्षमाणस्तु भिषक् चिकित्सायां न मुह्यति ॥

च०चि० ३०/३०६



- **Medicinal Plants for Primary Care**
- **65 to 80% world population use safety traditional Medicine**
- **Use based on historical and anecdotal evidence**
- **Little data with regard to efficacy**



Pharmacovigilance

- Any thing herbal is safe!!??????
- Adverse drug reactions (ADR)
- Drug-drug interactions
- Herb-Drug interactions
- Toxicity of the isolated ingredients
- Traditional process (Shodhana)





India



Herbal Drugs



Widely Prescribed



Lack of Systematic Evaluation



Adverse Drug Reactions



Traditional Medicine

Why ADR Monitoring Difficult

- ◆ Theories of application are difficult
- ◆ Too many products to monitor
- ◆ Multiple ingredient formulations - numerous
- ◆ Herbal and allopathic drugs taken together
- ◆ Formulations change keeping same brand name
- ◆ Methods of preparations differ
- ◆ Quality checking is ambiguous

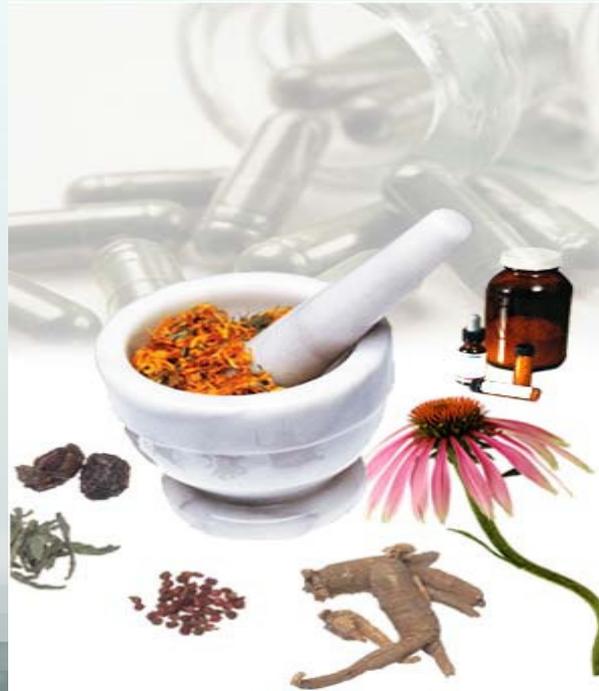
Health care system in India

- ***Allopathy – Disease oriented***
- ***Ayurveda - (Holistic system)***
- ***Unani - (Holistic system)***
- ***Siddha - (Holistic system)***
- ***Homeopathy Symptom based***



Principles of Treatment are different

- *Ayurveda* - *VATA*
- - *Pitta*
- - *Kafa*



Mijaz (Temperament)

Drug could be

Hot + Dry

Hot + Moist

Cold + Dry

Cold + Moist

- Hot, Cold, Dry, Moist - each has degrees from 1-3
- A drug hot and dry in 1st degree be substituted with hot and dry 1st degree

Why is ADR monitoring of 'Herbal' drugs even more difficult?

**Too many products
to monitor?**



Why is ADR monitoring of 'Herbal' drugs even more difficult?

**There are single and multiple
ingredient formulations**



Why is ADR monitoring of
'Herbal' drugs even more difficult?

The formulations can be
changed at will keeping the
same brand name



Why is ADR monitoring of
'Herbal' drugs even more
difficult?

**Quality checking is
ambiguous affecting the
causality of an ADR**



Why is ADR monitoring of
'Herbal' drugs even more
difficult?

**Herbal products are taken
OTC by patients**

Herbal
THERAPIES



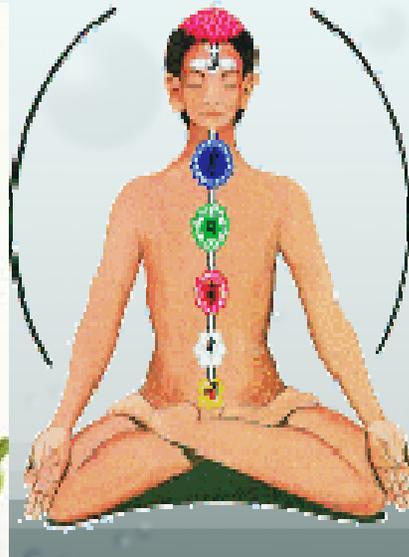
Why is ADR monitoring of 'Herbal' drugs even more difficult?

Herbal products are prescribed by
all specialities i.e. Allopaths,
Ayurveds, Homeopaths and RMPs



Why is ADR monitoring of 'Herbal' drugs even more difficult?

The ADR reporting terminology of multiple specialties can differ



Why is ADR monitoring of
'Herbal' drugs even more
difficult?

Herbal and Allopathic drugs are
taken together by the same
patient



Substitution of Drugs



PROTOCOL FOR NATIONAL PHARMACOVIGILANCE PROGRAMME FOR AYURVEDA, SIDDHA AND UNANI (ASU) DRUGS



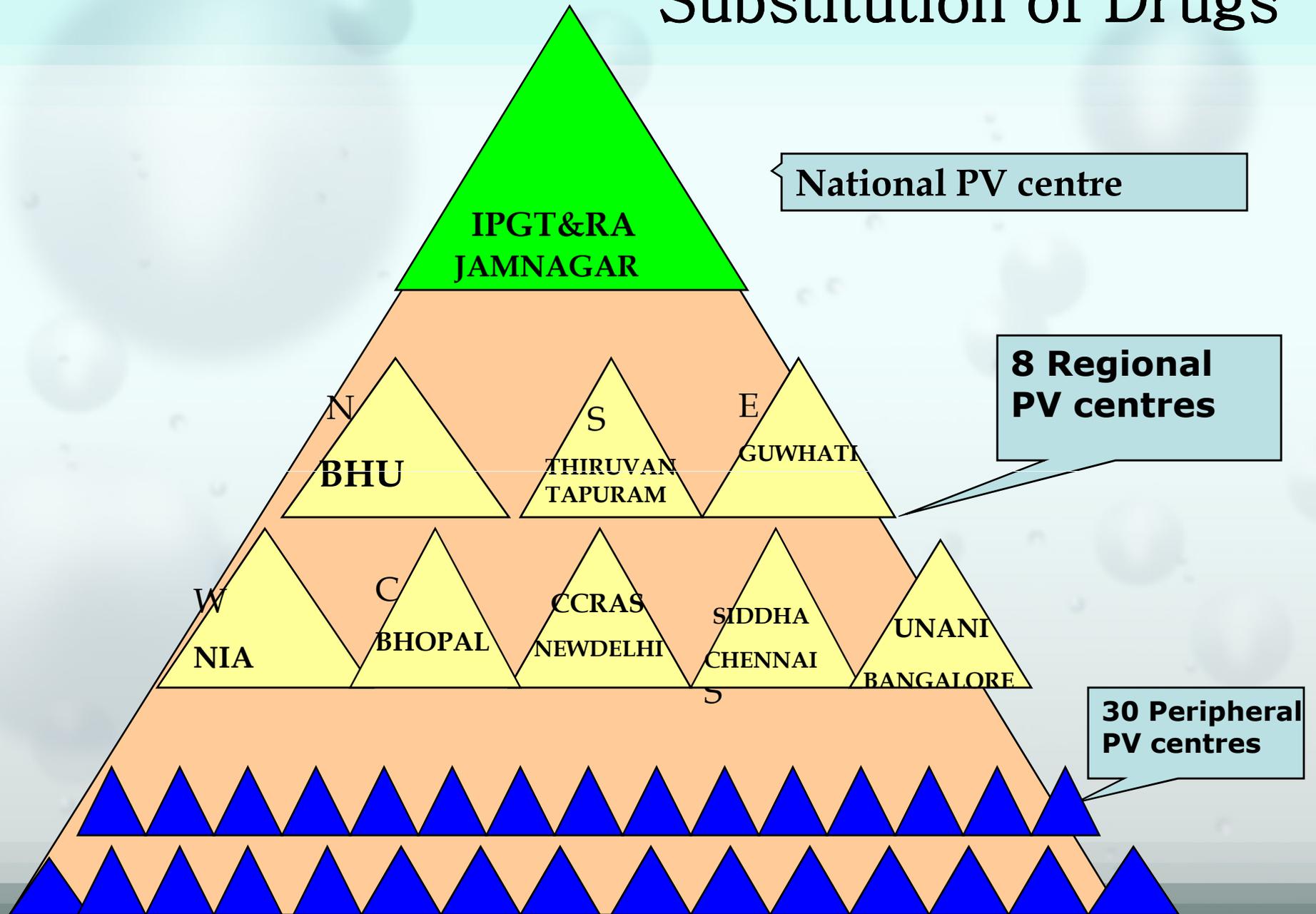
**National Pharmacovigilance Resource Centre,
for ASU Drugs
Institute for P. G. Teaching & Research in Ayurveda,
Gujarat Ayurved University,
Jamnagar 361008, Gujarat**

**Department of AYUSH,
Ministry of Health & Family Welfare,
Government of India, New Delhi,**

**in collaboration with
WHO Country Office for India, New Delhi**

2008

Substitution of Drugs



National Pharmacovigilance Programme For ASU Drugs



Ibn Sina
**The Author of Al Qanoon Fil Tibb (Canon of
Medicine)**

Abu Bakr Mohammad bin Zakariyya al Razi (Rhazes)

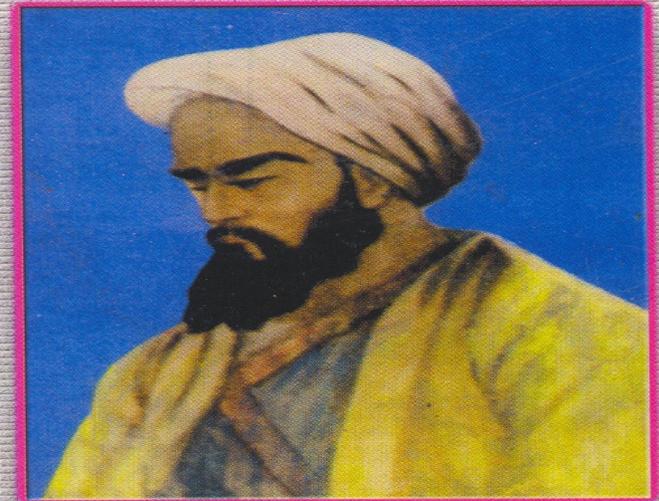
- Born in Iran 240 hijri
- Studied Indian Medicine
- Chief Medical Officer in hospital of Baghdad
- Became blind at 60
- 29 books written by Rhazes are available

MAQALA FI ABDAL AL-ADWIYA AL-MUSTAMALA FI AL-TIB WA AL-ILAJ

known as

KITAB AL-ABDAL

**(Book on Substitutes of Single Drugs)
ABU BAKR MOHAMMAD BIN ZAKARIYYA
AL-RAZI (Rhazes) (865-925 A.D.)
(English Translation)**



**CENTRAL COUNCIL FOR RESEARCH IN UNANI MEDICINE
(Department of Indian Systems of Medicine & Homoeopathy)
Ministry of Health & Family Welfare, Government of India
NEW DELHI**

Maqala Fi Abdal Al-Adwiya Al Mustamala FiAl-Tib wa Al-Ilaj (Kitab Al-Abdal)

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Roghan-Banafsha

Principles of

substitutions

- Avicenna - Substitute should only be used when original drug meant to be used is not available.
- Avicenna - No drug can be a complete substitute for another drug in all respects.
- Rhazes -
 - Drug should be substituted for original drug for specific activity
 - Different drugs may be substituted for different action
 - Substituted drug should match the original in mijaz (Temperament)

Substitution (Abdal al-adviya) Drug of one origin can be replaced with drug of another origin.

Example :

Drug

Jund Bedastar (Animal)

Calcinated & washed egg
shell

Substitute

Black pepper ($\frac{1}{2}$ by weight)
(Plant)

Tarasis (Gummiferum)

One species of plant may substitute for another species

Podina kohi (Mentha)

Podina Nahri (Panny Royal)

Another part of same plant may serve as substitute

Margosa flower

Margosa leave or bark

Sosan leaves (Lilly)

Sosan Root

Banafsha

Substitution of Drugs in Ayurveda

- Not mentioned in Charak and sushruta samhita
- According to three Nighantus (Materia Medica)
- Bhavprakash
- Yogaratnakar
- Bhashjya Ratnavali

Substitution of Drugs in Ayurveda

If any drug is not available then another drug similar can be substituted

- **RASA** **Physical Properties**
- **GUNA** **Pharmacological actions**
- **VIRYA** **Potency**
- **VIPAKA** **Effect on digestion and interaction**

Substitution of Drugs in Ayurveda

- *Main drug in any formulation should not be substituted .*
- *Other drugs can be substituted appropriately (Pratinidhi Dravya)*

Mile Stones for the launch of National Pharmacovigilance Programme for ASU Drugs:

Consultative Committee meeting :

at AYUSH, New Delhi

29th & 30th of August 08

under the sponsorship of

WHO, India Office

Protocol was finalized.



**National Consultative Meeting For
Adoption and Implementation of Pharmacovigilance Programme
for Ayurveda, Siddha and Unani (ASU) Drugs**

29th -30th August, 2008

Venue: Conference Hall, Department of AYUSH, Govt. of India, New Delhi

Organised by: Institute for Post Graduate Teaching & Research in Ayurveda,
Gujarat Ayurved University, Jamnagar

Sponsored By: WHO Country Office - India, New Delhi

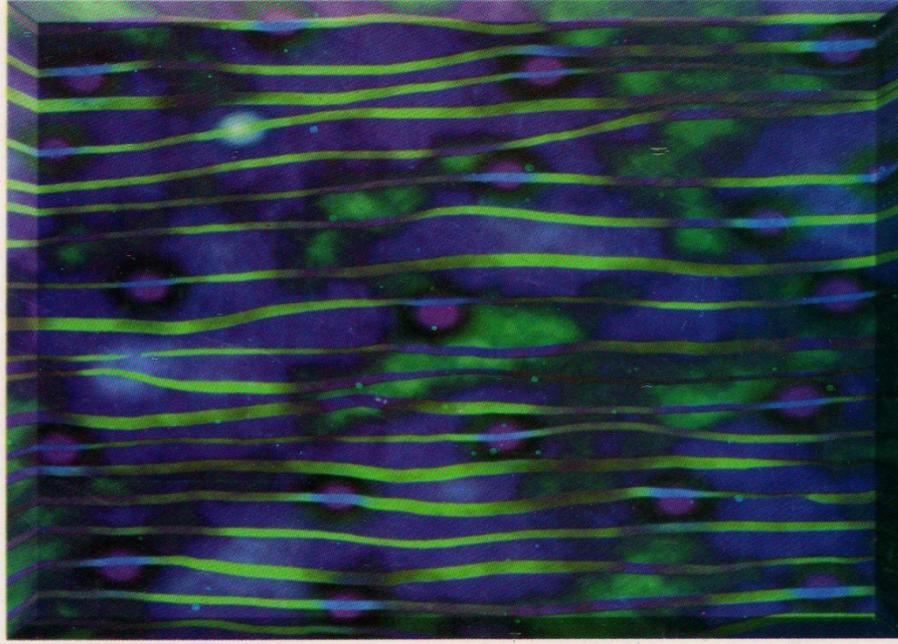
मुद्रण आर्षुद पुषुवणु
LAUNCH OF NATIONAL PHARMACOVIGILANCE PROGRAMME
FOR
AYURVEDA, SIDDHA AND UNANI DRUGS
NEW DELHI
29th September 2008

Department of AYUSH
Ministry of Health & Family Welfare
Government of India

Organized by

National Pharmacovigilance Resource Centre for ASU Drugs
Institute for Post Graduate Teaching & Research in Ayurveda
Gandhinagar, Gandhinagar, Gujarat





Adverse Reaction Terminology

औषधि प्रतिकूल प्रतिक्रिया शब्दावली

(For Physicians of Indian Systems of Medicine)



Society of Pharmacovigilance, India

ADVERSE REACTION TERMINOLOGY औषधि प्रतिकूल प्रतिक्रिया शब्दावली



THANK YOU