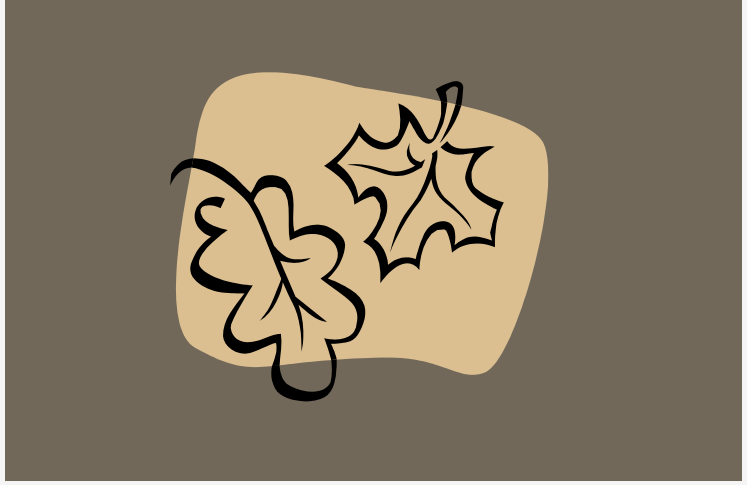

Worldwide Regulatory Perspective on Herbal Drugs & Herbal formulations

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Terminology

- **Herbal Substances** are mainly whole, fragmented or cut, plants or parts of plant, algae, fungi in an unprocessed dried fresh state.

- **Herbal Preparations** are obtained by subjecting herbal substances to treatment such as extraction, distillation, expression, fractionation, & purification.

- **Herbal medicines** are plant derived material or preparations with therapeutic or other Human health benefits, which contain either raw or processed ingredients from one or more plants.

Why Regulation?

- Protect consumer interest.
- Protect Product Integrity – evaluations parameters.
- Maintains requisite standards – batch to batch constituency.
- Ensure Public safety – not compromised.
- For safe, effective and beneficial to all.
- Products, practices leads to positive clinical outcomes.

Growing Popularity

2020
5 trillion $

Herbal Drugs

2009
62 billion $

Ref.: "Herbal Products : Regulatory requirements regarding Quality, clinical & pre-clinical perspective" by Prahlad Patki, Himalaya Herbal Healthcare

WHO Global Survey

- In 1994, WHO Contacted all countries to collect information regarding Regulation of Herbal Medicines.
- Unfortunately only 52 countries out of 191 responded.
- Therefore a global survey to collect primary information from national health authorities was necessary.
- In 2001, WHO developed the global regulatory survey questionnaire, in which 141 countries successfully respond to WHO via National Health Authorities.
- Among all 141 countries WHO build a one regional based structure into 6 different groups.

Regional Structure of countries by WHO

Africa

America

South East Asian

Europe

Eastern Mediterranean

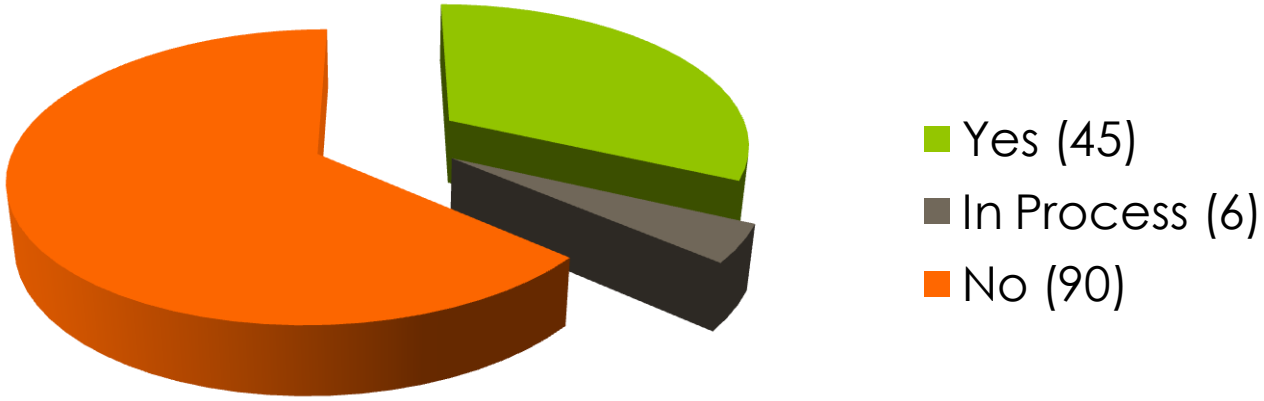
Western Pacific

AFRICAN	AMERICAN	EASTERN MEDITERRANEAN
Ethiopia	Argentina	Afghanistan
Gambia	Brazil	Bahrain
Ghana	Canada	Kuwait
Kenya	Colombia	Pakistan
Nigeria	Jamaica	S. Arabia
S. Africa	Mexico	Sudan
Zambia	Peru	Yemen
30 more…	11 more…	09 more…

EUROPEAN	SOUTH – EAST ASIAN	WESTERN PACIFIC
Austria	Bangladesh	Australia
Belgium	Bhutan	China
France	India	Japan
Germany	Indonesia	Malaysia
Ireland	Nepal	New Zealand
Spain	Sri Lanka	Singapore
Switzerland	Thailand	Vietnam
31 more…	03 more…	15 more…

WHO Survey Returns

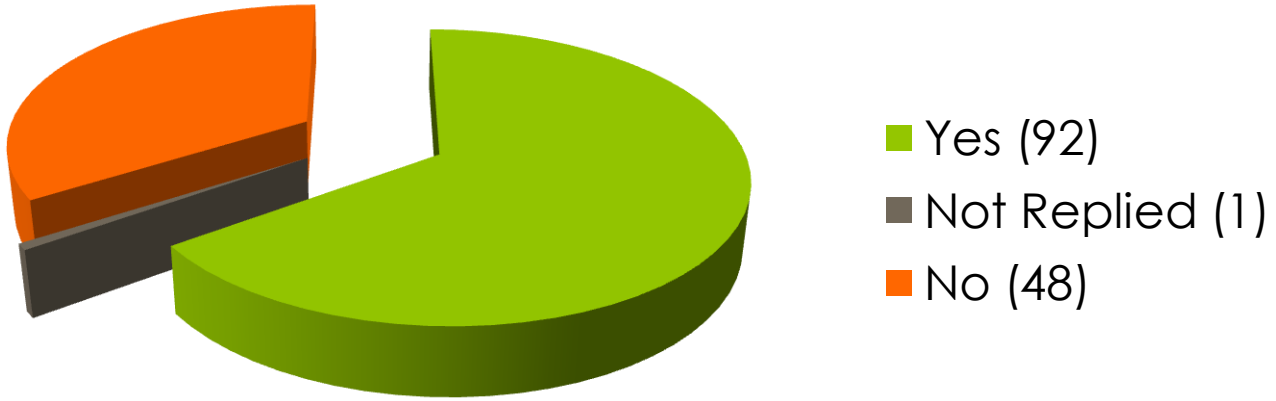
Que. 1
Is there a National Policy on Herbal Medicines?



Ref.: Report of a WHO global survey : "National Policy on Traditional Medicines & Regulation of Herbal medicines", May 2005

WHO Survey Returns

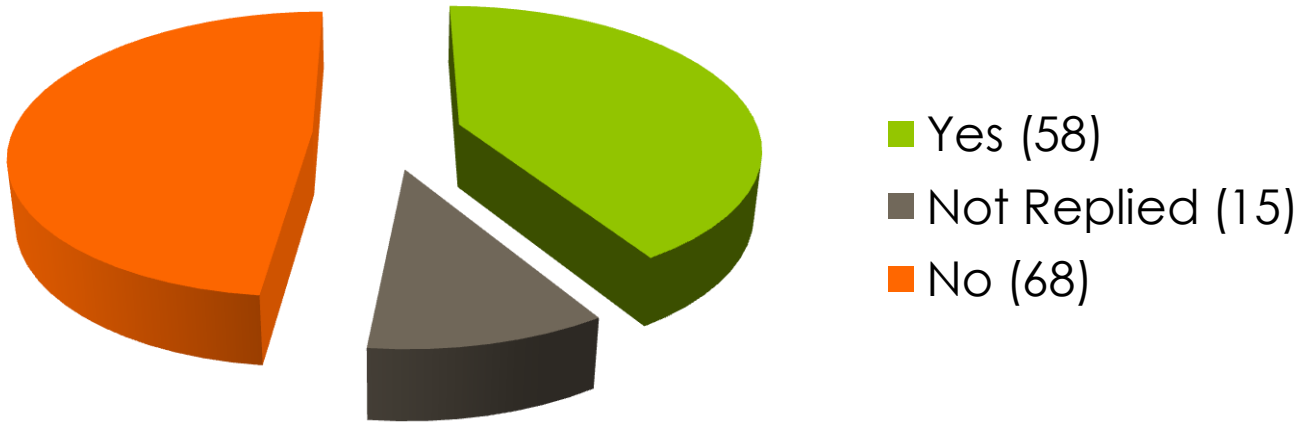
Que. 2
Have they a National law or regulations on Herbal Medicines?



Ref.: Report of a WHO global survey : "National Policy on Traditional Medicines & Regulation of Herbal medicines", May 2005

WHO Survey Returns

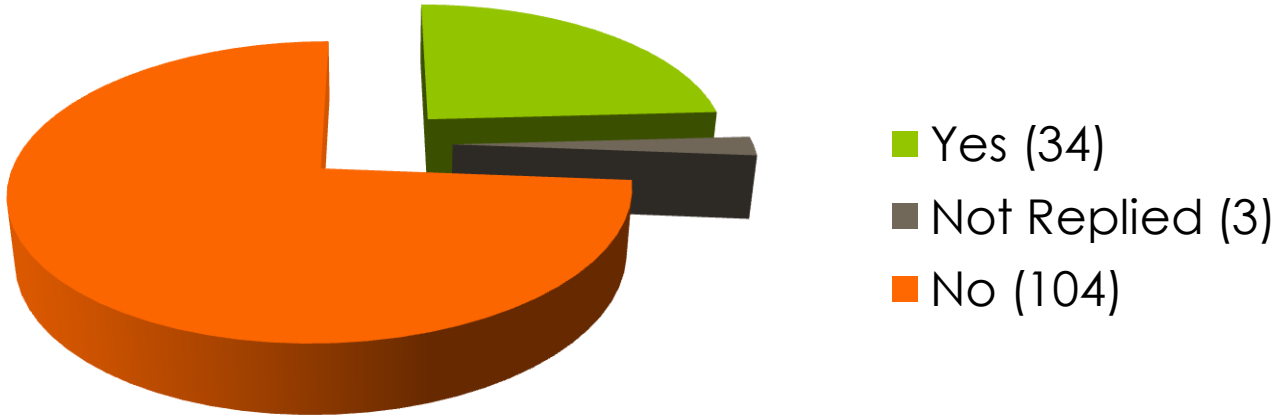
Que. 3
Have they a National Herbal Medicines Research Institutes?



Ref.: Report of a WHO global survey : "National Policy on Traditional Medicines & Regulation of Herbal medicines", May 2005

WHO Survey Returns

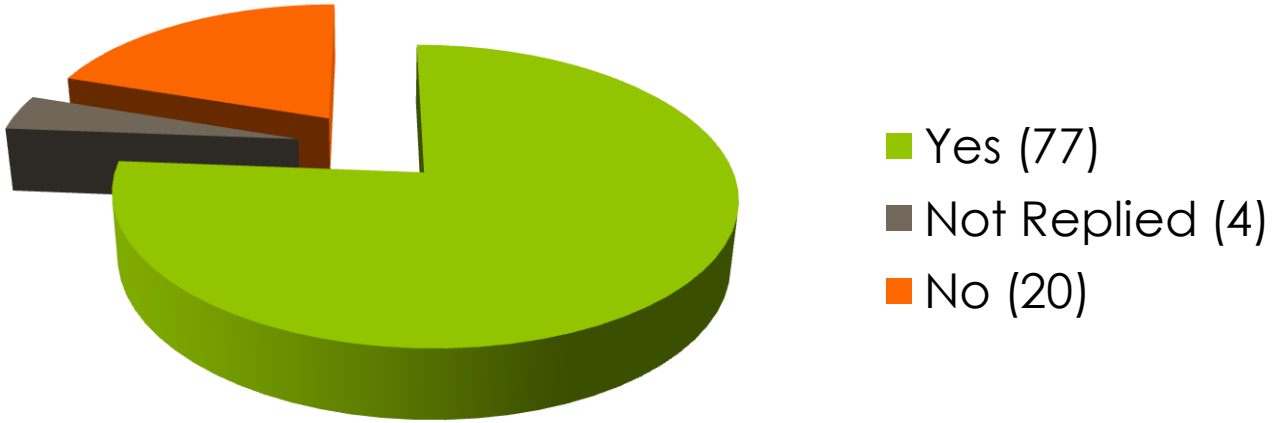
Que. 4
Have they a National Herbal Pharmacopoeia?



Ref.: Report of a WHO global survey : "National Policy on Traditional Medicines & Regulation of Herbal medicines", May 2005

WHO Survey Returns

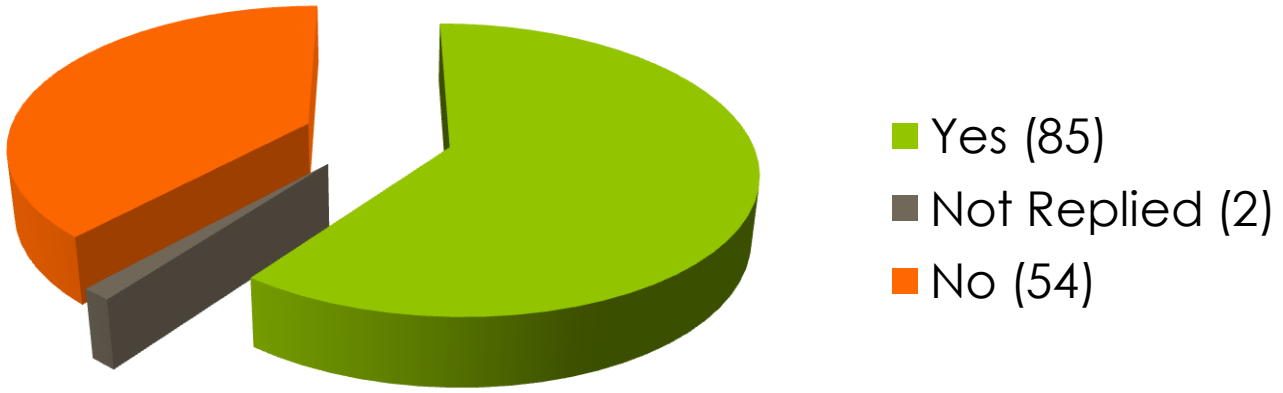
Que. 5
Have they control on Manufacturing of Herbal Medicines?



Ref.: Report of a WHO global survey : "National Policy on Traditional Medicines & Regulation of Herbal medicines", May 2005

WHO Survey Returns

Que. 6
Have they Registration System for Herbal Medicines?



Ref.: Report of a WHO global survey : "National Policy on Traditional Medicines & Regulation of Herbal medicines", May 2005

Regulatory Situation

Ref.: Report of a WHO global survey : "National Policy on Traditional Medicines & Regulation of Herbal medicines", May 2005
(For Regulatory Situation of all the countries)

1. Germany

- **Market Importance of Herbal Medicines:**
- The German herbal medicines market was worth US$ 1.7 billion (incl. VAT) in1989, which was equal to 10% of the total pharmaceutical market in Germany.
- Herbal medicines are distributed through over-the-counter sales in pharmacies and other distribution channels and on medical prescription through pharmacies.
- According to industry data for 2002, annual sales of herbal medicines in Germany had a value of 2.072 billion euros (US$ 2.432 billion).

- **Requirements for Marketing Authorizations for Herbal Remedies:**

- Since 1994, The Federal Institute for Drugs and Medical Devices, Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), is responsible for the assessment of medicines and the verification of submitted dossiers with respect to quality, safety and efficacy.

- Criteria for registration are set out by European directives and guidelines, such as the Note for Guidance on Quality of Herbal Remedies, the European Pharmacopoeia, and national guidelines and directives

- **German Medicines Act (Fifth Amendment):**
- In August 1994, the fifth amendment of the German Medicines Act became effective.
- It provides a new procedure with respect to proof of quality, safety and efficacy, widening the scope of existing legislation for products, including herbal medicines, already on the market.
- According to this act, Drugs Sold outside pharmacies and referring only to traditional uses without clinical evidence for efficacy have to be labeled as "traditionally used".

- **Control structure of Herbal Medicine in Germany:**

- In 1976 – National Policy, Laws & Regulations on Herbal Medicines were issued.
- In 1978 - National expert committee was established.
- In 1978 - Post-marketing surveillance system established.
- Till May, 2005 – No national Office for Herbal Medicines.
- Till May, 2005 - No national research institutes.
- A national pharmacopoeia, the *Deutsches Arzneibuch (German pharmacopoeia, DAB)* and the *European pharmacopoeia* are used as legal binding.

2. South Africa

- **Importance of Herbal Medicines:**
- A large number of South Africans consult traditional healers instead of medical practitioner.

- There are about 2,00,000 traditional healers in the country, and indigenous herbal medicines are in the main material medica. Herbal medicines are also used for self – care.

- **Legal Status of South African Herbal Market:**
- The herbal drug product is completely unregulated. However, once a health – related claim is made for a finished product, it has to go through the full drug evaluation procedure in the Medicines Control Council (MCC).

- No Specific regulation for registration and control of Herbal medicines.

- But some well – known old medicines including Aloes, Senna are registered already by MCC, according to internationally accepted standards of safety and efficacy.

- **Control structure of Herbal Medicine in S. Africa:**

- In 1994 – Traditional Medicine Programme (TRAMED) is arranged.
- In 2001 - National office was established under Ministry of Health.
- In 2002 – National Programme on TM / CAM was issued.
- Till May, 2005 – No Herbal Pharmacopoeia or any other legal binding.
- Till May, 2005 - No national research institutes.
- Till May, 2005 – No National Registration System.
- Herbal medicines are sold in pharmacies as OTC medicines, without any single restriction.

3. Argentina

- **Distribution Chain of Herbal Medicines:**
- The distribution Chain of Herbal Medicine is under control of Drug law & National Pharmacopoeia.

- The Chain include…
- One who grow herbal plants.
- Herbal Medicinal Industry
- Pharmacist who sell herbal medicines.
- Herboristerias who works as a Wholesaler.

- In Argentina, there is no difference between herbal medicines and chemical drugs.

- **Controls of Raw materials (Prior to 1993):**

- there was no control for the collection in the wild of medicinal plants;
- there were no scientific criteria for the collection of these plants;
- there was no control of the methods of drying, conservation or grinding;
- there was no official definition of what is a medicinal plant and what is not, some plants being used as food although they were included in the pharmacopoeia.
- In November 1993, a regulation for registration and commercialization of medicinal plants was published by the Health Ministry of the *Provincia de Buenos Aires*.

- **The Pharmacopea Nacional Argentina:**

- In 1965, *The Pharmacopea Nacional Argentina implemented as a* National Pharmacopoeia.

- Within the *Pharmacopea Nacional Argentina*, there are three categories of plants and their preparations:

  1. Crude Drugs.
  2. Pure active principles
  3. Extracts or fractions from medicinal plants.

- **Control structure of Herbal Medicine in Argentina:**

- In 1992 – National office on Traditional Medicine was established.
- In 1993 - post marketing surveillance system was established.
- In1998 - National Registration Procedure for herbal medicines established.
- In 1999 – Expert Committee on herbal medicines established.
- Till May, 2005 – No Single no. of registered herbal medicine.
- Till May, 2005 - No national research institutes.
- Herbal medicines are sold in pharmacies as OTC medicines.

4. INDIA

- **Market Importance of Herbal Medicines:**
- In India, there are currently about 2,91,000 (approx.) registered medical practitioner of the ayurvedic system as compared to about 7,00,000 of the modern medical system.
- Indian People use self-medication for minor ailments such as cough, cold, diarrhea and stomach problems.
- The present annual turnover of herbal products manufactured by large companies is estimated at approximately US $ 300 million, compared to a turnover of approximately US $ 2.5billion for modern drugs.

- **Legal status in India:**
- Two multivolume National Pharmacopoeia as legal binding…
  1. API
  2. Unani Pharmacopoeia of India

- The import, manufacture, distribution and sale of herbal medicines are governed by the Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of 1945.

- No products derived from traditional systems may be manufactured without a license from the State Drug Control Authorities.

- **Control structure of Herbal Medicine in India:**

- In 1940 – National policy on Herbal medicine was introduced.
- In 1940 – National laws & regulations were issued. (Updated in 1964, 1970 and 1982).
- In1962 – First Expert Committee on herbal medicines established. (Updated in 1993).
- In 1964 – National program was issued.
- In 1970 – First national research institute established.

  (Central Council of Indian Medicine, New Delhi).
- Till May 2005, - Post-marketing surveillance system was not established.

5. Japan

- **Japanese Herbal Medicine:**
- Herbal medicines have been used for the past 1400 years in Japan.
- Japanese Traditional Medicine divided into…
  1. Folk medicine
  2. Chinese medicine (Kampo medicine)
- Each Kampo drug is a formula usually consisting of 5-10 different herbs.
- The % usage of Kampo medicine by Physicians are…

In 1979 – 19% **In 1983 – 28%** **In 1989 – 69%**

- **Post marketing Surveillance System:**

- Three major system for the collection of adverse reaction data…

1. Adverse Drug Reaction monitoring system.
2. Pharmacy monitoring system.
3. Adverse Drug Reaction reporting from Mfg.

- **Control structure of Herbal Medicine in Japan:**

- In 1874 – First national research institute established (National Institute of Health Science).
- In 1960 – National laws & regulations were issued in Pharmaceutical Affairs Law.
- In 1993 – Post marketing surveillance system was established.
- In 2001 – Last update of Japanese Pharmacopoeia.
- Till May 2005, - No National Policy on Traditional Medicines.

6. Canada

- **Market Importance of Herbal Medicines:**
  - In Canada, herbal medicines are sold in pharmacies as over-the-counter medicines, in special outlets, by licensed and unlicensed practitioners

- Annual market sales based on a market survey of herbal medicines…
  - In 1999 – US$ 380 million
  - In 2000 - US$ 400 million
  - In 2001 - US$ 400 million

- Herbal medicines are regulated as drugs in Canada therefore they follow labeling.
- Canadian Health Protection Branch have a list of herbs considered hazardous or requiring cautionary labeling.
- They also allocated Drug Identification Numbers (DIN) to herbs based on pharmacological rationale.
- On 5 January, 1990, one **information letter** was issued to clarify the policy & to outline the regulatory requirements for application for DIN.

- **Control structure of Herbal Medicine in Canada:**

- In 1965 – Post marketing surveillance system was established.
- In October, 1990 – Guidelines on Traditional Herbal Medicines were published by MHW.
- In 1999 – National office for Traditional medicine was established by Ministry of Health.
- This office is also serves as the expert committee and national research institute.
- In 2003 – Regulation on Herbal medicines was introduced.
- Till May, 2005 – No National Pharmacopoeia developed.

- **Pharmacopoeias:**
- In place of a national pharmacopoeia and national monographs, the following materials are used:
- *Compendium of pharmaceuticals and specialties,*
- *Canadian drug reference for health professionals,*
- *United States pharmacopoeia,*
- *WHO monographs,*
- *Pharmacopoeia of the People's Republic of China,*
- *British herbal pharmacopoeia.*

7. Austria

- **Situation of Herbal regulation:**
- The Austrian drug law does not distinguish between medicinal products made from chemical substances and those made from plants or natural substances.
- Section 17a of the Austrian Drug Law principally stated that medicinal products can only be sold in pharmacies.
- An exemption is laid down in section 59, para 3 of the Austrian Drug Law stating that certain products which do not have any risk are allowed to be sold outside pharmacies.

- **Control structure of Herbal Medicine in Austria:**

- In 1989 – Herbal medicine regulation was introduced.
- Austrian Pharmacopoeia is referred as a legal binding.
- Till May, 2005…

1. No National policy,
2. No National programme,
3. No National office,
4. No expert committees,
5. No National Research Institutes,
6. No Post marketing surveillance system.

8. Australia

- **Legal Status:**
- According to Therapeutic Goods Act 1989, therapeutic goods for human use imported or manufactured in Australia must be included in the Australian Register of therapeutic goods.

- There are also special regulations on the expression of quantity or proportion of active ingredients in drug products, with special requirements for herbal ingredients.

- The *British Pharmacopoeia* is considered as legal binding due to lake of National Pharmacopoeia.

- **Control structure of Herbal Medicine in Australia:**

- In 1970 – Post marketing surveillance system was established.
- In 1989 – Regulation of Herbal medicine under Therapeutic Goods Act was established.
- In 1997 – Complimentary Medicines Evaluation Committee was established as expert committee.
- In 1999 – National Policy on Traditional medicine was established.
- In 1999 – National Programme and national office was established

Conclusion ???

- **References:**

- Guidelines for the Assessment of Herbal Medicines. Geneva, World Health Organization, 1991
- Guidelines for Formulation of National Policy on Herbal Medicines. Alexandria, WHO Office for the Eastern Mediterranean, 1994.
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- Regulatory Situation of World – wide medicine : A review by Dr. Xiaorui ZHANG
- GMP for Botanicals, Regulatory and quality issues on Phytomedicines by Robert Verpoorte and Pulok K Mukherjee, First Edition, Published by Business Horizones.

Thank you !!!

Costus (Kushtha) – the essential oil of roots has strong antiseptic, disinfectant & anti – inflammatory properties.