

INTERNATIONAL REGULATIONS AND AYURVEDA

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Contents

1) Introduction

2) Legal framework for HMP's (herbal medicinal products) -

EU

US

CANADA

3) Summary

Globalization

Globalization has fundamentally brought forward changes in the regulatory environment and created unique regulatory challenges for Ayurveda

Growing debate on “if it works lets use it versus if it works lets regulate it “

Changing global scenario –Why?

- In tune with increased international demand the safety, efficacy and quality of the products and practices used in Traditional and CAM have become important concerns for both health authorities and the public .

WHAT CAN GO WRONG WITH BOTANICALS OR HERBAL MEDICINES

- Wrong plant
- Right plant but a toxic one eg Aconitum
- Related species :inferior quality
- Contamination eg pesticides residue, microbial levels
- Deliberate adulteration /substitution /addition
- Foreign matter
- Poor information
- Incorrect diagnosis and inappropriate prescribing

WHAT CAN GO WRONG WITH BOTANICALS OR HERBALS

- Wrong plant – digitalis (foxglove) substituted for plantain (heart problems)

Podophyllum substituted for gentian causes cancer

Japanese star anise substituted for Chinese star anise causes convulsions

.

Potential drug /Herb interactions

- Growing recognition of potential problems due to drug/herb interactions

Hypericum (failure of the pill when taken with hypericum)

Warfarin –

Cranberry

Garlic

Ginseng

Ginkgo

CLASSIFICATION /CATEGORISATION

SYSTEM OF MEDICINE

AND

PRODUCTS

Decision taken by the national regulatory
authorities of the concerned country

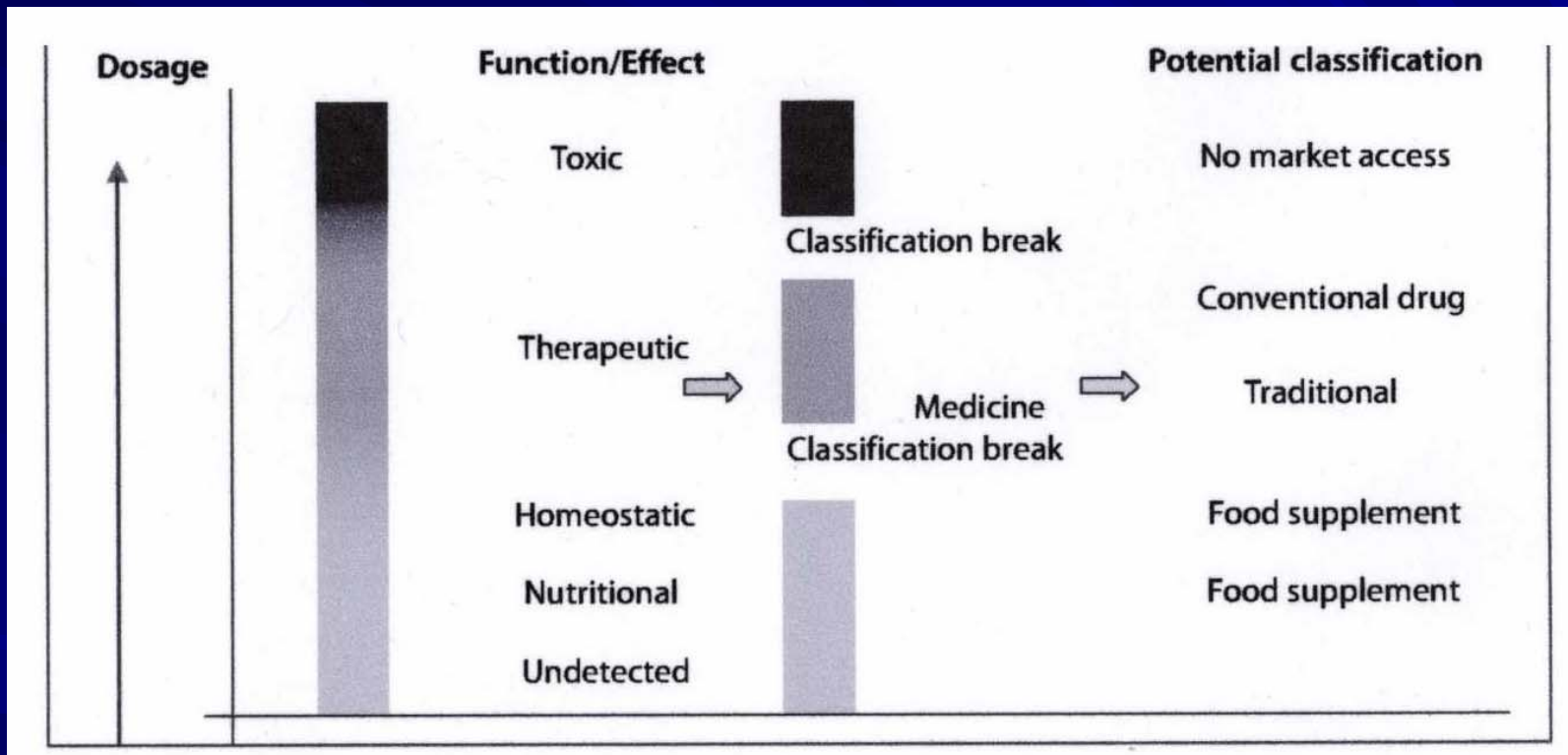
Categorization of the systems of medicine

NATURAL MEDICINE	CAM (broad set of health care practices not part of a country's own tradition)	NON- CONVEN- TIONAL MEDICINE
HOLISTIC MEDICINE	TRADITIONA L MEDICINE	PHYTO- THERAPY

COMPLEMENTARY MEDICINES (ARGCM)



Classification of products based on dosage and actions of a substance on the body

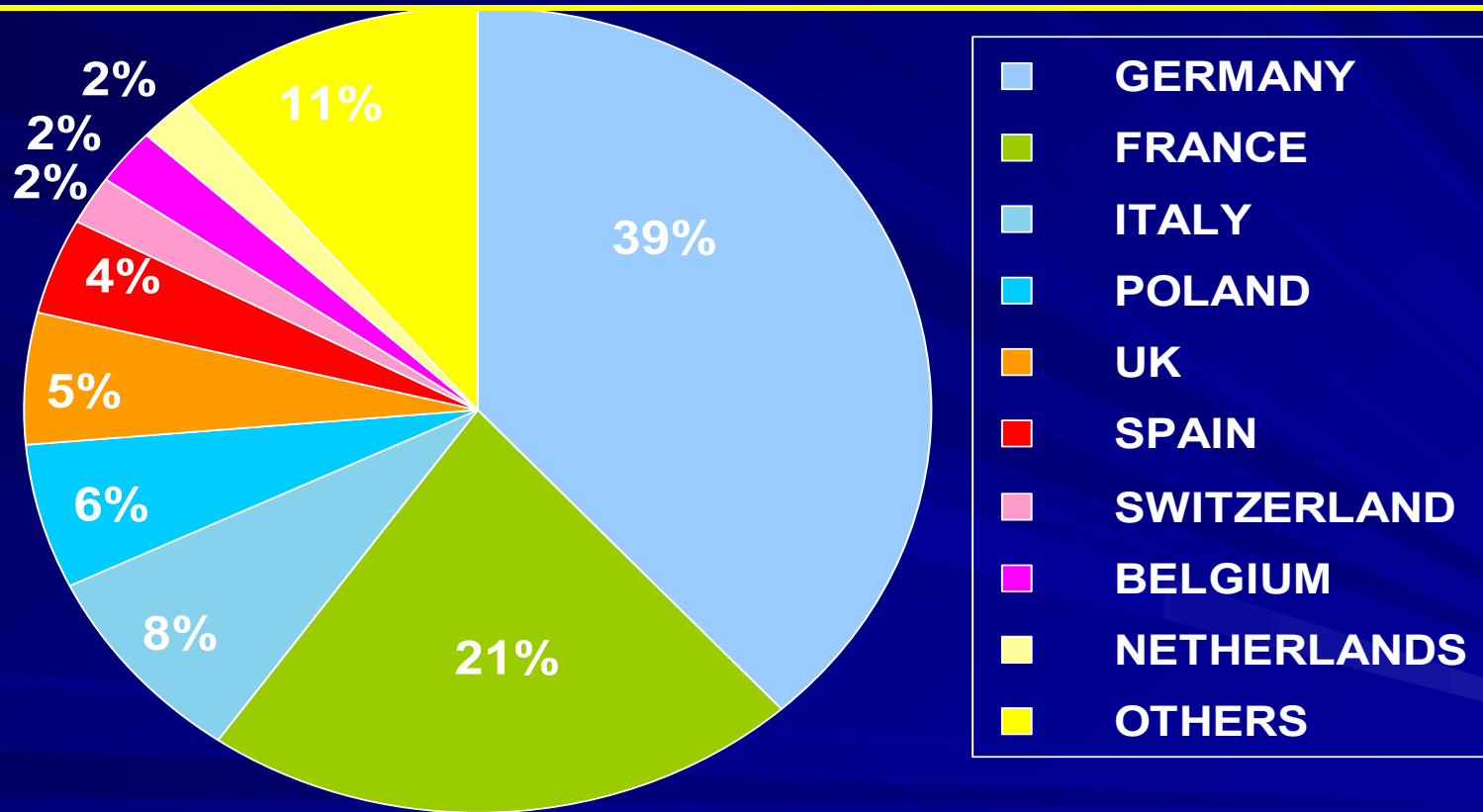


Worldwide categorization under which ASU products can be considered

- **Unlicensed OTC herbal medicines**
- **ASU Prescription medicines**
- **Herbal supplements**
- **Food supplements**
- **Nutraceuticals**
- **Botanicals**
- **Dietary supplements**
- **Novel foods**
- **Border line products**
- **Traditional Remedies**
- **Herbal extracts**
- **Raw herbs and**
- **Cosmetics**
- **Devices**

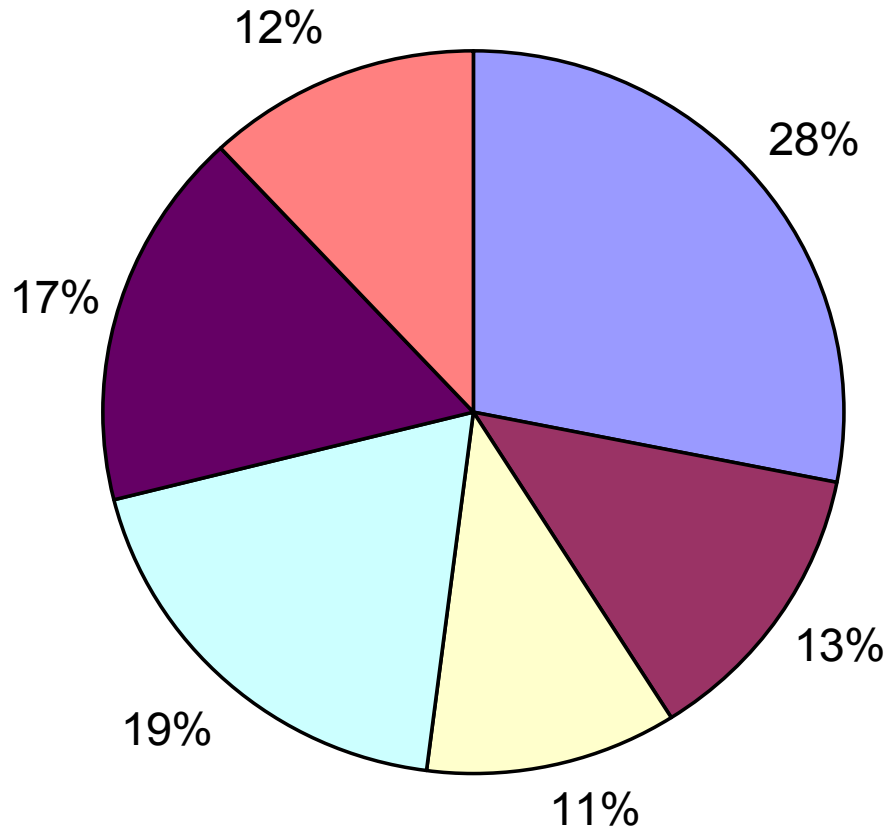
Germany & France dominate on the European herbal market

Total Market 09/2003-09/2004: ~ 3.7 billion € ex-factory



Source: IMS 2005

Global Herbal Medicine/Supplement Market



Germany France America Asia Japan Rest of Europe

Key Directives/Acts/Guidelines In Place For Herbals/ASU products As Of Today 2010

EU/UK – THMPD

US – DSHEA

CANADA – NHPD

AUSTRALIA - ARGCM

Legal framework for HMP's in the EU

- MA (Marketing Authorisation)
- MA of well established use HMP's (like Psyllium husk)
- Registration under the Traditional herbal medicinal products directive (A THR is a simplified form of a MA)

Summary of requirements –Marketing Authorization or Registration as THMP (EU)

		MA	Traditional Use
Module 1	Administrative Information	✓	✓
Module 2	Expert Summaries	✓	✓
Module 3	Quality Data	✓	✓
Module 4	Safety Data	Results of Tests	Bibliographic review of safety/expert Rpt
Module 5	Efficacy Data	Results of Trials	Evidence of traditional use

THMPD Key points

- Amends article 16 of 2001/83/EC as regards traditional herbal medicinal products.
- Adopted March 2004
- Transposed October 2005
- Transitional period to March 2011.

THMPD Keypoints

Simplified registration procedure for herbal products which fulfil the following criteria

- Use without supervision of medical practitioners
- Specified strength
- Oral/external or inhalation only
- Evidence of Traditional use
- Traditional use shows not harmful .

THMPD Key points

Objectives.

- **Protection of consumer health, providing access to medicines of their choice provided safeguards are met.**
- **To facilitate a single market in the EU for herbal medicines via harmonized rules.**

THMPD Keypoints

Quality

The normal quality requirements applicable to licensed medicines would apply.

- Compliance with GMP required.
- ML, WDL required as appropriate.
- QP required.
- Applicants will need full manufacturing and quality documentation.

Costs

- Significant for non-GMP structured companies.
- Companies may cease manufacturing.
- May lead to increased sub-contracting

Regulation of professionals in UK

A report has been submitted to the DoH, UK in 2009 on statutory regulation of practitioners of Traditional medicine systems practiced in the UK .

The recommendations in the report have taken account of the emerging health policy relevant to protecting patients and new ways of working for healthcare professionals .

This is a significant milestone in meeting the Government's objectives for public to safely access such herbal /traditional systems of medicine .

USA

US approach to Botanicals

DRUGS (FDA approval a must)

DIETARY SUPPLEMENTS (products
under DSHEA

FOOD (Depending on its labeling and
intended use)

Botanical Drug

Botanical drug products are finished labeled products that contain vegetable materials which may include plant materials, algae, macroscopic fungi or combinations thereof.

Dietary supplement

DSHEA (Dietary Supplement Health and Education act of 1994)

A Dietary supplement means a product intended to supplement the diet and contains one or more of the following dietary ingredients-

vitamin

mineral

herbs or other botanicals

Amino acid.....

Dietary supplement

Dietary supplements can also be extracts or concentrates and may be found in many forms such as tablets, capsules, softgels, liquids or powders.

Specific labeling requirements

CANADA

Legal framework under NHPD
and includes Traditional
medicines

Natural health product

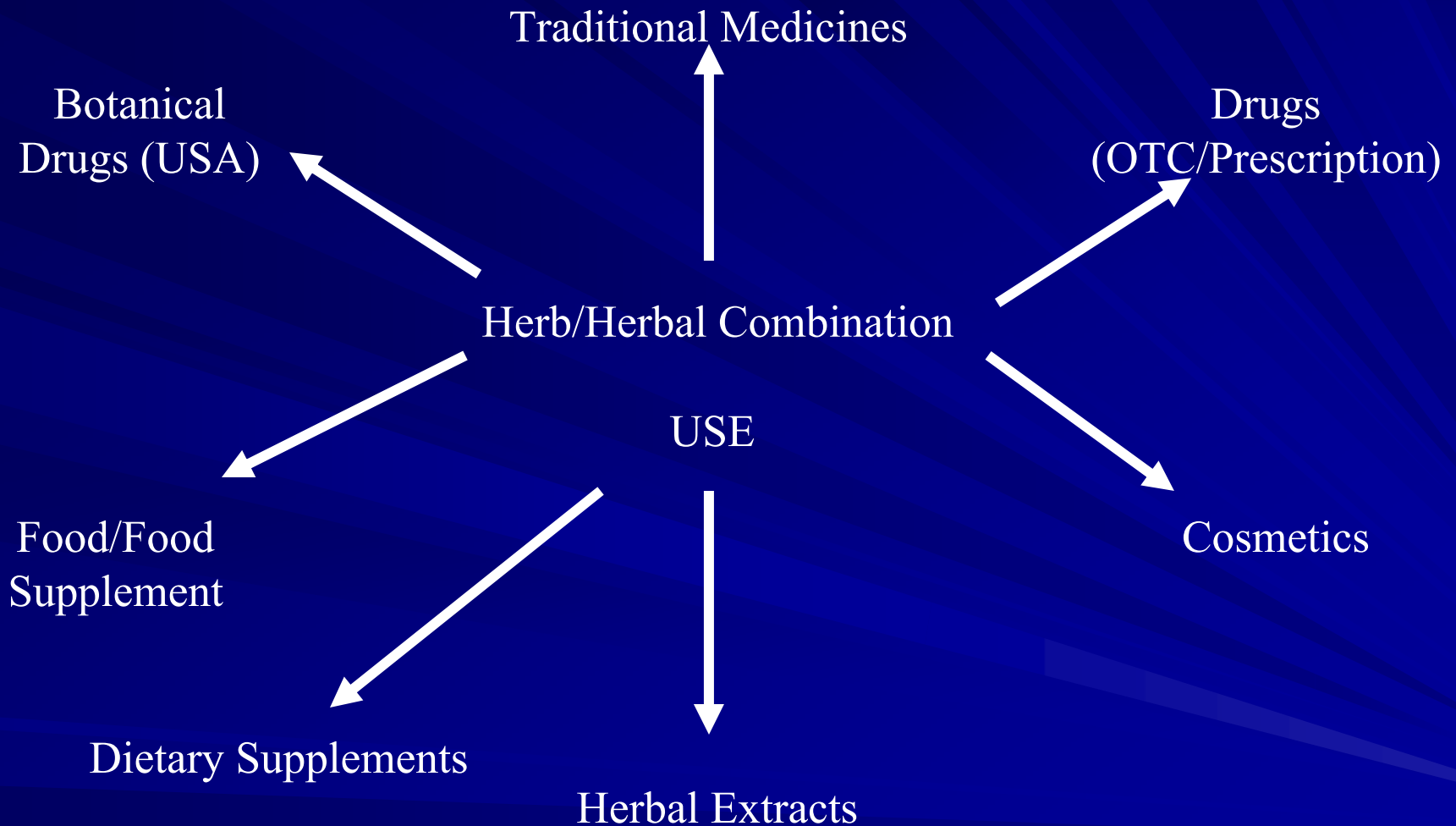
A natural health product is defined as a substance, or a combination of substances, described in Schedule 1 of the *Natural Health Product Regulations*, a homeopathic medicine or a traditional medicine, that is intended to provide a pharmacological activity or other direct effect in:

diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physiological state or its symptoms in humans;

Natural health product

restoring or correcting organic functions in humans; or
modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health

“GLOBAL APPROACH FOR AYURVEDIC HERBAL PRODUCTS”



Global requirements

- GACP
- GMP
- Quality
- Safety
- Pharmacovigilance

WAY FORWARD

Market expansion particularly in the self medication sectors is dependant on consumer education. As in everything else if the consumers do not understand the benefit of a product they will not buy it .

WAY FORWARD

- Compliance on quality (GACP and GMP)
- Compliance on safety
- Documentation of bibliographic evidence of safe use with reference to Ayurvedic Pharmacopoea, text books and available scientific literature .

Our Mission

Participate with representatives of other countries through suitable processes to reduce the burden of regulation

Harmonize regulatory requirements

And most importantly achieve proper reciprocal arrangements

MANY THANKS