

# Guidelines on Higher Claims for Complementary Medicine (NRC 2013)

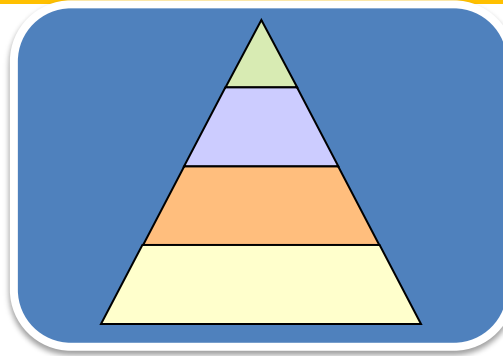


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# Presentation Outline



Definitions



Levels of claims



Challenges



The Way  
Forward



# Regulation of health claims

- Consumer protection and informed choices
- Confidence in claims by ensuring all claims are scientifically substantiated / evidence based
- Promote and protect innovation



# WHAT IS A PRODUCT?

## The Control of Drugs and Cosmetics 1984

**'product'** means

- a **'drug'** in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or animals for a **medical purpose**
- a drug to be used as an ingredients of a preparation for a medicinal purpose; or
- a cosmetic

## The Sale of Drugs Act 1952

- **'drug'** includes any substance, product or article intended to be used or capable, or purported or claimed to be capable of being used on humans or any animal, whether internally or externally for a medicinal purposes.

# What is a Traditional Medicine?

- Traditional medicine is defined as any product used in the practice of indigenous medicine, in which the drug consists solely of one or more naturally occurring substances of a plant, animal or mineral, or parts thereof, in the unextracted or crude extract form
- Indigenous medicine is defined as a system of treatment and prevention of disease established through traditional use of naturally occurring substances

# Traditional Medicine cont..

- Homeopathic<sup>2</sup> medicine : means any substance used in the homeopathic therapeutic system in which diseases are treated by the use of minute amount of such substance which is capable of producing in healthy persons symptoms similar to those of the disease being treated

# INGREDIENTS

TM

NOTE:

1. Natural sources
2. Standardized herbal extracts

PLANTS

ANIMALS

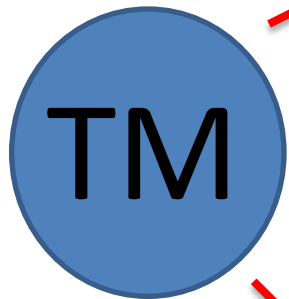
MINERAL

# Non-Registrable Traditional Products

- Extemporaneous medicine practiced by a TCM practitioner
- Herbal medicine that contains certain ingredients or mixture of plants, animals, minerals in which it is processed by drying, grinding or blending.
- Herbal medicine that contains certain ingredients or mixture of plants, animals, minerals or extract that is mainly used as food, spices or flavoring without a therapeutic labeling.



# SUBSTANCE TO BE EXCLUDED



## Active Ingredients:

- Toxic constituents/  
substances exceeding  
stipulated limits
- Narcotics
- Psycotropics

## Others:

- Isolated and chemical  
characterized substances
- Extemporaneous preparation
- Vaccine
- Human parts derivatives
- Sterile preparations
- Product in food presentation  
(incl. beverages)

# HEALTH SUPPLEMENTS

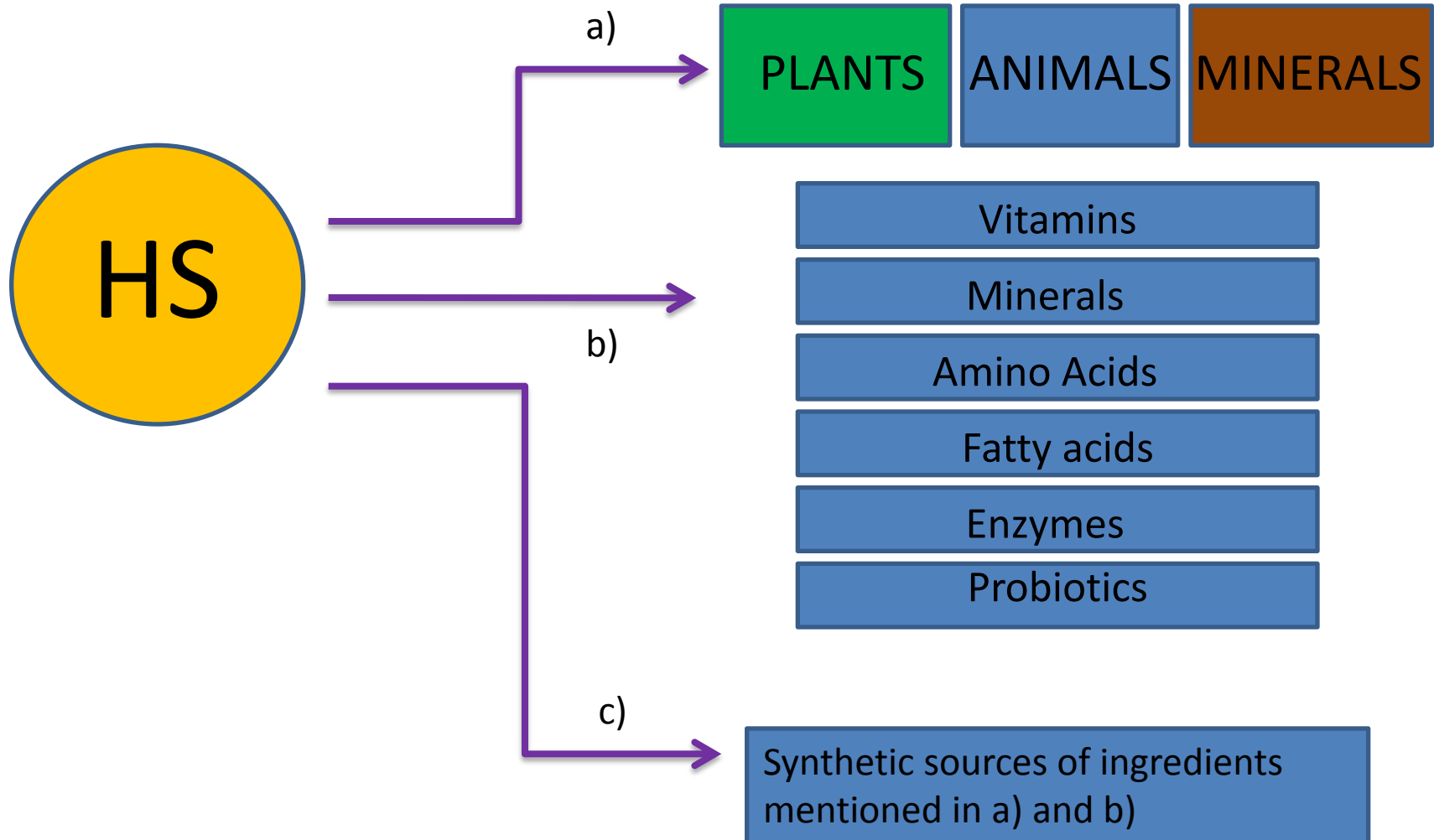
-Health Supplements shall mean product that are intended to supplement the diet taken by mouth in forms such as **pills, capsules, tablets, liquids or powders** and **not represented as a conventional food** or as a sole item of a meal or the diet

The dietary ingredients in these products may include:

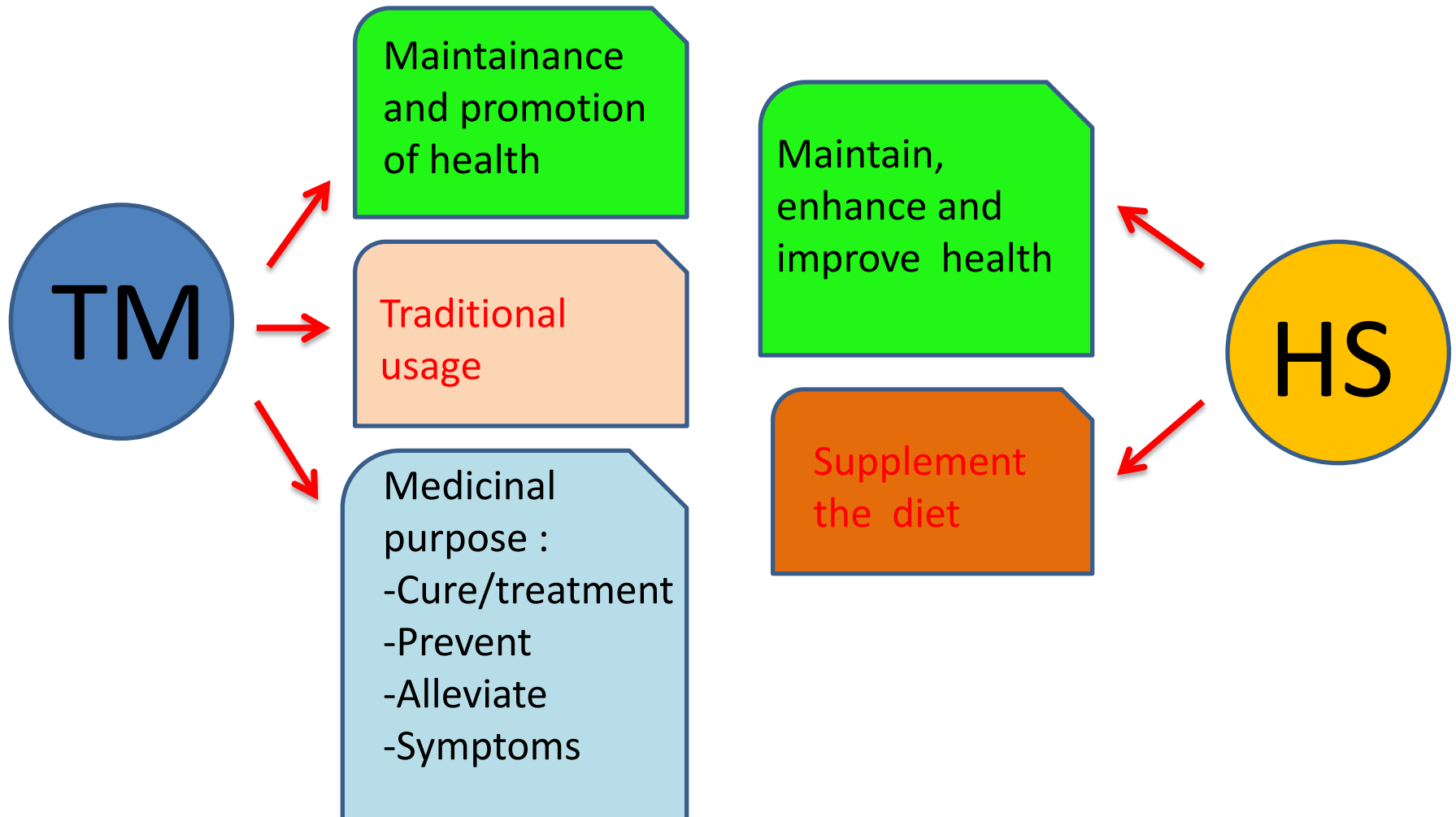
- **Vitamins, Minerals, Amino Acid**
- **Natural substances of plant/animal origin**
- **Enzymes, substances with nutritional /physiological function**

# INGREDIENTS

Extract, isolate, concentrate or metabolite



# FUNCTIONS



# HERBAL PRODUCTS

- **Finished herbal products:**

herbal preparations made from one or more herbs. If more than one herb is used, the term mixture herbal product can also be used. Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients. However, finished products or mixture products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be herbal.

***World Health Organization (WHO) Guidelines (4<sup>th</sup> October 2010)***

**COMPLEMENTARY HEALTH PRODUCTS (CHP)**

**HEALTH SUPPLEMENT**

**PURE TRADITIONAL**

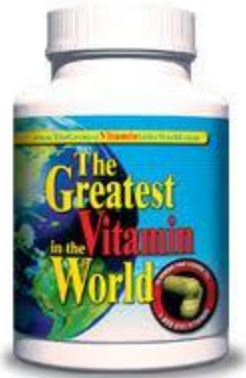
Formulations containing TRADITIONAL ingredients according to acceptable Pharmacopeias, traditional usage

**FINISHED HERBAL PRODUCTS**

Natural origin: plants (non Pharmacopeia formulation)

**HOMEOPATHY**

# Where are we?



VS



# Regulatory Requirements



## Quality

Status of  
manufacturer

Heavy metals



## Safety

maximum daily  
limits



## Efficacy

As claimed





# Health supplement claims

- General claims
  - Health supplement
- Functional claims
  - Beneficial effect may relate to maintenance/improvement of a function
- Disease risk reduction claims
  - Claimed effect relates to the reduction of a risk factor for the development of a human disease( not reduction of the risk of disease)



# EXAMPLES

INGREDIENT (dose dependent)	GENERAL CLAIMS	FUNCTIONAL CLAIMS	DISEASE RISK REDUCTION
Calcium	Maintenance of good health	Supports healthy bones & teeth	Ca contributes to strong bones, reduces the risk of osteoporosis
Fish oil	“	Maintains healthy triglyceride level	Omega- 3 fatty acids benefit the heart of people at high risk of or who have CV disease
Rose hip	Natural source of Vit C		Wound healing?

# Traditional medicine claims

*traditionally used...*

- **Traditional general claims**
  - general health
- **Traditional medium claims**
  - reduction of risk of a disease/disorder
  - relief of symptoms
  - aids/assists in the management of a named symptom/ disease
  - prevents/stops/ slows down the progress of a mild/ self-limiting disease or medical condition



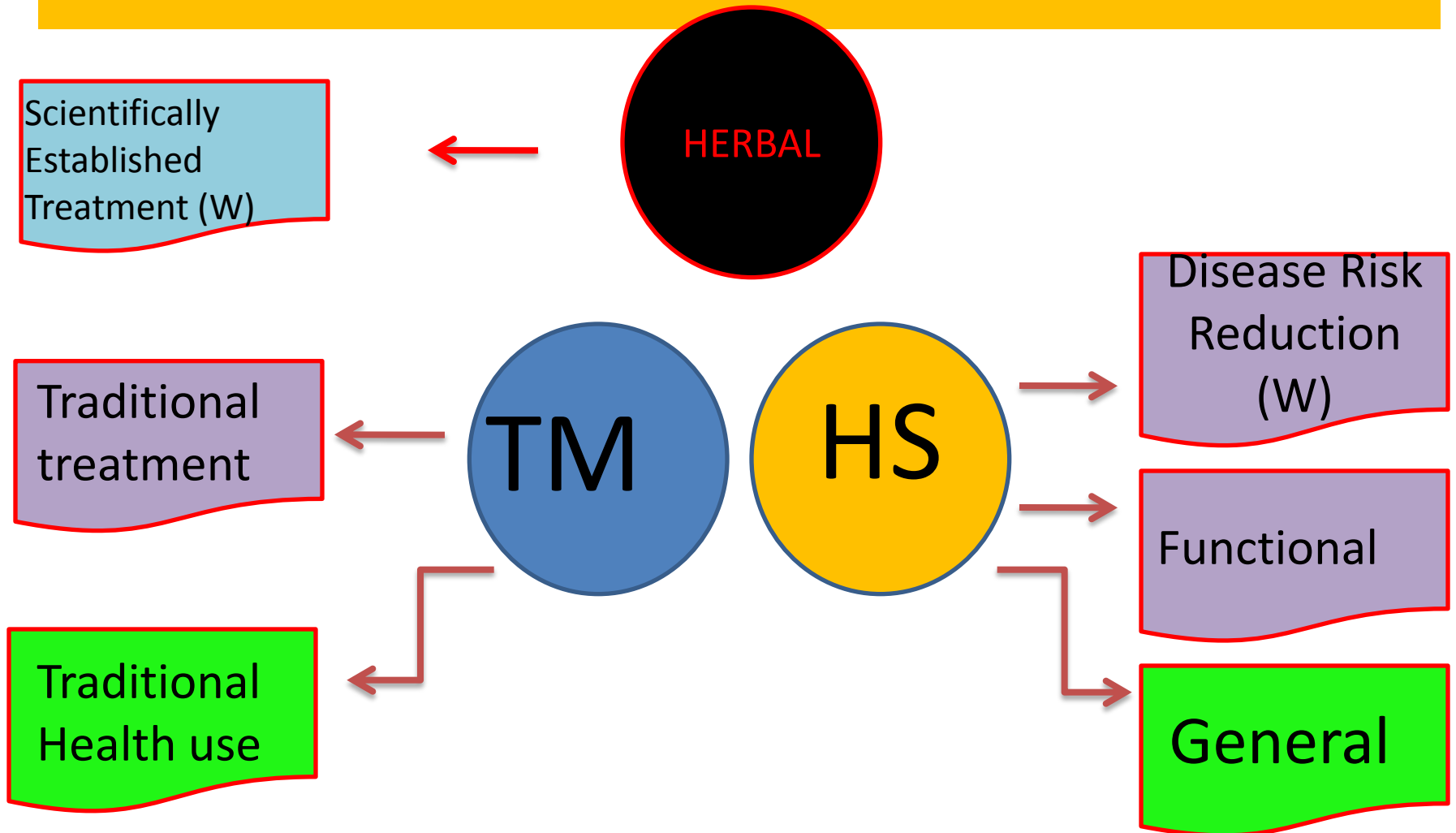
# Herbal product claims

*herbal product used ...*

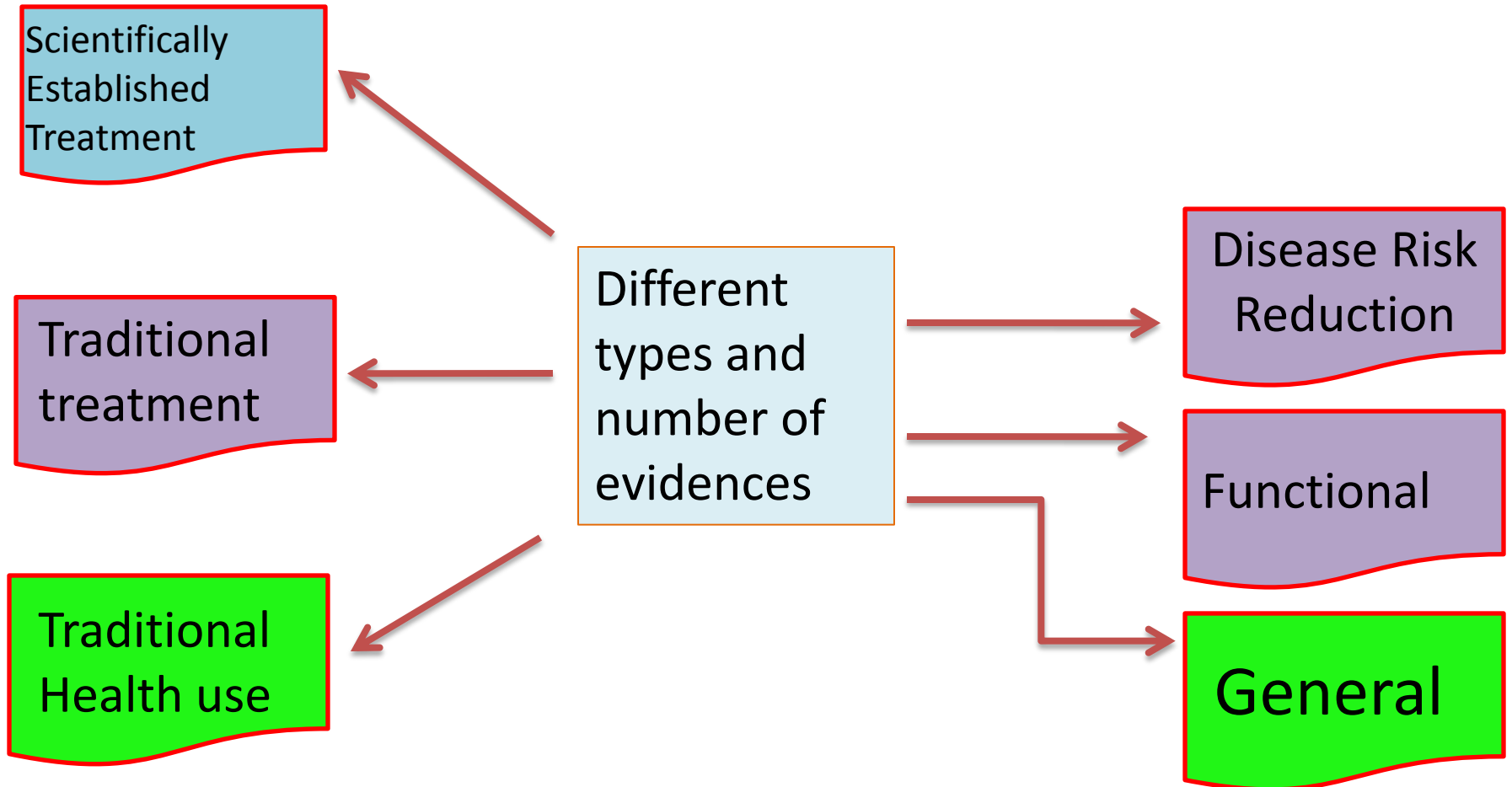
- General health maintenance
- Medium claims
  - reduction of risk of a disease/disorder
  - relief of symptoms
  - aids/assists in the management of a named symptom/ disease
- High claims
  - treats/ cures/manages any disease/disorder
  - adjunct / to complement any treatment



# TYPE OF CLAIMS: Intended use



# SUPPORTING DATA



# LEVEL OF RISKS

**HIGHER**

## INGREDIENTS:

### -Inherent risks:

- use of herbs with potent component
- use of unsafe ingredients
- Toxic side effects of ingredients

### • External risks:

- Adulteration with potent substance (drug substance)
- Poor manufacturing practices

### • Unknown risks:

- Lack of history of safe use
- Inadequate reports on safety studies
- Due to unknown interactions

### • Known risks:

- Potent ingredients
- Toxic effect

**TM**

## CLAIMS:

- Mild and serious medicinal purposes

Accumulated ethno-traditional knowledge

## INGREDIENTS:

- Comprising of ingredients with well established safety

**HS**

## CLAIMS:

- General health claim

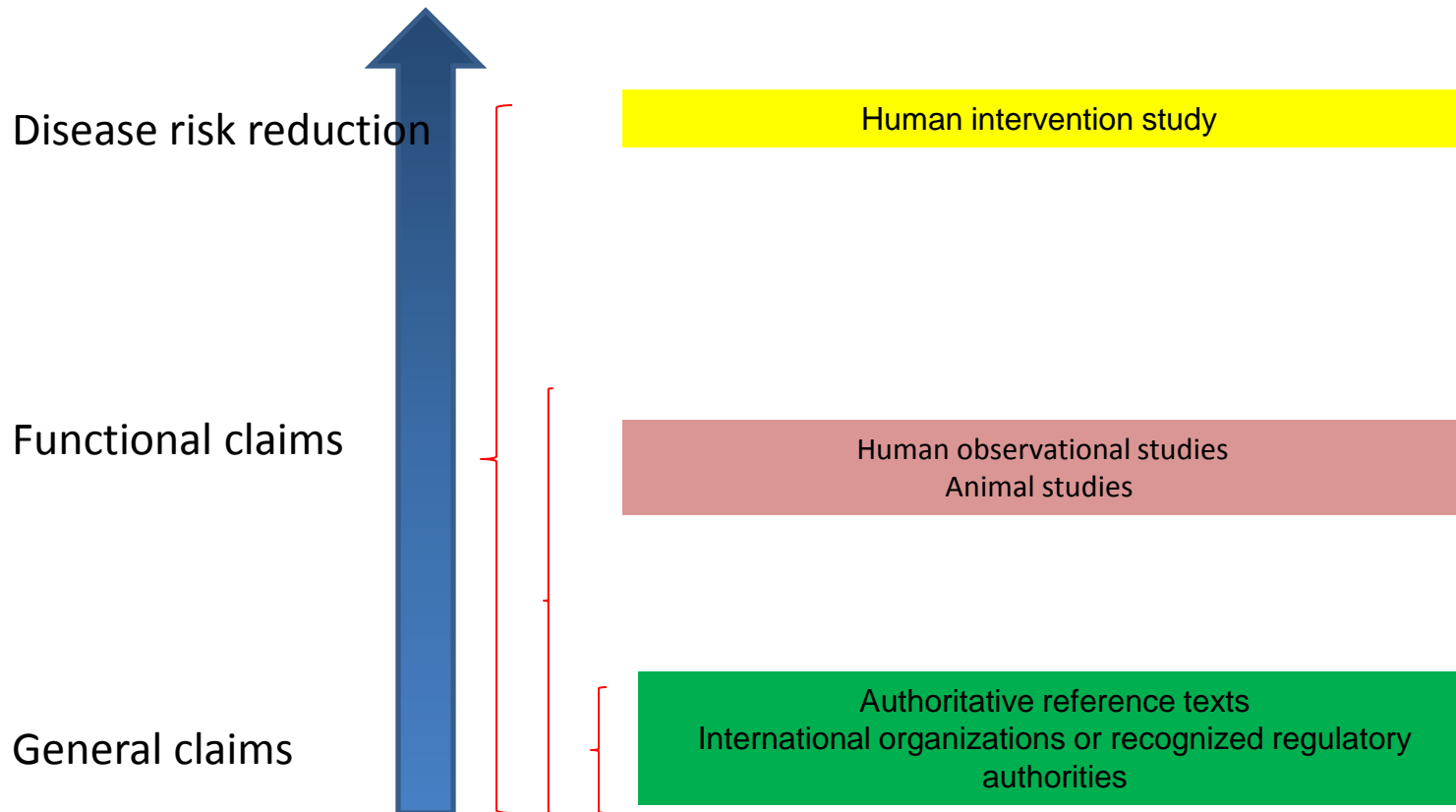
**LOWER**

# Type of Evidence

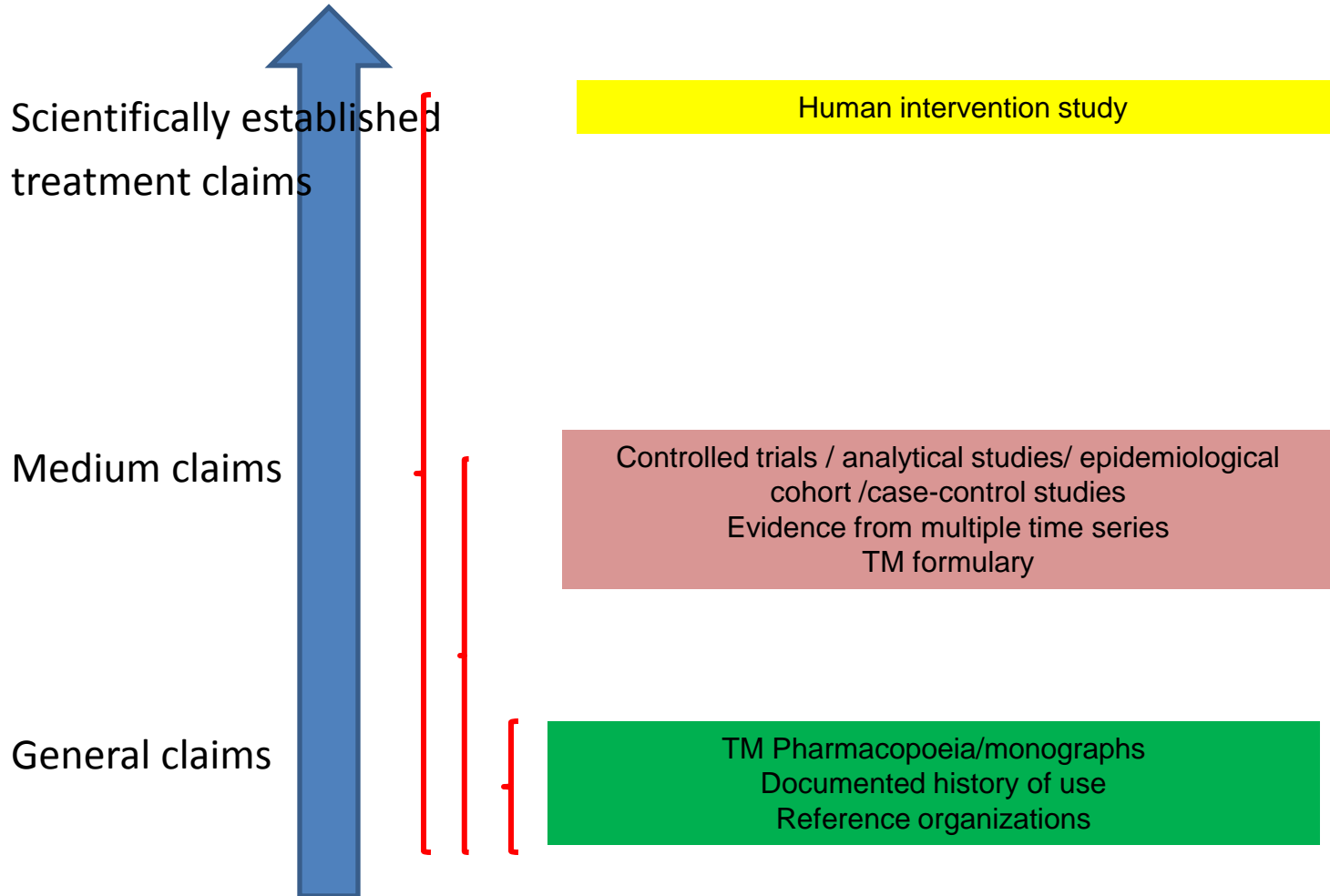
- well-designed meta-analysis of random controlled trials, or one well designed random controlled trial
- other clinical trials: well-designed controlled trials without randomization, well-designed experimental studies
- well-designed descriptive and observational studies, comparative studies, case controlled studies
- expert committee reports, peer reviewed published review,
- conclusions of reputable regulatory agencies
- traditional references



# Sources of evidence - HS



# Sources of evidence - TM



# Systematic review of the totality of evidence – wish list

- Preclinical & clinical studies directly linked to the claim
- Reproducible methodology
- Explicit definitions of terminology used
- Inclusion & exclusion criteria stated
- Evaluated and presented in an objective and unbiased manner
- Data summarized

# Challenges :

- ✓ Chinese Medicine

traditional medicine based on the philosophy of Yin & Yang and the flow of Chi energy based on the meridians

- ✓ Indian Medicine – Ayurvedic

to bring body, mind and spirit into harmony within an individual

- ✓ Malay traditional medicine

# Challenges :

- ✓ TM and HS are having differences in their functions, that requiring different 'tools' for the pre market control and assesment for the risks.
- ✓ TM can not only be seen as a trade commodity but also comprehensive health care involving traditional practitioner.
- ✓ Doses and usage of the same ingredients may be different
- ✓ Selective publication of study results (limited research budget)
- ✓ CAM products in most countries are not required to be registered
- ✓ Ingredient or product ?
- ✓ Slick marketing campaigns involving unsubstantiated gimmicky products

# THE WAY FORWARD

- ✓ Educating the public about current CAM evidence
- ✓ More quality research
- ✓ Intellectual property protection
- ✓ CAM to be used as adjunct to modern medicine (complementary)
- ✓ CAM to be used in place of conventional therapy (alternative)
- ✓ Physicians being oriented to CAM modalities and philosophy



# Websites

- **National Pharmaceutical Control Bureau :**  
[www.bpfk.gov.my](http://www.bpfk.gov.my)
- **Malaysian Adverse Drug Advisory Committee ( MADRAC ) :**  
[www.madrac.gov.my](http://www.madrac.gov.my)



**THANK YOU**