

**Traditional Herbal Medicinal Products: implications in healthcare education**

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**Putting Herbal Medicines into Practice...**

- GPs, Pharmacists, Nurses, Herbalists and Nutritionists put HMs into practice.
- However, **Pharmacists** were / are the only healthcare professionals who receive full training on these products.
- **Pharmacognosy** is the pharmaceutical discipline dealing with the multiple aspects of the use of natural products in medicine.

**Healthcare professionals' duty to inform the Public on CAM**

'We recommend that every medical school ensures that all their medical undergraduates are exposed to a level of CAM familiarisation that makes them aware of the choices their patients might make '

House of Lords –Science & Technology – Sixth report

**A.1. Why they are of importance in Community Pharmacy?**

- Pharmacists' duty to inform the Public on healthcare
- Particular Patient's groups at risk
- Economic significance for the Community Pharmacy
  - Good service
  - Revenues

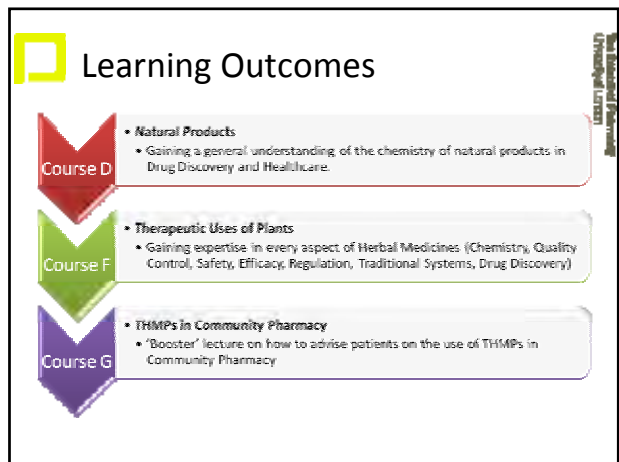
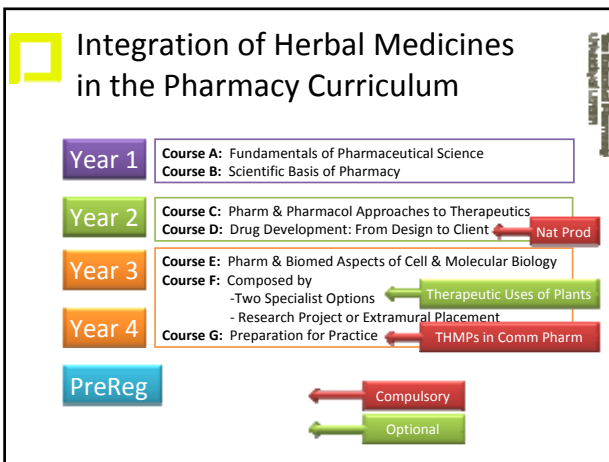
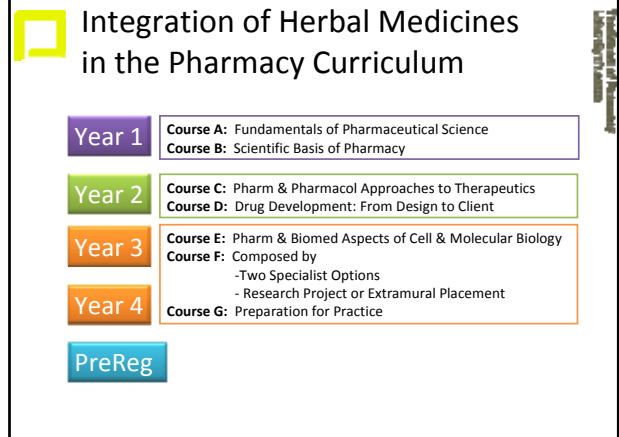
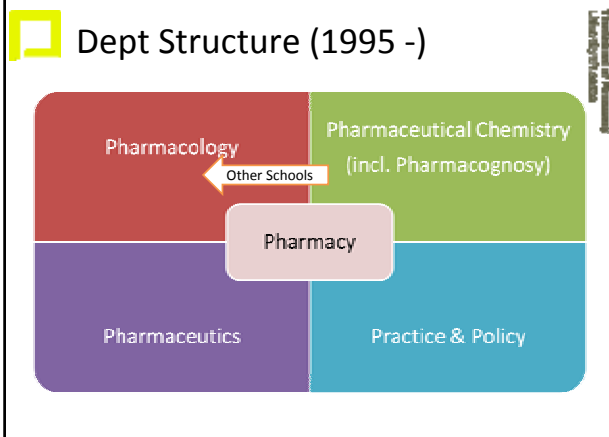
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**Pharmacists' knowledge of herbal medicines**

Quinn CG. Survey of community pharmacists in Glasgow (n = 112)  
University of Strathclyde, 1997

**School of Pharmacy (1842 – 1994)**

Presentation at the College of Medicine Science Council Seminar "Putting Herbal Medicines into Practice", 6 July 2011 at the Royal Botanic Gardens, Kew. Distributed with permission from presenter. The views expressed in this presentation are that of the speaker and do not necessarily reflect the views or policies of the College of Medicine. The College of Medicine does not guarantee the accuracy of the data included in this paper and accepts no responsibility for any consequence of their use.



### TEACHING IN COURSE D

### Registered & Unregistered

**Range of Herbal / Natural Products in a Community Pharmacy**

- Registered Medicines
- Traditional (Registered) Herbal Medicines**
- Homeopathic medicines
- Unlicensed Herbal remedies
- Nutraceuticals / Food supplements
- Functional food

## Registered Medicines of Herbal Origin

- They are medicines as any other.
- Leaflet offers all necessary information.
- Problems: some current herbal medicines were granted a registration after the Medicines Acts 1968 came into force, and not necessarily have proven efficacy.



Senokot  
LARDOX

## Traditional Herbal Medicinal Products (THMPs)

**Article 16a directive 2004/24/EC of the European parliament and of the council**

- (a) they have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;
- (b) they are exclusively for administration in accordance with a specified strength and posology;
- (c) they are an oral, external and/or inhalation preparation;
- (e) the data on the traditional use of the medicinal product are sufficient; in particular the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience.

**THEY ARE REGULATED BY HEALTH AUTHORITIES AND THE LEAFLET CONTAINS ADEQUATE INFORMATION FOR PATIENT'S ADVICE AND SAFE USE**

[Guidance for Retailers, Wholesalers, Importers and Manufacturers on Registering Herbal Medicine under the THMR Scheme](#)



Kaloba  
Atrisan

## Homeopathic medicines

- Despite the lack of clinical evidence, homeopathy remains a popular complementary therapy and it is available on the NHS. In the UK, there are several NHS homeopathic hospitals and some GP practices also offer homeopathic treatment. Homeopathy is also practised privately.
- There are several associations for practitioners of homeopathy which have a range of positions on the integration of homeopathy with orthodox medicine. See the 'useful links' section for more information about this.
- Unlike doctors, nurses, and other conventional healthcare professionals, homeopaths do not have to be registered with a regulatory body. The 'Complementary and Natural Healthcare Council' is a voluntary organisation which practitioners can register with, but they do not have to.



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## Unlicensed Herbal remedies 1

Herbal remedies placed on the market through Section 12(2) of the Medicines Act must:

- be made from only herbal active ingredients. The inclusion of vitamins, minerals, animal derivatives or any other non-herbal active ingredient are not permitted;
- make no medicinal claims or recommendations for use;
- hold no brand names. The remedy can only be sold or supplied under a designation which only specifies the plant or plants and the process by which it was made, for example, Echinacea extract;
- comply with any [restrictions on specific herbal ingredients](#).

- Most manufactured, finished, over-the-counter (OTC) herbal remedies, like the ones available in high street health food stores or super markets, are supplied as unlicensed herbal remedies through Section 12(2) of the Medicines Act 1968.
- They are not required to meet any specific standards of safety or quality. Also, there is no requirement for these products to be accompanied by the necessary information for their safe use, such as safety warnings.
- A number of safety concerns (highlighted in our 'Herbal Safety News' section) have arisen as a result.

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## Herbalist's exemption

**Key facts**

- Unlicensed herbal remedies made up to meet the need of individual patients: Section 12(1) of the Medicines Act 1968.
- The existence of this regime is greatly valued by herbal practitioners and by many members of the public.
- A number of public health risks associated with the supply of herbal medicines by such practitioners have been identified.
- There are no restrictions in terms of those who operate under the regime.

**The solution**

**Herbalists 'must sign register of healers'**



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## Nutraceuticals / Food supplements

- **Nutraceutical:** any substance that may be considered as a food or part of a food and provides medical or health benefits including the prevention and treatment of disease.
- **In general containing isolated compounds or enriched extracts together with vitamins, minerals, etc.**

**Functional foods** are ordinary foods that have components or ingredients incorporated into them to give them a specific medical or physiological benefit, other than a purely nutritional effect. The product should also carry a health claim on the packaging.

**INCREASED EXPOSITION OF PHARMACISTS TO THESE PRODUCTS AS A RESULT OF THE MANY PHARMACIES LINKED TO SUPERMARKETS**

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## Formats

	Functional food	Nutraceuticals	
	Spreading fats	Solid forms (powders, capsules, etc.)	
	Yoghurts	Teas	
	Cereals and grains	Liquids	
	Drinks		

## Indication vs. Advertising

## Sorting out: the key

Do they have a PL or THR number?

- Yes**
  - PL: Medicine
  - THR: Traditional Herbal Medicinal product
- No**
  - Refers itself as a Food Supp. Or contains a table with the nutritional value
    - Yes**: Food Supplement
    - No**: Contains ONLY a herb And does not have Registered Name → Unlicensed Herbal Remedy

## THMP vs Unlicensed

**Licensed = Contains medically relevant information**

**Unlicensed = information given is not endorsed by MHRA**

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## Practical Lecure

**Design**

- Each student is assigned three products (leaflets + package)
- They have to analyse the information contained and answer a MCQ
- All the practical is online and literature is also electronic (Medicines Complete®, Pharmacopoeia, MHRA web site)

**Conceptual Map**

## Medicines Complete

## Pharmacopoeia

The screenshot shows a 'Knowledge Database' page with text and a blue arrow pointing to a specific section.

## Results

- Two thirds of the students could average 7 out of 10
- They identified the right regulatory status and its implications in quality and efficacy, clearly differentiating licensed from unlicensed products

- However in the exam paper they were asked to write on the similarities and differences between products endowed with a PL number and Traditional Herbal Medicines (THR) and they **failed to treat the THMPs as medicines.**

## Misconceptions

**Kwai** contains garlic and vitamins A, C and E to help maintain a healthy heart and circulation.  
**Other Ingredients:** Sorbitol, talc, corn starch, gelatine, Sucrose, lactose, magnesium silicate, hydroxypropylmethylcellulose, bulking agent cellulose powder, vegetable oil, magnesium stearate, glucose syrup, microcrystalline cellulose, stearic acid, colours (titanium dioxide, riboflavin, carotene), carnauba wax and bees wax.

Garlic is not a herb, is a spice, so it cannot be the active herbal ingredient

I do not see any binomial Latin name, so it is not a herbal medicine

Cellulose is from herbs, so this might be a herbal active ingredient

## HMPs' Legal Framework confounds Course D students

The diagram shows a multi-level pyramid structure with various text boxes and arrows, representing a complex legal framework. A cartoon student is shown looking confused.

## Lost in translation

**Lectures**

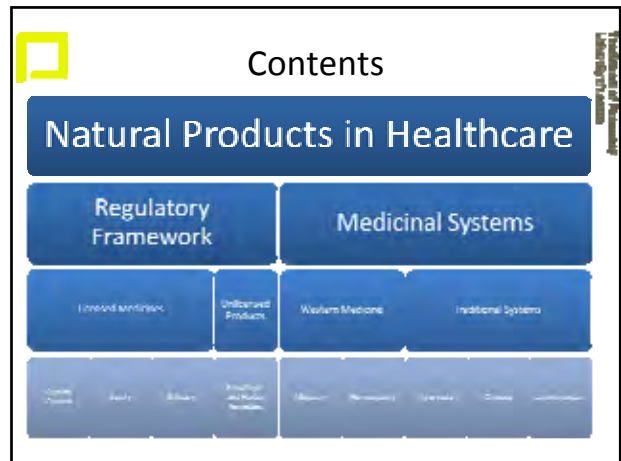
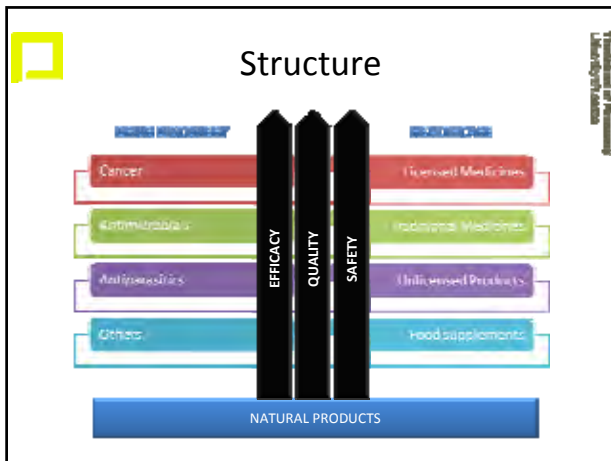
- HMPs are licensed by the MHRA
- Efficacy is based on Traditional Use Only
- Quality is based on GMP and other standards
- These products may interact with other medicines and undergo other pharmacological effects

**Exam**

What? I think medicines must be only those with clinical efficacy and they should be completely safe

'THMPs are licensed by the MHRA but they do not have any efficacy and its quality is doubtful. In addition they pose a risk of interactions'

## TEACHING IN COURSE F (SPECIALIST MODULE)



## Course Design and Students

- Lectures with an important input by external speakers (37 hours)
- Case Studies and practical exercises (6 hours)
- Coursework on Pharmacopoeial Quality Control (15 hours)
- Student seminar presentations (8 hours).

**Survey: Students taking Herbal Medicines Specialist Module**

Legend: TUP, Other

## Workshop

- A 35 yrs old male patient suffers from mild migraines and comes to your Pharmacy looking for your advice about Herbal medicines.
  - Which herbal medicine would you recommend him?
  - He is not having any other therapy at the moment but he is worried about any side effect this herbal medicine may have. What can you say to him about this particular?
  - This patient tells you that migraines have been a traditional problem in his family. His 87- yrs grandfather has also migraines and would like to know if he may also benefit from this herbal remedy. What do you advise in this case?
  - As winter is approaching he would like to know if he could have some Echinacea to prevent colds or flu. Is it possible to combine this herbal remedy with the one to treat migraines?
- 2. (a) A Muslim patient is complaining about insomnia. Is Valerian Tincture a good choice? (b) A vegan patient suffers from joints pain and asks your advice about glucosamine sulphate. Discuss the case.

## Herbal Medicines in Textbooks

**Part 1: Introduction**

Plants in medicine: the origins of pharmacology  
The scope and practice of pharmacology  
Herb collection and analysis

**Part 2: The plant and animal kingdoms as sources of drugs**

Biological and geographical sources of drugs  
A historical approach to the study of medicine  
Pharmacological activities of natural products  
Special and anti-infective properties of biological products  
Discovering new lead compounds in pharmaceutical research and development

**Part 3: Principles related to the commercial production, quality and standardisation of natural products**

Control of crude drugs  
Production of crude drugs  
Plant growth regulators  
Phytochemical constituents within a species  
Development of herbal drugs  
Quality control

**Part 4: Pharmacology**

General methods associated with the physicochemical investigation of herbal products  
Basic methods common to the origin of secondary metabolites

**Part 5: Pharmacological and related drugs of biological origin**

Introduction  
Hydrocarbons and derivatives, Carbohydrates, Phenols and phenolic glycosides  
Alkaloids and their salts, Saponins, Quinoline drugs and other terpenes  
Miscellaneous terpenoids, Cyclic terpenes, glycoside compounds and other terpenes  
Miscellaneous glycosides, Alkaloids. The search for specific chemical and biological targets  
Phytochemicals: Chemical, biological and medicinal drugs with antitumor and anti-angiogenic activities, Anticancer and anti-oxidant drugs, Vitamins and hormones  
The plant metabolites, Contraceptive and anti-fertility agents, Antiviral products

**Part 6: Plants in complementary and traditional systems of medicine**

Introduction  
Herbal medicine in Britain and Europe: regulation and practice  
Herb medicine  
Chinese herbs in the West  
Plants in African traditional medicine - some perspectives  
**Part 7: Non-medicinal toxic plants and poisons**  
Heterocyclic, alkaloids, terpenoids and other toxic plants  
Poisons of natural origin  
**Part 8: Morphological and microscopic examination of drugs**  
Herb identification, morphology and anatomy  
Cell observation and organic cell contents  
Technique in microscopy

## Herbal Medicines in Textbooks

**Section 1: Phytotherapy and Pharmacognosy**

1. Importance in modern pharmacy and medicine
2. Pharmacognosy and its history: people, plants and natural products

**Section 2: Basic plant biology**

3. General principles of botany: morphology and systematics
4. Families yielding important phytopharmaceuticals
5. Ethnobotany and ethnopharmacology

**Section 3: Natural products chemistry**

6. Natural products chemistry
7. Principles of natural product chemistry and separation
8. Anticancer natural products

**Section 4: Plant product derived phytopharmaceuticals and nutraceuticals**

9. Production, standardisation and quality control
10. Characteristics of phytopharmaceuticals
11. Medicinal Plants in selected other health care systems
12. Traditional systems of herbal medicine
13. Complementary/alternative medicine

**Part B: Important Natural Products and Phytopharmaceuticals used in Pharmacy and Medicine**

14. The gastrointestinal and biliary system
15. The Cardiovascular system
16. The respiratory system
17. The central nervous system
18. Infectious diseases
19. The endocrine system
20. The reproductive and urinary tracts
21. The skin
22. The eye
23. Ear, nose and orthopharynx
24. Miscellaneous supportive therapies for stress, ageing, cancer and debility



## TEACHING IN COURSE G (PREPARATION FOR PRACTICE)



## Design

### Lecture

Lecture (1 hour)

- Same content as in Course D but the seniority of the public allows to go faster.
- Importance on the regulatory status and its implications.

### Workshop

Case Studies and practical exercises (1 hour)

- Same as in Course F



## Summary

### HMs in Pharmacy Education

- Introduction of HMs is made very early (2<sup>nd</sup> yr) (Lectures 3 h + Practicals 3h)
- Specialist Module (50 h)
- A “booster lecture” on HMs (1h) illustrated with case studies (1h) before they enter the Pre Reg

### Effects on the students

- the students cannot fully assimilate the subtlety of HMs but at least their premade concepts are challenged.
- About 14% of the cohort will choose the Specialist option on HMs thus becoming “experts” in therapeutic uses of plants from a community pharmacy perspective.
- The whole cohort is exposed again to HMs particularities. They are more mature and can better follow with great interest



## Future 1

- The new MPharm curriculum emphasises clinical content and integrates Pre Reg in the course structure > possibilities for a better placement of the HMs lectures at key stages
- Bringing HMs into practice very much depends on a critical mass of well trained pharmacists.



## Future 2

- The integration of the School of Pharmacy into UCL may facilitate / open possibilities to teach MDs and Nurses on this subjects.
- AND ABOVE ALL....



Do not make Herbal Medicines a boring experience...





Thank You!



HMs in Education  
*Bringing Herbal  
Medicines into  
Practice*  
Wed 6<sup>th</sup> July 2011