Lecture synopsis Sub: **NATURAL PRODUCTS: COMMERCE, INDUSTRY & REGULATIONS**

Subject I/C: Mohini Upadhye

Lecture No: 1

Name of topic/lesson – Commerce: Global & domestic market size of various natural products in commerce

Subtopic: Global & domestic market size of various natural products in commerce- Crude drugs

Objective: To study Global & domestic market size of various natural products in commerce- Crude drugs

Topic Outcomes: At the end of topic you should be

1 Able to know Global & domestic market size of various natural products in commerce- Crude drugs

2. Knowledge of factors which affects Global & domestic market size of various natural products in commerce- Crude drugs

India has 2.4 % of world's area with 8 % of global biodiversit y. It is one of the 12 mega-diversit y hot-spot reg ions of the world.

Over 800 species of medicinal plants are used in production of traditional medicines by industry. Of these about 90 % are collected from the wild. Less than 20 species of plants are under commercial cultivation.

It is estimated that medicinal drug-manufacturing units in India, which consume about 2000 tonnes of herbs annually.

Around 70 % of India's medicinal plants are found in tropical areas mostly in the various forest types spread across the Western and Eastern ghats, the Vindhyas, Chotta Nagpur plateau, Aravalis & Himalayas.

the temperate and alpine areas, higher altitudes, dry and moist deciduous vegetation (30 %) they include species of high medicinal value

References

1. Natural Product Commerce, Industry and Regulation, S. B. Gokhale, Nirali Prakashan

Lecture synopsis Sub: **NATURAL PRODUCTS: COMMERCE, INDUSTRY & REGULATIONS**

Subject I/C: Mohini Upadhye

Lecture No: 2

Name of topic/lesson – Commerce: Global & domestic market size of various natural products in commerce

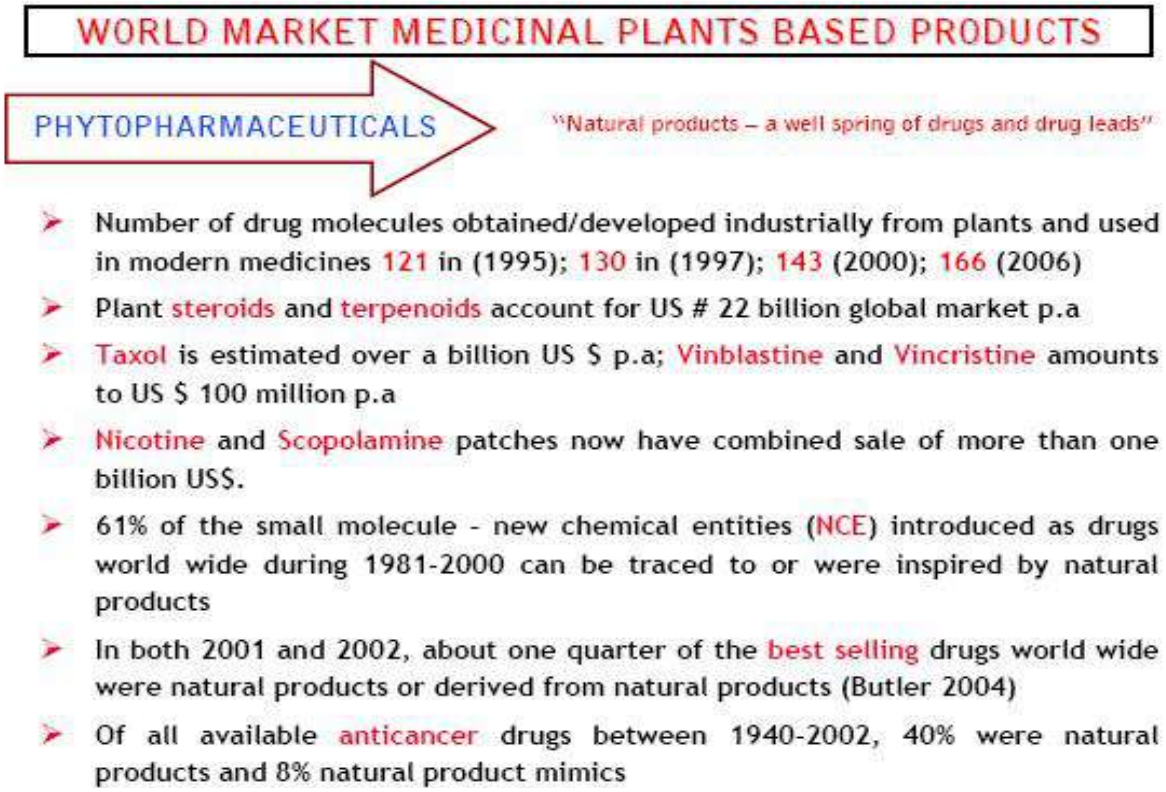
Subtopic: Global & domestic market size of various natural products in commerce- Phytopharmaceuticals

Objective: To study Global & domestic market size of various natural products in commerce- Crude drugs

Topic Outcomes: At the end of topic you should be

1 Able to know Global & domestic market size of various natural products in commerce- C Phytopharmaceuticals

2. Knowledge of factors which affects Global & domestic market size of various natural products in commerce- Phytopharmaceuticals



References Natural Product Commerce, Industry and Regulation, S. B. Gokhale, Nirali Prakashan

Lecture synopsis Sub: **NATURAL PRODUCTS: COMMERCE, INDUSTRY & REGULATIONS**

Subject I/C: Mohini Upadhye

Lecture No: 3

Name of topic/lesson – Commerce: Global & domestic market size of various natural products in commerce

Subtopic: Global & domestic market size of various natural products in commerce- Drug leads/Biomarkers, Drug intermediates, precursors

Objective: To study Global & domestic market size of various natural products in commerce- Drug leads/Biomarkers, Drug intermediates, precursors

Topic Outcomes: At the end of topic you should be

1.Able to know Global & domestic market size of various natural products in commerce- Drug leads/Biomarkers, Drug intermediates, precursors

2. Knowledge of factors which affects Global & domestic market size of various natural products in commerce- Drug leads/Biomarkers, Drug intermediates, precursors

References Natural Product Commerce, Industry and Regulation, S. B. Gokhale, Nirali Prakashan

Lecture synopsis Sub: **NATURAL PRODUCTS: COMMERCE, INDUSTRY & REGULATIONS**

Subject I/C: Mohini Upadhye

Lecture No: 4

Name of topic/lesson – Commerce: Global & domestic market size of various natural products in commerce

Subtopic: Global & domestic market size of various natural products in commerce- Neutraceuticals

Objective: To study Global & domestic market size of various natural products in commerce- Neutraceuticals

Topic Outcomes: At the end of topic you should be

Able to know Global & domestic market size of various natural products in commerce- Neutraceuticals and get the Knowledge of factors which affects Global & domestic market size of various natural products in commerce- Neutraceuticals

NUTRACEUTICALS → **Promising Sector with enormous growth**

- Health foods are known under different names throughout the world Nutraceuticals are food products supplemented with herbal ingredients, vitamins, minerals and nutrients or ingredients isolated/purified from conventional foods.
- These are the latest products in a succession of health food evolution constituting dietary supplement, fortified foods, foods and beverages with added bioactive ingredients.
- The strongest market driver for Nutraceuticals is the 'baby boomer generation' which will be the largest buying consumer group in the years ahead.
- The USA leads the Nutraceutical market followed by the countries of Western Europe and Japan, will remain largest global producers and consumers.
- Asia and Pacific, Latin America, Africa and middle East are set to provide the fastest growth for the nutraceutical industry. China will see the most impressive jump in nutraceutical production & consumption USA ($ 10 - 37 billion); EUC ($ 15-20 billion); JAPAN ($ 10-14 billion)

References Natural Product Commerce, Industry and Regulation, S. B. Gokhale, Nirali Prakashan

Lecture synopsis Sub: **NATURAL PRODUCTS: COMMERCE, INDUSTRY & REGULATIONS**

Subject I/C: Mohini Upadhye

Lecture No: 5

Name of topic/lesson – Commerce: Global & domestic market size of various natural products in commerce

Subtopic: Global & domestic market size of various natural products in commerce- Spices and Condiments

Objective: To study Global & domestic market size of various natural products in commerce- Spices and Condiments

Topic Outcomes: At the end of topic you should be

1.Able to know Global & domestic market size of various natural products in commerce- Spices and Condiments

2. Knowledge of factors which affects Global & domestic market size of various natural products in commerce- Spices and Condiments

ESSENTAIL OILS: GLOBAL VIEW

- World Production of Essential oils (Estimated) 150,000 tons excluding Turpentine oil which alone is 300,000 tons
- Developing countries have great potential for production of E.O. 65% produced in developing countries, 35% in industrialized countries
- Seven leading countries Brazil, China, India, Indonesia, Egypt, Morocco and Turkey produce 85% among developing nations
- Major exporters of E.O.: Brazil, China, India, European Union, USA and Indonesia account for 66% of essential oil exports
- Major importers: E.U., USA, Japan, Canada, Switzerland account for more than 70% of the total volume import
- Basic requirements for establishing an E.O. business:
  a) Market demand b) Raw material availability c) E.O. quality

References Natural Product Commerce, Industry and Regulation, S. B. Gokhale, Nirali Prakashan

Lecture No: 6

Name of topic/lesson – Commerce: Global & domestic market size of various natural products in commerce

Subtopic: Global & domestic market size of various natural products in commerce- Herbal Cosmetics

Objective: To study Global & domestic market size of various natural products in commerce- Herbal Cosmetics

Topic Outcomes: At the end of topic you should be

1.Able to know Global & domestic market size of various natural products in commerce- Spices and Condiments

2. Knowledge of factors which affects Global & domestic market size of various natural products in commerce- Spices and Condiments

BOTANICAL EXTRACT DEMAND IN COSMETIC AND TOILETRIES FROM 1989 TO 2008

ITEM	DEMAND VALUE (MILLION US $)			
	1989	1993	1998	2008 *
ALOE EXTRACT	38	46	63	115
BOTANICAL EXTRACTS	180	230	345	720
OTHERS	22	34	67	174
PLANT ACIDS & ENZYMES	19	37	65	173
ESSENTIAL OILS	101	113	150	258
OTHER NATURAL PRODUCTS	85	115	180	385
TOTAL	265	345	525	1,105

* Estimates; Source : FREEDONIA GROUP

References Natural Product Commerce, Industry and Regulation, S. B. Gokhale, Nirali Prakashan

Lecture synopsis Sub: **NATURAL PRODUCTS: COMMERCE, INDUSTRY & REGULATIONS**

Subject I/C: Mohini Upadhye

Lecture No: 7

Name of topic/lesson – Commerce: Global & domestic market size of various natural products in commerce

Subtopic: Global & domestic market size of various natural products in commerce- Pharmaceutical Excipients

Objective: To study Global & domestic market size of various natural products in commerce- Pharmaceutical Excipients

Topic Outcomes: At the end of topic you should be

1.Able to know Global & domestic market size of various natural products in commerce- Pharmaceutical Excipients

2. Knowledge of factors which affects Global & domestic market size of various natural products in commerce- Pharmaceutical Excipients

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An excipient is a substance formulated alongside the active ingredient of a medication, included for the purpose of long-term stabilization, bulking up solid formulations that contain potent active ingredients in small amounts (thus often referred to as "bulking agents", "fillers", or "diluents"), or to confer a therapeutic enhancement on the active ingredient in the final dosage form, such as facilitatingdrug absorption, reducing viscosity, or enhancing solubility. Excipients can also be useful in the manufacturing process, to aid in the handling of the active substance concerns such as by facilitating powder flowability or non-stick properties, in addition to aiding *in vitro*stability such as prevention of denaturation or aggregation over the expected shelf life. The selection of appropriate excipients also depends upon the route of administration and the dosage form, as well as the active ingredient and other factors. A comprehensive classification system based on structure-property-application relationships has been proposed for excipients used in parenteral medications.

Pharmaceutical regulations and standards require that all ingredients in drugs, as well as their chemical decomposition products, be identified and shown to be safe. Often, more excipient is found in a final drug formulation than active ingredient, and practically all marketed drugs contain excipients As with new drug substances and dosage forms thereof, novel excipients themselves can be patented

References Natural Product Commerce, Industry and Regulation, S. B. Gokhale, Nirali Prakashan

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Lecture No: 8

Name of topic/lesson – Commerce: Global & domestic market size of various natural products in commerce

Subtopic: Global & domestic market size of various natural products in commerce- Biofuels

Objective: To study Global & domestic market size of various natural products in commerce- Biofuels

Topic Outcomes: At the end of topic you should be

1.Able to know Global & domestic market size of various natural products in commerce- Biofuels

2. Knowledge of factors which affects Global & domestic market size of various natural products in commerce- Biofuels

A biofuel is a fuel that is produced through contemporary processes from biomass, rather than a fuel produced by the very long-winded geological processes involved in the formation of fossil fuels, such as oil. Since biomass technically can be used as a fuel directly (e.g. wood logs), some people use the terms «biomass» and «biofuel» interchangeably.

Biodisel is produced from oils or fats using transesterification and is the most common biofuel in Europe. It can be used as a fuel for vehicles in its pure form (B100), but it is usually used as a diesel additive to reduce levels of particulates, carbon monoxide, andhydrocarbons from diesel-powered vehicles.

In 2018, worldwide biofuel production reached 152 billion liters (40 billion gallons US), up 7% from 2017,[12] and biofuels provided 3% of the world's fuels for road transport. The International Energy Agency want biofuels to meet more than a quarter of world demand for transportation fuels by 2050, in order to reduce dependency on petroleum.

References Natural Product Commerce, Industry and Regulation, S. B. Gokhale, Nirali Prakashan

Lecture synopsis Sub: **NATURAL PRODUCTS: COMMERCE, INDUSTRY & REGULATIONS**

Subject I/C: Mohini Upadhye

Lecture No: 9

Name of topic/lesson – Commerce: Demand and Supply Status

Subtopic: Demand and Supply Status

Objective: To study Demand and Supply Status

Topic Outcomes: At the end of topic you should be

Able to know Demand and Supply Status and get the Knowledge of factors affecting the same.

To assess the current Demand and Supply scenario of medicinal plants, NMPB has extensively surveyed the herbal market of India in collaboration with ICFRE, Dehradun. The estimate of consolidated commercial demand of herbal raw drugs for the year 2014-15 has been has been estimated at 5,12,000 MT. Estimated Exports of Herbal Raw Drugs, including Extracts has been estimated 1,34,500 MT in 2014-15. Estimated Consumption by Domestic Herbal Industry has been estimated 1,95,000 MT 2014-15. An Estimated 1,67,500 MT of Herbal Raw Drugs are also Used by Rural Households every year. About 1178 medicinal plant species recorded in the practices of trade. Out of which, 242 plant species are used in annual quantities of more than 100MT.

India has very strong traditional health care practices that are represented by the classical systems of medicine like Ayurveda, Siddha, Unani, and Swa-rigpa on one hand, and by a very diverse area-specific and community-specific folk healthcare practices on the other. The major commonality of the Indian classical and the folk health care traditions is their dependence upon the raw material derived from a large diversity of plant species, which is estimated to be about 6,500

References Natural Product Commerce, Industry and Regulation, S. B. Gokhale, Nirali Prakashan

Lecture No: 10

Name of topic/lesson – Commerce: Import & Export

Subtopic: Import & Export

Objective: To study **:** Import & Export

Topic Outcomes: At the end of topic you should be

Able to know **:** Import & Export and get the Knowledge of factors affecting the same.

Medicinal plants also play an important role in the lives of rural people in India with few health facilities. The plants that possess therapeutic properties or exert beneficial pharmacological effects on the animal body are generally designated as "Medicinal Plants". They play a significant role in providing primary health care services to rural India. They serve as therapeutic agents as well as important raw materials for the manufacture of traditional and modern medicine. Substantial amount of foreign exchange can be earned by exporting medicinal plants to other countries. In India there are 880 medicinal plants species involved in all India trade. Of this, 48 species are exported and about 42 spices are imported. The Ministry of Environment and Forests, Government of India, reveals that there are over 8000 species of medicinal plants grown in the country. About 70 percent of these plants are found in the tropical forest; spread across the Western and Eastern Ghats. The Export-Import Bank of India, in its report for the year 1997, puts medicinal plants related trade in India at $.5.5 billion and the same is growing rapidly. According to World Health Organisation (WHO) the international market of herbal products is around $6.2 billion, which is poised to grow to $5 trillion by the year 2050. Unfortunately, India's share in the global medicinal plants related export trade is just 0.5 percent. The export of Medicinal plants is Rs.33453.23 lakhs during 1991-92 to 2002-2003. Its overall trend has been increased in 0.21 percent. And the average Import of Rs.2827.01 lakhs. Also its trend has been increased in 0.39 percent.

References

Export and import pattern of medicinal plants in India, M. Ramesh Kumar, Indian Journal of Science and Technology, Vol. 4 issue 3 (March 2011)

Lecture No: 11

Name of topic/lesson – Herbal Drug Industry

Subtopic: Present Scope & Future Prospect

Objective: To study Present Scope & Future Prospect

Topic Outcomes: At the end of topic you should be

Able to know Present Scope & Future Prospect and get the Knowledge of factors affecting the same.

Use of herbal medicines for therapeutic purpose is now well-established and widely acknowledged to be safe and effective. Many drugs commonly used today in the developing countries are of herbal origin and about of all modern prescription drugs contain at least one active ingredient derived from plant material, either obtained from plant extracts or synthesized to mimic natural plant compound. Many of the pharmaceuticals currently available to Physicians have a long his-history of use as herbal remedies. According to the World Health Organization (WHO), approximately 25 per cent of modern drugs used in the United States have been derived from plants. More than 120 active compounds isolated from higher plants are widely used in modern allopathic medicine today and 80 per cent of them show a positive co-relation between their modern therapeutic use and the traditional use of the plants from which they are derived. At least 7,000 medicinal compounds derived from plants, the ingredients of herbal medicine, are included in the modern pharmacopoeia of drugs.

WHO estimates that 80 per cent of the world's population currently use herbal medicines for some aspects of primary healthcare. They are also highly lucrative in the international market, generating billions of dollars in revenue. To cite a few examples, annual revenue from herbal medicines and herbal products in Western Europe reached US$ 5 billion in 2003-2004. In China, sales of herbal products totalled US$ 14 billion in 2005. Herbal medicine revenue in Brazil was US$ 160 million in 2007.

References Herbal medicines: Present status, future prospects, Dr. Abdul Ghani

Lecture No: 12

Name of topic/lesson – Herbal Drug Industry

Subtopic: OTC and TSM products

Objective: To study OTC and TSM products

Topic Outcomes: At the end of topic you should be

Able to know Present scenario, future aspects of OTC and TSM products

There are about 9000 AYUSH (Ayurvedia Unanni, Sidhha & Homoeopathy) manufacturing units in India.

Private (99.6 %) & Government (0.4%) units

Turnover of Indian Herbal Industry app. 80 billions

Indian share in international market is less than 1%.

Growing trends in AYUSH products during 2003-2008 with respect to export.

About 70% export is of raw materials (10 billion / annum) & 30% export consist of herbal extract & finished products.

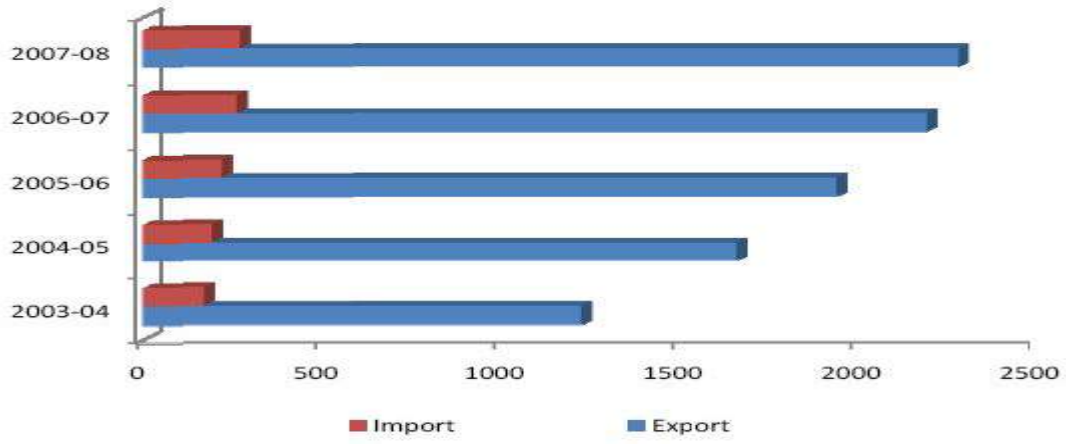


Fig 2. Foreign trade of AYUSH products (2003-2008)
Source: AYUSH Annual Report-2008.

References Natural Product Commerce, Industry and Regulation, S. B. Gokhale, Nirali Prakashan

Lecture No: 13

Name of topic/lesson – Herbal Drug Industry

Subtopic: Plant based industries

Objective: To study Plant based industries

Topic Outcomes: At the end of topic you should be

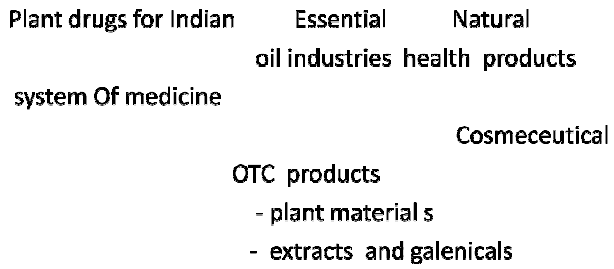
Able to know Present scenario, future aspects of Plant based industries

Leading companies of herbal drugs are located in- Germany, France,Italy,Switzerland,China and India.

India is one of the top twelve mega – biodiversity centers of world and since from 5 thousands year supplying medicinal and fragrant material to western civilization in Greece and Rome.

India is major supplier of sandal wood oil and lemon grass oil.

CLASSIFICATION OF HERBAL INDUSTRIES



References Natural Product Commerce, Industry and Regulation, S. B. Gokhale, Nirali Prakashan

Lecture No: 14

Name of topic/lesson – Herbal Drug Industry

Subtopic: Plant based industries

Objective: To study Plant based industries

Topic Outcomes: At the end of topic you should be

Able to know Present scenario, future aspects of Plant based industries

References Natural Product Commerce, Industry and Regulation, S. B. Gokhale, Nirali Prakashan

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Lecture synopsis Sub: **NATURAL PRODUCTS: COMMERCE, INDUSTRY & REGULATIONS**

Subject I/C: Mohini Upadhye

Lecture No: 15

Name of topic/lesson – Herbal Drug Industry

Subtopic: Plant based institutes

Objective: To study Plant based institutes

Topic Outcomes: At the end of topic you should be

Able to know Present scenario, future aspects of Plant based institutes

A large number of academic, industrial and government institutes are conducting research on the medicinal plants of India. There has been no systematic review of the massive work that is available from this nation. Many international data-bases and web-sites do not cover even the work published in the Indian Journals. Hence, there is a global lack of awareness of the mass and nature of work carried out on diverse aspects *viz.* ethnobotany, phytochemistry.

CSIR

ICMR

MNPB

NCL etc

References:

Current Status of Herbal Drugs in India: An Overview, J Clin Biochem Nutr. 2007 Jul; 41(1): 1–11

Lecture No: 16

Name of topic/lesson – Herbal Drug Industry

Subtopic: Industry oriented R&D Institutes

Objective: To study Industry oriented R&D Institutes

Topic Outcomes: At the end of topic you should be

Able to know working of Industry oriented R&D Institutes

For overall development of medicinal plants sector in the country the NMPB has been implementing following Schemes since year 2008-09: 1. Central Sector Scheme for "Conservation, Development and Sustainable Management of Medicinal Plants "aimed at providing support for Survey, Inventorization, in-situ conservation, ex-situ conservation / herbal gardens, Research and Development, linkage with peoples collectives like Self Help Groups (SHGs), Joint Forests Management Committees (JFMCs) etc. The Scheme is being continued during the 12th Plan. 2. Centrally Sponsored Scheme of "National Mission on Medicinal Plants" is primarily aimed at supporting cultivation of medicinal plants on private land with backwards linkages, for establishment of nurseries for supply of quality planting material etc. and forward linkages for post-harvest management, marketing infrastructure, certification etc. Currently this Scheme is being implemented as a component (Medicinal Plants) of the National AYUSH Mission (NAM).

References:

Development of Medicinal Plants Sector in India –An Empirical Study, nternational Journal of Engineering Technology, Management and Applied Sciences, January 2016, Volume 4, Issue 1

Lecture No: 17

Name of topic/lesson – Herbal Drug Industry

Subtopic: Technical and Funding assistance Schemes

Objective: To study Technical and Funding assistance Schemes

Topic Outcomes: At the end of topic you should be

Able to know Technical and Funding assistance Schemes and their working.

1. UGC: UGC strives to promote teaching and research in emerging areas in Humanities, Social Sciences, Languages, Literature, Pure Sciences, Engineering & Technology, Pharmacy, Medical, Agricultural Sciences etc
2. AICTE: The All India Council for Technical Education (AICTE) has been performing its regulatory, planning and promotional functions through its Bureaus, namely: Administration; Finance; Planning and Coordination; Under Graduate Studies; Post Graduate Education and Research; Faculty Development; Quality Assurance; and Research and Institutional Development Bureaus; and through its Regional Offices located in various parts of the country.
3. CSIR: The major functions of CSIR include promotion, guidance and coordination of scientific and industrial research in India; establishment or development of and assistance to existing special institutions or departments for scientific study of problems affecting particular industries and trades; award of fellowship; utilization of Council's R&D results for industrial development; collection and dissemination of S&T information; and technology generation, absorption and transfer. The Human Resource Development (HRD) Group of Council of Scientific & Industrial Research (CSIR) has a mandate to develop and nurture S&T manpower at the national level. It also promotes, guides and co-ordinates scientific & industrial research through research grants to Scientists/Professors working in Universities/R&D Institutes of Higher learning etc.

References Natural Product Commerce, Industry and Regulation, S. B. Gokhale, Nirali Prakashan

Lecture synopsis Sub: **NATURAL PRODUCTS: COMMERCE, INDUSTRY & REGULATIONS**

Subject I/C: Mohini Upadhye

Lecture No: 18

Name of topic/lesson – Regulation& Patenting

Subtopic: Regulations

Objective: To study Licensing requirements for production and scale of herbal drugs in India

Topic Outcomes: At the end of topic you should be

Able to know Licensing requirements for production and scale of herbal drugs in India

To manufacture Ayurvedic / Herbal products in India, we need a license from AYUSH and not from FSSAI. The Ministry of AYUSH is located at INA and The AYUSH Department of Delhi is located in Tibbia college, Karol Bagh.

Below are 3 types of manufacturing licenses issued by AYUSH :

1. Complete Manufacturing License - full fledged manufacturing license. In this case you will be both marketing and manufacturing the product. Thus you will have to setup your own manufacturing unit.

2. Loan License - manufacturing license where you loan a manufacturing unit of a third party manufacturer to make your products. Thus you will not have to own a manufacturing unit. You will have to apply for a Loan license and it will be issued to your company. Then you will have to get an approval for your product from authorities. Post that you liaison with a GMP certified manufacturer to manufacture your product. Either you can provide the raw materials and packaging material or manufacturer can arrange it from his sources. Finally manufacturer gives you the ready product.

3. Contract Manufacturing / Third party manufacturing / White label Manufacturing / Product to Product manufacturing - License where you will use the manufacturing license of a third-party manufacturer to manufacture the product. You will be just marketing the product. Thus you dont have to own any manufacturing unit and dont have to get any license. All liasoning with AYUSH office will be done by the manufacturer

Reference:

Pharmacognosy and Phytochemistry, A comprehensive Approach, Dr. S. L. Deore, PharmaMed Press.

Lecture synopsis Sub: **NATURAL PRODUCTS: COMMERCE, INDUSTRY & REGULATIONS**

Subject I/C: Mohini Upadhye

Lecture No: 19

Name of topic/lesson – Regulation& Patenting

Subtopic: Regulations: Schedule T-GMP practices of Indian system of Medicine

Objective: To study Schedule T-GMP practices of Indian system of Medicine

Topic Outcomes: At the end of topic you should be Able to know Licensing requirements for production and scale of herbal drugs in India

The Good Manufacturing Practices are prescribed to ensure that I. Raw materials used in the manufacture of drugs are authentic, of prescribed quality and are free from contamination II. The manufacturing process is as has been prescribed to maintain the standards. III. Adequate quality control measures are adopted. IV. The manufactured drug which is released for sale is of acceptable quality V. To achieve the objectives above each licensee shall evolve methodology and procedures for following the prescribed process of manufacture of drugs which should be documented as a manual and kept for reference and inspection.

Factory Premises

General Requirements

Water Supply

Disposal of Waste

Working space

Health Clothing Sanitation and Hygiene of Workers

Machinery and Equipments

Batch Manufacturing Records

Distribution Records

Record of Market Complaints

Quality Control

LIST OF EQUIPMENT RECOMMENDED FOR IN HOUSE QUALITY CONTROL SECTION

Reference: Pharmacognosy and Phytochemistry, A comprehensive Approach, Dr. S. L. Deore, PharmaMed Press

Lecture No: 20
Name of topic/lesson – Regulation& Patenting

Subtopic: Components of GMP and its objectives

Objective: To study Components of GMP and its objectives

Topic Outcomes: At the end of topic you should be Able to Components of GMP and its objectives

Good Manufacturing Practice (GMP) ensures that quality is built into the organisation and processes involved in manufacture z GMP covers all aspects of "manufacture" including collection, transportation, processing, storage, quality control and delivery of the finished product.
It is considered as a part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their use. GMP is an integral part of Quality Assurance.
All manufacturing processes are clearly defined, systematically reviewed, and shown to be capable of consistently manufacturing medicinal products of the required quality and complying with specifications. z Critical steps of the process and significant changes to the process are validated.
Requirements are now defined in statute z Blood Establishments are inspectable z Non-compliance is subject to legal sanction z Strict product liability applies z Key to regulatory expectations are z Arrangements made for quality assurance z Operation of defensible GMP z Clearly –defined individual responsibilities.

Quality Management
Personnel
Premises and Equipment
Documentation
Production/Processes
Quality Control
Contract Manufacture
Complaints & Product Recall
Self Inspection

Reference: Pharmacognosy and Phytochemistry, A comprehensive Approach, Dr. S. L. Deore, PharmaMed Pres

Lecture synopsis Sub: **NATURAL PRODUCTS: COMMERCE, INDUSTRY & REGULATIONS**

Subject I/C: Mohini Upadhye

Lecture No: 21

Name of topic/lesson – Regulation& Patenting

Subtopic: Infrastructural requirements-working space, storage area, machinery and equipments, SOP, Health & Hygiene

Objective: To study Infrastructural requirements-working space, storage area, machinery and equipments, SOP, Health & Hygiene

Topic Outcomes: At the end of topic you should be Able to know about the Infrastructural requirements-working space, storage area, machinery and equipments, SOP, Health & Hygiene.

The premises and equipment must be located, designed, constructed, validated and maintained to suit the intended operations. Lay out, design and operation must be designed so as to minimise the risk of errors and permit effective cleaning and maintenance. There is adequate and safe provision of lighting, heating, ventilation, power gases water and drainage.

A planned, independent investigation of selected elements of a quality assurance system to collect objective evidence that the system has been implemented, is effective and is being complied with.

All aspects of production; from the starting materials, premises and equipment to the training and personal hygiene of staff. • Detailed, written procedures are essential for each process that could affect the quality of the finished product. • There must be systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process - every time a product is made.

Reference: Pharmacognosy and Phytochemistry, A comprehensive Approach, Dr. S. L. Deore, PharmaMed Press.

Lecture No: 22
Name of topic/lesson – Regulation& Patenting

Subtopic: Documentation & Records

Objective: To study Documentation & Records

Topic Outcomes: At the end of topic you should be Able to know about the Documentation & Records

Documentation

Documentation is the key to GMP compliance and ensures traceability of all development, manufacturing, and testing activities. Documentation provides the route for auditors to assess the overall quality of operations within a company and the final production.

All documents related to the manufacture of intermediates, active pharmaceutical ingredients (API), and finished products should be prepared, reviewed, approved, and distributed according to written procedures. Such documents can be paper-based or in electronic form. Documents should be approved, signed, and dated by the appropriate responsible persons. No document should be changed without authorization and approval.

Each specification for raw materials, intermediates, final products, and packing materials should be approved and maintained by the quality control department. Periodic revisions of the specifications must be carried out whenever changes are necessary.

Documents should have unambiguous contents: the title, nature, and purpose should be clearly stated. They should be laid out in an orderly fashion and be easy to check. Reproduced documents should be clear and legible. The process of reproduction of working documents from master documents must not allow any error to be introduced through the reproduction process.

A procedure should be established for retaining all appropriate documents (e.g., development history reports, scale-up reports, technical transfer reports, process validation reports, training records, production records, control records, and distribution records). The retention periods for these documents should be specified.

Reference: Pharmacognosy and Phytochemistry, A comprehensive Approach, Dr. S. L. Deore, PharmaMed Press.

Lecture No: 23
Name of topic/lesson – Herbal Drug Patenting

Subtopic: Intellectual Property Rights

Objective: To study Intellectual Property Rights

Topic Outcomes: At the end of topic you should be Able to know Intellectual Property Rights

Intellectual property (IP) is a category of property that includes intangible creations of the human intellect. Intellectual property encompasses two types of rights: industrial property rights (trademarks, patents, designations of origin, industrial designs and models) and copyright. It was not until the 19th century that the term "intellectual property began to be used, and not until the late 20th century that it became commonplace in the majority of the world.

The main purpose of intellectual property law is to encourage the creation of a large variety of intellectual goods. To achieve this, the law gives people and businesses property rights to the information and intellectual goods they create – usually for a limited period of time. This gives economic incentive for their creation, because it allows people to profit from the information and intellectual goods they create. These economic incentives are expected to stimulate innovation and contribute to the technological progress of countries, which depends on the extent of protection granted to innovators.

Reference: Pharmacognosy and Phytochemistry, A comprehensive Approach, Dr. S. L. Deore, PharmaMed Press.

Lecture No: 24
Name of topic/lesson – Herbal Drug Patenting

Subtopic: Definition and Introduction of Patent

Objective: To study Definition and Introduction of Patent

Topic Outcomes: At the end of topic you should be Able to know Definition and Introduction of Patent

Definition

A patent is protection granted by a national government for an invention. This protection excludes others from making, using or selling an invention for a period of up to 20 years. Many drug companies and university researchers seek patent protection to recover research and development costs for patents related to specific genes and proteins, laboratory techniques and drugs. In order for patents to be issued by a granting agency such as a Patent Office they need to be new, useful and not obvious to others working in the same field.

Requirements for patentability

1. Usefulness/Utility - The claimed invention must be useful/functional. A machine must work according to its intended purpose and a chemical must exhibit an activity or have some use.
2. Novelty -The invention must be different than anything known before; it must not have been described in a prior publication and it must not have been publicly used or sold.
3. Non-obviousness/Ingenuity -The invention must be a development or an improvement that would not have been obvious beforehand to workers of average skill in the technology involved.

Novelty and non-obviousness are judged against everything publicly known before the invention, as shown in earlier patents and other published material.

Reference: Pharmacognosy and Phytochemistry, A comprehensive Approach, Dr. S. L. Deore, PharmaMed Press.

Lecture No: 25
Name of topic/lesson – Herbal Drug Patenting

Subtopic: Farmers Right & Breeders Right

Objective: To study Farmers Right & Breeders Right

Topic Outcomes: At the end of topic you should be Able to know Farmers Right & Breeders Right

The PPV&FR Act, 2001 was enacted to grant intellectual property rights to plant breeders, researchers and farmers who have developed any new or extant plant varieties. The Intellectual Property Right granted under PPV&FR Act, 2001 is a dual right – one is for the variety and the other is for the denomination assigned to it by the breeder. The rights granted under this Act are heritable and assignable and only registration of a plant variety confers the right. Essentially Derived Varieties (EDV) can also be registered under this Act and it may be new or extant. Farmers are entitled to save, use, sow, re-sow, exchange or sell their farm produce including seed of a registered variety in an unbranded manner. Farmers' varieties are eligible for registration and farmers are totally exempted from payment of any fee in any proceedings under this Act. The period of protection for field crops is 15 years and for trees and vines is 18 years and for notified varieties it is 15 years from the date of notification under section 5 of Seeds Act, 1966. Annual fee has to be paid every year for maintaining the registration and renewal fee has to be paid for the extended period of registration. Farmers can claim for compensation if the registered variety fails to provide expected performance under given conditions. The rights granted under this Act are exclusive right to produce, sell, market, distribute, import and export the variety.

Reference: Pharmacognosy and Phytochemistry, A comprehensive Approach, Dr. S. L. Deore, PharmaMed Press.

Lecture No: 26
Name of topic/lesson – Herbal Drug Patenting

Subtopic: Biopyracy

Objective: To study Biopyracy

Topic Outcomes: At the end of topic you should be Able to know Biopyracy

Biopiracy, a term originally coined by ETC Group, refers to the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions that seek exclusive monopoly control (patents or intellectual property) over these resources and knowledge. ETC Group believes that intellectual property is predatory on the rights and knowledge of farming communities and indigenous peoples. Through nanotechnology- and synthetic biology-related patents, intellectual property claims are now being extended to elements of the periodic table and to key metabolic pathways involved in cellular functioning (and resulting in natural products with high commercial value).

Reference: Pharmacognosy and Phytochemistry, A comprehensive Approach, Dr. S. L. Deore, PharmaMed Press.

Lecture No: 27
Name of topic/lesson – Herbal Drug Patenting

Subtopic: Trademark & Copyright

Objective: To study Trademark & Copyright

Topic Outcomes: At the end of topic you should be Able to know Trademark & Copyright

A copyright is a collection of rights automatically vested to you once you have created an original work. To understand how these rights can be used or licensed, it is helpful to analogize them to a bundle of sticks, where each stick represents a separate right vested to you as the owner. These rights include the right to reproduce the work, to prepare derivative works, to distribute copies, to perform the work publicly, and to display the work publicly. A trademark is a word, phrase, symbol, and/or design that identifies and distinguishes the source of the goods of one party from those of others. A service mark is a word, phrase, symbol, and/or design that identifies and distinguishes the source of a service rather than goods. Examples include brand names, slogans, and logos. (The term “trademark” is often used in a general sense to refer to both trademarks and service marks.) Similar to copyright, a person does not need not register a trademark or service mark to receive protection rights, but there are certain legal benefits to registering the mark with the USPTO. There is rarely an overlap between trademark and copyright law but it can happen — for instance, when a graphic illustration is used as a logo the design may be protected both under copyright and trademark.

Reference: Pharmacognosy and Phytochemistry, A comprehensive Approach, Dr. S. L. Deore, PharmaMed Press.

Lecture synopsis Sub: **NATURAL PRODUCTS: COMMERCE, INDUSTRY & REGULATIONS**

Subject I/C: Mohini Upadhye

Lecture No: 28

Name of topic/lesson – Toxicity in herbals and their interaction

Subtopic: Toxicity in herbals and their interaction

Objective: To study Herbal-Drug & Herbal-Food interactions, General introduction to interaction and classification

Topic Outcomes: At the end of topic you should be Able to know Herbal-Drug & Herbal-Food interactions, General introduction to interaction and classification

Millions of people today use herbs either as food or in the form of medicine along with prescription and non prescription medications. Although considered natural and safe, many of these herbs can interact with other medications, causing either potentially dangerous side effects and/or reduced benefits from the medication. Both pharmacokinetic and pharmacodynamic mechanisms are involved in these interactions and majority of the herb-drug interactions were found to be mediated by metabolic inductions or inhibitions

Knowledge of the mechanism by which a given herb-drug interaction occurs is often clinically useful, since the mechanism may influence both the time course and methods of circumventing the interaction. Herb–drug interactions based on the mechanism involved are classified into pharmacokinetic and pharmacodynamic interactions.

Pharmacokinetic interactions:

Pharmacokinetic interactions are caused by alterations in the absorption, distribution, metabolism, or excretion of drugs which results in altered levels of the drug or its metabolites.

Reference: Herbs: Toxicities and Drug Interactions, Medical Author: William C. Shiel

Lecture No: 29

Name of topic/lesson – Toxicity in herbals and their interaction

Subtopic: Toxicity in herbals and their interaction

Objective: To study Herbal-Drug & Herbal-Food interactions of Liquorice

Topic Outcomes: At the end of topic you should be Able to know Herbal-Drug & Herbal-Food interactions of Liquorice

Licorice is taken by mouth for various digestive system complaints including stomach ulcers, heartburn, colic, and ongoing inflammation of the lining of the stomach (chronic gastritis).

Some people take licorice for sore throat, bronchitis, cough, and infections caused by bacteria or viruses.

Licorice is also taken for Addison's disease, a type of diabetes caused by a hormone deficiency (diabetes insipidus), menopausal symptoms, osteoporosis, osteoarthritis, systemic lupus erythematosus (SLE), liver disorders, malaria, tuberculosis, high potassium levels in the blood, food poisoning, chronic fatigue syndrome (CFS), a condition in which there is too much muscle tone (hypertonia), abscesses, recovery after surgery, rash, high cholesterol.

Licorice along with the herbs Panax ginseng and Bupleurum falcatum to improve the function of the adrenal glands, especially in people who have taken steroid drugs long-term. Steroids tend to suppress the activity of the adrenal glands. The adrenal glands produce important hormones that regulate the body's response to stress.

Licorice is also taken by mouth in combination with peony to increase fertility in women with a hormonal disorder calledpolycystic ovary syndrome, to treat people with abnormal levels of a hormone prolactin, for muscle cramps, and to reduce cancer pain. In combination with other herbs, licorice is also used to treat prostate cancer and the skin disorder known as eczema. Licorice is also taken in combination with andrographis, Siberian ginseng, and schisandra to treat familial Mediterranean fever

Reference: Herbs: Toxicities and Drug Interactions, Medical Author: William C. Shiel

Lecture synopsis Sub: **NATURAL PRODUCTS: COMMERCE, INDUSTRY & REGULATIONS**

Subject I/C: Mohini Upadhye

Lecture No: 31

Name of topic/lesson – Toxicity in herbals and their interaction

Subtopic: Toxicity in herbals and their interaction

Objective: To study Herbal-Drug & Herbal-Food interactions of Cinnamon and Amla

Topic Outcomes: At the end of topic you should be Able to know Herbal-Drug & Herbal-Food interactions of Cinnamon and Amla

Ethanolic extract of the fruit was shown to protect against cardiotoxicity of doxorubicin by increasing the IC50 12-fold without impacting its antitumor activity on HeLa cells (in vitro).2859 The aqueous extracts of the dried fruit increased the cytotoxicity of both doxorubicin and cisplatin against human liver cancer cells and lung cancer cells (in vitro).

Diabetes: Cassia cinnamon can lower blood sugar levels in people with diabetes. Watch for signs of low blood sugar (hypoglycemia) and monitor your blood sugar carefully, if you have diabetes and use cassia cinnamon in amounts larger than the amounts normally found in food.

Liver disease: Cassia cinnamon contains a chemical that might harm the liver. If you have liver disease, do not take cassia cinnamon in amounts larger than the amounts normally found in food.

Surgery: Cassia cinnamon might lower blood sugar and might interfere with blood sugar control during and after surgery. Stop taking cassia cinnamon as a medicine at least 2 weeks before a scheduled surgery

Reference: Herbs: Toxicities and Drug Interactions, Medical Author: William C. Shiel

Lecture No: 32

Name of topic/lesson – Toxicity in herbals and their interaction

Subtopic: Toxicity in herbals and their interaction

Objective: To study Herbal-Drug & Herbal-Food interactions of Ginseng and Garlic

Topic Outcomes: At the end of topic you should be Able to know Herbal-Drug & Herbal-Food interactions of Ginseng and Garlic

Garlic is POSSIBLY SAFE when taken by mouth and appropriately for a short-term in children. However, garlic is possibly unsafe when taken by mouth in large doses. Some sources suggest that high doses of garlic could be dangerous or even fatal to children. The reason for this warning is not known. There are no case reports available of significant adverse events or mortality in children associated with taking garlic by mouth. When applied to the skin, garlic might cause damage to the skin that is similar to a burn.
Bleeding disorder: Garlic, especially fresh garlic, might increase the risk of bleeding.
Stomach or digestion problems: Garlic can irritate the gastrointestinal (GI) tract. Use with caution if you have stomach or digestion problems.

Low blood pressure: Garlic can lower blood pressure. In theory, taking garlic might make blood pressure become too low in people with low blood pressure.

Surgery: Garlic might prolong bleeding and interfere with blood pressure. Stop taking garlic at least two weeks before a scheduled surgery.

The common ginsengs (*P. ginseng* and *P. quinquefolia*) are generally considered to be relatively safe even in large amounts. One of the most common and characteristic symptoms of an acute overdose of *P. ginseng* is bleeding. Symptoms of mild overdose may include dry mouth and lips, excitation, fidgeting, irritability, tremor, palpitations, blurred vision, headache, insomnia, increased body temperature, increased blood pressure, edema, decreased appetite, dizziness, itching, eczema, early morning diarrhea, bleeding, and fatigue. Symptoms of severe overdose with *P. ginseng* may include nausea, vomiting, irritability, restlessness, urinary and bowel incontinence, fever, increased blood pressure, increased respiration, decreased sensitivity and reaction to light, decreased heart rate, cyanotic (blue) facial complexion, red facial complexion, seizures, convulsions, and delirium

Reference: Herbs: Toxicities and Drug Interactions, Medical Author: William C. Shiel

Lecture No: 33

Name of topic/lesson – Toxicity in herbals and their interaction

Subtopic: Toxicity in herbals and their interaction

Objective: To study Herbal-Drug & Herbal-Food interactions of Digitalis

Topic Outcomes: At the end of topic you should be Able to know Herbal-Drug & Herbal-Food interactions of Digitalis

The side effects related to toxicity are used to assess the therapeutic range in a person. In toxicity, the usual supportive measures are provided. If arrhythmias prove troublesome, or malignant hyperkalaemia occurs (inexorably rising potassium level due to paralysis of the cell membrane-bound, ATPase-dependent Na/K pumps), the specific antidote is antidigoxin (antibody fragments against digoxin, trade namesDigibind and Digifab). Digoxin is not removed by hemodialysis or peritoneal dialysis with enough effectiveness to treat toxicity. Side effects can become more pronounced due to the drug interactions between digoxin and the following: Thiazide and loop diuretics,piperacillin, ticarcillin, amphotericin B, corticosteroids, and excessive laxative use. Amiodarone,
some benzodiazepines, cyclosporine,diphenoxylate, indomethacin, itraconazole, propafenone, qu inidine, quinine, spironolactone, and verapamil may lead to toxic levels and increased incidence of side effects.

Digoxin plasma concentration increases while on antimalarial medication hydroxychloroquine.

Reference: Herbs: Toxicities and Drug Interactions, Medical Author: William C. Shiel

Lecture No: 34

Name of topic/lesson – Toxicity in herbals and their interaction

Subtopic: Toxicity in herbals and their interaction

Objective: To study Herbal-Drug & Herbal-Food interactions of Turmeric

Topic Outcomes: At the end of topic you should be Able to know Herbal-Drug & Herbal-Food interactions of Turmeric

Special Precautions & Warnings Hormone-sensitive condition such as breast cancer, uterine cancer, ovarian cancer, endometriosis, or uterine fibroids: Turmeric contains a chemical called curcumin, which might act like the hormone estrogen. In theory, turmeric might make hormone-sensitive conditions worse. However, some research shows that turmeric reduces the effects of estrogen in some hormone-sensitive cancer cells. Therefore, turmeric might have beneficial effects on hormone-sensitive conditions. Until more is known, use cautiously if you have a condition that might be made worse by exposure to hormones.

Hormone-sensitive condition such as breast cancer, uterine cancer, ovarian cancer, endometriosis, or uterine fibroids: Turmeric contains a chemical called curcumin, which might act like the hormone estrogen. In theory, turmeric might make hormone-sensitive conditions worse. However, some research shows that turmeric reduces the effects of estrogen in some hormone-sensitive cancer cells. Therefore, turmeric might have beneficial effects on hormone-sensitive conditions. Until more is known, use cautiously if you have a condition that might be made worse by exposure to hormones.
Medications that slow blood clotting (Anticoagulant / Antiplatelet drugs) interacts with TURMERIC.

Reference: Herbs: Toxicities and Drug Interactions, Medical Author: William C. Shiel

Lecture No: 35

Lecture synopsis Sub: **NATURAL PRODUCTS: COMMERCE, INDUSTRY & REGULATIONS**

Subject I/C: Mohini Upadhye

Name of topic/lesson – Toxicity in herbals and their interaction

Subtopic: Toxicity in herbals and their interaction

Objective: To study Herbal-Drug & Herbal-Food interactions of Ephedra

Topic Outcomes: At the end of topic you should be Able to know Herbal-Drug & Herbal-Food interactions of Ephedra

- Medications that can cause an irregular heartbeat (QT interval-prolonging drugs) interacts with EPHEDRA

- Methylxanthines interacts with EPHEDRA

  Ephedra can simulate the body. Methylxanthines also stimulate the body. Taking ephedra along with methylxanthines might cause side effects such as jitteriness, nervousness, a fast heartbeat, high blood pressure, and anxiety. Methylxanthines include aminophylline, caffeine and theophylline.

- Stimulant drugs interacts with EPHEDRA

  Stimulant drugs speed up the nervous system and can make you feel jittery and speed up your heartbeat. Ephedra can also speed up the nervous system. Taking ephedra along with stimulant drugs might cause serious problems including increased heart rate and high blood pressure. Avoid taking stimulant drugs along with ephedra.

 Some stimulant drugs include diethylpropion (Tenuate), epinephrine, phentermine (Ionamin), pseudoephedrine (Sudafed), and many others.

- Medications for depression (MAOIs) interacts with EPHEDRA

- Medications for diabetes (Antidiabetes drugs) interacts with EPHEDRA

- Medications used to prevent seizures (Anticonvulsants) interacts with EPHEDRA

Reference: Herbs: Toxicities and Drug Interactions, Medical Author: William C. Shiel

Lecture No: 36
Name of topic/lesson – Toxicity in herbals and their interaction

Subtopic: Toxicity in herbals and their interaction

Objective: To study Herbal-Drug & Herbal-Food interactions of Cinchona

Topic Outcomes: At the end of topic you should be Able to know Herbal-Drug & Herbal-Food interactions of Cinchona

- **Medications that slow blood clotting (Anticoagulant / Antiplatelet drugs) interacts with CINCHONA**
- **Quinidine interacts with CINCHONA**
- **Quinine interacts with CINCHONA**
- **Carbamazepine (Tegretol) interacts with CINCHONA**

  The body breaks down carbamazepine to get rid of it. Cinchona contains quinine. Quinine can cause the body to break down carbamazepine (Tegretol) too quickly. Taking cinchona along with carbamazepine (Tegretol) can decrease the effectiveness of carbamazepine (Tegretol).
- **Phenobarbital (Luminal) interacts with CINCHONA**
- **Antacids interacts with CINCHONA**

  Cinchona might increase stomach acid. By increasing stomach acid, cinchona might decrease the effectiveness of some medications that decrease stomach acid, called H2-Blockers.
<nb>Some medications that decrease stomach acid include cimetidine (Tagamet), ranitidine (Zantac), nizatidine (Axid), and famotidine (Pepcid). **Medications that decrease stomach acid (Proton pump inhibitors) interacts with CINCHONA**

  Cinchona might increase stomach acid. By increasing stomach acid, cinchona might decrease the effectiveness of medications that are used to decrease stomach acid, called proton pump inhibitors.
<nb>Some medications that decrease stomach acid include omeprazole (Prilosec), lansoprazole (Prevacid), rabeprazole (Aciphex), pantoprazole (Protonix), and esomeprazole (Nexium).

Reference: Herbs: Toxicities and Drug Interactions, Medical Author: William C. Shiel

Lecture No: 37
Name of topic/lesson – Pharmacovigilance of herbal medicines

Subtopic: Pharmacovigilance of herbal medicines

Objective: To study Meaning of Pharmacovigilance of herbal medicines

Topic Outcomes: At the end of topic you should be Able to know Meaning of Pharmacovigilance of herbal medicines.

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of the adverse effects of drugs or any other possible drug-related problems.

Recently, its concerns have been widened to include the following:

♦ herbals

♦ traditional and complementary medicines

♦ blood products

♦ biologicals

♦ medical devices

♦ vaccines.

The specific aims of Pharmacovigilance are to:

♦ improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions

♦ improve public health and safety in relation to the use of medicines

♦ contribute to the assessment of benefit, harm, effectiveness, and risk of medicines, encouraging their safe, rational, and more effective (including cost-effective) use

♦ promote understanding, education, and clinical training in pharmacovigilance and its effective communication to the public.

Reference: Pharmacovigilance of herbal medicines: Current state and future directions, Pharmacogn Mag. 2011 Jan-Mar; 7(25): 69–73

Lecture No: 38
Name of topic/lesson – Pharmacovigilance of herbal medicines

Subtopic: Pharmacovigilance of herbal medicines

Objective: To study Need of Pharmacovigilance of herbal medicines

Topic Outcomes: At the end of topic you should be Able to know Need of Pharmacovigilance of herbal medicines.

Safety is a fundamental principle in the provision of herbal medicines and herbal products for health care, and a critical component of quality control. These guidelines provide practical technical guidance for monitoring the safety of herbal medicines within the pharmacovigilance systems. The safety monitoring of herbal medicines is compared and contrasted with that of other medicines currently undertaken in the context of the WHO International Drug Monitoring Program. Although there are regulatory and cultural differences in the preparation and use of different types of medicines, they are all equally important from a pharmacovigilance perspective.

The guidelines were developed with the view that, within the current pharmacovigilance systems, monitoring of the safety of medicines should be enhanced and broadened in ways that will allow the successful monitoring of herbal medicines.

Reference: Pharmacovigilance of herbal medicines: Current state and future directions, Pharmacogn Mag. 2011 Jan-Mar; 7(25): 69–73

Lecture No: 39
Name of topic/lesson – Pharmacovigilance of herbal medicines

Subtopic: Pharmacovigilance of herbal medicines

Objective: To study significance of Pharmacovigilance of herbal medicines

Topic Outcomes: At the end of topic you should be Able to know significance of Pharmacovigilance of herbal medicines.

Safety is a fundamental principle in the provision of herbal medicines and herbal products for health care, and a critical component of quality control. These guidelines provide practical technical guidance for monitoring the safety of herbal medicines within the pharmacovigilance systems. The safety monitoring of herbal medicines is compared and contrasted with that of other medicines currently undertaken in the context of the WHO International Drug Monitoring Program. Although there are regulatory and cultural differences in the preparation and use of different types of medicines, they are all equally important from a pharmacovigilance perspective.

The guidelines were developed with the view that, within the current pharmacovigilance systems, monitoring of the safety of medicines should be enhanced and broadened in ways that will allow the successful monitoring of herbal medicines. The inclusion of herbal medicines in pharmacovigilance systems is becoming increasingly important given the growing use of herbal products and herbal medicines globally.

Reference: Pharmacovigilance of herbal medicines: Current state and future directions, Pharmacogn Mag. 2011 Jan-Mar; 7(25): 69–73

Lecture No: 40
Name of topic/lesson – Pharmacovigilance of herbal medicines

Subtopic: Pharmacovigilance of herbal medicines

Objective: To study significance of Pharmacovigilance of herbal medicines

Topic Outcomes: At the end of topic you should be Able to know significance of Pharmacovigilance of herbal medicines.

The World Health Organization (WHO) is a specialized agency of the United Nations (UN) that is concerned with international public health. The Uppsala Monitoring Centre (UMC) is an independent foundation and a centre for international service and scientific research. The operational responsibility for the ADR monitoring programme rests with the WHO Collaborating Centre for International Drug Monitoring, Uppsala Monitoring Centre, (UMC), in Sweden. The system started with 10 countries that had already established national systems for spontaneous adverse reaction reporting and who agreed to contribute data. For an effective international system to become operative, a common reporting form was developed, agreed guidelines for entering information formulated, common terminologies and classifications prepared and compatible systems for transmitting, storing and retrieving and disseminating data were created. The ADRs database in Uppsala currently contains over eight million reports of suspected ADRs.

Reference: Pharmacovigilance: need and future prospective in herbal and ayurvedic medicines, The Pharma Innovation Journal 2014; 3(7): 18-22

Lecture No: 41
Name of topic/lesson – Pharmacovigilance of herbal medicines

Subtopic: Pharmacovigilance of herbal medicines

Objective: To study significance of Pharmacovigilance of herbal medicines

Topic Outcomes: At the end of topic you should be Able to know significance of Pharmacovigilance of herbal medicines.

The purpose of pharmacovigilance is to detect, assess, understand and to prevent the adverse effects or any other possible drug-related problems, related to herbal, traditionally and complementary medicines Herbal medicines are widely used in both developed and developing countries however, in recent years, there are several highprofile herbal safety concerns having an impact on the public health. Herbal medicines are traditionally considered as harmless but as medicinal products they require drug surveillance in order to identify their risks. Various methods in pharmacovigilance are passive surveillance includes spontaneous reporting and stimulated reporting, active surveillance by sentinel sites, drug event monitoring, registries, comparative observational studies by survey study, case control study, targeted clinical investigations by investigate drug-drug interactions and food- drug interactions . The importance of genetic factors in determining an individual susceptibility to adverse drug reactions is well documented and this implies to herbal medicines as well as to conventional drugs. Pharmacovigilance is therefore one of the important postmarketing safety tools in ensuring the safety of pharmaceutical and related health products.

Reference: Pharmacovigilance: need and future prospective in herbal and ayurvedic medicines, The Pharma Innovation Journal 2014; 3(7): 18-22

Lecture No: 42
Name of topic/lesson – Plant Allergens

Subtopic: Plant Allergens

Objective: To study Definition & classification

Topic Outcomes: At the end of topic you should be Able to know Definition & classification of Plant Allergens

An allergen is a type of antigen that produces an abnormally vigorous immune response in which the immune system fights off a perceived threat that would otherwise be harmless to the body. Such reactions are called allergies.

In technical terms, an allergen is an antigen that is capable of stimulating a type-I hypersensitivity reaction in atopic individuals throughImmunoglobulin E (IgE) responses.

Types of Allergens:

Allergens can be found in a variety of sources, such as dust mite excretion, pollen, pet dander, or even royal jelly. Food allergies are not as common as food sensitivity, but some foods such as peanuts (a legume), nuts, seafood and shellfish are the cause of serious allergies in many people.

Another allergen is urushiol, a resin produced by poison ivy and poison oak, which causes the skin rash condition known as urushiol-induced contact dermatitis by changing a skin cell's configuration so that it is no longer recognized by the immune system as part of the body. Various trees and wood products such as paper, cardboard, MDF etc. can also cause mild to severe allergy symptoms through touch or inhalation of sawdust such as asthma and skin rash.

An allergic reaction can be caused by any form of direct contact with the allergen—consuming food or drink one is sensitive to (ingestion), breathing in pollen, perfume or pet dander (inhalation), or brushing a body part against an allergy-causing plant (direct contact). Other common causes of serious allergy are wasp, fire ant and bee stings, penicillin, and latex.

Reference:

"Wood Allergies and Toxicity". *The Wood Database*. Archived *from the original on 2 May 2014*. Retrieved 24 April 2014.

Lecture No: 43
Name of topic/lesson – Plant Allergens

Subtopic: Plant Allergens

Objective: Plants causing Hay fever, allergy, Idiosyncracy

Topic Outcomes: At the end of topic you should be Able to know Plants causing Hay fever, allergy, Idiosyncracy.

Hay fever occurs when the immune system mistakes a normally harmless airborne substance for a threat.

The body produces an antibody called immunoglobulin E (IgE) to attack the threat, and it releases the chemical histamine. Histamine causes the symptoms.

Seasonal hay fever triggers include pollen and spores that only cause symptoms at certain times of the year.

Examples of hay fever triggers include:

- tree pollen in the spring
- grass pollen in late spring and summer
- weed pollen, especially during fall
- fungi and mold spores, more common in warm weather

Other triggers include pet hair or dander, dust mites, mold, and cockroach dust. Irritants that can lead to symptoms of hay fever are cigarette smoke, perfumes, and diesel exhaust fumes.

Reference:

"Wood Allergies and Toxicity". *The Wood Database*. Archived *from the original on 2 May 2014*. Retrieved 24 April 2014.

Lecture No: 44
Name of topic/lesson – Plant Allergens

Subtopic: Plant Allergens

Objective: Applications of allergens in diagnosis & treatment

Topic Outcomes: At the end of topic you should be Able to know Applications of allergens in diagnosis & treatment

Medications
Drugs can help treat the symptoms of an allergic reaction, but they will not cure the allergy. The majority of allergy medications are over-the-counter (OTC). Before taking a particular type of medication, speak to a pharmacist or doctor.

- **Antihistamines**: These block the action of histamine. Caution is recommended, as some antihistamines are not suitable for children.
- **Decongestants**: These can help with a blocked nose in cases of hay fever, pet allergy, or dust allergy. Decongestants are short-term medications.
- **Leukotriene receptor antagonists, or anti-leukotrienes**: When other asthma treatments have not worked, anti-leukotrienes can block the effects of leukotrienes. These are the chemicals that cause swelling. The body releases leukotrienes during an allergic reaction.
- **Steroid sprays**: Applied to the inside lining of the nose, corticosteroid sprays help reduce nasal congestion.

Immunotherapy
Immunotherapy is also known as hyposensitization. This type of therapy rehabilitates the immune system. The doctor administers gradually increasing doses of allergens over a period of years.
The aim is to induce long-term tolerance by reducing the tendency of the allergen to trigger IgE production.
Immunotherapy is only used to treat severe allergies.

Reference:

Christian Nordqvist, Everything you need to know about allergies.

Lecture No: 45
Name of topic/lesson – Plant Allergens

Subtopic: Plant Allergens

Objective: Method of preparation of allergenic extracts.

Topic Outcomes: At the end of topic you should be Able to know Method of preparation of allergenic extracts.

Purity, The extract should contain the allergen(s) derived from its source material and should not be contaminated with allergens from other source materials. Other extraneous, possibly harmful substances, such as those derived from microorganisms, should not be present. Potency, Allergenic extracts should be defined in terms of a specific potency. Most extracts lack reliable standardization. Stability, The duration of extract potency and the conditions necessary to maintain this stability must be determined. Sterility, Each batch of allergenic extract must be sterile. Safety, Allergenic extracts must be safe for human use both in relationship to their allergenic properties and to any other short- or long-term effects which might result from recurrent administration.

Steps involved are:

Grinding

Defatting

Extraction

Clarification

Dialysis

Concentration

Sterilization

Lyophilization

Testing

Standerdization

Storage

Reference: Prepartion of Allergenic extract, Pharmdsr.

PES MODERN COLLEGE OF PHARMACY (FOR LADIES), MOSHI

Lecture synopsis Sub: **NATURAL PRODUCTS: COMMERCE, INDUSTRY & REGULATIONS**

Subject I/C: Mohini Upadhye