THE UNIVERSITY OF NAIROBI
SCHOOL OF MEDICINE
DEPARTMENT OF FORENSIC PATHOLOGY

Week 24.

CONTROL OF DRUGS, PHARMACY & POISONS ACT

Patent life – time during which a drug is being formulated, during which other companies cannot reproduce the drug
- Shortened if the drugs are life saving

Food Drug Administration
- Put in place by the US government
- Authoritative administrative body
- Oversees drug evaluation and grants approval to market new drugs
- Sees that the drug is effectively tested to be safe and effective

Drug safety
- Not possible to say a drug is free from all risk
- Possible to identify most of the hazards likely to be associated with the drug
- Statistical data can be obtained on the frequency of occurrence of events in the population under study
- Operational definition of safety can be based on the incidence of drug abuse effects

Therapeutic Substances & Control of Drugs in Kenya
- Legislation, regulation & policy provide necessary laws, rules, structures and guidelines for support, coordination 7 implementation of appropriate medicine use
- Most relevant:
  a. Pharmacy & poisons Act of 1957 – Cap 244
     - Amended in 1983 & reviewed in 1994
  b. Dangerous Medicines Ordinance of 1993 – Cap 245
     - Changed to Narcotic Drugs and Psychotropic Substances Act of 1994
  c. Use of Poisonous Substances Act – Cap 247
  d. The Medical Practitioners and Dentists Act – Cap 253
  e. Food, Medicines and Chemical Substances Act of 1965 – Cap 254
  f. Trading in Prohibited Goods act – Cap 519
  g. The Public Health Act – Cap 242
  h. Pesticides Control Act – Cap 346
  i. Veterinary Surgeons Act – Cap 366

Pharmacy & Poisons Act, Narcotic drugs & Psychotropic Substances Control Act
- Control sale and supply of medicines
- Underlying principle is that medicines should normally be sold under supervision of a pharmacist BUT enables the health Minister to modify the application of the principle

Cap 244
- An Act of Parliament to make better provision of the control of the profession of pharmacy and trade in drugs & poisons
- Regulatory body is the Pharmacy & Poisons Board which consists of DSM (chairman), chief pharmacist, four other pharmacists, two medical practitioners and the director of veterinary services
- Regulations are based on laws, specific & have a positive outlook

Pharmacy & Poisons Board
- Administers laws and regulations regarding medicines; registration, marketing, supply and use
- Ensures:
  - Registration of safe, efficacious and quality pharmaceutical products
  - Provision of unbiased information on medicines in the market to all customers
  - Post marketing surveillance to assure pharmaceutical product quality in the market
  - Developing and implementing principles and criteria for promotion of health products and services
  - Control of direct to customer advertising of health related products
- Prepares Poisons List and submits it to the Minister of Health for approval
- Sets up:
  - Various committees e.g. drug registration, clinical studies etc.
  - National Quality Lab
  - Inspectorate

Poisons List

- Part I Poisons sold by authorized seller of poisons, wholesale dealers and dealers in mining, agricultural or horticultural accessories
- Part II Poisons sold by persons entitled to sell Part I Poisons and persons licensed to sell Part II Poisons
- Part II Poisons are restricted to articles in common use and adequate facilities should be available for the public to obtain them

Possession of Part II Poisons:

- Wholesale dealer on licensed premises
- Pharmacist on licensed premises
- Licensed seller on premises licensed for that purpose
- A person, institution or department to whom the person has been lawfully sold for the purpose for which the sale was made
- A person for whom the Poison has been lawfully supplied or dispensed
- Representative of a person engaged in the business of selling and supplying pharmaceutical goods for the purpose of giving samples to persons who may lawfully be in possession of Part I Poisons

Professional Misconduct

By the pharmacist or their employee:

- May lead to failure of registration of the Pharmacist
- Deletion of the name from the register of pharmacists practicing in Kenya and the certificate surrendered to the Board such that they cannot practice
- The aggrieved pharmacist can appeal to the Board

Records

- Order of purchase of Part I Poisons in writing & signed; includes purchaser's name, address, occupation, name and quantity of the Poison and the purpose for which it is required
- In emergencies the order can be delivered but the purchaser must furnish the seller with the written order within 24 hours
- Particulars entered in a prescribed poisons register for sale of poisons and in prescription register for prescribed drugs
- Signed orders and prescription records retained in the premises for 2 years or for the prescribed period

Narcotic Drugs & Psychotropic Substances Control Act

- Act of Parliament to make provision with respect to control and trafficking in narcotic and psychotropic substances and cultivation of some plants; to provide for forfeiture of property derived from, or used in, illicit traffic of narcotics and psychotropic drugs
- Regulatory body is the board comprising the Attorney General or his representative, Permanent Secretary of Internal Security, Permanent Secretary of Health, Commissioner of police or his representative and three others appointed by the Minister one of whom is elected Chairman

Prohibited plants

- Cannabis, Coca bush, Popover somniferum (opium poppy) and Popover setegerum
- Penalty is a fine and/or imprisonment, forfeiture of land used for cultivation
- The Government may appoint police officers to inspect land suspected of being used to grow the prohibited plants
- The Government has the power to burn the plants as prescribed

Drugs in the Act

- Narcotics: cocaine, morphine, pethidine, heroine, codeine, opium
- Psychotropic substances: LSD, benzodiazepines, some barbiturates, benzamphetamines, amphetamine, glutethimide

The Board

- Issues licenses for export, import, manufacture, diversion, sale, production or distribution of drugs in the Act
- Specifies ports of entry or export, manner of packing
- Forfeiture of narcotic drugs to the Government
- If one has no authority to possess them
- If one has excess of what is allowed
- Drugs placed in a place where they should not be
- In case of aircraft or ships, the responsible officers have to answer
- Machinery, equipment, implements used to commit the offence

Public Health Act

- Prohibits advertisements intended to promote the sale of any medicine, appliance or article for alleviation or cure of venereal disease or disease affecting generative organs or functions or of sexual impotence or any complaint of sexual intercourse
- Not applicable to publications by a Medical department

Cap 253 – Practitioner

- Authorized to stock drugs he considers necessary for patients in his premises especially if the practice is not near a pharmacy
- Should have at least disposable syringes and needles, analgesics, antibiotics, corticosteroids, spirit, antispasmodics etc.
- Should carry a bag in case of emergencies which should contain injections of antibiotics, analgesics, antipyretics, bronchodilators, antiemetics, oral preparations, disposable syringes and needles, spirit swabs
- Destroy all disposable equipment to avoid re-use