Option B: Drugs and Medicine

Definition of Medicine

- Any chemical substance that:

    o Alters a physiological state (consciousness, activity level, coordination)

    o Alters mood or emotions

    o Alters incoming sensory sensations

- Sometimes it is difficult to determine whether a drug has any medicinal value.

- The legitimate purpose of a drug is usually to improve health.

- Use of drugs in some cases is controversial.

Methods of Administering Drugs

- Drugs must reach blood stream to be transported to critical tissues.

- The method of administration determines the rate at which the drug is absorbed in the blood.

- The 5 common points of entry of a drug:

    o Oral

        ▪ Advantage: easy, can be self-administered

    o Inhalation

    o Topical (patches)

        ▪ Advantage: gradual absorption

    o Injection (Parenteral)

        ▪ Advantage: put directly where needed rather than all over the body

    o Rectal

Injection Methods

- Intradermal – between layers of skin

- Subcutaneous – under the skin

- Intramuscular – in the muscle

- Intravenous – directly in the vein
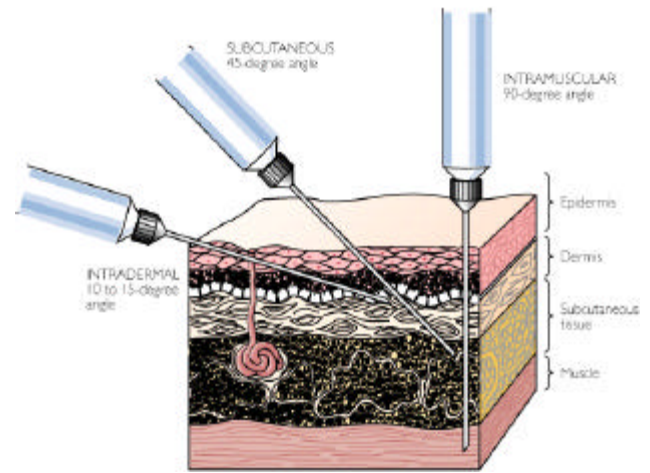
Research, Development and Drug Testing

- Development of new drugs is a long and expensive process,

  (10–15 years, up to $500 million).

- Several stages in development include:

  o Isolation or chemical synthesis

  o Laboratory studies

  o Animal testing to determine LD_{50}, (Preclinical trials), testing on patients to assess toxicology (Phase I trial)

  o Clinical testing to determine effectiveness, (Phase II and III trials)

  o Approval by the FDA (Food and Drug Administration) for market

  o Post launch monitoring of the drug, (Phase IV trials)

- The development of a new drug is a time consuming process.

- Determining the **Lethal Dose or LD_{50}.** This is the concentration that will kill 50 % of the animals in a test sample.

- The **Effective Dose or ED_{50}** is the concentration necessary to bring about a noticeable effect in 50% of the test sample.

- The **Therapeutic Index** is the ratio of **LD_{50} / ED_{50}**

Clinical Trials

- All drugs that are approved for market must be clinically tested multiple times.

- Most clinical tests are done on volunteers using double blind study.

- Some of the volunteers receive a placebo while others receive the therapeutic medicine.

    o **Placebo Effect**: hints at our brain's ability to influence our physiology. A sugar pill can still result in remarkable recoveries because the patient believes they are getting better so they actually do.

- Neither the researcher nor the participants know in advance who receives which.

Drug Development

- To determine the following must be considered:

    o Lethal dose or LD_{50}

    o Effective dose or ED_{50}

    o Therapeutic Index

    o Toxic Range

    o Therapeutic Level

    o Sub-therapeutic level

Risk to Benefit Ratio

- The prescribing physician must weigh the benefits from the use of a drug against the undesirable side effects when determining a suitable level of risk.

- The level of risk that is acceptable is related to the severity and the degree to which the condition is life threatening.

- Examples: Chemotherapy, Pain Killers, etc.

Tolerance

- Over time the body adapts the presence of drug

    o The person receiving the drug needs ever larger doses to achieve the original effect.

    o Tolerance results in increased risks of dependency/addiction.

    o Increased risks of toxic levels.

    o Possibility of immunity in anti-bacterials.

Thalidomide – An Example of Improper Drug Approval

- Developed in Germany in 1953.

- Used as a tranquilizer (1957-1962)

- Prescribed to combat morning sickness in the early months of pregnancy.

- Marketed widely in Europe but never approved by the FDA in the USA

- Caused major birth defects in about 10 000 children whose mothers had taken thalidomide.

- Thalidomide has two optical isomers, one of which is a powerful teratogen (An agent or factor that causes malformation of an embryo).

- It is sometimes used to treat leprosy (Hansen`s Disease)

R-Thalidomide
(sleep-inducing)

S-Thalidomide
(teratogenic)
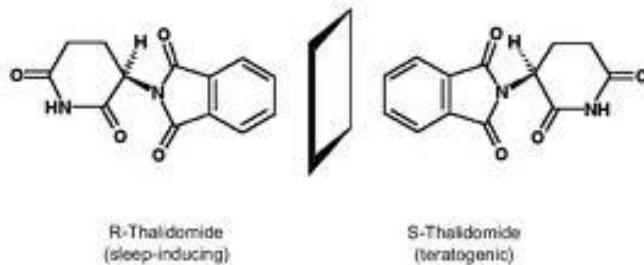
Assignment

1. Give three effects of a molecule on the body, any of which would allow it to be called a drug. (3)

2. Give a brief account of the process for developing and testing new drugs. Mention four distinct stages. (4)

3. There are several ways of administering drugs.

    a) State three ways in which drugs may be taken by a patient, mention one advantage of using that particular method. (6)

    b) Predict, giving a reason, which of the tree methods will result in the drug having the most rapid effect. (2)

4. State what is meant by the term:

    a) Side effect   b) LD_{50} c) Placebo effect   d) Tolerance

5. (a) Many drugs are taken orally. State **three** other ways in which drugs may be taken by a patient. 2

    (b) State what is meant by the term *side effect*.   1

6. Outline four methods of drug administration and state their relative advantage and disadvantage.

7. List the effects of medicines and drugs on the functioning of the body.   3

8. State what a placebo is and describe the placebo effect.   2

9. Many drugs are taken orally. State **three** other ways in which drugs may be taken by a patient.