Pharmaceutical products

THE EFFECTS OF DRUGS AND MEDICINES

For centuries man has used natural materials to provide relief from pain, heal injuries, and cure disease. Many of these folk remedies have been shown to be very effective and the active ingredients isolated and identified.

Morphine was extracted from the poppy *Papaver somniferum* early in the nineteenth century and later salicylic acid, the precursor of aspirin, was isolated from willow bark. The words 'drug' or 'medicine' are commonly applied to these substances, but they have different connotations in different countries and are difficult to define precisely. For example, the pineal gland in humans, a small lump of tissue that resides at the base of the brain, produces a substance called melatonin. This substance is known to bring on the onset of sleep and is often taken by people suffering from 'jet-lag'. As it occurs naturally in very low amounts in many foods it is classed as a food in America and can readily be bought. However, it is unavailable in Europe since it is classed as a drug because of its potential to modify physiological functions in humans. Generally a drug or medicine is any chemical (natural or man-made), which does one or more of the following:

- alters incoming sensory sensations
- alters mood or emotions
- alters the physiological state (including consciousness, activity level, or co-ordination).

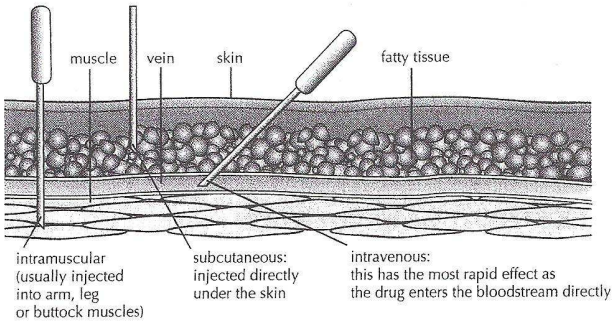
Drugs and medicines are commonly (but not always) taken to improve health. They accomplish this by assisting the body in its natural healing process. The mechanism of drug action is still not fully understood, and there is evidence that the body can be 'fooled' into healing itself through the 'placebo' effect.

METHODS OF ADMINISTERING DRUGS

In order to reach the site where their effects are needed the majority of drugs must be absorbed into the bloodstream. The method of administering the drug determines the route taken and the speed with which it is absorbed into the blood. The four main methods are: by mouth (oral); inhalation; through the anus (rectal), and by injection (parenteral).

Drugs may also be applied topically so that the effect is limited mainly to the site of the disorder, such as the surface of the skin. Such drugs may come in the form of creams, ointments, sprays, and drops.

The three different methods of injection



THALIDOMIDE – HOW IT CAN ALL GO WRONG

In 1958 a German pharmaceutical company launched a massive publicity campaign for a new tranquilizer to combat 'morning sickness' in pregnant women. The drug was sold world-wide under brand names such as Thalidomide and Contergan. In many countries it was sold without prescription and marketed as completely innocuous. Reports of severe adverse side-effects began to appear in 1959, and it later transpired that as early as 1956 clinical trials by the company itself had revealed problems. Nevertheless because it was so profitable the company continued to market the drug heavily and sales kept increasing until it was withdrawn in 1961. By that time many children had been born with absent or severely malformed limbs.

RESEARCH, DEVELOPMENT, AND TESTING OF NEW PRODUCTS

The research and development of new drugs is a long and expensive process. Traditionally a new product is isolated from an existing species, or synthesized chemically and then subjected to thorough laboratory and clinical pharmacological studies to demonstrate its effectiveness. Before studies are allowed on humans it must be tested on animals to determine the **lethal dose** required to kill fifty percent of the animal population, known as the LD_{50}. The effective dose required to bring about a noticeable effect in 50% of the population is also obtained, so that the safe dose to administer can be determined. The drug can then be used in an initial clinical trial on humans. This is usually on volunteers as well as on patients, half of whom are given the drug and half of whom are given a placebo. This initial trial is closely monitored to establish the drug's safety and possible side effects.

Drugs usually have unwanted **side effects**, for example aspirin can cause bleeding of the stomach and morphine, which is normally used for pain relief, can cause constipation. Side effects can be relative depending on why the drug is taken. People with diarrhoea are sometimes given a kaolin and morphine mixture, and people who have suffered from a heart attack are advised to take aspirin as it is effective as an anti-clotting agent. The severity of the complaint will determine an acceptable **risk-to-benefit ratio**. If an effective treatment is found for a life threatening disease then a high risk from side effects will be more acceptable.

The **tolerance** of the drug is also determined. Drug tolerance occurs as the body adapts to the action of the drug. A person taking the drug needs larger and larger doses to achieve the original effect. The danger with tolerance is that as the dose increases so do the risks of dependence and the possibility of reaching the lethal dose.

If the drug passes the initial clinical trial it will then go through a rigorous series of further phases, where its use is gradually widened in a variety of clinical situations. If it passes all these trials it will eventually be approved by the drug administration of a particular country, for use either as an OTC (over the counter) drug or for use only through prescription by a doctor.