

Testing Drugs

Level: PSE, years 9 to 11

3

NOTES

Background information

For every drug sold, about 10,000 never get on to the market. This is because every drug that is used in the country and in most of the western world has to be tested on animals by law. There are three stages involved:

1. Tests are first carried out in tissue culture in the laboratory or, more commonly, by combinational chemistry, with large throughput screens.
2. If the results are promising, tests then begin on whole animals. Rats and mice are the most common, although dogs and monkeys are also used. Tests on animals are carried out to find out whether the drug works and to discover any side-effects (e.g. cancer). Other questions addressed might be the effect on unborn animals of administering the drug to a pregnant mother. It should be born in mind, however, that animals do not have the same illnesses as humans and do not necessarily respond in the same way to a particular drug.

Scientists are trying to use fewer and fewer animals than they used to. For example, they can sometimes use clumps of cells grown in the laboratory. However, until satisfactory alternatives are found, drugs will continue to be tested on animals. There are very few humans who would want to take drugs that had not been tested.

3. Once the scientists involved are satisfied with the results of the animal tests, clinical trials on humans can begin. There are several stages:
 - (i) The drug is first introduced to 20–30 healthy volunteers, each person being carefully monitored for side-effects. This stage of the trial should give a better indication of the ideal dose for the drug.
 - (ii) The drug is then administered to people suffering from the illness. Anti-cancer drugs, for example, are first tested on terminally-ill patients for whom there is no other known treatment. If the drug does not kill them, and perhaps shows a hint of response (PHASE 1), it may then be tested on a group of patients with less terminal disease and their responses recorded (PHASE 2). If some responses are seen, the drug is then tested randomly against the best existing treatment. Patients with other diseases may often be divided into two groups: one receives the drug and the other receives a dummy (or PLACEBO). This is necessary because some people will feel better even when given an inactive drug. The trials must take this into account.

The clinical trials become progressively larger and more complicated, involving several groups of patients taking a variety of drugs at different doses. The data are compiled and sent to the official licensing body. An advisory committee of medical experts (the Committee on Safety of Medicines) analyses the data and, if satisfied, grants a licence for the drug to go on the market.

A new drug continues to be monitored in its early days. For example, particular care must be taken with children, the elderly and pregnant women. Doctors must report unusual side-effects to the official licensing body. If problems become apparent, a decision will need to be made as to whether the drug should be banned or restricted.

Despite all the safety checks, a number of dangerous drugs have found their way on to the market. The THALIDOMIDE drug was administered to pregnant women in the late 1950s as a sedative and to help pre-

vent morning sickness. As a direct result of the drug, many of their babies were born with severely deformed limbs. (Interestingly, thalidomide is becoming quite widely used again in the treatment of leprosy. It is also currently in trial as an antiangiogenic agent in cancer.) In 1982, the anti-arthritis drug OPREN was banned in Britain because it was linked to liver and kidney problems. Some patients died and others suffered long-term sensitivity to light (they blistered and burnt in the sun). Despite this, many people did benefit from Opren, and some doctors still believe that the drug should be available to certain patients if monitored carefully. A group of tranquillizers (including VALIUM) were on the market for 20 years before their addictive nature was recognized. Many people suffered serious withdrawal problems when they tried to stop taking the drugs. In 1991, one of this group of drugs, HALCION, was banned in Britain because of the personality and memory disorders it was found to cause.

When people are injured by drugs, they may claim compensation from the company that manufactured the drug. This can take many years. In some cases, companies have compensation funds from which payments may be made, but usually the victims must go to court. In the USA, the relatives of some of the victims who died after taking Opren received millions of dollars each (more than all of the British victims put together). Many Britons try to take their claims through the American courts because they tend to get faster results and higher rewards, especially if the drug is made by an American company. Companies can insure themselves against such claims, but the large insurance premiums are passed on to the consumer in higher-priced drugs.

Group work

After briefly introducing the topic, split the class into groups and instruct them to use pages 112 and 113 of the book to help them to complete the student worksheet on 'Testing Drugs'.

(10–15 minutes)

Class discussion

Using the worksheet as a basis, lead a class debate on the reasons for testing drugs, emphasizing the procedures of (i) animal testing and (ii) human testing. Find out the students' views on testing drugs on animals. For example, a child in hospital is in need of a drug that has been tested on animals. Should the parents give their consent? Find out from the class who would be prepared to take a medical drug that had not been tested? Are there exceptions? What about terminally ill patients? (You may wish to develop these themes by requesting pupils to prepare role plays to illustrate particular points.)

(20 minutes)