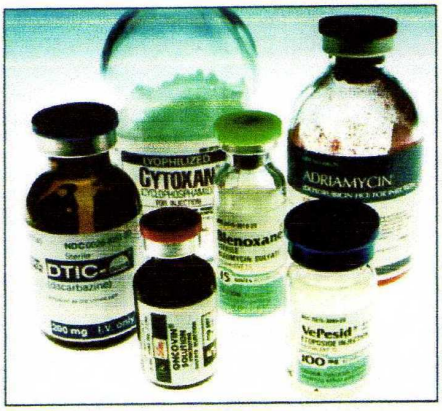
OUTPUT **Read the following newspaper article.**

Experimental Drugs on Trial

The parents of a 21-year-old woman challenged the FDA. They took the authority to court after their daughter had died of cancer. The parents firmly believe that their daughter might have had a chance of surviving if she had been given access to a potentially life-saving experimental cancer drug that her doctor had recommended.

Many terminally ill people fall victim to the 'therapeutic misconception' that the objective of trials is to cure them. In truth, clinical trials are mainly aimed at answering scientific questions. In general, their goal is to gather statistics to determine whether an experimental drug is safe and effective.

On the whole, subjects in a trial must be willing to be randomly assigned to either the group which receives the unapproved medication or the one which gets a placebo. This is the only way to make sure clinical trials serve a scientific purpose. Subjects also have to be aware that the pharmaceutical company which is sponsoring the clinical trial can stop the trial at any time.



Do terminally ill patients have the legal right to try to prolong their lives by taking experimental drugs? The FDA has a clear position on this subject. It maintains that it would be difficult to find a sufficient number of patients to participate in clinical trials if it were possible to obtain the drug without actually being a subject in a trial. The safety and efficacy of a drug can only be determined by conducting rigorous clinical trials, according to the FDA.

OVER TO YOU

- Is it ethically justifiable to deny terminally ill patients access to potentially life-saving, experimental drugs and medicine?
- Would easier access to experimental drugs have an effect on obtaining reliable data on the safety and efficacy of the drugs?
- What can authorities do to provide terminally ill patients with drugs that could help them?

OUTPUT **Read the article.**

5

BOY KILLED BY POTENT PAIN PATCH

A few years ago, a mother was convicted of negligence leading to her son's death. It was claimed that he had died from a pain medication overdose. Now the woman has taken measures to ensure that other children do not die the same way.

A four-year-old boy was found dead after he had stuck a highly potent, pain-relieving patch to his leg. His mother was sentenced to several years' community service for leaving a used patch in a place where her young son could have access to it. The patches had been prescribed for her as treatment for a serious intestinal disorder.

She claimed that she always put her used patches into an empty soda can, whenever possible. One day, however, she did not have one available, so she put the used patch directly into the garbage. Her son later found it and stuck it onto his leg, just the way he had seen his mother do it.

The authorities became interested in this case. The boy's death highlighted a problem that no one had anticipated up to that time. Because of her son's death, the young mother demanded that safe-disposal boxes be included in the packages of medicated patches. These boxes should have a small slit at the top to discard used patches and it should be impossible to open them.

In the meantime, many medications, especially those that involve needles, come with disposal boxes for discarding them. However, besides a warning about the effects of the medication, authorities have unfortunately not made the requirements regarding the disposal of potentially dangerous materials any stricter. Fortunately, though, many pharmaceutical companies have recognized the problem and now supply boxes for disposal with their products. ◆

OVER TO YOU

- Who do you think is responsible for the boy's death? The mother? The pharmaceutical company? Someone else?
- Do you know of any similar cases involving pharmaceutical products?
- Pharmaceutical companies are required to package their products in a childproof, but elderly-accessible way. Why is this so difficult?

OUTPUT **Read the following newspaper article.**

Drug contamination: lessons to be learned?

A few years ago, a well-known European pharmaceutical company was forced to recall one of its drugs due to claims of product contamination. The recall took place following reports from patients that their medication had a strange odour. Several patients from a number of different countries made the complaint within a short period of time. A few patients experienced nausea immediately after taking the medication. Unfortunately, the drug manufacturer was unable to say just how many patients were taking this drug at the time. However, it estimated the global figure at over 40,000 people.

Immediate investigations showed that samples of the tablets contained abnormally high levels of a harmful genotoxic substance. The contamination was traced back to its manufacturing plant. According to reports, it seems that an unanticipated reaction between the drug's active ingredient and the chemicals used as part of the cleaning processes at the site was the cause of the contamination.

The company claims that a cleaning error was the reason for the entire incident. This clearly underlines the danger of underestimating the importance of the cleaning process in pharmaceutical manufacturing. Validation of cleaning processes is essential in this industry, because chemical or bacterial contamination of drug products can potentially lead to severe public health risks. Regulatory bodies, such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMEA), require validation of cleaning processes. In fact, if there is evidence that a company is trying to save money by reducing their cleaning activities, these agencies take action.

In the above case, no other products manufactured by the pharmaceutical company were affected by the mistake and the contamination error was quickly rectified. However, the recall left seriously ill patients without proper medicine. The World Health Organization recommended that patients try to find a suitable alternative.

OVER TO YOU

- What role did pharmaceutical manufacturing processes play in this incident?
- How could the company have avoided this recall? Consider the role of quality assurance, quality control, audits, and inspections.
- What effect do product recalls have on a pharmaceutical company?
- Has your company ever been involved in a product recall?

OUTPUT **Read the article below about different classes of drugs in different countries.**

How many drug categories do we need?

On the whole, countries establish specific rules and regulations not only on the type of drugs made available, but also on how they reach the consumer. On the one hand, medicine needs to be easily accessible. This is, of course, a question of public health. On the other hand, these same products can do harm if used incorrectly. This danger must be avoided.

For this reason, regulatory authorities in every country set the number of categories for drugs. For example, in Canada, there are four:

1) drugs available only with a prescription
2) those without a prescription, but only with the personal involvement of a pharmacist
3) medicine which customers can pick off open shelves, but only in a pharmacy, and
4) products which can be openly sold in any kind of retail outlet.

By contrast, the US only has two official categories: drugs needing a prescription and drugs that do not. The former are prescription drugs and are available in pharmacies and only by prescription. The latter are over-the-counter drugs which can be sold in any type of retail outlet that chooses to stock them.

In general, in the US, medication must meet four criteria in order to obtain the status of a non-prescription or over-the-counter (OTC) product. It must have:

- a large margin of safety
- low incidence of side effects
- low potential for misuse and abuse, and
- labelling that provides adequate directions for sale and effective use.

At present, the Food and Drug Administration is reviewing its current policy on the number of categories. It is discussing the introduction of a new intermediate category for the US market called 'behind-the-counter' (BTC) medicine. Drugs of this type would need no prescription, but would require a pharmacist's intervention and resemble category 2) in Canada. One reason is that consumers in many Western countries have found this new category beneficial.

In Europe, the concept of BTC has been practised with great success for years. People can just go to their local pharmacy and describe their medical need. The pharmacist simply recommends an appropriate drug without first requiring a doctor's prescription. He or she can also suggest a less expensive drug in generic form. The disadvantage, however, for many Europeans is that the cost of these drugs or medications is not taken on by the health insurance system.

Currently, the FDA is faced with a difficult decision. If it decides to add the category BTC, this will have definite consequences for the pharmaceutical industry in the US. In the short term, this change would immediately force the pharmaceutical companies to reorganize their marketing efforts. In the long term, companies and research institutes would need to reassess their own potential and reconsider which type of drugs are worth testing. ■

12

OVER TO YOU

- What are the advantages of providing drugs and medications by prescription, BTC, and OTC?
- How are drugs and medications made available in your country?
- Which method(s) do you prefer?
- Should patients have the right to obtain drugs and medication online from other countries?