Medicolegal

Strict product liability arrives: implications for doctors

CLARE DYER

Strict product liability becomes a reality in the United Kingdom next week, when part I of the Consumer Protection Act 1987 comes into force on 1 March. Yet little guidance has so far emerged on what the new régime will mean for doctors, and most doctors probably assume it will have little effect on their practices. Representatives of the BMA's General Medical Services Committee and the department of health are discussing the matter with a view to issuing guidance to general practitioners, and the Central Committee for Hospital Medical Services is pursuing the question of guidance for hospital doctors.

In fact, the act will impose a considerable burden of record keeping on doctors if they are not to find themselves legally liable for the supply of a defective drug or other medical product. The act makes producers of defective products liable without the need to prove negligence, but suppliers will also become liable unless they can identify the producer.

Not only dispensing general practitioners will become suppliers but also any doctors who give patients drugs or appliances from their bags or consulting rooms. In the case of items supplied by doctors in hospitals the health authority will be the supplier. Doctors and health authorities will therefore need to keep full records identifying the source of every item supplied, and records will need to be preserved for 10 years, the cut off point for taking legal action; draft guidelines from the BMA suggest that this may well have to include the cat gut used in operations. Doctors fitting intrauterine contraceptive devices, for instance, must keep a note of the brand fitted. The litigation over the Dalkon Shield has shown that in the 1970s when the shield was popular, many doctors simply wrote "intrauterine contraceptive device" without identifying the type. Doctors who cannot identify the supplier of a device fitted after 1 March could be liable in subsequent litigation.

Doctors could also become strictly liable as producers if they mix their own medicines or modify drugs or appliances before supplying them to the patient. The Pharmaceutical Society of Great Britain has issued guidelines for pharmacists that dispensing doctors would also do well to follow. The society suggests that when making bulk quantities of medicine for sale as a nostrum or for subsequent dispensing records should be kept of the suppliers, batch numbers, dates received, and dates issued. A BMA internal memorandum has raised the question of doctors who introduce additives into intravenous fusions, which is common practice in operating theatres and intensive care units. Under the act it seems that they could be considered producers.

What is a product?

Products are defined as "any goods or electricity" but include not only manufactured products but products that have been "won or abstracted." Are blood and blood products included? Over 50 haemophiliacs and wives of haemophiliacs infected with human immunodeficiency virus through contaminated factor VIII are about to issue writs against health authorities, the Secretary of State for Social Services, and the Committee on Safety of Medicines; and

non-haemophiliacs infected through blood transfusions are also considering legal action. If blood products were to be regarded as products under the act and the act had been in force when the haemophiliacs were given the faulty factor VIII the patients would have been able to sue the manufacturers without the need to prove fault; though the manufacturers would undoubtedly have invoked the defence of "state of the art" or "development risks," which allows producers to escape liability for defects they could not have been expected to foresee. In the United States most states have passed legislation categorising blood as a service rather than a product, and in one case a haemophiliac has been told that he cannot therefore invoke strict liability laws but must fall back on the law of negligence. It would, however, be unsafe to assume that blood and blood products would not be considered products under the Consumer Protection Act.

A defective product is defined as one that is not as safe as people generally are entitled to expect. In deciding what people are entitled to expect the act lays down that all the circumstances will be taken into account, including the manner in which and the purposes for which the product was marketed, warnings about the product, what might reasonably be expected to be done with the product, and when the product was supplied.

Opinions differ about whether drugs supplied as part of clinical trials are covered by the act. The Department of Trade and Industry and the Department of Health and Social Security take the view that such drugs are not included in the act because they are not supplied in the course of a business with a view to profit, but this seems a highly debatable conclusion. The state of the drug as a research product would, however, be relevant in deciding whether it was defective, and the state of the art defence would apply in most cases.

British implementation of a European act

The Consumer Protection Act has been brought in to implement the European Directive on Product Liability, under which all members of the European Community were obliged to introduce strict liability laws for defective products. The directive, which was designed to facilitate the free movement of goods within the community, left each member state free to decide whether to allow manufacturers to invoke a defence of development risks. Several countries will not be allowing such a defence. France, Belgium, and Luxemburg will maintain their existing position, under which producers are already strictly liable, even for development risks. Denmark, The Netherlands, and the Republic of Ireland do not intend to allow a defence of development risk. The Federal Republic of Germany, which has had strict liability for drugs since 1978, will allow this defence but not for pharmaceutical products.

Not only has the United Kingdom introduced a defence of development risks but, arguably, it has gone further in protecting manufacturers than allowed by the directive. This is the conclusion of an opinion obtained by the Consumers' Association from a leading community law firm, the Belmont European Community Law Office in Brussels. The opinion, from Nicholas Forward QC, has been sent to the European Commission, which is understood to be considering infringement proceedings against the United Kingdom for breach of its obligations under the treaty of the European Community.

London NW1

CLARE DYER, BA, BLS, legal correspondent