

# DEFECTIVE DEFENCE

No-fault liability for defective products was introduced into English law nearly 20 years ago. The Consumer Protection Act 1987 implemented European Directive 85/374. It was thought at the time that it would herald a deluge of consumer-led claims and a number of industry sectors — particularly pharmaceuticals — had serious concerns about the likelihood of claims even where the safety of medicines, for example, is strictly regulated by sector-specific mechanisms.

It is, therefore, something of a surprise to note that the level and intensity of claims under the 1987 provisions have been extraordinarily low.

The 1985 Directive was a harmonising measure, part of a wider range of legislative steps introduced as the European single market matured. It was, however, hard-won and a number of political compromises had to be reached to get the legislation through to law. Accordingly, member states were given and have adopted certain freedoms or derogations.

For that and other reasons, the Directive requires that there be a regular review of the 'efficiency' of the legal framework. The latest such review — the third — was completed and the

Legislation enacted nearly 20 years ago threatened to expose the pharmaceutical industry to a tide of liability claims over defective products. **Anthony Warnock-Smith** examines why the floodgates have yet to open

European Commission's (EC's) report published a month ago.

The EC had organised legal and economic research into the operation of the Directive and concluded that it was working substantially as required at present. No change, therefore, was recommended, notwithstanding the significant and widely acknowledged differences across Europe in the application or interpretation of the Directive in national jurisdictions.

The basic tenet of the legislation is that consumers are entitled to purchase and use products that are not defective and, if they suffer harm as a result of using a defective product, they are entitled to compensation without having to prove that the defect was the result of a breach of contract or the negligent act or omission of the manufacturer — as had previously been the case in English law.

It was intended to introduce into the local legislation a standardised system

of no-fault liability for producers of defective products. However, a claimant seeking to rely on the Directive — or, rather, the national implementation of it — is not given an entirely easy ride, for two principal reasons.

Firstly, the concept of defectiveness has turned out to be more complicated than had been anticipated. A product is defective if it is not as safe as the consumer is entitled to expect. The expectation of the consumer is assessed by taking into account all the surrounding circumstances which, in practical terms, means looking at the claims made for the product in advertising and promotion, instructions for use and general consumer awareness — rather than quality control or manufacturing standards, which are taken for granted as a matter of principle.

The EC's review has highlighted two issues on the meaning of 'defect'. Primarily, in dealing with a claim, should a court look to assess the risk/benefit of

tion medicine. The safety expectation of the consumer will be set by a number of factors, not least the role that the doctor plays in the process of selecting and prescribing the particular medicine for the patient. That is one issue for the claimant to resolve and, as indicated earlier, that is not necessarily a foregone conclusion. However, it is much more difficult for the claimant to prove that the damage was caused by the use or consumption of the product and/or by the defect in the product.

Assuming, in the case of the prescription medicine, that there was no quality or manufacturing problem with the product, the injured participant is faced with the daunting twin challenges of showing that the medicine was defective and that it caused, pharmacologically, the harm suffered by the claimant.

As mentioned earlier, medicines are highly regulated and in the approval process the manufacturer must demonstrate to the regulator that the product is not only effective for its intended purpose (the indication) but also that it is safe. The decision of how appropriate a medicine is for a patient is usually made by the expert medical professional who prescribes it, in effect imposing his opinion on the patient.

Yet it is the patient's expectation of safety which is the determinant of defectiveness. If the patient suffers damage, their ability to show that particular hurt was unexpected and not warned against (at least by the doctor) but was caused by the medicine — which had been approved for use in that particular way — is a very demanding burden indeed.

It is perhaps little wonder, at least in hindsight, that the fears of the pharmaceutical industry in the mid-1980s have not been realised for that reason alone.

Then add into the mix the development risk defence; it was one of the derogations accorded to member states not to make the defence available, but all bar two have chosen not to do so. In simple terms, if the manufacturer can show that no-one knew any better at the time the product was devised, there is no liability. That was seized on by manufacturers as being of great importance and remains significant in the assessment of the impact of the legislation, notwithstanding that it has hardly ever been pleaded in proceedings.

The EC's report now concludes that the defence is a significant factor in achieving what it describes as a balance between the need to preserve incentives to innovation and consumers' interests, particularly in the context of high-tech/high-risk sectors in which the availability and the cost of insurance are a major concern.

Accordingly, the view is that the current balance between competing stakeholders is favourable, should be maintained and, therefore, that there is no demand for major reform at present.

The one negative element is the diversity of decisions under the Directive by the courts of member states and that relatively few matters had been referred to the European Court of Justice. ■

Anthony Warnock-Smith is a partner at Morgan Lewis.

## CONSUMERS ARE ENTITLED TO PURCHASE AND USE PRODUCTS THAT ARE NOT DEFECTIVE AND, IF THEY SUFFER HARM AS A RESULT OF USING A DEFECTIVE PRODUCT, THEY ARE ENTITLED TO COMPENSATION WITHOUT HAVING TO PROVE THAT THE DEFECT IN THE PRODUCT WAS THE RESULT OF A BREACH OF CONTRACT OR THE NEGLIGENT ACT OR OMISSION OF THE MANUFACTURER

the consumer's expectation and determine whether the defence of care taken by the manufacturer is relevant? Contrasting and inconsistent decisions of the English courts illustrate the artificialities here (see *A and Others v National Blood Authority* and *Sam Bogle v McDonald's Restaurants*).

Secondly, what is required of the consumer to prove the defect in legal proceedings? The issue is whether the consumer has to show not only that the product caused the injury suffered but also what the precise cause of the defect was. Or is it sufficient for the claimant to show that there was some (not demonstrated) failure in the product leading to the harm suffered? Decisions in courts in several member states in Europe have produced differing conclusions.

The second issue facing the consumer in considering these and other issues which have arisen from the legislation is the fundamental and particularly noteworthy question of causation. The product may be defective and the consumer may have suffered harm, but there is no liability — even no-fault liability — if the claimant cannot prove that the defect caused the harm.

Consider the example of a prescrip-

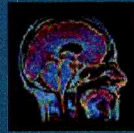
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