
**REGULATORY STANDARDS & LIABILITY:
THE LEGAL LIABILITY OF MEDICINES**

**British Institute of International and
Comparative Law**

Alison McAdams

amcadams@dac.co.uk

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THE ISSUE

What is the test for legal liability ?

Does benefit risk assessment have an impact ?

TWO FRAMEWORKS

Medicines Authorisation – 2001/83/EC

as amended, Medicinal Products for Human Use

Medicines Liability – 1985/374/EEC

Liability for Defective Products

MEDICINES / PRODUCT LIABILITY

- Different aims
- Different timeframes
- Different terminology

MEDICINAL PRODUCTS DIRECTIVE

Preamble 7

The concepts of **harmfulness** and **therapeutic efficacy** can only be examined in relation to each other and have only a relative significance depending on the progress of scientific knowledge and the use for which the medicinal product is intended.

The particulars and documents which must accompany an application for marketing authorisation for a medicinal product demonstrate that **potential risks are outweighed by the therapeutic efficacy** of the product.

Article 21, Article 24, Article 26...

PRODUCT LIABILITY DIRECTIVE

- Purpose of Directive was to increase consumer protection.
- Directive introduced an obligation on producers which was irrespective of fault, by way of strict liability, but not absolute liability.
- Directive's aim was to render compensation of the injured consumer easier, by removing the concept of negligence.
- Directive left an escape clause if producer could bring himself within the development risks defence.

Per Burton J. in the Hepatitis C Litigation,

A v National Blood Authority, 2001 3 ALL ER

PRODUCT LIABILITY DIRECTIVE

Preamble

Liability without fault on the part of the producer is the sole means of adequately solving the problem peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production.

PRODUCT LIABILITY DIRECTIVE

Preamble

A fair apportionment of risk between the injured person and the producer implies that the producer should be able to free himself from liability if he furnishes proof as to the existence of certain exonerating circumstances.

ARTICLE 1 - SUMMARY

The producer shall be liable for damage caused by a defect in his product.

ARTICLE 4 - CAUSATION

The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage.

CASES DECIDED ON CAUSATION

- *Loveday v Renton*, Whooping cough vaccine litigation
- *Hope and Reay v BNFL*, Sellafield leukaemia litigation
- *XYZ v Schering Health Care*, Oral contraceptive litigation
- MMR Vaccine Litigation

ARTICLE 6 – WHEN IS A PRODUCT DEFECTIVE?

(1) A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:

- a. presentation of the product;
- b. the use of which it could reasonably be expected that the product would be put;
- c. the time when the product was put into circulation.

DETERMINING THE STANDARD OF SAFETY

- Consumer expectation - consider legitimate expectation of public
- Not real or actual expectation
- As decided by the court
- Taking all/relevant circumstances into account

OFF-LIMIT CONSIDERATIONS

- Knowledge of the medical profession/learned intermediary
- Benefit to society or utility of the product
- Avoidability of a harmful characteristic
- Feasibility of precautions

ARTICLE 7 (e) - DEFENCES

The producer shall not be liable if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered.

ARTICLE 12 - WARNINGS

The liability of the producer arising from this Directive may not, in relation to the injured person, be limited, or excluded by a provision of limiting his liability or exempting him from liability.

WHAT PLACE FOR BENEFIT RISK ANALYSIS ?

A product is not defective if the risk is fully known and socially acceptable to the public.

Can benefit risk analysis inform this debate?

Should the operation of the PLD be reviewed on its own terms?

Should the operation of the PLD be reviewed as against developments in benefit risk analysis?