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New Technology, New Risks

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Law and science

- From Thalidomide…
- Opren, benzodiazepines, Lariam
- Vaccines - whooping cough, MMR
- Contaminated blood products – HIV, Hepatitis C
- … to TGN 1412 clinical trial at Northwick Park

Two Frameworks

Medicines Authorisation – 2001/83/EC

as amended, Medicinal Products for Human Use

Medicines Liability – 1985/374/EEC

Liability for Defective Products

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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.

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Medicinal Products Directive

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: 1985/374/EEC

- 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.

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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

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How to apportion the risks fairly

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

Can better communication and education about a product's benefits and risks inform this debate?

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

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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

Personalised medicine

Pharmacogenetics – the study of how DNA influences an individual's response to medicines

Companion diagnostics – tests, identifying genes or biomarkers, which allow doctors to establish in which patient groups medicines will be most effective

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Personalised medicine – examples

- Warfarin – DNA tests enable screening for genes that affect dosage
- Codeine – no analgesic benefit if gene present which stops medicine metabolising
- Herceptin / Iressa – cancer drugs tailored to target particular genetic mutations in tumours
- Vemurafenib – skin cancer drug for metastatic melanoma patients with particular gene mutation

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Nanotechnology – examples

Many products use nanoparticles' physical, biological, thermal or optical properties

- Nanosilver - antimicrobial agent in toothpastes
- Gold nanoparticles – in skin cream
- Titanium dioxide/zinic oxide – in sunscreens

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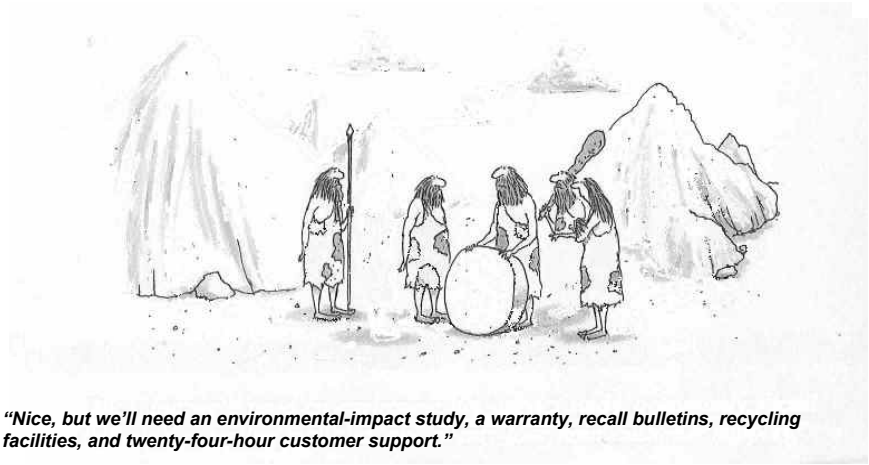
Producers and Insurers

- Directive not in your favour
- Need to reconsider the fair apportionment of risks
- Clear information on risks and benefits is needed by all
- Engage with public expectation
- Understand developing markets and ensure you are aware of the risks before product launch and agreeing premiums and coverage



"Nice, but we'll need an environmental-impact study, a warranty, recall bulletins, recycling facilities, and twenty-four-hour customer support."