



Product risk and liability news

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US US Supreme Court allows product liability suit against pharmaceutical company

The US Supreme Court recently held that federal approval of drug labelling does not prevent state law claims against the drug's manufacturer for alleged failure to warn of the risks of the product.

In *Wyeth v Levine* 555 US ___ (2009), the Supreme Court held by a majority of six to three that labelling approval by the US Food and Drug Administration (FDA) does not automatically pre-empt state law and so protect pharmaceutical companies from product liability claims. In so doing, it departed from an earlier ruling that shielded manufacturers of medical devices from liability in similar circumstances. A day after the decision, Democratic lawmakers in the House of Representatives and the Senate proposed new legislation that would make it easier to bring claims against manufacturers of medical devices.

A jury awarded \$6.8m in standard damages to Mrs Levine, a professional musician from Vermont whose arm had to be amputated following an incorrect injection of the anti-nausea drug Phenergan manufactured by Wyeth. The jury found that the drug's labelling had not adequately warned about the risks of the technique that was used to inject it.

Wyeth contended that the claim was pre-empted by federal law because the Phenergan label had been reviewed and approved by the FDA. The company argued that FDA regulations prohibited it from strengthening the warning without the agency's approval and that any

attempt to do so would run contrary to the legislator's intention to entrust the FDA alone with complex scientific labelling questions.

The Supreme Court was not persuaded. It agreed with Wyeth that a drug manufacturer may generally change a drug label only once the FDA had approved the change. However, the court said the FDA regulations allowed certain pre-approval labelling changes to add or strengthen a warning, in particular through the so-called 'changes being effected' provision. It was therefore not impossible for Wyeth, said the court, to comply with its state law duties on which the claim was based and the federal labelling duties under the FDA regulations.

The Supreme Court agreed with Wyeth that federal laws and regulations can in some cases pre-empt conflicting state law requirements and therefore product liability claims based on state law. However, the history of the Food, Drug and Cosmetic Act showed, according to the court, that the legislator did not intend to pre-empt product liability claims against drug manufacturers.

CANADA/SWITZERLAND

New federal product safety legislation proposed

Canada and Switzerland have recently proposed new federal legislation that would overhaul their product safety regimes and introduce notification and corrective action requirements that will be similar to the provisions of the European Product Safety Directive and therefore familiar to many European businesses.

In Canada, the federal government has again proposed the adoption of a new consumer product safety act to replace its existing consumer safety legislation, some of which is over 40 years old. The act, which is a key component of the food and consumer safety action plan adopted last year in response to a number of high-profile recalls in the jurisdiction, would, among other things:

- apply to all products used in the domestic context, except those that are regulated under specific legislation – eg food and medicines;
- include a general prohibition against the manufacture, import, advertising or sale of consumer products that pose an unreasonable danger to human health or safety;
- require reporting by manufacturers and importers of any safety incident or grounds that may lead to serious injury or death on strict deadlines;
- require suppliers to maintain records to ensure product traceability;
- give inspectors the power to order mandatory recalls or other corrective measures if there is reasonable belief that the product poses a danger to public health or safety; and
- provide for increased fines and penalties with fines.

Switzerland's draft product safety act, meanwhile, has passed the Parliamentary Commission stage and has received the approval of the Council of States. The act, if adopted, would apply horizontally to all products and would introduce obligations on manufacturers and importers to monitor products, ensure traceability, notify regulators in the event of a safety issue and take corrective action to prevent risks to consumers.

EU

Report on first years of implementation of the GPSD

The European Commission recently adopted a communication to the European Parliament and Council reporting on the implementation of the General Product Safety Directive (GPSD) from 2004 to 2008.

The communication concludes that the GPSD has been a powerful tool for ensuring a high level of consumer protection, helping to track down and eliminate a large number of unsafe products from the European market. It also finds that the rapid alert system for non-food consumer products (RAPEX) complements existing

regulatory frameworks applying to key consumer products, including toys, and suggests that the increases in RAPEX notifications are a clear indication that market surveillance under the GPSD has been successful.

Recommendations for improvements in the future include clarification of the mandatory nature of the requirement for the product or its packaging to identify the producer, ensuring manufacturers or importers of unsafe products can be traced. The report also points to the need to avoid inconsistencies in transposition of the Directive between the member states.

Pesticide review finally completed

The European Commission has announced that it has finally completed a safety assessment review of some 1,000 pesticides placed on the EU market before 1993. The review was required to be completed under Directive 91/414/EEC, which lays down a comprehensive risk assessment and authorisation procedure for active substances and pesticide products containing these substances.

Originally scheduled for completion in 2003, the review showed that 250 substances and products passed the safety assessment and have been placed on an approved list and 70 failed and were subsequently withdrawn from the EU market. The remaining 640 substances and products were eliminated from the review for a variety of reasons, including the voluntary withdrawal of dossiers by industry.

The review has, however, been somewhat overtaken by recent events – late last year, the European institutions reached agreement on a new regulation setting out new market authorisation rules for pesticides. The regulation, set to enter into force later in 2009, will restart the assessment process for approved substances because it contains tighter environmental and health criteria to be met before approval is granted.

DMF banned in consumer products

The use of the biocide dimethylfumarate (DMF) in consumer products such as couches and shoes was recently banned across the EU. The ban results from the recent adoption by EU member states of a draft decision of the European Commission and will ensure

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- The United Nations Environment Programme governing council has agreed to launch negotiations on a global legal agreement to control the supply and use of mercury. Negotiations will begin next year, with final adoption planned for 2013.
- The European Commission recently announced that there were 1,545 alerts for dangerous consumer products in 2008 through the EU RAPEX system, compared with 1,355 in 2007. The 2008 RAPEX report containing these and many more results will be presented by Commissioner Kuneva on 20 April.
- The UK Health and Safety Executive (HSE) has published an information sheet on risk management in relation to the manufacture and manipulation of carbon nanotubes (CNTs), in response to emerging evidence about the toxicology of these materials. According to the document, the HSE views CNTs as substances of very high concern. It calls for the adoption of a precautionary approach to the risk management of all CNTs and for effective measures to be taken in the workplace to prevent exposure where use is unavoidable.
- The French government recently proposed a bill to curb mobile phone use by children. If it is adopted, it would prohibit any advertisements encouraging children under the age of 12 to use mobile phones and would set new radiological emissions limits.
- The UK Medicines and Healthcare Products Regulatory Agency (MHRA) has issued a precautionary drug alert about batches of a meningitis vaccine manufactured by Novartis, following the identification of a sterility issue with the solvent used in the vaccination. A precautionary recall was undertaken by the manufacturer after tests suggested that samples from the same batch did not pass sterility tests under varying air pressure. No evidence of any risk to UK patients has been identified.
- The German Association of Ear, Nose and Throat Specialists (HNO) has reported that hearing problems associated with old age are now being seen in the 16 to 20-year-old age group as a result of the use of personal music players. It has called on manufacturers of the devices to inform consumers of the risk and to modify product designs. The HNO also called for a reduction in the 100-decibel limit for portable audio devices placed on the market in the EU. The warning comes after the EU scientific committee on emerging and newly identified health risks identified late last year that listening to personal music players at high volume over a sustained period may lead to permanent hearing damage. The Commission is now examining possible measures that could be taken better to protect young people from excessive noise exposure. In January, it organised a one-day stakeholders' conference on personal music players, to consider precautions that may be taken by consumers, technical solutions that may be adopted by industry and whether there is a need for further regulation in this regard.
- A new Product Liability Act came into force in Thailand at the end of February. Under the Act, all 'operators' will be jointly and severally liable for any damage arising from unsafe products sold to consumers. A product that has caused injury to a consumer is presumed to be unsafe unless the operator can prove otherwise. The Act provides for the award of punitive damages if the operator knew or was grossly negligent in not knowing that a product it had placed on the market was unsafe and it failed to take appropriate corrective action.

that consumer products, such as leather furniture or footwear, containing DMF are not imported into or otherwise placed on the market in the EU. Products that contain DMF and are already on the EU market must be withdrawn or recalled without delay.

The ban follows reports of health problems including skin itching, irritation, redness, burns and in some cases acute respiratory difficulty in some consumers exposed to products containing DMF. Group litigation has been started in the UK against a number of suppliers of furniture that is alleged to have been supplied with sachets of DMF.

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