Chapter 5: PRODUCT LIABILITY: COMPLIANCE AND SAFETY ISSUES

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Extract

While healthcare digitalisation brings enormous upsides to patients by delivering faster, more efficient and more comfortable solutions to their health problems than analogue or human-driven healthcare, it also results in new and unforeseen types of incidents. As in other technology-driven industries, product malfunctions may occur in HealthTech and put patients’ health and safety at risk despite all due care. This chapter examines key challenges posed by the EU product liability legislation for HealthTech products and businesses. It covers recent EU initiatives in this area and describes the remaining grey zones. The chapter further considers the interplay between the product safety and regulatory compliance required under the Medical Devices Regulation and product liability standards. It highlights the challenges that manufacturers must face, but also the opportunities that the Regulation offers for HealthTech companies seeking to protect their businesses against product liability risks.
Product liability refers to a manufacturer or seller being held liable for placing a defective product into the hands of a consumer. Responsibility for a product defect that causes injury lies with all sellers of the product who are in the distribution chain. In general terms, the law requires that a product meet the ordinary expectations of the consumer. When a product has an unexpected defect or danger, the product cannot be said to meet the ordinary expectations of the consumer. There is no federal product liability law. By eliminating the issue of manufacturer fault, the concept of no-fault, or "strict" liability allows plaintiffs to recover where they otherwise might not.

Unavoidably Unsafe Products. By their nature, some products simply cannot be made safer without losing their usefulness. Product liability is the area of law in which manufacturers, distributors, suppliers, retailers, and others who make products available to the public are held responsible for the injuries those products cause. Although the word "product" has broad connotations, product liability as an area of law is traditionally limited to products in the form of tangible personal property. Product Liability Laws and Regulations covering issues in USA of Liability Systems, Causation, Defences and Estoppel, Procedure, Time Limits, Remedies, Updates. While highly uncommon, criminal penalties may be imposed if a product defect violates federal or state safety regulations and the entity responsible for the defect acted with the requisite criminal intent or, in even more limited instance, if criminal responsibility can be imputed to the defendant. Criminal sanctions may also be imposed for an entity's fraudulent or intentionally misleading conduct in connection with a particular product. Products liability refers to the liability of any or all parties along the chain of manufacture of any product for damage caused by that product. This includes the manufacturer of component parts (at the top of the chain), an assembling manufacturer, the wholesaler, and the retail store owner (at the bottom of the chain). Products containing inherent defects that cause harm to a consumer (or someone to whom the product was loaned, given, etc.) of the product would be the subjects of products liability suits. While products are generally thought of as tangible personal property, products liabil... Dr. Sebastian Polly discusses liability, safety, and compliance issues associated with the launch of innovative products, and how addressing these issues early in the process can help avoid litigation later on. Before any new product is released into the market, companies should assess its product liability, safety, and compliance. But the launch of an innovative product presents a unique set of challenges: typically, they involve state-of-the-art technology, engineering, and design. When products break new ground in making something easier, or allow users to do something they've never been able to do before, new safety and quality standards and expectations might also have to be assessed and established.