New drugs are a constant target of substantial product liability lawsuits

Pharmaceutical Risks

Global pharmaceutical market

The pharmaceutical market worldwide sees stable conditions since many years with annual growth rates of about 5%. The value of the global prescription drug market is expected to reach over 1 trillion USD within the next years. The most important global players are still located in Western industrial countries with a majority in the United States.

Research and Development (R&D)

R&D activities in pharmaceutical companies focus on substances for long-term use like cancer, chronic inflammatory diseases, diabetes, rare (orphan) diseases, or chronic neurological and psychiatric conditions.

Substantial research is currently done on biopharmaceuticals (monoclonal antibodies and immunosuppressants). Drugs derived from monoclonal antibodies are the fastest growing sub segment of the market. Sales represent roughly 10% of the entire global market for prescription drugs. Another major topic for pharmaceutical research relates to drug delivery. Studies look at the design and evaluation of drug delivery systems, emphasizing some methods of delivery such as liposomes and liquid crystals. Research in the area of pharmaceutical cell biology aims to understand basic cell biology and relate the findings to diseases in humans. Scientists deal with topics such as inflammation process in human diseases, mechanisms for cell-to-cell communications and mechanism of carcinogenesis. Two major concepts of individualised gene therapies are in the centre of worldwide research and development activities, CAR T cell therapy and genome editing (CRISPR/cas-method). CAR T cell therapy is an immunological therapy concept where patients' blood is used to produce the drug. In 2017, the first drug got FDA approval in US to treat certain types of leukaemia.

Drug approval process

In the recent years it could be noted that particularly in the USA and in the EU, lawmakers appear to place a heightened emphasis on accelerating the drug approval process, especially where drugs designed to treat specific subgroups of diseases are concerned. The consensus appears to be that accelerated drug approval will incentivize drug research and development by reducing the administrative burden and cost of novel drug development.

One of the reasons of this development was that the pharmaceutical industry has experienced difficulty in maintaining the pace of new drug development, which in turn has endangered the continued potential profit return of investors. Furthermore, on both sides of the Atlantic, politicians increasingly argue that present licensing systems constitute an impediment to providing patients with much-needed live-saving medicines. Whether and to what extent this argument may be perceived as valid is one question, but in any event it would appear that the wheels are in motion and that full acceptance and execution of adaptive licensing is only a matter of time.

However, adaptive licensing may have not only a positive commercial effect. By their very nature adaptive licensing systems may bring pharmaceutical products to the market, which have not been subject to full clinical testing and review as we know it. For one, adaptive licensing well could force supervisory authorities to issue more label warnings. But more importantly, patients may suffer from side effects that have not yet been detected and therefore are not reflected in the warnings. Adaptive licensing may therefore adversely affect the pharmaceutical industry and their insurers and reinsurers.

Claims experience

The development of pharmaceutical liability claims in particular in the United States has been concerning because of the multi-million dollar amounts the manufactures and the insurance industry have had to pay in the last years due to alleged adverse and unforeseeable side-effects (main accusation: failure to warn and design defect). One factor contributing to this scenario involves the fact that most of the drugs developed are intended for a high number of patients, which itself essentially leads to a high number of possible claimants. Moreover, patients taking such drugs thereby expect to become healthier which leads to an increased willingness to act against the doctor or the manufacturer in the event that such a drug should be (deemed) deficient. While pharmaceutical risks are not a specialty in most markets, the various peculiarities of the American legal system make it particularly difficult for international (re)-insurers to write product liability for pharmaceutical risks there.

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