

Product liability, clinical trials and environmental risks

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Product liability is the risk that most occupies the insurance managers of the pharmaceutical groups. Under the Swiss Product Liability Act of 1993, which follows the European Product Liability Directive of 1985, the producer is liable without fault for damage caused by a defective product. Development risks are excluded in principle, but the exclusion does not apply in all jurisdictions, and courts in the United States apply their own rules on liability, damages and class actions.¹ The mass tort litigation of the past decades, in which thousands of plaintiffs sued pharmaceutical companies over the side effects of medicines, showed that a single product can generate liabilities of billions. The commercial insurance market reacted by restricting cover for pharmaceutical product liability, raising deductibles and excluding certain products and classes of claims. Many groups responded by increasing their retentions and by financing a larger share of their product liability risks through their captives.²

Clinical trials raise a different question. Swiss law requires the sponsor of a clinical trial to be liable for damage suffered by participants in connection with the trial and to provide security for this liability, usually in the form of insurance. The Human Research Act and the Clinical Trials Ordinance set out the requirements, including minimum sums insured.³ Comparable rules exist in Germany under the Medicines Act, in other member states of the European Union under the Clinical Trials Regulation of 2014 and in many other countries. Because these laws usually require cover from an insurer authorised in the country of the trial, a captive cannot issue the policies directly. It participates through fronting, by reinsuring the local trial policies issued by commercial insurers.⁴ A group that runs several hundred trials each year in dozens of countries can thus channel a large volume of small premiums into its captive while the local requirements are met.

Environmental liability completes the picture. As Part G explained, the revision of the Environmental Protection Act after Schweizerhalle introduced a strict liability for enterprises posing particular environmental risks and empowered the Federal Council to require security. The insurers, for their part, restricted the cover of environmental damage in general liability policies to sudden and accidental events. Gradual pollution, the cost of remediating contaminated sites and the liabilities from historical landfills are in large part uninsurable in the commercial market. Groups finance these risks from their own balance sheets through provisions, and in some cases through their captives.⁵ The European Environmental Liability Directive of 2004 has added a public law liability for the prevention and remediation of environmental damage, which applies to the production sites of the Basel groups in neighbouring Germany and France and which several member states back with requirements for financial security.⁶

Property and business interruption cover is the fourth major line. A fire, flood or explosion at a plant producing a critical active ingredient can halt the supply of a medicine for months, causing lost profits far in excess of the physical damage. Insurers assess these risks through engineering surveys, while the Basel groups have invested heavily in sprinklers, fire walls and redundant production. Because the loss experience of a well-protected group is often better than the market average, retaining the lower layers in a captive allows the group to benefit from its own investment in prevention. The higher layers, which protect against a catastrophic loss at a single site, remain with commercial insurers and reinsurers, among them the large Swiss and German reinsurers.⁷

1 Notes

1. Federal Act on Product Liability of 18 June 1993 (PrHG, SR 221.112.944), modelled on Council Directive 85/374/EEC of 25 July 1985; on the development risk defence (Art. 5(1)(e) PrHG) and the revised European Product Liability Directive (EU) 2024/2853, see the literature on product liability law. Status to be verified. ↩
2. On the development of the pharmaceutical product liability insurance market and the increase in retentions by the large groups, see the publications of the major brokers and the trade press; on the mass tort litigation in the United States, see the literature on pharmaceutical product liability. To be verified. ↩
3. Federal Act on Research involving Human Beings of 30 September 2011 (Human Research Act, HRA, SR 810.30), Arts. 19 and 20 (liability

- and security), and Ordinance on Clinical Trials in Human Research of 20 September 2013 (ClinO, SR 810.305), Arts. 10 ff. To be verified. ↩
4. On the insurance of clinical trials in Germany (§ 40(1) no. 8 and § 40(3) of the Arzneimittelgesetz) and in the European Union under Regulation (EU) No 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use (Art. 76), see the literature on clinical trial insurance. To be verified. ↩
 5. See Part G, chapter I of this book; on the limits of the insurability of gradual pollution and the use of provisions and captives for environmental liabilities, see the literature on environmental liability insurance and the annual reports of the groups concerned. To be verified. ↩
 6. Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage, Art. 14 (financial security); in Germany the Umweltschadensgesetz of 10 May 2007. To be verified. ↩
 7. On property and business interruption insurance for pharmaceutical and chemical plants, the role of loss prevention engineering and the layering of programmes between captives and commercial insurers, see the literature on industrial insurance and the publications of the major industrial insurers. To be verified. ↩

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