Product: Life Sciences Liability

Manufacturer Information

Product information

Life Sciences liability is a form of insurance against the risk of persons or entities incurring liabilities to third parties that can include bodily injury, illness, property damage, and financial loss.

The Life Sciences Liability market operates on (re)insurer manuscript wordings with cover specific for the Life Sciences industry.

Coverage is designed to be purchased in a modular form so that customers can attain the bespoke coverage required for their business activities. This offers the customer the ability to extend coverage when required and reduce the opportunity for gaps in coverage.

- **Product Liability** is the legal liability of the insured to pay damages and/or compensation to any party, other than the insured or employees, in respect of bodily injury and or property damage arising out of or from the insured's products anywhere within the territorial limits.
- **Professional Indemnity** is the legal liability of the insured to pay damages and/or compensation to any party, other than the insured or employees, in respect of negligent act, error or omission of the insured when providing a professional service, anywhere within the territorial limits.
- **Medical Malpractice** is the legal liability of the insured to pay damages and/or compensation for any negligent act, error or omission resulting in bodily injury committed by the insured when providing a healthcare service or as part of a Good Samaritan Act.
- **Public Liability** is the legal liability of the insured to pay damages and/or compensation to any party other than the insured or employees, in respect of personal injury or property damage, arising out of any act or default of the insured in the conduct of the business within the territorial limits.
- **Clinical Trials Liability** is the legal liability of the insured to pay damages and/or compensation to research subjects in respect of bodily injury arising out of any clinical trial directed by or on behalf of the insured.
- **Intellectual Property Liability** insurance protects the client in the event of an allegation of intellectual property infringement, covering representatives fees and expenses, and resulting liability, damages and/or settlement.is the legal liability of the insured to pay damages and/or compensation for any claim including associated claimant's costs and expenses and legal defence costs resulting from an action, licensing request, or circumstance.
- **Cyber Liability** covers;
  • Data Breach costs associated with a breach of personal data including IT forensic, notification costs, regulatory defence or fines, legal costs, and damages.
  • Extra expense and Business interruption following a computer network outage.
  • Ransomware costs including extortion payment and ensuing business interruption.
  Cyber breach response hotline – Insureds who purchase a policy with Cyber cover selected will benefit from a free 24/7 emergency hotline to receive advice in the situation of a breach response triggered claim.

Target market

This product is designed for commercial entities operating within the Life Sciences sector, including but not limited to:

- Pharmaceutical manufacturers
- Biotechnology and R&D firms
- Medical device and MedTech companies
- Clinical trial sponsors and CROs
- Nutraceutical and cosmetic producers
- Laboratories and diagnostic service providers

These customers typically require bespoke liability coverage due to the complexity, regulatory sensitivity, and potential severity of third-party claims arising from their operations. The product is structured to offer modular coverage across multiple heads of liability, including Product Liability, Professional Indemnity, Medical Malpractice, Clinical Trials Liability, Intellectual Property, and Cyber.

The product's modular design allows customers to select coverage relevant to their operations, avoiding unnecessary costs while ensuring comprehensive protection.

Customer Characteristics:

- **Size & Scale:**
  Target customers range from micro-enterprises to large commercial organisations.
- **Geographic Reach:**
  The product is distributed globally, with risk and policyholder domiciles including the UK, EEA, Australia/NZ, and Rest of World. The product is not approved for sale to US-domiciled entities.
- **Risk Profile & Insurance Needs:**
  Customers typically operate in high-risk environments involving clinical trials, product development, and patient interaction, necessitating high limits of indemnity (up to £50M) and tailored coverage to mitigate exposures such as bodily injury, IP infringement, and cyber breaches.
- **Sophistication & Insurance Literacy:**
  While many customers are technically sophisticated, particularly in mid-to-large commercial segments, micro-enterprises may have lower insurance literacy, which is mitigated through distribution via specialist brokers and coverholders.
- **Vulnerability Exposure:**
  The product has negligible exposure to vulnerable customers, and is not specifically targeted at individuals or consumer segments.

Types of customer for whom the product would be unsuitable

This product is not appropriate for the following customer types and scenarios:

1. Individuals and Consumer Customers
- The product is designed exclusively for commercial entities and is not suitable for individual consumers.

2. Entities Outside the Life Sciences Sector
- Businesses that do not operate within the Life Sciences industry, such as general manufacturing, retail, hospitality, or construction, are outside the scope of this product.
- The coverage is tailored to risks specific to pharmaceutical, biotech, MedTech, and clinical research operations.

3. US-Domiciled Customers
- The product is not authorised for distribution to customers domiciled in the United States.

4. Customers with High Vulnerability or Low Insurance Literacy
- While the product may be distributed through both advised and non-advised sales channels, it may be unsuitable for customers with low insurance literacy where they are unable to fully understand the product's modular structure, coverage options, or technical exclusions
- The product is not specifically designed for vulnerable customers, however TMKs vulnerable customer policies will be applied in the event that a vulnerable customer is identified at claims or complaints stage.

5. Trades or Professions with No Exposure to Third-Party Liability in Life Sciences
- Entities whose operations do not involve product development, clinical trials, healthcare services, or intellectual property creation are unlikely to benefit from the coverage offered.

Any notable exclusions or circumstances where the product will not respond

Exclusions (available as extensions upon request and approval):

- Auto or Motor Liability – offered to customers on an excess basis to protect against claims arising from injury or damage to third parties only.
- Care, Custody, and Control – provides coverage to a customer in respect of non-owned property that suffered damage whilst in the care, custody or control of the insured.
- Opioids and Nitrosamine product exclusions
- Cover besides Public Liability offered on an Occurrence basis
- Employers Liability covers a business in the event of bodily injury sustained by an employee within the course of their employment.
- Medical Malpractice Liability covers the provision of medical or paramedical services or the failure to render thereof. The provision of prescription drugs, the provision of diagnostic equipment and clinical trials.

- Terrorism Liability covers bodily injury, property damage, personal injury or advertising liability arising directly or indirectly in whole or in part by Terrorism.
- Intellectual Property notable Exclusions:
  • Cyber & Data Exclusion
  • Known Circumstances Exclusion
  • TMKS will not be liable for any action or circumstance notified but that does not mature into an action or claim following 36 months from the notification.
  • Insured to not make and payments, assume any obligations, incur expenses, enter into any settlement without TMKS written consent.
- Cyber notable Exclusions:
  • Bodily injury
  • Betterment
  • Breach of contract, warranty, guarantee or promise and assumed liability.
  • Loss of funds
  • Property damage
  • Terrorism
  • Use of illegal or unlicensed programs or software
  • War or uprising
  • Insured misconduct

Further extensions can include but not be limited to:

- Medical expenses
- Advertising Liability – offers coverage to protect a company in the event that they are sued for slander, defamation, libel or copyright infringement.
- Cyber Liability covers third party bodily injury and/or property damage arising from a cyber breach.
- Medical Malpractice Liability covers the provision of medical or paramedical services or the failure to render thereof. The provision of prescription drugs, the provision of diagnostic equipment and clinical trials.
- Sudden and Accidental Pollution Liability covers a business for a pollution loss as a result of a sudden and accidental pollution event. This is not coverage for gradual pollution events.
- Product Recall covers a business for the expenses related to a withdrawal of a product from the marketplace. This can include costs for shipping and disposal.

Limits of liability:
Each section of cover, additional extra(s) and/or extension(s) will be offered with their own limit of liability (and sub-limits where applicable), as requested by the customer to reflect their exposure to risk, and as stated in the policy schedule.

Excesses
Each section of cover, additional extra(s) and/or extension(s) will be offered with their own applicable excesses and stated in the policy schedule.

Other information which may be relevant to distributors

This product should be sold in line with FCA regulations and can only be sold by a regulated insurance distributor.

This product is permitted for sale via the following distribution chain:

- Lloyd's Broker;
- a delegated authority arrangement with a coverholder;
- By wholesale brokers which have been approved by the coverholder as suitable distributors for the target market and
- by brokers which have been approved by the coverholder as suitable distributors for the target market.

No further brokers in the chain are permitted without the coverholders prior approval. Any such approval will include consideration of their impact on product value.

Where Distributor 1 sells this Product via multiple other distributors (via sub-delegations or sub-broking), it is their responsibility to ensure all distributors have been provided this document, have reviewed it and understand the content. If there is any additional remuneration, including commissions, fees or other 'non-standard' remuneration charge to the customer by other distributors, it is the responsibility of Distributor 1 to inform TMK of these details accurately and in full.

Sales journeys must identify customer eligibility and ensure that key information and choices to be made are presented to customers in a way that supports a customer through the process of understanding core cover and configuring optional elements of insurance to suit their specific demands and needs.

This product can be sold face to face, via telephone, electronic communications or a mix of these methods, as long as customers are provided with sufficient information to make an informed decision regarding the suitability of the product.

This product can be sold with or without advice in line with FCA regulations or local regulations if the distributor is regulated outside of the UK.

Distributors may offer Premium Finance as an optional, opt-in ancillary service alongside the product. Any Premium Finance facility must be offered separately from the core insurance product, with customers making an informed choice as to whether the service meets their needs and circumstances.

Distributors are responsible for ensuring that the inclusion of Premium Finance does not adversely impact the overall fair value of the product offering, that the service represents a genuine customer benefit, and that all applicable regulatory and contractual disclosure requirements relating to costs, charges, remuneration and terms are clearly communicated to customers. Premium Finance is not a mandatory component of the product and customers remain able to purchase the insurance policy without electing to use any financing arrangement.

Commission & Fees

If there is a coverholder in the chain, they are expected to ensure that maximum commission rates do not exceed those stipulated within the Binding Authority Agreement.

The coverholder is expected to maintain oversight of all broker commissions (where applicable) and, where there may be a risk to product value, remedial action should be taken immediately including notification to Tokio Marine Kiln.

Coverholders are expected to ensure that maximum commission rates and any fees do not exceed those stipulated within the Binding Authority Agreement. In addition, the combined distribution costs associated with the product, including commission, brokerage, fees and any other distributor remuneration or charges applied throughout the distribution chain, must not equal or exceed 50% of the gross written premium. This requirement is intended to support fair value considerations and ensure customers receive appropriate value from the product.

Brokers are reminded of their own regulatory obligations in relation to remuneration under PROD 4.3.6 as well as the requirements to make all necessary disclosures to the customer.

Where there are any fees charged by any member of the distribution chain these should be:

- commensurate with the service provided by the distribution.
- not have an adverse impact on customer value; and
- distributor should ensure that TMKS is made aware of the fee amount and/ or method of calculation.

How value is assessed

Value is assessed based on a number of metrics, including underwriting, claims and complaints information as well as through broker and coverholder engagement.

Remuneration paid as set out in our agreements with distributors has been considered as part of the value assessment. If additional add-ons (including premium finance) are sold alongside this product or additional remuneration is charged, this may affect the value for the customer. Further information on our product approval processes can be obtained on request.	
Date Fair Value assessment completed	December 2025
Expected date of next assessment	December 2026