



PROPOSAL FORM

## Pharmaceutical Product Recall

[libertyinternational.com/au](http://libertyinternational.com/au)



# Proposal form



## Important Notice

Before you enter into a contract of general insurance with an insurer, you have a duty, under the Insurance Contracts Act 1984 (Cth), to disclose to the insurer every matter that you know, or could reasonably be expected to know, is relevant to the insurer's decision whether to accept the risk of the insurance and, if so, on what terms.

You have the same duty to disclose those matters to the insurer before you renew, extend, vary or reinstate a contract of general insurance.

Your duty however does not require disclosure of matter:

- that diminishes the risk to be undertaken by the insurer;
- that is of common knowledge;
- that your insurer knows or, in the ordinary course of its business, ought to know;
- as to which compliance with your duty is waived by the insurer.

## Non Disclosure

If you fail to comply with your duty of disclosure, the insurer may be entitled to reduce their liability under the contract in respect of a claim or may cancel the contract. If your non-disclosure is fraudulent, the insurer may also have the option of avoiding the contract from its beginning.

## Inadequate Space To Answer

If there is inadequate space to answer any of the questions or make any comment or you need to disclose something to us because of your duty of disclosure, please attach a separate piece of paper to this questionnaire giving full details of additional information.

# Proposal form



## 1. THE APPLICANT

- a. Name of applicant to be insured under this policy \_\_\_\_\_
- b. Nature of business \_\_\_\_\_
- c. No. of years in business \_\_\_\_\_
- d. Address of insured  
Street \_\_\_\_\_  
Suburb \_\_\_\_\_ State \_\_\_\_\_ Postcode \_\_\_\_\_
- e. List all subsidiary companies to be included under this policy \_\_\_\_\_
- f. Applicant's website \_\_\_\_\_

## 2. PARENT COMPANY

- a. Parent company of applicant \_\_\_\_\_
- b. Address of parent company \_\_\_\_\_

## 3. FINANCIALS

- a. Actual total turnover for the last 12 months AU\$ \_\_\_\_\_
- b. Estimated turnover for the next 12 months AU\$ \_\_\_\_\_
- c. Actual gross earnings for the last 12 months AU\$ \_\_\_\_\_

## 4. SCOPE OF OPERATION

- a. Is the applicant the
- |                           |     |    |
|---------------------------|-----|----|
| 1. Manufacturer           | Yes | No |
| 2. Distributor/wholesaler | Yes | No |
| 3. Importer               | Yes | No |
| 4. Exporter               | Yes | No |
| 5. Sponsor                | Yes | No |

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## 5. PRODUCT CLASSIFICATION

a. Product information (attach additional pages as needed)

Product(s)	% of total sales
	%
	%
	%
	%
	%

b. Do any of the insured products fall into any of the following categories:

	Yes	No		Yes	No
Vaccines			Cell therapies		
Sunscreens			Gene therapies		
Opioids			Biological medicines		
Medicinal cannabis			Biosimilars		
Monoclonal antibodies					

c. Are all products approved by applicable regulatory body (e.g. TGA, FDA, MHRA, etc.)? Yes No

Others (please specify)

d. Do all of the products which are the subject of this proposal form, conform in all respects with requirements of law or regulation, including applicable industry guidelines? Yes No

e. Are any products being supplied under expanded access, compassionate use, unapproved schemes, fast-track approval or any other alternative pathway? Yes No

If yes, provide details:

f. What percentage (%) of products sold as ingredients %

g. What percentage (%) of your products are manufactured by 3rd parties %

h. Does the applicant contract or toll manufacture for any third parties? Yes No

i. **Geographical distribution:**

Region	Product(s)	Turnover AU\$
North America, Europe, ANZ, Japan		\$
Asia excluding Japan		\$
Other (please specify)		\$

j. **Top three (3) products (by turnover):**

	Product 1	Product 2	Product 3
Product name			
Annual turnover (AU\$)	\$	\$	\$
Batch size (number of units)			
Batch size (AU\$)	\$	\$	\$

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k. Does the applicant import any goods? Yes    No

If yes, please provide details:

Country	Goods/use of goods	Value AU\$
		\$
		\$
		\$
		\$

l. Production by site

Total number of manufacturing sites

If three or more plants, please attach a schedule with the following information:

Plant	Max daily output per plant in AU\$	Max daily output any one production line AU\$
	\$	\$
	\$	\$
	\$	\$

m. Has the applicant agreed to indemnify or hold harmless any suppliers of goods or services? Yes    No

## 6. QUALITY MANAGEMENT

a. Do all manufacturing premises hold a valid GMP certificate/licence? Yes    No

b. When was the date of the last GMP audit conducted by the applicable regulatory body?

c. Any critical or major non-conformities raised during this audit? Yes    No  
Please attach a copy of the most recent audit performed by an independent third party.

d. Is there a quality control and quality assurance department? Yes    No

e. Please provide details on how frequently internal quality/GMP audits are conducted:

f. What steps are taken to assess the quality standards adhered to by your suppliers? (e.g. on-site audits, health inspection reports, incoming quality inspection, etc)

g. How do you collect and monitor customer complaints?

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## 7. PRODUCT TESTING AND TRACEABILITY

- a. Is product testing utilised? Yes No  
If yes, at what point in the process is testing performed?  
In line      End product      Raw materials      Other
- 
- b. Is the laboratory used for testing internal or external? Internal External
- 
- c. Is this lab certified under applicable standards? (e.g. ISO/IEC 17025, etc.) Yes No
- 
- d. Are labels routinely inspected for accuracy and content? Yes No
- 
- e. How often are labels reviewed?
- 
- f. Is batch coding system utilised? Yes No  
Provide details of coding (e.g. Julian date, shift number, production line, operator, etc.):
- 
- g. Can all products be tracked so that the source and destination of individual batches can be identified? Yes No
- 

## 8. RECALL PREPAREDNESS

- a. Does the applicant have a documented recall plan? Yes No  
If yes, please attach a copy
- 
- b. Are mock recalls conducted? Yes No  
If yes, what was the date of the of last mock recall:
- 
- c. Estimate the cost to recall your leading brand
- 

## 9. WORKPLACE AND HISTORY

- a. Has the applicant had strikes/riots/work stoppages/plant closings in the past three (3) years? Yes No
- 
- b. Has the applicant been the subject of or been threatened with a wrongful termination legal action? Yes No
- 
- c. Have any products or any of applicant's premises been the subject of warning letters, infringement notices, safety alerts and/or product safety investigations by any government or department in the past five (5) years? Yes No
- 
- d. Have any products been recalled in the past five (5) years? Yes No
- 
- e. Does the applicant, its directors, officers or any other person to the knowledge of the applicant have knowledge of or information about any fact or circumstance which may reasonably give rise to a claim under the proposed policy? Yes No
- 
- f. Has any insurer:
1. declined to insure the applicant in respect of any coverage(s) proposed for in this application? Yes No
  2. cancelled or refused to renew the applicant's insurance? Yes No
  3. imposed special terms to insure the applicant? Yes No
- If you have answered yes to any of the above questions, please provide details:

# Proposal form



## 11. DECLARATION

(To be signed by a Partner, Principal or Director.)

I, the undersigned understand, declare and acknowledge that:

- I am to disclose in this form, fully and faithfully, all the facts that I know or ought to know, otherwise the Policy may not respond to any claim;
- I am, after enquiry, authorised by all person(s) or entities seeking insurance, to make this proposal;
- After enquiry, all information supplied in this proposal and any supporting documents attached to this proposal or supplied separately, is true and correct and that until a Contract of Insurance is entered into, I am obliged to inform Liberty of any changes to any information supplied or of any new information that is relevant;
- Liberty relies on the accuracy of the information and documentation supplied proposing for this insurance;
- If a Contract is entered into, all information and documentation supplied in proposing for this insurance shall be incorporated into and form part of such Contract of Insurance;
- I have read the Important Notices including the Privacy Notice which form part of this proposal;
- No insurance is in force until a Contract of Insurance is entered into, which is upon the Proposers acceptance of an offer by Liberty, if any.

Signature

Date

Name (please print)

Title

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## Privacy Notice

Liberty Mutual Insurance Company, Australia Branch (ABN 61 086 083 605) incorporated in Massachusetts, USA (the liability of members is limited) (**Liberty, "we"**) is part of the Liberty Mutual Group headquartered in the United States.

We collect personal information to provide insurance products and services, manage claims and support related business operations. This may include information collected from insurance brokers, intermediaries, or directly from you. If you do not provide the personal information requested, we may be unable to offer the appropriate type or level of service.

If you provide Liberty with personal or sensitive information about another individual, you must ensure they are aware of this notice and have consented to the disclosure. If you have not done so, please inform Liberty before sharing their data.

Your personal information may be disclosed to Liberty's related entities, reinsurers, insurance intermediaries, loss adjusters, legal and professional advisors and other service providers. We may also store your information with third party cloud or electronic storage providers.

Some recipients may be located overseas in the United States, Canada, United Kingdom, European Union, India, China, Australia, Hong Kong, Singapore and Malaysia. Where reasonably necessary, your information may be transferred to countries without comparable data protection laws to deliver the services you request. By engaging with Liberty, you consent to these cross-border transfers unless you notify us otherwise in writing.

We are committed to protecting your privacy and ensuring transparency in how we use your personal information. As part of this commitment, we confirm Liberty does not currently use automated decision making (**ADM**).

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For more information, and to view the relevant privacy policy for your jurisdiction, visit: [Australia Privacy Policy](#).