

Proposal Form

Pharmaceutical/Medical/Chemical Public & Products Liability Insurance

Arranged through ASR Underwriting Agencies Pty Ltd Underwritten by Certain Underwriters at Lloyd's



IMPORTANT NOTES

PLEASE READ THESE GUIDANCE NOTES BEFORE COMPLETING THE PROPOSAL FORM. WHERE FURTHER INFORMATION IS REQUIRED PLEASE ATTACH IT TO THIS PROPOSAL FORM.

This proposal must be typed, or completed in ink and signed and dated by such person (Proposer/You/Your) who must be of legal capacity and authorised by the Proposer to seek a quotation for Liability Insurance and any additional coverage that may be provided by the Insurer. Please answer every question fully, and state "NIL" or "NONE" as applicable. Incomplete answers may not be accepted and can delay quotation.

Should there be insufficient room in the Proposal Form for full details, please attach further information on signed and dated sheets, wherever possible following the same format and paragraph number. It is the duty of the Proposer to disclose all material facts to Insurers. Where this is omitted, the Insurers may avoid their obligation under the Policy.

For the purpose of the Proposal and for all purposes relating to any policy issued pursuant to this Proposal, a 'material fact' shall be deemed to be one that would be likely to influence an Insurer's judgement and acceptance of Your Proposal. Upon acceptance of the Insurers' terms and conditions and payment of the premium, all information provided by the Proposer together with the guidance notes will be deemed to be incorporated in the contract between Insurers and the Proposer.

Your Duty of Disclosure

Before you enter into an insurance contract, you have a duty to tell us anything that you know, or could reasonably be expected to know, may affect our decision to insure you and on what terms. You have this duty until we agree to insure you. You have the same duty before you renew, extend, vary or reinstate an insurance contract.

You do not need to tell us anything that:

- reduces the risk we insure you for; or
- is common knowledge; or
- we know or should know as an insurer; or
- we waive your duty to tell us about.

If you do not tell us something:

If you do not tell us anything you are required to, we may cancel your contract or reduce the amount we will pay you if you make a claim, or both. If your failure to tell us is fraudulent, we may refuse to pay a claim and treat the contract as if it never existed.

Privacy

We are committed to protecting your privacy. We use the information you provide to us to assist with your insurance needs. We provide your information to insurance underwriters, brokers and agents that provide insurance quotes and offer insurance terms to you or the companies that deal with your insurance claim (such as loss assessors and claims administrators). Your information may be given to certain Underwriters at Lloyd's when we are seeking insurance terms from them, or to reinsurers who are located overseas. We also supply your information to the providers of our policy administration and underwriting systems that help us to maintain our products and services. You will be advised where those companies are located at the time any advice is given to you. We do not trade, rent or sell your information. If you do not provide us with full information, we cannot properly seek insurance terms for you, or assist with claims and you could breach your duty of disclosure. For more information about how to access the personal information we hold about you and how to have the information corrected and how to complain if you think we have breached the privacy laws, ask us for a copy of our Privacy Policy by telephone to our Privacy Officer on 07 3442 3301 or visit our website www.asruw.com.au

Excess

The policy provides that You will be required to bear a specified amount of all claims and this is for each and every claim made against You including defence costs. We will let You know when the excess is payable.

Your Legal Liability

If you take out a Liability cover section, the financial risk of court awards through litigation is ever increasing and we recommend that You select a Limit of Liability that takes into account the future cost of claims including legal fees and costs of defence. Even higher limits are available than your current limit if required. Defence costs are included within the limit of liability, when you take out a Liability cover section.

Waiver of Rights

If You have entered into an agreement with another party, which prevents your Insurer from taking recovery action for compensation from that party it may affect Your rights to cover under this Policy. Should You now be a party to such an agreement or be requested to enter such an agreement in the future, please advise your Broker in writing so we may notify the Insurer.

Broker

Contact Name

Phone

Fax

Email

Company Information

Full Name of Insured(s)

ABN

Address of Registered Office

State Postcode

Address(es) of any Overseas Offices to be Insured

Full Business Description

Website Address

On what date was the Company first established / commenced trading

Is your company involved in Clinical Trials? If yes, then please contact us for a specific proposal form yes no

Operational Information

Estimated annual turnover split between:

i) Own Manufacture (where you hold the Product Licence) A\$

ii) Where you hold the Product licence but manufacture is contracted to third party A\$

iii) Where you Contract Manufacture for third parties A\$

iv) Wholesale (unaltered from manufacturers) A\$

v) Parallel Import / Repackaged or relabelled Wholesale Products A\$

vi) Other (Please provide full details of how income is generated - if appropriate, please provide specimen contracts) A\$

Show percentage of work performed in each state.

NSW	<input type="text"/> %	ACT	<input type="text"/> %	QLD	<input type="text"/> %	WA	<input type="text"/> %
VIC	<input type="text"/> %	TAS	<input type="text"/> %	SA	<input type="text"/> %	NT	<input type="text"/> %

Please list your three largest selling products

Product	Are they Own Manufacture?		Date first supplied
	yes	no	
<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>

1. Exports

Please state estimated annual turnover to	Own Manufacture	Product Licence Holder	Contract Manufacture	Wholesale	Other
USA	<input type="text"/> A\$	<input type="text"/> A\$	<input type="text"/> A\$	<input type="text"/> A\$	<input type="text"/> A\$
Canada	<input type="text"/> A\$	<input type="text"/> A\$	<input type="text"/> A\$	<input type="text"/> A\$	<input type="text"/> A\$
OECD Countries	<input type="text"/> A\$	<input type="text"/> A\$	<input type="text"/> A\$	<input type="text"/> A\$	<input type="text"/> A\$
Rest of World	<input type="text"/> A\$	<input type="text"/> A\$	<input type="text"/> A\$	<input type="text"/> A\$	<input type="text"/> A\$

Are any exports sent direct to customer from manufacturers outside of Australia? yes no

If yes, please advise territory sent from

Is there a formal contract in place regarding Quality Control? yes no

2. USA / Canada

Please answer these questions ONLY if you export to the USA / Canada

(a) Please provide a full description of all products exported

(b) How long have you been producing each product?

(c) Do you comply with the State / Federal Laws applicable to each product? yes no

(d) Do you have any Power of Attorney or assets in the USA / Canada? yes no

i) If yes, do they arrange separate insurance including Completed Operations/Products? yes no

(e) Are you required to indemnify any Vendors and/or Distributors in USA / Canada? yes no

i) If yes, please provide names and addresses

ii) If no, do they maintain their own insurance for Completed Operations/Products? yes no

iii) State limit if known

3. Imports

If you import products, please state from which countries obtained and approximately percentage of total turnover against each.

Country	Percentage
<input type="text"/>	<input type="text"/> %
<input type="text"/>	<input type="text"/> %
<input type="text"/>	<input type="text"/> %
<input type="text"/>	<input type="text"/> %

4. Products

Do Products comply with all relevant:

(a) Australian Standard, Industry and Trade Standards or Government Safety Licensing Regulations or equivalent local legislation. yes no

(b) Official Standard or Government Regulations laid down in countries to which Products are exported? yes no

(c) Are any new Products likely to be marketed during the next 12 months?
If yes, please advise Product name and Product type.

5. Design/Specification

(a) Please give full details and percentage of total turnover of Products that are:

i) manufactured/supplied to own design/specification/formulation

 %

ii) manufactured/supplied to a design/specification/formulation laid down by a customer

 %

(b) Do you have a separate design team? yes no

(c) Describe extent and type of tests and checks undertaken before Product goes into production

6. Quality Control

- (a) Do you have a written policy relating to Quality Control? yes no
- i) If yes, how often is it reviewed?
- (b) Do you have a specific Quality Control Team? yes no
- i) If yes, who has overall responsibility?
- ii) Can control be overridden by Design Production or Marketing Personnel? yes no
- (c) Does Quality Control involve the testing of a sample percentage of Product? yes no
- i) If yes, please state percentage of Products checked %
- ii) If yes, please state failure rate %
- (d) Are sampling inspections made on incoming raw materials? yes no
- (e) What is the procedure for dealing with customers complaints?
- (f) Are records of complaints retained? yes no
- i) If yes, for how long?

7. Recall

- (a) Is it possible to trace the ultimate customer of individual Products or batches in order to recall the Products? yes no
- (b) Is there a formal procedure for re-emergency Product recall? yes no
- (c) Has recall ever been necessary or been considered? yes no
- i) If yes, please provide details
- (d) Please provide details of Product lines discontinued because of incidence or injury or damage, or where potential hazards have been identified - stating when manufacture or supply ceased

8. Marketing

- (a) Are products labelled and supplied with clear instructions in the language of the country to which they are supplied? yes no
- (b) Are products hazard warnings clearly shown on Products, Packaging and/or Instruction Manuals? yes no
- (c) Do your Legal and/or Design departments have sight of all advertising material, sales brochures, operating manuals etc., to check for misleading statements? yes no
- (d) Are your Representatives warned against overstating usage or effectiveness of Products? yes no

9. Records

- (a) Do you maintain an adequate system of records which would enable identification of:
- | | yes | no | Period records are kept for |
|---|--------------------------|--------------------------|-----------------------------|
| i) Source of Product/raw materials/component parts purchased? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> |
| ii) Source of design of Products manufactured? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> |
| iii) Quality control and testing procedures effective at the time of design and/or manufacture? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> |
| iv) Research undertaken to minimise risk to health and safety? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> |

10. Specified Products

Please tick if any of the following Products are used. Unless it is specifically agreed with, Underwriters cover provided may exclude any liability arising out of the following.

- Any Product that does not have regulatory approval
- Bupropion
- Cerivastatine
 - i) the concomitant or combined use of two or more different products which contain
 - a) a Statin and
 - b) a Fibrate
 - ii) Rhabdomyolysis arising out of either of the above
- Contraceptives (including birth control pills), fertility drugs and Products specifically designed and marketed for use during and in connection with pregnancy
- Cox - 2 Inhibitors
- Diethylstilbestrol or Stilbestrol or DES
- Ephedrine Ma Huang Pseudoephedrin
- Chinese Ephedra Mahuang Extract
- Ephedra Ephedra Sinica Ephedra Extract
- Ephedra Herb Powder Epitonin or any derivative thereof
- Fluoxetine
- Isotretinoin or Accutane
- Latex &/or latex protein &/or latex derivatives &/or latex substances howsoever the latex, latex protein, latex derivatives or latex substances are named, identified, described or classified
- L-tryptophan
- LYMERix
- Methyl Tertiary Butyl Ether (MTBE)
- Paroxetine
- Pertussis Vaccine
- Phenylpropanolamine (PPA)
- Prozac
- Retinoic Acid
- Selective Seritonin Reuptake Inhibitors
- Silicone - any product containing silicone which is in any form implanted or injected in the body
- Thimerosal or Thiomersal
- Tobacco or any tobacco products (or ingredients thereof)
- Troglitazone

If you have ticked any of the Products above, please provide full details as follows:

- (a) Are Products supplied on a Named Patent Basis only or in Accordance with Specials Licence granted? yes no

i) If yes, please provide details of licence held

ii) If no, please provide the following:

- Product details enclosing Data Safety Sheets where possible
- If manufactured, to whose formula/specification
- If marketed only, are rights of recourse maintained against manufacturers/suppliers?
- How long have you marketed or manufactured the Products?
- Estimated annual turnover per specific product
- If exports involved details of territories to be supplied and estimated turnover

11. Premises

- (a) Have all Manufacturing locations been inspected by TGA/FDA or other regulatory bodies? yes no
 i) If yes, what was the date of the last inspection?
- (b) Have you ever had a manufacturing licence withdrawn? yes no
 i) If yes, please provide details including remedies

12. General

- (a) Has any Insurer ever:
 i) Declined your proposal for Public &/or Products Liability Insurance? yes no
 ii) Refused your renewal for Public &/or Products Liability Insurance? yes no
 iii) Terminated your Insurance for Public &/or Products Liability Insurance? yes no
 If yes, please provide full details

- (b) Have any incidents occurred during the last five years resulting, or alleged to have resulted in death, injury or disease to third parties or damage to their property? yes no
 If yes, please provide full details below:

Date	Brief details of Incident whether or not an insurance claim has been made	Paid Amount	Insurers Outstanding Reserve
<input type="text"/>	<input type="text"/>	\$ <input type="text"/>	\$ <input type="text"/>
<input type="text"/>	<input type="text"/>	\$ <input type="text"/>	\$ <input type="text"/>
<input type="text"/>	<input type="text"/>	\$ <input type="text"/>	\$ <input type="text"/>

If possible please supply confirmed claims experience from previous / current insurers

- (c) Are you aware of any circumstances that might give rise to a claim? yes no
 If yes, please provide full details

- (d) Please state the basis of your existing cover for Products Liability Claims Made Losses Occurring
 i) If on a "Claims Made" basis, please state retroactive date currently applied to your policy

- (e) Who are your current Insurer(s)? If currently uninsured please state

- (f) What is the renewal date of your current Insurance policy covering Public and Products Liability?

- (g) Please state Limit(s) of Indemnity for which a quotation is required or local currency equivalent \$

Additional Information

Declaration of Your Duty of Disclosure

I confirm that:

I am authorised on behalf of the insured(s) to sign this proposal.

I understand that the duty of disclosure applies to all insured(s). The answers are provided on behalf of all persons/entities comprising the insured(s).

I understand the questions in the proposal.

Whilst some or all of the answers to the questions may not be checked by me I certify they are correct to the best of my knowledge and belief.

Do you consider that your establishment is a good insurance risk? yes no

AUTHORISED SIGNATORY

X

Dated

NAME OF SIGNATORY

Position