

# 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 policy, it is Your duty to disclose every matter that You know, or could reasonably be expected to know, to be relevant to the Insurer's decision whether to give You insurance cover and, if so, on what terms.

#### Consequences of Non-Disclosure or Misrepresentation

If You breach Your duty of disclosure; the Insurer(s) may be able to refuse to pay a claim or to cancel Your policy. The same applies where You have made a misrepresentation, if fraudulent (ie. done deliberately for the purpose of obtaining insurance, or for obtaining it on favourable terms) the Insurer(s) may be able to 'avoid' Your policy. This means that the Insurer(s) can treat the policy as never having existed. Non-disclosure or misrepresentation in relation to one policy may affect Your ability to obtain other insurance in the future.

If You are unsure whether some information may be disclosable or not we suggest You call Your insurance broker and seek guidance.

#### Privacy

We are committed to protecting Your privacy. We only use the personal information You provide to us to quote on and insure this risk. We only provide Your personal information to our Insurer(s) and Reinsurers (and their representatives) and those we appoint to assist us with claims under Your policy (ies). We do not trade, rent or sell Your information. Some or all of the Insurer(s) and Reinsurers may be overseas.

If You don't provide us with complete information, we cannot properly quote for Your insurance and we cannot insure You. You can check the information we hold about You at any time. For more information about our Privacy Policy, ask us for a copy. Copies of the Proposal Form should be retained for Your own records.

#### 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

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?  yes  no  
If yes, then please contact us for a specific proposal form

## Operational Information

### Estimated annual turnover split between:

i) Own Manufacture (where you hold the Product Licence)	<input type="text" value="A\$"/>
ii) Where you hold the Product licence but manufacture is contracted to third party	<input type="text" value="A\$"/>
iii) Where you Contract Manufacture for third parties	<input type="text" value="A\$"/>
iv) Wholesale (unaltered from manufacturers)	<input type="text" value="A\$"/>
v) Parallel Import / Repackaged or relabelled Wholesale Products	<input type="text" value="A\$"/>
vi) Other (Please provide full details of how income is generated - if appropriate, please provide specimen contracts)	<input type="text" value="A\$"/>
<input type="text"/>	

### Please list your three largest selling products

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

## 1. Exports

### Please state estimated annual turnover to

	Own Manufacture	Product Licence Holder	Contract Manufacture	Wholesale	Other
USA	<input type="text" value="A\$"/>	<input type="text" value="A\$"/>	<input type="text" value="A\$"/>	<input type="text" value="A\$"/>	<input type="text" value="A\$"/>
Canada	<input type="text" value="A\$"/>	<input type="text" value="A\$"/>	<input type="text" value="A\$"/>	<input type="text" value="A\$"/>	<input type="text" value="A\$"/>
OECD Countries	<input type="text" value="A\$"/>	<input type="text" value="A\$"/>	<input type="text" value="A\$"/>	<input type="text" value="A\$"/>	<input type="text" value="A\$"/>
Rest of World	<input type="text" value="A\$"/>	<input type="text" value="A\$"/>	<input type="text" value="A\$"/>	<input type="text" value="A\$"/>	<input type="text" value="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 answers 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 reemergency 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:
- Period records are kept for*
- i) Source of Product/raw materials/component parts purchased? yes  no
- ii) Source of design of Products manufactured? yes  no
- iii) Quality control and testing procedures effective at the time of design and/or manufacture? yes  no
- iv) Research undertaken to minimise risk to health and safety? yes  no

## 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: yes  no

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

Dated

NAME OF SIGNATORY

Position