



ASR Underwriting Agencies

Proposal Form

PUBLIC & PRODUCTS LIABILITY INSURANCE

PHARMACEUTICAL/MEDICAL/CHEMICAL

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 DETAILS

Broker Name		Contact Name	
Phone Number		Fax Number	
Email Address			

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.				<input type="checkbox"/> Yes <input type="checkbox"/> No	

OPERATIONAL INFORMATION

Estimated annual turnover split between	1. Own manufacture (where you hold the product licence)	A\$						
	2. Where you hold the product licence but manufacture is contracted to a third party	A\$						
	3. Where you contract manufacture for third parties	A\$						
	4. Wholesale (unaltered from manufacturers)	A\$						
	5. Parallel import/repackaged or relabelled wholesale products	A\$						
	6. 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	%	ACT	%	QLD	%	WA	%
	VIC	%	TAS	%	SA	%	NT	%

Please list your three largest selling products:

Product	Are they own manufacture?	Date first supplied
	<input type="checkbox"/> Yes <input type="checkbox"/> No	/ /
	<input type="checkbox"/> Yes <input type="checkbox"/> No	/ /
	<input type="checkbox"/> Yes <input type="checkbox"/> No	/ /
	<input type="checkbox"/> Yes <input type="checkbox"/> No	/ /
	<input type="checkbox"/> Yes <input type="checkbox"/> No	/ /
	<input type="checkbox"/> Yes <input type="checkbox"/> No	/ /
	<input type="checkbox"/> Yes <input type="checkbox"/> No	/ /

1. EXPORTS

Please state estimated annual turnover to	Own manufacture	Product licence holder	Contract manufacture	Wholesale	Other
USA	A\$	A\$	A\$	A\$	A\$
Canada	A\$	A\$	A\$	A\$	A\$
OECD countries	A\$	A\$	A\$	A\$	A\$
Rest of world	A\$	A\$	A\$	A\$	A\$
Are any exports sent direct to customer from manufacturers outside Australia?					<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, please state territory					

Is there a formal contract in place regarding quality control?	<input type="checkbox"/> Yes <input type="checkbox"/> No
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2. USA/CANADA

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

1. Please provide a full description of all products exported	
2. How long have you been producing each product?	
3. Do you comply with the state/federal laws applicable to each product?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. (a) Do you have any power of attorney or assets in the USA/Canada?	<input type="checkbox"/> Yes <input type="checkbox"/> No
(b) If yes, do they arrange separate insurance including completed operations/products?	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. (a) Are you required to indemnify any vendors and/or distributors in USA/Canada	<input type="checkbox"/> Yes <input type="checkbox"/> No
(b) If yes, please provide names and addresses	
(c) If no, do they maintain their own insurance for complete operations/products?	<input type="checkbox"/> Yes <input type="checkbox"/> No
(d) State limit if known	\$

3. IMPORTS

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

Country	Percentage
	%
	%
	%
	%

4. PRODUCTS

Do products comply with all relevant:	1. Australian standard, industry and trade standards or government safety licensing regulations or equivalent local legislation?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	2. Official standard or government regulations laid down in countries to which products are exported?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	3. Are any new products likely to be marketed during the next 12 months? If yes, please advise product name and product type	<input type="checkbox"/> Yes <input type="checkbox"/> No

5. DESIGN/SPECIFICATION

1. Please give full details and percentage of total turnover of products that are:	(a) Manufactured/supplied to own design/specification/formulation		%
	(b) manufactured/supplied to a design/specification/formulation laid down by a customer		%
2. Do you have a separate design team?		<input type="checkbox"/> Yes <input type="checkbox"/> No	
3. describe extent and type of tests and checks undertaken before product goes into production.			

6. QUALITY CONTROL

1. (a) Do you have a written policy relating to quality control?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
(b) If yes, how often is it reviewed?			
2. (a) do you have a specific quality control team?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
(b) If yes, who has overall responsibility?			
3. (a) Does quality control involve the testing of a sample percentage of product?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
(b) If yes, please state percentage of products checked		%	
(c) If yes, please state failure rate		%	
4. Are sampling inspections made on incoming raw materials?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
5. What is the procedure for dealing with customer complaints?			
6. (a) Are records of complaints retained?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
(b) If yes, for how long?			

7. RECALL

1. Is it possible to trace the ultimate customer of individual products or batches in order to recall the products?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
2. is there a formal procedure for emergency product recall?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
3. (a) Has recall ever been necessary or been considered?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
(b) If yes, please provide details			
4. Please provide details of product lines discontinued because of incidence or injury or damage, or when potential hazards have been identified – stating when manufacture or supply ceased.			

8. MARKETING

1. Are products labelled and supplied with clear instructions in the language of the country to which they are supplied?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
2. Are products hazard warning clearly shown on products, packaging and/or instruction manuals?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
3. Do your legal and/or design departments have sight of all advertising material, sales brochures, operating manuals etc., to check for misleading statements?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
4. Are your representatives warned against overstating usage or effectiveness of products?		<input type="checkbox"/> Yes	<input type="checkbox"/> No

9. RECORDS

			Period records are kept for
1. Do you maintain an adequate system of records which would enable identification of:	(a) Source of product/raw materials/component parts purchased?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	(b) Source of design of products manufactured?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	(c) Quality control and testing procedures effective at the time of design and/or manufacture?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	(d) Research undertaken to minimise risk to health and safety?	<input type="checkbox"/> Yes	<input type="checkbox"/> 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:

<input type="checkbox"/>	Any product that does not have regulatory approval	
<input type="checkbox"/>	Bupropion	
<input type="checkbox"/>	Cerivastatine	1. the concomitant or combined use of two or more different products which contain (a) a statin and (b) a fibrate 2. Rhabdomyolysis arising out of either of the above
<input type="checkbox"/>	Contraceptives (including birth control pills), fertility drugs and products specifically designed and marketed for use during and in connection with pregnancy	
<input type="checkbox"/>	Cox - 2 inhibitors	
<input type="checkbox"/>	Diethystibestrol or stibestrol or DES	
<input type="checkbox"/>	Ephedrine mahuang pseudoephedrine	
<input type="checkbox"/>	Chinese ephedra mahuang extract	
<input type="checkbox"/>	Ephedra ephedra sinica ephedra extract	
<input type="checkbox"/>	Ephedra herb powder epitonin or any derivative thereof	
<input type="checkbox"/>	Fluoxetine	
<input type="checkbox"/>	Isotretinoin or accutane	
<input type="checkbox"/>	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	
<input type="checkbox"/>	L-tryptophan	
<input type="checkbox"/>	LYMERix	
<input type="checkbox"/>	Methyl tertiarl butyl ether (MTBE)	
<input type="checkbox"/>	Paraoxetine	
<input type="checkbox"/>	Pertussis vaccine	
<input type="checkbox"/>	Phenylpropanolamine (PPA)	
<input type="checkbox"/>	Prozac	
<input type="checkbox"/>	Retinoic acid	
<input type="checkbox"/>	Selective serotonin reuptake inhibitors	
<input type="checkbox"/>	Silicone - any product containing silicone which is in any form implanted or injected in the body	
<input type="checkbox"/>	Thimerosal or thiomersal	
<input type="checkbox"/>	Tobacco or any tobacco products (or ingredients thereof)	
<input type="checkbox"/>	Troglitazone	

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

1. Are products supplied on a named patent basis only or in accordance with special licence granted?		<input type="checkbox"/> Yes <input type="checkbox"/> No
(a) If yes, please provide details of licence held		
(b) If no, please provide the following:	<ul style="list-style-type: none"> - 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	
1. (a) Have all manufacturing locations been inspected by TGA/FDA or other regulatory bodies?	<input type="checkbox"/> Yes <input type="checkbox"/> No
(b) If yes, what was the date of the last inspection?	/ /
2. (a) Have you ever had a manufacturing licence withdrawn?	<input type="checkbox"/> Yes <input type="checkbox"/> No
(b) If yes, please provide details including remedies	

12 GENERAL			
1. Has any insurer ever:	(a) Declined your proposal for public &/or products liability insurance?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	(b) Refused your renewal for public &/or products liability insurance?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	(c) Terminated your insurance for public &/or products liability insurance? If yes, please provide full details	<input type="checkbox"/> Yes	<input type="checkbox"/> No
2. 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? If yes, please provide full details below:			<input type="checkbox"/> Yes <input type="checkbox"/> No
Date	Brief details of incident whether or not an insurance claim has been made	Paid amount	Insurers outstanding reserve
/ /		\$	\$
/ /		\$	\$
/ /		\$	\$
If possible, please supply confirmed claims experience from previous/current insurers			
3. Are you aware of any circumstances that might give rise to a claim? If yes, please provide full details.			<input type="checkbox"/> Yes <input type="checkbox"/> No
4. (a) Please state the basis of your existing cover for products liability.		<input type="checkbox"/> Claims made	<input type="checkbox"/> Losses occurring
(b) If on a "claims made" basis, please state retroactive date currently applied to your policy		/ /	
5. Who are your current insurer(s)? If currently uninsured, please state.			
6. What is the renewal date of your current insurance policy covering public and products liability?			/ /
7. Please state limit(s) of indemnity for which a quotation is required or local currency equivalent.			\$

ADDITIONAL INFORMATION

DECLARATION – 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.		
Do you consider that your establishment is a good insurance risk?		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Authorised signatory		Dated	/ /
Name of signatory		Position	

CANCELLATION CHARGES

If we are requested to cancel the policy, we will charge the following short period rate premiums. We will hold you and or your insurance intermediary liable to pay these amounts

Within 1 month of inception:	25% of the quoted premium	Thereafter at terms to be agreed with underwriters
Within 2 months of inception:	20% of the quoted premium	
Within 3 months of inception:	15% of the quoted premium	