

Pharmaceutical/Medical/Chemical New Business Questionnaire

PUBLIC LIABILITY PRODUCTS LIABILITY

IMPORTANT NOTICES

For your protection under legislation, we are required to inform you of your duty of disclosure and draw your attention to the following important information.

DUTY OF DISCLOSURE

The Insurance Contracts Act 1984 requires insurance companies to provide certain information to people intending to insure with them. The information concerns the duty of disclosure of an intending Insured and the effect of particular types of clauses in a proposed insurance policy. Where an Insurance Broker is involved in the transaction, the information is to be provided by the broker. The Insurance (Agents and Brokers) Act 1984 also requires us to inform you about some other matters where they are relevant to particular policies.

WHAT INFORMATION DOES AN INSURANCE COMPANY/BROKER HAVE TO GIVE YOU?

In general terms, the kind of information which an insurance company/broker must give you is as follows:

YOUR DUTY OF DISCLOSURE – CONTRACTS OF GENERAL INSURANCE SUBJECT TO INSURANCE CONTRACTS ACT

Before you enter into a contract of general insurance with an Insurer, you have a duty, under the Insurance Contracts Act 1984, to disclose to the Insurer every matter that you know, or could reasonably be expected to know, that 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 his 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.

CLAIMS MADE INSURANCE

Your attention is drawn to the fact that if the Errors & Omissions section of this policy is selected, the cover will be placed on a "claims made" basis which means that claims first advised to you (or made against you) and reported to your insurer during the Period of Insurance are recoverable irrespective of when the incident causing the claim occurred, subject to the provisions of any clause relating to a "retroactive date".

You should also note that, in terms of the provisions of Section 40(3) of the Insurance Contracts Act 1984, where you give notice in writing to the Insurer of facts that might give rise to a claim against you as soon as is reasonably practicable after you become aware of those facts (but before the insurance cover provided by the contract expires) then the Insurer is not relieved of liability under the contract in respect of the claim, when made, by reason only that it was made after the expiration of the Period of Insurance cover provided by the contract.

Please note that your duty applies also when you seek to renew, extend, alter or reinstate a policy.

QUESTIONS**ANSWERS**

Full Name (s) of all companies to be included:

Address of Registered Office:

Address(es) of any Overseas Offices to be Insured:

Full Business Description:

Website Address:

When established:

Is your company involved in Clinical Trials?

YES / NO

If 'YES' then please contact us for specific proposal form

PLEASE ATTACH PRODUCT BROCHURES AND ADDITIONAL COMPANY INFORMATION AS APPROPRIATE

PUBLIC AND PRODUCTS LIABILITY

Please complete all below

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* | A\$ |

* Please provide full details of how income is generated (if appropriate please provide specimen contracts):

Please list your three largest selling products / are they Own Manufacture / date first supplied :

- | | | |
|----|---|---|
| 1. | / | / |
| 2. | / | / |
| 3. | / | / |

1. EXPORTS

Please state estimated annual turnover to:		i) Own Manufacture	ii) Product Licence Holder	iii) Contract Manufacture	iv) Wholesale	vi) Other
i)	USA	A\$.....	A\$.....	A\$.....	A\$.....	A\$.....
ii)	Canada	A\$.....	A\$.....	A\$.....	A\$.....	A\$.....
iii)	OECD Countries	A\$.....	A\$.....	A\$.....	A\$.....	A\$.....
iii)	Rest of World	A\$.....	A\$.....	A\$.....	A\$.....	A\$.....

Are any exports sent direct to customer from manufacturers outside Australia

YES / NO

If 'YES' please advise territory sent from:

Is there a formal contract in place regarding Quality Control?:

2. USA/CANADA

Please answer this question ONLY if you export to the USA/Canada.

- (a) 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?
- (d) Do you have any Power of Attorney or assets in the USA/Canada?

If 'YES' do they arrange separate insurance including Completed Operations/Products

- (e) Are you required to Indemnify any Vendors and/or Distributors in USA/Canada
- If 'YES' please provide names and addresses
- If 'NO' do they maintain their own insurance for Completed Operations/Products?
State limit if known

3. IMPORTS

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

4. PRODUCTS

Do products comply with all relevant:-

- a) Australian Standard, Industry and Trade Standards or Government Safety Licensing Regulations or equivalent local legislation.
- b) Official Standard or Government Regulations laid down in countries to which Products are exported?

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?
- 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?

How often is it reviewed?

b) Do you have a specific Quality Control Team?

If YES:

(i) who has overall responsibility?

(ii) can control be overridden by Design Production or Marketing Personnel?

c) Does Quality Control involve the testing of a sample percentage of product?

If Yes, please state:

a) percentage of products checked

b) Failure rate.

d) Are sampling inspections made on incoming raw materials?

e) What is the procedure for dealing with customers complaints?

f) Are records of complaints retained?

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?

b) Is there an formal procedure for emergency product recall?

c) Has recall every been necessary or been considered?

If YES, please give details

d) Please give 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

MARKETING

- a) Are products labelled and supplied with clear instructions in the language of the country to which they are supplied?
- b) Are products hazard warnings clearly shown on Products, Packaging and/or Instruction Manuals?
- c) Do your Legal and/or Design Departments have sight of all advertising material, sales brochures, operating manuals etc. To check for misleading statements?
- d) Are your Representatives warned against overstating usage or effectiveness of Products?

9. RECORDS

- a) Do you maintain an adequate system of records which would enable identification of:-
(please indicate period records are kept for)
 - i) source of Product/raw materials/component parts purchased?
 - ii) source of design of Products manufactured
 - iii) Quality control and testing procedures effective at the time of design and/or manufacture?
 - iv) Research undertaken to minimise risk to health and safety.

10 SPECIFIED PRODUCTS

UNLESS IT IS SPECIFICALLY AGREED WITH UNDERWRITERS COVER PROVIDED MAY EXCLUDE ANY LIABILITY ARISING OUT OF THE FOLLOWING.

Agent Orange – Dichlorophenoxyacetic Acid (2,4-D) and Trichlorophenoxyacetic Acid (2,4,5-T)		LYMErix	
Alosetrin		Methylphenidate	
Amiodarone		Methyl Tertiary Butyl Ether (MTBE)	
Any product that does not have regulatory approval		Metronidazole	
Apomorphine		Mibefradil	
Astemizole		Nefazodone	
Benoxaprofen		Oxycodone	
Blood Borne Pathogens		Paroxetine	
Blood/Plasma Products		Pertussis Vaccine	
Bromfenac Sodium		Phenylpropanolamine (PPA)	
Bromocriptine		Primodos/Amenorone Forte	
Bupropion		Propulsid	
Butorphanol		Prozac	
Canthaxanthin		Rapacuronium Bromide	
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		Remoxipride	
Chromated Copper Arsenate (CCA)		Retinoic Acid	
Cisapride		Rosiglitazone	
Clindamycin		RotaShield Vaccine	
Contraceptives (including birth control pills) fertility drugs and products specifically designed and marketed for use during and in connection with pregnancy		Selective Serotonin Reuptake Inhibitors	
Cox – 2 Inhibitors		Sertraline	
Danthron		Sibutramine	
Debendox		Sildenafil	
Dexfenfluramine Fenfluramine or Phentermine		Silicone – any product containing silicone which is in any form implanted or injected in the body	
Dicyclomine when give to children under 4 years of age		Skin whitening and lightening agents.	
Diethylstilbestrol or Stilbestrol or DES		Stavudine	

Dioxins		Sumatriptan	
Encainide		Swine-Flu Vaccine	
Ephedrine Ma Huang Pseudoephedrin Chinese Ephedra Mahuang Extract Ephedra Ephedra Sinica Ephedra Extract Ephedra Herb Powder Epitonin or any derivative thereof		Tadalafil	
Ethylenediaminetetraacetic Acid (EDTA)		Temafloxacin	
Fialuridine		Terbinafine	
Flosequinan		Terfenadine	
Fluoxetine		2,3,8 – Tetrachlorodibenzo-p- dioxin (2,3,7,8 – TCDD)	
Germanium		Thalidomide	
Grepafloxacin		Theophyllin	
Halogenated 8 & Hydroxy Quinoline		Thiazolidinones	
Hormone Replacement Therapy of Animal Origin		Thimerosal or Thiomersal	
Hydroquinone		TNF Blockers	
Isotretinoin or Accutane		Tobacco or any tobacco products (or ingredients thereof)	
Itraconazole		Tretinoin	
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.		Troglitazone	
Leflunomide		Trovafloxacin or Alatrofloxacin	
Levonorgestrel		Tryptophan	
Lincomycin		Urea Formaldehyde or any products containing Formaldehyde	
Lindane		Vardenafil	
L-tryptophan		Vigabatrin	

If you have answered YES to any of the products above please provide full details as follows:

<p>a) Are products supplied on a Named Patient Basis only or in accordance with Specials Licence granted?</p> <p>If YES please provide details of licence held</p> <p>If NO please provide the following:</p>	
<p>i Product details enclosing Data Safety Sheets where possible</p> <p>ii If manufactured, to whose formula/specification.</p> <p>iii If marketed only, are rights of recourse maintained against manufacturers/suppliers?</p> <p>iv How long have you marketed or manufactured the products.</p> <p>v Estimated annual turnover per specific product</p> <p>vi If exports involved details of territories to be supplied and estimated turnover.</p>	

11. PREMISES

<p>a) Have all Manufacturing location by inspected by TGA/FDA or other regulatory body?</p> <p>If YES what was date of lost inspection</p> <p>b) Have you ever had a manufacturing licence withdrawn?</p> <p>If YES please give details including remedies</p>
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12. GENERAL

<p>a) Has any Insurer ever:-</p> <p style="margin-left: 20px;">i Declined your proposal for Public &/or Products Liability insurance</p> <p style="margin-left: 40px;">refused your renewal for Public &/or Products Liability insurance</p> <p style="margin-left: 40px;">Terminated your Insurance for Public &/or Products Liability.</p> <p>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?</p> <p style="margin-left: 20px;">If YES, please give full details below:</p>	
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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

<p>c) Are you aware of any circumstances that might give rise to a claim?</p> <p style="margin-left: 20px;">If YES, please give details</p> <p>d) Please state if your existing cover for Products Liability is on a "Claims made" basis or a "Losses occurring" basis.</p> <p style="margin-left: 20px;">If on a "Claim made" basis please state retroactive date currently applied to your policy</p> <p>e) Who are your current Insurer(s)? If currently uninsured please state.</p> <p>f) What is the renewal date of your current Insurance policy covering Public and Products Liability?</p>	
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g) Please state Limit(s) of Indemnity for which a quotation is required or local currency equivalent

A\$.....

I/We declare that to the best of my/our knowledge and belief the above statements are true and complete and will form part of the contract between me/us and the Underwriters.

Name and position of person completing this
Questionnaire:-

Name:

Position:

Signed:

Date: