



# Pharmaceutical Liability Proposal Form

## Products Liability Insurance

The Pavilion | Wanderers Office Park  
52 Corlett Drive | Illovo | 2196  
Telephone: +27 11 731 3600  
[www.santam.co.za](http://www.santam.co.za)  
Registration number: 1918/001680/06



Santam is an authorised financial services provider (FSP 3416),  
a licensed non-life insurer and controlling company for its group companies.

## SECTION 1 - COMPANY DETAILS

Name:	
Trade Description:	
Contact tel:	Contact email:
Website:	

Principle address	Trading address if different
Line 1:	Line 1:
Line 2:	Line 2:
Line 3:	Line 3:
Town:	Town:
County:	County:
Country:	Country:
Postcode:	Postcode:
Is your company involved in clinical trials?	NO YES
If "yes" please list details on blank page provided at the back of this proposal form	

## Corporate Structure

Please Note: Accurate completion of this Section is crucial to the underwriting process and failure to disclose any relevant information might adversely affect policy coverage.

Does your company own shares in any other legal entity?		
If "YES" please list the following details on blank page provided at the back of this proposal form:	NO	YES
1. Name of the legal entity		
2. Percentage of shareholding owned by your company		
3. Business Description of the legal entity		
Does any legal entity own shares in your company?		
If "YES" please list the following details on blank page provided at the back of this proposal form:	NO	YES
1. Name of the legal entity		
2. Percentage of shareholding owned by such legal entity		

## Specialist | Liability

Has your company acquired any other legal entity during the past year?

If "YES" please list the following details on blank page provided at the back of this proposal form:

NO YES

1. Name of the legal entity
2. Percentage of shareholding acquired by your company
3. Business Description of the legal entity

Will your company be acquiring any other legal entity in the upcoming year?

If "YES" please provide full available details on the blank page provided at the back of this proposal form, including:

NO YES

1. Name of the legal entity
2. Percentage of shareholding to be acquired by your company
3. Business Description of the legal entity

Please provide us with a complete organogram of your company's structure.

## SECTION 2 - TURNOVER DETAILS

Estimated annual turnover split between:

Own manufacture (where you hold the Product Licence):

Where you hold the Product Licence but manufacturing is contracted to a third party:

Where you contract manufacture for third parties:

Wholesale:

Parallel import / repackaged or relabelled wholesale products:

Other (please provide details):

## SECTION 3 - TOP SELLING PRODUCTS

Please list your ten largest selling products and approximate turnover derived from each:

	Product	Turnover
1		
2		
3		
4		
5		
6		

7		
8		
9		
10		

**SECTION 4 – EXPORTS**

Please state estimated annual turnover to:						
	Own Manufacture	Product Licence holder	Contract Manufacture	Wholesale	Other	
USA						
Canada						
OECD countries						
Rest of World						

**SECTION 5 - USA / CANADA**

<b>5.1</b> Please answer this question only if you export to USA / Canada		
A list of top 5 products exported and turnover derived from each:		
	Product	Turnover
1		
2		
3		
4		
5		

<p>5.2 If you import products please state from which countries obtained and approximate percentage of total turnover against each:</p>	<p>NO YES</p>
<p>If <b>YES</b>, please provide names and addresses</p>  <p>If <b>NO</b> do they maintain their own Products Liability insurance?</p>	

**SECTION 6 – IMPORTS**

<p>If you import products please state from which countries obtained and approximate percentage of total turnover against each:</p>    
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**SECTION 7 - PRODUCTS**

Do all products comply with the relevant:	YES	NO
<p>7.1 British Standard, Industry and Trade Standards or Government Safety Licensing Regulations or equivalent local legislation?</p>		
<p>7.2 Official Standard or Government Regulations laid down in countries to which products are exported?</p>		
<p>7.3 Are any new products likely to be marketed during the next 12 months?</p>		
<p>If <b>YES</b>, please advise product name, type, territories to be exported, and estimated turnover in the next 12 months</p>		

## SECTION 8 – RECALL

<b>8.1</b> Is it possible to trace the ultimate customer of individual products or batches in order to recall the products? Please provide details		
<b>8.2</b> Is there a formal procedure for emergency product recall? Please provide details		
<b>8.3</b> Has an emergency product recall ever been necessary or been considered?	NO	YES
If <b>YES</b> please provide full details		

## SECTION 9 – MARKETING

<b>9.1</b> Are products labelled and supplied with clear instructions in the language of the country to which they are supplied?	NO	YES
<b>9.2</b> Are product hazard warnings clearly shown on products, packaging and / or instruction manuals?	NO	YES
<b>9.3</b> Do your Legal and / or Design Departments have sight of all advertising material, sales brochures, operating manuals etc. in order to check for misleading statements?	NO	YES

## SECTION 10 – RECORDS

Do you maintain an adequate system of records which would enable identification of the following:		
<b>10.1</b> Source of product / raw materials / component parts purchased?	NO	YES
<b>10.2</b> Source of design of products manufactured?	NO	YES
<b>10.3</b> Research undertaken to minimise risk to health and safety?	NO	YES

## SECTION 11 - SPECIFIED PRODUCTS

Please confirm whether you are involved with any of the following products (or any derivatives thereof). Please note that some of these specific products may be excluded within the policy but can be covered with further information.	YES	NO
Alosetron Hydrochloride		
Antipsychotics		
Any product that does not have regulatory approval		
Bupropion		
Canthaxanthin		
Corvastatin and/or any other Statins and/or Fibrates		
Cisapride		
Contraceptives (including Birth Control Pills), Fertility Drugs and products specifically designed and marketed for use during and in connection with pregnancy		
Cox-2 Inhibitors		
Danthron		
Debendox		
Defenfluramine, Fenfluramine, Phentermine or any other weight control product		
Dicyclomine (when given to children under 4 years of age)		
Diethylstilbestrol (DES)		
Dioxins		
Doxazosin		
Drugs used to treat Erectile Dysfunction		
Ephedrine / Pseudoephedrine		
Fentanyl		
Germanium		
Hormone Replacement Therapies (HRT's)		
Latex, latex protein, latex derivatives and / or latex substances		
Leflunomide		
Methylphenidate		

Monoclonal Antibodies		
Metoclopramide		
Nefazodone		
Oxycodone		
Phenylpropanolamine (PPA)		
Primodos / Amenorone Forte		
Selective Serotonin Reuptake Inhibitors (SSRI's) and Serotonin Norepinephrine Reuptake Inhibitors (SNRI's)		
Skin Whitening or Lightening Agents		
Tacrolimus		
Thalidomide		
Thimerosal and/or Thiomersal		
Thiazolidinediones		
Tretinoin (retinoic acid or its salts)		
Vigabatrin		

**SECTION 12 - NAMED PATIENT PRODUCTS**

Are any products supplied on a Named Patient Basis or in accordance with Specials Licence granted?	NO	YES
If YES please provide details		

### SECTION 13 – PREMISES

<b>13.1</b> Have all manufacturing locations been inspected by the MHRA, FDA or other regulatory body?	NO   YES
If <b>YES</b> please confirm date(s) of last inspection(s)	
<b>13.2</b> Have you ever had a manufacturing licence withdrawn?	NO   YES
If <b>YES</b> please provide full details including remedy action taken	

### SECTION 14 - PREVIOUS INSURANCE DETAILS AND CLAIMS HISTORY

<b>14.1</b> Have you had insurance before?	NO   YES
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**14.2** Please give full details of your previous insurance cover. Provide 5 years history or since trading if earlier:

Insurer	From (dd/mm/yyyy)	To (dd/mm/yyyy)	Limit of indemnity	Excess	Premium

<b>14.3</b> Have there been any gaps in your insurance during the last ten years?	NO   YES
If you have answered <b>YES</b> please confirm the dates and the reason for any gap below.	

<p><b>14.4</b> Are you aware of any complaints or claims that have ever been brought or threatened against you, or any circumstances which could lead to a complaint or claim against you?</p>	<p>NO YES</p>
<p>If <b>YES</b> please provide full details below or use the claims history template addendum</p>	
<p>Has any Insurer ever:</p>	
<p>Declined to insure you?</p>	<p>NO YES</p>
<p>Imposed special conditions?</p>	<p>NO YES</p>
<p>Declined to renew / cancelled your insurance?</p>	<p>NO YES</p>

## SECTION 15 - INDEMNITY REQUIREMENTS

Please advise the date that cover is first required:

<p><b>15.1</b> Was previous cover on a claims made basis?</p>	<p>NO YES</p>
<p><b>15.2</b> If <b>YES</b> what retroactive date is required?</p>	
<p><b>15.3</b> Please indicate the limit of indemnity now required?</p>	

## SECTION 7 - DECLARATION

I/We declare that after full investigation I/we are unaware of any claims and/or circumstances that could give rise to a claim, other than those already declared in the proposal

I/We declare that the statements and particulars contained in the proposal are true and that I/we have not mis-stated or suppressed any material facts.

I/We agree that this proposal together with any other information supplied by me/us shall form the basis of any contract of insurance effected thereon.

I/We undertake to inform Insurers of any material alteration to these facts occurring before completion of the contract of insurance. However, the duty to disclose material facts continues after the completion of the proposal form and throughout any period of insurance (and any extension thereto), upon which this proposal form was used as the basis of the contract of insurance.

Signing this proposal form does not bind the proposer to complete this insurance.

Signature of authorised Individual/Partner/Principal/Director:

Date:

Print Name:

Position: