

Life Sciences Liability

Renewal Proposal Form

Completing The Proposal Form

- Please read all the “Statutory Notices” before completing this Proposal Form.
- Please answer all questions in full leaving no blank spaces. If a question is not applicable, please answer NA. If the answer to a questions is None, please answer None or 0.
- If you have insufficient space to complete any of your answers, please attach a separate signed and dated sheet and identify the question number concerned.

Section I - General Information

Item 1 - Applicant Information

1. Name:						
2. Street address:						
	City:		State:		Postcode:	
3. Mailing address (if different):						
	City:		State:		Postcode:	
4. Website address:						
5. Type of organisation:	<input type="checkbox"/> Corporation <input type="checkbox"/> Limited Liability Company <input type="checkbox"/> Joint Venture <input type="checkbox"/> Partnership <input type="checkbox"/> Individual <input type="checkbox"/> Other					
6. Please provide a brief description of any changes in the past twelve (12) months to your operations below:						

7. Any acquired subsidiaries in the past twelve (12) months?	<input type="checkbox"/> Yes <input type="checkbox"/> No
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If Yes to above, please provide entity name and date acquired below:

Entity Name	Date Acquired (DD/MM/YY)

8. Any subsidiaries sold in the past twelve (12) months?	<input type="checkbox"/> Yes <input type="checkbox"/> No
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If Yes to above, please provide entity name and date sold below:

Entity Name	Date Acquired (DD/MM/YY)

9. In the past twelve (12) months, have you been cited for any regulatory violations (such as those contained in a FDA form 483 or warning letter)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
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If Yes to above, has the applicable regulatory authority accepted your response(s) and closed the matter?

Yes No

If No to above, please provide details below:

10. Please list any third parties you have agreed to name as an insured under your insurance Policy in the past twelve (12) months below:

Additional insured	Explain relationship to your business

11. Mark any items below where you have products, studies or services involving any of the following. Include past and future activities.

Diseases

- Viral Hepatitis HIV TSE

Classes of Products

- | | | | |
|---|---|---|--|
| <input type="checkbox"/> Anticonvulsants | <input type="checkbox"/> Birth control or fertility | <input type="checkbox"/> Cox-2 inhibitor | <input type="checkbox"/> Diazepines, Oxazepines or Thiazepines |
| <input type="checkbox"/> Dopamine Agonists | <input type="checkbox"/> Fibrates | <input type="checkbox"/> Hormone Replacement | <input type="checkbox"/> HMG COA reductase inhibitors |
| <input type="checkbox"/> Impotence | <input type="checkbox"/> Infusion Pumps | <input type="checkbox"/> SSRIs or SNRIs | <input type="checkbox"/> Vaccines |
| <input type="checkbox"/> Hip replacement products | <input type="checkbox"/> Thiazolidinediones | <input type="checkbox"/> Hydroxyquinoline derivatives | <input type="checkbox"/> Surgical Mesh |

12. Mark any items below where you have products, studies or services involving any of the following. Include past and future activities.

Specific Products

- | | | | |
|---|--|---------------------------------------|---|
| <input type="checkbox"/> Botulinum toxin | <input type="checkbox"/> Bupropion | <input type="checkbox"/> Cisapride | <input type="checkbox"/> Clopidogrel |
| <input type="checkbox"/> Dexfenfluramin | <input type="checkbox"/> DEHP | <input type="checkbox"/> DES | <input type="checkbox"/> Dextropropoxyphene |
| <input type="checkbox"/> Fenfluramin | <input type="checkbox"/> Ephedra or Ephedrine | <input type="checkbox"/> Hydroquinone | <input type="checkbox"/> Fentanyl |
| <input type="checkbox"/> Gadolinium | <input type="checkbox"/> Isotretinoin | <input type="checkbox"/> Latex Gloves | <input type="checkbox"/> Mercury |
| <input type="checkbox"/> Metaclopramide | <input type="checkbox"/> Orlistat | <input type="checkbox"/> Phentermine | <input type="checkbox"/> Propoxyphene |
| <input type="checkbox"/> PPA | <input type="checkbox"/> Remoxipride | <input type="checkbox"/> Risperidone | <input type="checkbox"/> Silicone (implanted) |
| <input type="checkbox"/> Thalidomide | <input type="checkbox"/> Thimerosal | <input type="checkbox"/> Troglitazone | <input type="checkbox"/> Varencliline |
| <input type="checkbox"/> Piper Methysticum (Kava) | <input type="checkbox"/> L-Tryptophan (ingested) | <input type="checkbox"/> Opioids | |

13. What are your projected annual prescriptions / units to be sold next year?

14. What are your projected number of annual product users in the next year?

15. Please indicate any trade association memberships:

16. Please provide a break-up of your actual gross sales for the past twelve (12) months and your projected gross sales for the next twelve (12) months.

Country	Actual Gross Sales past twelve (12) months	Projected Gross Sales next twelve (12) months
Australia		
New Zealand		
United States of America		
Canada		
Belgium, France, Ireland		
Austria, Germany, Italy, Netherlands, Spain, Switzerland, U.K.		
Denmark, Norway, Sweden		

Country	Actual gross sales past twelve (12) months	Projected gross sales next twelve (12) months
Rest of Europe (all other European countries not listed above)		
Asia		
Latin America		
Middle East		
Africa		
Other (please specify):		

17. Projected percentage of sales by area:

Prescription medicines or biologics:		Patent Protected		Generic / Multi-Source
Over the counter medicines or biologics:		Patent Protected		Generic / Multi-Source
Medical Devices:				
Dietary supplements or nutritional products:				
Contract services:				
Distribution:				
Research:				
Other (please explain):				

18. Please provide percentage split of sales or clinical trial participants between each state, territory and overseas:

NSW	VIC	QLD	SA	WA	ACT	NT	TAS	O/S

19. Annual Payroll Estimate:

Management, Administration:				
Manufacturing:				
Sales, Onsite Training or Instruction:				
Installation, Onsite Service:				
Research & Development:				
Other:				
Number of Employees:	Full Time:		Part Time:	

20. Host Employer Activities

i. Do you employ contractors?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If Yes to above, how many?	
Estimated annual payments?	
Activities performed:	
ii. Do you employ labour hire workers?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If Yes to above, how many?	
Estimated annual payments?	
Activities performed:	
iii. Do you require that all contractors and labour hire workers participate in training that instructs them on all applicable company policies and safety procedures?	

Item 2 - Loss History and Potential Loss

1. Any claims not yet reported to us or your previous insurer(s)? Yes No

If Yes to above, please provide details below:

2. Please indicate any of your products or services, past or present, that have been involved with any certified, or attempted, representative action, class action or multi-district litigation below:

3. Are you aware of any fact, circumstance or situation which one might reasonably expect could give rise to a claim (or multiple claims) that would fall within the scope of the insurance being requested? Yes No

If Yes to above, please provide details below:

The information requested in this application is for underwriting purposes only and does not constitute notice to the company under any policy of a claim or potential claim.

Section II - Products and Services (Including Human Clinical Trials)

If you are involved in this....	Then only complete these items...	And provide these additional documents as applicable...
Drug or biologic products in trials	1	<ul style="list-style-type: none"> Consent forms and protocols for actively sponsored trials
Medical device products in trials	1	<ul style="list-style-type: none"> Consent forms and protocols for actively sponsored trials
Drug or biologic products approved	2	
Medical device products approved	2	
Complementary medicines / Dietary supplements / Nutritional products	2	
Wholesale / Distribution of medical products	2, 4 and 5	<ul style="list-style-type: none"> Copies of largest standard contracts
Contract professional services	3 and 5	<ul style="list-style-type: none"> Copies of largest standard contracts
Not-for-profit / Independent research institution	6	

Item 1 - Human Clinical Trials

If you require insurance for Human Clinical Trials that you sponsor then complete this item, otherwise go to Item 2 - Regulatory.

- A. Please List:
- i. Active Trials Currently Being Sponsored (including Phase 4); and
 - ii. Sponsored trials (present and planned); for the next 12 month period.

Product Name and Protocol Number	No. of New Subjects to Enrolled Over Next Policy Period	Indication	Trial Phase	Country(ies)	Countries where local insurance is placed

Item 1 - Human Clinical Trials (Continued)

B. Number of expanded access / compassionate use subjects anticipated in the coming policy period?	
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C. Total number of human subjects enrolled in the last three (3) years:	
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D. Have there been any clinical trials during the past three (3) years involving your product which have been discontinued or suspended in whole, or in part, because of safety reasons?	<input type="checkbox"/> Yes <input type="checkbox"/> No
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If Yes to above, please provide details below:

E. Have any clinical investigators been cited during the past three (3) years for regulatory violations in connection with your trials?	<input type="checkbox"/> Yes <input type="checkbox"/> No
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If Yes to above, please provide details below:

F. Have you provided material or product for investigator-sponsored trials in the past twelve (12) months?	<input type="checkbox"/> Yes <input type="checkbox"/> No
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G. Have you provided material or product for another organisation's clinical study / trial the past twelve (12) months?	<input type="checkbox"/> Yes <input type="checkbox"/> No
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H. During the past twelve (12) months, have you agreed to use any new clinical trial compensation guidelines to compensate participants injured in your clinical trial(s)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
--	--

If Yes to above, please indicate which guidelines below:

- | | |
|---|--|
| <input type="checkbox"/> Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Trial | <input type="checkbox"/> The Association of the British Pharmaceutical Industry (ABPI) Clinical Trial Compensation Guidelines |
| <input type="checkbox"/> The Medical Technology Association of Australia (MTAA) Guidelines for Compensation for Injury Resulting from Participation in a Company Sponsored Clinical Investigation | <input type="checkbox"/> Other Compensation Guidelines not specified above (Please attach copy of such guidelines with this application) |

New Zealand Researched Medicines Industry Guidelines on Clinical Trials Compensation for Injury Resulting From Participation in an Industry-Sponsored Clinical Trial

Item 2 - Regulatory

If you market your own Medical Products or Wholesale / Distribute Medical Products of others then complete this item, otherwise go to Item 3 - Contract Professional Service.

A. Have any of your products discontinued for safety reasons during the past twelve (12) months?	<input type="checkbox"/> Yes <input type="checkbox"/> No
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If Yes to above, please provide details below:

B. How many product recalls have you had in the past twelve (12) months?	
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Please describe any Class 1 recalls below:

C. Identify any product requiring the addition of a black box or other significant safety warning to existing labelling or instructions in the past twelve (12) months:

D. Identify any product requiring a Risk Evaluation & Mitigation Strategy (REMS), or relevant regulatory equivalent in the past twelve (12) months:

E. Are there any safety surveillance team recommendations involving any of the following remedial actions, which have yet to be implemented or completed?

i. "Healthcare Professional" Letter	<input type="checkbox"/> Yes <input type="checkbox"/> No
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ii. Additional studies	<input type="checkbox"/> Yes <input type="checkbox"/> No
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iii. Expanded product monitoring	<input type="checkbox"/> Yes <input type="checkbox"/> No
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Item 3 - Contract Professional Service

If you provide Contract Professional Services then complete this item, otherwise go to Item 4 - Distribution.

A. How many of your customers each represent more than 10% of your total revenue? 0 1 2 3 4+

Please provide more detailed information about these customers:

Customer	Revenue	Product or Service

B. How many distinct products or services do you offer? 1-3 4-6 7+

C. Have you modified your customised customer management procedures in the past twelve (12) months? Yes No

If Yes to above, please explain changes:

D. Have you discontinued any products or services in the past twelve (12) months? Yes No

If Yes to above, do you continue to provide service or maintenance?

Yes No

If Yes to above, please provide more detailed information about these discontinued products or services:

Product / Service	Date Discontinued (DD/MM/YY)	Still Service / Maintain?
		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No

E. Do you have any services you will be offering to the market within the next year that are substantially different in scope or end-use than your current services? Yes No

If Yes to above, please provide details below:

Item 4 - Distribution

If you Wholesale/Distribute Medical Products then complete this item, otherwise go to Item 5 - Contracts.

A. Projected percentage of your total revenue by area for products that you purchase from Australian suppliers, import from foreign suppliers and/or for which you are the registered sponsor with TGA:

Product Category	Purchased From Australian Supplier	Imported or Sponsored By You
APIs		
Dietary Supplements		
Drug/Biologics		
Drug/Biologic/Dietary Supplementary Ingredients		
Equipment		
Medical devices		
Medical device components/software		
Other (please describe):		

B. Do you sell any medical implants? Yes No

If Yes to above, please indicate revenues that they represent for the following categories:

Implant Category	Actual Revenue Past 12 months	Estimated Revenue Next 12 months
Orthopaedic - Hip or Knee		
Cardiovascular, Obstetrics & Gynaecology, Orthopaedic - Spine		
Dental, Ear/Nose/Throat (ENT), Gastrointestinal (GI) / Urological, Neurological, Ophthalmic		
Orthopaedic - Other than Hip, Knee or Spine		
Other (please describe):		

Item 5 - Contracts

If you provide Contract Professional Services or Wholesale / Distribute Medical Products of others then complete this item, otherwise go to Item 6 - Research Institutions.

A. What is the value of your average performance-based contract, purchase order or agreement?

<\$50K <\$100K <\$250K <\$1M \$1M+

B. What is the duration of your average performance-based contract, purchase order or agreement?

1-3 Months 4-6 Months 6-12 Months 12 Months +

C. Does the value of any performance-based contract, purchase order or agreement exceed \$2.5M?

Yes No

D. In the past three (3) years, have you been involved in any contract disputes or have any contracts past due acceptance?

Yes No

If Yes to the above, please provide details below:

E. Provide the following information for your five largest contracts, purchase orders or agreements:

Customer	Contract Amount	Product or Service	Duration

Item 6 - Research Institutions

If you are a Medical Research Institution then complete this item, otherwise go to Section III - Errors or Omissions Liability

A. Projected percentage of total activities by area:

	Basic Research		Pre-clinical testing
	Clinical testing		Product commercialisation
	HREC / IRB Services		Product licensing
	Medical product research		Other (please describe):

B. Do you have any unpaid volunteers or students working in your organisation?

Yes No

If Yes to above, how many?

C. What are your top two sources of funding?

Section III- Errors or Omissions Liability

If you do not wish to apply for errors or omissions liability, or only require the errors or omissions cover automatically included in our 'Advantage' and 'Essentials' product options, then skip this item and go to Section IV Signature / Certification.

Item 1 - Types Of Products & Services, Industries Served, Revenue.

If you have completed Item 3 - Contract Professional Service of Section II Products and Services (including Human Clinical Trials), then skip this item and go to Item 2 - Contracts.

A. How many of your customers each represent more than 10% of your total revenue? 0 1 2 3 4+

Please provide the following details for these customers:

Customer	Revenue	Product or Service

B. How many distinct products or services do you offer? 1-3 4-6 7+

C. Have you discontinued any products or services in the past twelve (12) months? Yes No

If Yes to above, do you continue to provide service or maintenance? Yes No

If Yes to above, please provide more detailed information about these discontinued products or services:

Product / Service	Date Discontinued (DD/MM/YY)	Still Service/Maintain?
		<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

D. Will you be offering any services to the market within the next year that are substantially different in scope or end-use than your current services? Yes No

If Yes to above, please provide details:

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E. Have you modified your customised customer management procedures in the past twelve (12) months? Yes No

If Yes to above, please provide details:

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Item 2 - Contracts

If you have completed Item 5 - Contracts Of Section II - Products and Services (including Human Clinical Trials), then skip this item and go to Item 3 - Historical Information Below.

A. What is the value of your average performance-based contract, purchase order or agreement?

<\$50K <\$100K <\$250K <\$1M \$1M+

B. What is the duration of your average performance-based contract, purchase order or agreement?

1-3 Months 4-6 Months 6-12 Months 12 Months +

C. Does the value of any performance-based contract, purchase order or agreement exceed \$2.5M? Yes No

D. In the past five (5) years, have you been involved in any contract disputes or have any contracts past due acceptance? Yes No

If Yes to above, provide details below:

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E. Provide the following information for your five largest contracts, purchase orders or agreements:

Customer	Contract Amount	Product or Service	Duration

Item 3 - Historical Information

A. In the past twelve (12) months, have you been sued or threatened with suit for any act, error or omission relating to your products or services?	<input type="checkbox"/> Yes <input type="checkbox"/> No
B. In the past twelve (12) months, have any of your products or services been recalled from use?	<input type="checkbox"/> Yes <input type="checkbox"/> No
C. In the past twelve (12) months, has there been any current or past administrative, civil or criminal investigation or litigation by any governmental or regulatory authority?	<input type="checkbox"/> Yes <input type="checkbox"/> No
D. Are you aware of any act, error or omission, unresolved contract dispute, or any other circumstance that may reasonably be expected to result in a claim or suit to which this insurance applies?	<input type="checkbox"/> Yes <input type="checkbox"/> No

If Yes to above, please provide details below:

Section IV - Signature/Certification

Notice to applicant - Please read carefully

Information or data contained in or submitted in connection with this application (or otherwise to any of the member insurers of Chubb Group of Insurance Companies (“Chubb”) in connection with the underwriting process) does not constitute notice of an occurrence, wrongful act, claim, suit or other circumstance and does not satisfy any of the reporting notification or other provisions of any Insurance policy. All such notices must be given separately in accordance with the applicable policy conditions. Completion of this application does not bind insurance. Applicant’s acceptance of the company’s quotation is required prior to binding insurance and policy issuance.

Certification

For the purposes of this application, the undersigned declares and acknowledges by clicking where indicated below that, he/she has reviewed this application and the statements contained therein with his/her Chief Executive Officer, Chief Financial Officer, Chief Operating Officer or their equivalents, and that to the best of their knowledge and belief, after reasonable inquiry, the statements in this application, and in any attachments, are true and complete.

Chubb is authorised to make inquiry in connection with this application. Signing this application shall not constitute a binder or obligate Chubb to complete this insurance, but it is agreed that this application shall be the basis upon which a policy may be issued.

If the statements in this application or in any attachment change materially before the effective date of any proposed insurance, the applicant must notify Chubb, and Chubb may modify or withdraw any quotation.

You understand the limit of liability under any policy issued based on this Renewal Proposal Form shall include both indemnity payments for claims and payment of claim and defence expenses, as defined in the policy.

Name:	
Title:	
Date:	
Authorised Signature of Applicant:	

Statutory Notice

For the purposes of this statutory notice, Chubb Insurance Australia Limited ABN: 23 001 642 020 AFSL: 239687 means “we”, “us” and “our”.

Duty of Disclosure

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.

What you do not need to tell us

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 Statement

Chubb Insurance Australia Limited (Chubb) is committed to protecting your privacy. This document provides you with an overview of how we handle your personal information. Our Privacy Policy can be accessed on our website at www.chubb.com/au.

Personal Information Handling Practices

Collection, Use and Disclosure

We collect your personal information (which may include sensitive information) when you are applying for, changing or renewing an insurance policy with us or when we are processing a claim in order to help us properly administrate your insurance proposal, policy or claim.

Personal information may be obtained by us directly from you or via a third party such as your insurance intermediary or employer (e.g. in the case of a group insurance policy).

When information is provided to us via a third party we use that information on the basis that you have consented or would reasonably expect us to collect your personal information in this way and we take reasonable steps to ensure that you have been made aware of how we handle your personal information.

The primary purpose for our collection and use of your personal information is to enable us to provide insurance services to you. Sometimes, we may use your personal information for our marketing campaigns, in relation to new products, services or information that may be of interest to you.

We may disclose the information we collect to third parties, including service providers engaged by us to carry out certain business activities on our behalf (such as assessors and call centres in Australia). In some circumstances, in order to provide our services to you, we may need to transfer personal information to other entities within the Chubb Group of companies (such as the regional head offices of Chubb located in Singapore, UK or USA), or third parties with whom we or those other Chubb Group entities have sub-contracted to provide a specific service for us, which may be located outside of Australia (such as in the Philippines or USA). Please note that no personal information is disclosed by us to any overseas entity for marketing purposes.

In all instances where personal information may be disclosed overseas, in addition to any local data privacy laws, we have measures in place to ensure that those parties hold and use that information in accordance with the consent you have provided and in accordance with our obligations to you under the Privacy Act 1988 (Cth).

Your Choices

In dealing with us, you agree to us using and disclosing your personal information as set out in this statement and our Privacy Policy. This consent remains valid unless you alter or revoke it by giving written notice to our Privacy Officer. However, should you choose to withdraw your consent it is important for you to understand that this may mean we may not be able to provide you or your organisation with insurance or to respond to any claim.

How to Contact Us

If you would like a copy of your personal information, or to correct or update it, please contact our customer relations team on 1800 815 675 or email CustomerService.AUNZ@chubb.com.

If you have a complaint or would like more information about how we manage your personal information, please review our Privacy Policy for more details or contact the Privacy Officer, Chubb Insurance Australia Limited, GPO Box 4907, Sydney NSW 2001, Tel: +61 2 9335 3200 or email Privacy.AU@chubb.com

Claims-Made and Claims-Made and Notified Coverages

These coverages apply only to claims that are either first made against you during the period of insurance or both first made against you and notified to us in writing before the expiration of the period of the insurance cover provided by the Policy. If your Policy does not have a continuity of cover provision or provide retrospective cover then your Policy may not provide insurance cover in relation to events that occurred before the contract was entered into.

Notification of Facts that might give rise to a claim

Section 40(3) of the ICA only applies to the claims-made and the claims-made and notified coverages available under the Policy. Pursuant to Section 40(3) of the ICA, and only pursuant to that section, if you give notice in writing to us of facts that might give rise to a claim against you as soon as reasonably practicable after you become aware of such facts but before the insurance cover provided by the Policy expires, then we are not relieved of liability under the Policy in respect of the claim, when made, by reason only that it was made after the expiration of the period of the insurance cover provided by the Policy.

About Chubb in Australia

Chubb is the world's largest publicly traded property and casualty insurance company. With operations in 54 countries, Chubb provides commercial and personal property and casualty insurance, personal accident and supplemental health insurance, reinsurance and life insurance to a diverse group of clients. As an underwriting company, we assess, assume and manage risk with insight and discipline. We service and pay our claims fairly and promptly. The company is also defined by its extensive product and service offerings, broad distribution capabilities, exceptional financial strength and local operations globally. Parent company Chubb Limited is listed on the New York Stock Exchange (NYSE: CB) and is a component of the S&P 500 index. Chubb maintains executive offices in Zurich, New York, London and other locations, and employs approximately 31,000 people worldwide.

Chubb, via acquisitions by its predecessor companies, has been present in Australia for over 50 years. Its operation in Australia (Chubb Insurance Australia Limited) provides specialised and customised coverages, including Marine, Property, Liability, Energy, Professional Indemnity, Directors & Officers, Financial Lines, Utilities, as well as Accident & Health insurance, to a broad client base. Chubb is a major insurer of many of the country's largest companies. With five branches and over 500 staff in Australia, it has a wealth of local expertise backed by its global reach and breadth of resources.

More information can be found at www.chubb.com/au

Contact Us

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