

# Medical & Commercial International – International Pharmaceutical and Biotechnology Liability Insurance



## Medical & Commercial International – International Pharmaceutical and Biotechnology Liability Insurance

The **Insurer** in consideration of the payment of premium by the **Insured** and subject to all terms, definitions, **Limits of Indemnity**, exclusions, conditions and any endorsements included hereon will indemnify the **Insured** as provided herein.

Except where otherwise stated the **Insurer** will also pay **Legal Costs** in addition to the **Limits of Indemnity**.

**IMPORTANT:** Section B of this policy ("Products Liability") operates on a 'Claims made and notified' basis. This means that the policy covers **Claims** that are made against an **Insured** and notified to the **Insurer** within the **Period of Insurance**.

**Signed on behalf of certain Underwriters at Lloyd's**



Dan Starmer  
Class Underwriter  
Medical & Commercial International – signed on behalf of certain Underwriters at Lloyd's

Date: **TBA**

## SCHEDULE

<b>Policy Number:</b>	TBA
<b>Insured:</b>	TBA and subsidiary companies and other interests as provided herein
<b>Address:</b>	TBA
<b>Business:</b>	All past, present and future activities of the <b>Insured</b> , as advised to the <b>Insurer</b>
<b>Period of Insurance:</b>	From: 00:00 on TBA To: 23:59 on TBA Local standard time at the <b>Insured's</b> address stated above and for such further period or periods as may be mutually agreed upon.
<b>Limit of Indemnity:</b>	
Section A - Public and Pollution Liability:	USD TBA any one <b>Occurrence</b> but in the annual aggregate in respect of liability arising from <b>Pollution</b>
Section B - Products Liability:	USD TBA any one <b>Claim</b> and in the annual aggregate
<b>Combined Single Limit</b> (in respect of Sections A and B)	USD TBA
<b>Deductible:</b>	
Section A - Public and Pollution Liability:	USD TBA any one <b>Occurrence</b> inclusive of <b>Legal Costs</b>
Section B - Products Liability:	USD TBA any one <b>Claim</b> inclusive of <b>Legal Costs</b>
<b>Territorial Limits:</b>	TBA
<b>Claim Jurisdiction:</b>	TBA
North American Jurisdiction Extension:	<i>Excluded / Included</i>
Policy Disputes Law and Jurisdiction:	TBA
Endorsements attaching to this policy:	TBA
Retroactive Date (Section B only):	TBA
Annual Policy premium:	Minimum and Deposit USD TBA Adjustable in accordance with General Condition 15 at TBA% on turnover
Taxes payable by <b>Insured</b> and administered by the <b>Insurer</b> :	State tax with % or "none" if not applicable
Taxes payable by the <b>Insurer</b> :	State tax with % or "none" if not applicable
Premium Payment Date:	TBA
Broker:	TBA
<b>Claim</b> Notification address:	Claims Manager, Medical & Commercial International
<b>Policy</b> issued by:	Medical & Commercial International
Dated in London:	TBA

Medical & Commercial International is a division of Castel Underwriting Agencies Limited, a company incorporated in England and Wales under company number 07774336 with registered office situated at 33 Gracechurch street, London, EC3V 0BT. Castel Underwriting Agencies Limited is authorised and regulated by the Financial Conduct Authority.

Security:

100% Syndicates at Lloyd's of London

## **SECTION A - PUBLIC AND POLLUTION LIABILITY**

### **OPERATIVE CLAUSE**

The **Insurer** agrees to indemnify the **Insured** by the terms of this Section against their legal liability to pay compensation (including claimants' costs and expenses) as a result of **Injury** or **Property Damage** that occurs within the **Territorial Limits** during the **Period of Insurance** and provided it arises out of and in connection with the **Business**.

### **LIMIT OF INDEMNITY**

The liability of the **Insurer** under this Section for any one **Occurrence** or all **Occurrences** consequent upon one source or original cause shall not exceed the **Limit of Indemnity** in the **Schedule**. In respect of liability arising out of **Pollution**, the **Limit of Indemnity** represents the total amount of the **Insurer's** liability during the **Period of Insurance**.

An **Occurrence** or **Occurrences** consequent upon one source or original cause shall be deemed to be one **Occurrence** regardless of the number of persons or organisations who sustain **Injury** or **Property Damage**. All such **Occurrences** shall be deemed to have happened on the day of the first **Occurrence**.

The phrase "consequent upon one source or original cause" as used in this Section of the **Policy** shall be defined as: arising from the same event, condition, defect or hazard, or failure to warn.

### **LEGAL COSTS**

Following any **Occurrence** which is or may be the subject of indemnity under this Section the **Insurer** agrees to indemnify the **Insured** for **Legal Costs** which will be in addition to the **Limit of Indemnity** stated in the **Schedule**.

### **SECTION A SPECIFIC EXCLUSIONS**

This Section does not cover liability arising out of:

- (1) (a) **Injury, Property Damage**, financial loss, loss of use of property directly or indirectly arising out of the discharge, dispersal, release, or escape of **Pollutants**;
- (b) the cost of removing, nullifying or cleaning up **Pollutants**;
- (c) fines, penalties, punitive or exemplary damages arising directly or indirectly out of the discharge dispersal, release or escape of **Pollutants**.

Notwithstanding the foregoing, this **Policy** covers liability otherwise excluded under paragraphs 1(a) and 1(b) above which:

- (i) is caused by a sudden, identifiable, unintended and unexpected happening which takes place in its entirety at a specific time and place, and
  - (ii) is indemnified in not more than one annual **Period of Insurance**.
- (2) the ownership, possession, maintenance or use by or on behalf of the **Insured** of any motor vehicle or trailer for which compulsory insurance is required by legislation, other than liability:
    - (a) arising from the use of any tool or plant forming part of or attached to or used in connection with any motor vehicle or trailer;
    - (b) arising beyond the limits of any carriageway or thoroughfare caused by the loading or unloading of any motor vehicle or trailer;

except where indemnity is provided by any motor insurance contract or where insurance or security is required by law.

- (3) liability for which compulsory insurance is required by legislation governing the use of any motor vehicle or trailer.

- (4) the ownership, possession, maintenance or use by or on behalf of the **Insured** of any
- (a) aircraft or other aerial device or satellite;
  - (b) waterborne vessel or craft (other than watercraft not exceeding fifteen metres in length and only whilst on inland waterways);
  - (c) hovercraft.
- (5) damage to property owned, leased or hired or under hire purchase or on loan to the **Insured** or otherwise in the **Insured's** care, custody or control other than:
- (a) in premises (or the contents thereof) temporarily occupied by the **Insured** for work therein, or other property temporarily in the **Insured's** possession for work thereon (but no indemnity is granted for damage to that part of the property on which the **Insured** is working and which arises out of such work);
  - (b) **Employees'** and visitors' clothing and personal effects;
  - (c) premises tenanted by the **Insured** to the extent that the **Insured** would be held liable in the absence of any specific agreement.
- (6) legal liability arising from the **Insured's Products** (other than food or drink for consumption on the **Insured's** premises.
- (7) arising from any **Occurrence** or series of **Occurrences** which is recovered by a policy of insurance preceding this **Policy**.

#### **SECTION A SPECIFIC EXTENSIONS**

Unless otherwise stated the following Extensions are subject to the overall **Limit of Indemnity** stated in the **Schedule**.

##### **(1) OVERSEAS PERSONAL LIABILITY**

The **Insurer** will indemnify the **Insured** and if the **Insured** so request any director or partner of the **Insured** or **Employee** against legal liability incurred in a personal capacity while temporarily outside the **Territorial Limits** stipulated in the **Schedule** in connection with the **Business** provided that the **Insurer** shall not be liable for:

- (a) legal liability arising out of the ownership or occupation of land or buildings;
- (b) where indemnity is provided by other insurance.

##### **(2) CONTINGENT MOTOR LIABILITY**

Notwithstanding Exclusions (2) and (3) of this Section the **Insurer** will provide indemnity to the **Insured** against legal liability arising out of the use in the course of the **Business** of any motor vehicle not the property of nor provided by the **Insured**.

The indemnity will not apply to legal liability

- (a) in respect of **Property Damage** to such vehicle or to property conveyed therein;
- (b) in respect of which the **Insured** is entitled to indemnity under any other insurance;
- (c) arising from the use of any motor vehicle outside the **Territorial Limits** stipulated in the **Schedule**.

Solely, for the purposes of this Extension the term "Insured" shall mean only the **Insured** named in the **Schedule** and no other party.

## **SECTION B - PRODUCTS LIABILITY ("CLAIMS MADE AND NOTIFIED BASIS")**

### **OPERATIVE CLAUSE**

The **Insurer** agrees to indemnify the **Insured** by the terms of this Section against their legal liability to pay compensation (including claimants' costs and expenses) in respect of any **Claim** first made by a third party against the **Insured** and notified to the **Insurer** (in accordance with General Condition 1b) during the **Period of Insurance** arising solely by reason of:

- (1) **Injury**; and/or
- (2) **Property Damage**

happening within the **Territorial Limits** and resulting from an **Occurrence** in connection with the **Business** and caused by any of the **Insured's Products**.

### **LIMIT OF INDEMNITY**

The **Insurer's** total liability to pay compensation (including claimants' costs and expenses) arising from all **Claims** made against the **Insured** during the **Period of Insurance** shall not exceed the **Limit of Indemnity** stated in the **Schedule**.

A **Claim** or series of **Claims** consequent upon one source or original cause shall be deemed to be one **Claim** regardless of the number of persons or organisations who sustain **Injury** or **Property Damage**. All such **Claims** shall be deemed to have been made on the day of the first **Claim** (or on the day that the first **Circumstance** was notified by the **Insured** if this date precedes the day of the first **Claim**) of the **Claims** series.

The phrase "consequent upon one source or original cause" as used in this Section of the **Policy** shall be defined as: arising from an identifiable design, error or defect in the **Insured's Product** or the failure to warn of the same potential hazard by the **Insured** which results in similar **Injury** or **Property Damage**.

### **LEGAL COSTS**

Following any **Claim** or **Circumstance** which is or may be the subject of indemnity under this Section the **Insurer** agrees to indemnify the **Insured** for **Legal Costs** which will be in addition to the **Limit of Indemnity** stated in the **Schedule**.

### **SECTION B SPECIFIC EXCLUSIONS**

This Section does not cover liability for claims arising out of:

- (1) **Injury** or **Property Damage** (whether forming part of a claims series or otherwise) resulting:
  - (a) from a **Claim** first made, threatened or intimated against the **Insured** prior to the **Period of Insurance**;
  - (b) directly or indirectly arising out of, or in any way involving any fact or **Circumstance**:
    - (i) of which written notice has been given under any previous policy (whether such policy was provided by the **Insurer** or not); or
    - (ii) of which the **Insured** first became aware prior to the **Period of Insurance** or which the **Insured** knew or ought reasonably to have known may give rise to **Injury**, **Property Damage** or **Legal Costs**; or
    - (iii) disclosed on the latest **Proposal** made to the Insurer or any other previous proposal released to the **Insurer** or other insurers.
- (2) **Injury** or **Property Damage** occurring prior to the retroactive date in the **Schedule**. Provided always that in the event of any **Injury** or **Property Damage** arising from continuous or continual inhalation, ingestion or application of any substance and where the **Insured** and the **Insurer** cannot agree when the **Injury** or **Property Damage** occurred, then:

- (a) **Injury** shall be deemed to have occurred when the claimant first consulted a qualified medical practitioner;
- (b) **Property Damage** shall be deemed to have occurred when it first became evident to the claimant, even if the cause was unknown.

It being further understood that where a) no retroactive date is specified in the **Schedule**; or b) "Unlimited" is specified in the **Schedule** coverage shall apply (subject to all other **Policy** terms, conditions and exclusions) irrespective of when the **Injury** or **Property Damage** occurred.

- (3) any **Product** or part thereof which with the **Insured's** knowledge is intended to be incorporated into the structure, machinery or controls of any aircraft or other aerial device or satellite.
- (4) for costs incurred by the **Insured** or others in the repair, reconditioning, modification or replacement of any **Product** or part thereof and / or any financial loss consequent upon the necessity for such repair, reconditioning, modification or replacement.
- (5) for costs incurred by the **Insured** or others arising out of the recall of any **Product** or part thereof.
- (6) from the non-performance or inadequacy of the **Insured's Product** to cure, alleviate, prevent, monitor, detect, eliminate or retard any illness, malady, condition or syndrome.
- (7) any **Product** that is not
  - (a) licensed in accordance with legislation or regulations relating to licensing of medicines, drugs, cosmetics, dietary supplements or medical devices in the country in which the **Product** is sold; or
  - (b) approved for marketing by the applicable regulatory body in the country in which the **Product** is sold where prior approval is required by legislation or regulations; or
  - (c) exempt from any requirement for a license or marketing authorisation in the country in which the **Product** is sold.
- (8) any **Product** causing or failing to cure or alleviate any condition directly or indirectly caused by or associated with:
  - (a) Hepatitis; or
  - (b) Human Immunodeficiency Syndrome (HIV) initially named as either HTLV III or LAV or the mutants, derivatives or variations thereof or in any way related to Acquired Immune Deficiency Syndrome (AIDS) or AIDS related complex (ARC) or any syndrome or condition of a similar kind howsoever it may be named; or
  - (c) Bovine Spongiform Encephalopathy (BSE), Transmissible Spongiform Encephalopathy (TSE) Creutzfeldt-Jakob Disease (CJD) variant Creutzfeldt-Jakob Disease (vCJD) or new variant Creutzfeldt-Jakob Disease (nvCJD).
- (9) **Injury** or **Property Damage** brought about by or contributed to by **Pollution**.
- (10) **Injury** or **Property Damage** not arising out of the **Insured's Products** but occurring in the course of the **Business**.
- (11) damage to the **Insured's Product** or any part thereof arising from a defect or unsuitability thereof and pure financial loss arising therefrom.
- (12) the production, sale or provision of the following (or any derivatives thereof):
  - (a) Alosetron Hydrochloride
  - (b) Antipsychotics
  - (c) Aprotinin (Bovine Pancreatic Trypsin Inhibitor)



- (d) Canthaxanthin
- (e) Cerivastatin and/or any other Statins and/or Fibrates
- (f) Cisapride
- (g) Contraceptives (including Birth Control Pills), Fertility Drugs and products specifically designed and marketed for use during and in connection with pregnancy
- (h) Cox-2 Inhibitors
- (i) Danthron
- (j) Debendox
- (k) Dicyclomine (when given to children under 4 years of age)
- (l) Diethylstilbestrol (DES)
- (m) Dioxins
- (n) Doxazosin
- (o) Drugs used to treat Erectile Dysfunction
- (p) Ephedrine (but this exclusion shall not apply to cough and/or cold medications sold over the counter)
- (q) Fenfluramine (whether individually or in combination with Phentermine)
- (r) Germanium
- (s) Hormone Replacement Therapies (HRT's)
- (t) Leflunomide
- (u) Methylphenidate
- (v) Monoclonal Antibodies
- (w) Metoclopramide
- (x) Nefazodone
- (y) Phenylpropanolamine (PPA)
- (z) Primodos / Amenorone Forte
- (aa) Selective Serotonin Reuptake Inhibitors and Serotonin Norepinephrine Reuptake Inhibitors
- (ab) Skin Whitening or Lightening Agents
- (ac) Tacrolimus
- (ad) Thalidomide
- (ae) Thimerosal and/or Thiomersal
- (af) Thiazolidinediones
- (ag) Tretinoin (retinoic acid or its salts)
- (ah) Vigabatrin.

## **SECTION B SPECIFIC EXTENSIONS**

Unless otherwise stated the following Extensions are subject to the overall **Limit of Indemnity** stated in the **Schedule**.

### **(1) NOTIFICATION EXTENSION CLAUSE**

Should the **Insured** notify the **Insurer** during the **Period of Insurance** in accordance with General Condition 1b) of any specific event or **Circumstance** which the **Insurer** accept may give rise to a **Claim** or **Claims** which form the subject of indemnity by this **Policy**, then acceptance of such notification means that the **Insurer** will deal with such **Claim** or **Claims** as if they had first been made against the **Insured** during the **Period of Insurance**.

### **(2) VENDORS**

The definition of **Insured** is extended to include any person or organisation (herein referred to as "Vendor"), but only with respect to the distribution or sale in the regular course of the Vendor's business of the Insured's **Products**, subject to the following additional provisions:

- (1) The Insurance with respect to the Vendor does not apply to:
  - (a) any express warranty, or any distribution or sale for a purpose, unauthorised by the Insured.
  - (b) **Injury** or **Property Damage** arising out of:
    - (i) any act of the Vendor which changes the condition of the **Products**; or

- (ii) any failure to maintain the **Product** in merchantable condition; or
  - (iii) any failure to make such inspections, adjustment, tests or servicing as the Vendor has agreed to make or normally undertakes to make in the usual course of business, in connection with the distribution or sale of the **Products**; or
  - (iv) **Products** which after distribution or sale by the Insured have been labelled or relabelled or used as a container, part or ingredient of any other thing or substance by or for the Vendor.
  - (v) **Injury** or **Property Damage** occurring within the Vendor's premises.
- (2) The Insurance does not apply to any person or organisation, as Insured, from whom the **Insured** has acquired such **Products** or any ingredient, part or container, entering into, accompanying or containing such **Products**.

## GENERAL EXCLUSIONS

This **Policy** does not cover liability:

- (1) arising out of or from or directly or indirectly caused by or contributed to by **War** or any act of **Terrorism**.
- (2) arising out of or from or caused by any work involving the manufacture, mining, processing, use, installation, storage, removal, stripping out, demolition, disposal, distribution, inspection or testing of or exposure to asbestos, asbestos fibres, asbestos dust, or asbestos containing materials.
- (3) arising out of the deliberate, conscious or intentional disregard by the **Insured's** technical or administrative management of the need to take all reasonable steps to prevent **Occurrences** and **Claims**.
- (4) arising from **Injury** sustained by any **Employee** where such **Injury** arises out of the execution of such employment contract or contract of apprenticeship.
- (5) for which the **Insured** may be held liable under any workers compensation, unemployment compensation, disability benefits law or any similar law.
- (6) for fines, penalties, aggravated damages, liquidated damages, multiple damages, punitive damages, or any other increase in damages resulting from multiplication of compensatory damages.
- (7) arising out of or from any **Claim** brought in or under any jurisdiction outside of the **Claim Jurisdiction** (as stipulated in the **Schedule**) including any enforcement action or transfer proceedings.
- (8) arising from an **Occurrence** outside the **Territorial Limits** (as stipulated in the **Schedule**) including any contract, or arising from the **Business** carried out from the **Insured's** own offices situated outside the **Territorial Limits**.
- (9) arising directly or indirectly out of or alleged to have arisen from any wrongful act of directors or officers of the **Insured** in the discharge or performance of their duties as such other than **Claims** for compensation (including claimants costs and expenses) consequent upon **Injury** or **Property Damage**.

For the purpose of this exclusion wrongful act shall mean any actual or alleged error or misstatement or misleading statement or act or omission or neglect or breach of duty by the directors or officers in the discharge of their duties individually or collectively or any matter claimed against them solely by reason of their being directors or officers of the **Insured**.

- (10) arising out of:
  - (a) a dispute between an employer / prospective employer and **Employee** / prospective **Employee** referred or capable of being referred to any Employment Tribunal including such appeal courts or tribunals as are available from an Employment Tribunal; or
  - (b) a settlement or adjudication of or under the auspices of an Employment Tribunal; or
  - (c) or from any **Employee**, former **Employee** or prospective **Employee** in respect of employment-related libel, slander, humiliation or defamation, unfair or wrongful dismissal, repudiation or breach of any employment contract or arrangement, termination of a training contract or contract of apprenticeship, harassment, discrimination or like conduct; or
  - (d) anything which is capable of being insured under a generally available employment practices liability insurance policy.
- (11) arising out of or from advice, design, plans, specifications, formulae, surveys, or directions prepared or given by the **Insured** for a fee but this shall not exclude such advice arising in conjunction with **Products** supplied.
- (12) arising out of passing off or infringement of patent, copyright, trade mark or trade name or other intellectual property rights.
- (13) for pure financial loss not consequent upon **Injury** or **Property Damage**.

- (14) assumed by the **Insured** by contract or agreement (other than liability arising out of a condition or warranty of goods implied by law) and which would not have attached in the absence of such agreement.
- (15) either expected or intended by the **Insured** but this exclusion does not apply to **Injury** (save for mental injury or disease) or **Property Damage** which is not otherwise excluded.
- (16) arising out of or from
- (a) any deliberate act in violation of any law or ordinance; or
  - (b) any deliberate or wilful misconduct of the **Insured**; or
  - (c) any dishonest, fraudulent, or criminal act of the **Insured**; or
  - (d) any conduct of the **Insured** or **Employee** while under the influence of intoxicants or narcotics.
- (17) arising out of or from or in any way connected with actual or attempted sexual relations, sexual contact or intimacy, sexual harassment, or sexual exploitation.
- (18) directly or indirectly caused by or contributed to or arising from
- (a) ionizing radiation's or contamination by radioactivity from any nuclear fuel or from any nuclear waste;
  - (b) the radioactive, toxic, explosive or other hazardous properties of any explosive nuclear assembly or nuclear component thereof.
- (19) arising out of or from or caused by any work involving the manufacture, sale of, provision of, or use of (or any derivatives thereof):
- (a) Agent Orange - Dichlorophenoxyacetic Acid (2,4-D) and Trichlorophenoxyacetic Acid (2,4,5-T)
  - (b) Any product containing Silicone which is any form implanted or injected in the body
  - (c) Chlorinated Hydro-carbons (CHC's)
  - (d) Chlorofluorocarbons / Chloro Fluoride Carbons
  - (e) Chromated Copper Arsenate (CCA)
  - (f) Ethylenediaminetetraacetic Acid (EDTA)
  - (g) Latex
  - (h) Lead
  - (i) Lindane
  - (j) Methyl Tertiary Butyl Ether (MTBE)
  - (k) Polychlorinated Biphenyls (PCBs), the harmful properties of Polychlorinated Biphenyls, or any Polychlorinated Biphenyls-containing product or material or derivative thereof or to the presence of or the actual or threatened use, installation, withdrawal, or disposal of any such product or material
  - (l) Tobacco or any Tobacco Products (or ingredients thereof)
  - (m) Urea Formaldehyde or any products containing Formaldehyde
  - (n) 2, 3, 7, 8-tetrachlorodibenzo-p-dioxin (TCDD).
- (20) for the amount of the **Deductible** as applicable and stated in the **Schedule**.
- (21) which forms the subject of insurance by any other policy and this **Policy** shall not be drawn into contribution with such other insurance.
- (22) arising out of or from:
- (a) any fungus, mould, mildew or yeast; or
  - (b) any spore or toxins created or produced by or emanating from such fungus, mould, mildew or yeast; or

- (c) any substance vapour gas or other emission or organic or inorganic body substance produced by or arising out of any fungus, mould, mildew or yeast; or
- (d) any material product building component, building structure or any concentration of moisture, water or other liquid within such material product building component, building or structure that contains, harbours, nurtures or acts as a medium for any fungus, mould, mildew, yeast, spore or toxins emanating therefrom.

(23) arising out of or from or alleging or attributable to the existence of legionella.

(24) arising out of or from a **Clinical Trial**.

(25) arising out of or from work carried out by the **Insured**, for and in the name of any other company or association of which the **Insured** forms part for the purpose of undertaking any joint venture unless the **Insurers** prior agreement has been obtained and the inclusion of such work endorsed upon this Policy with the acceptance of any such other terms and conditions as may be imposed.

(26) damage to property owned, leased or hired or under hire purchase or on loan to the **Insured** or otherwise in the **Insured's** care, custody or control.

(27) to pay any claim or provide any benefit hereunder to the extent that the provision of such cover, payment of such claim or provision of such benefit would expose the **Insurer** to any sanction, prohibition or restriction under United Nations resolutions or the trade or economic sanctions, laws or regulations of the European Union, United Kingdom or United States of America.

But in respect of risks domiciled in Australia or any of its territories, the following applies:

to pay any claim or provide any benefit hereunder to the extent that the provision of such cover, payment of such claim or provision of such benefit would expose the **Insurer** to any sanction, prohibition or restriction under United Nations resolutions or the trade or economic sanctions, laws or regulations of the European Union, United Kingdom, United States of America or Australia.

(28) arising out of or from or directly or indirectly caused by or contributed to by medical **Malpractice**.

## GENERAL CONDITIONS

(Conditions 1, 2, 3, 4, 6, 12, 13 and 18 are precedent to the **Insurer's** liability to provide indemnity under this **Policy**)

(1) The **Insured** shall give immediate written notice (but in any event no later than 45 days after the **Insured** first became aware of such **Occurrence, Claim, or Circumstance**) to the **Insurer** of:

(a) In respect of Section A:

any **Occurrence** that may give rise to a **Claim** under this Section. Every **Claim**, writ, summons or process and all documents relating thereto shall be forwarded to the **Insurer** immediately they are received by the **Insured**.

(b) In respect of Section B:

any **Claim** first made against the **Insured** (or any specific event or **Circumstance** that in the opinion of the **Insured** may give rise to a **Claim** made against the **Insured**) and which forms the subject of indemnity under this Section. Every **Claim**, writ, summons or process and all documents relating to the **Claim, event or Circumstance** shall be forwarded to the **Insurer** immediately they are received by the **Insured**.

All matters in respect of Section B should be notified prior to expiry of the **Period of Insurance** within the timeframe stated above in Condition (1) unless the **Insured** is prevented from doing so by virtue of such matter coming to their attention immediately prior to the expiry of the **Period of Insurance**. In such cases the **Insurer** will allow the timeframe stated above in (1) to extend beyond expiry of the **Period of Insurance**, but only in respect of **Claims** made or first awareness of **Circumstance** happening during the period immediately prior to the expiry of the **Period of Insurance** and provided that such period shall not exceed a maximum of 45 days from the end of the **Period of Insurance**. Such extension will not operate to increase the **Insurer's Limit of Indemnity**.

The **Insured** and **Insurers** agree that any circumstance notified to them and accepted as such by **Insurers** during the **Period of Insurance** which subsequently gives rise to a **Claim** after expiry of the **Period of Insurance** will be deemed to be a **Claim** first made during the **Period of Insurance**.

(2) The **Insured** shall give all such information, assistance and forward all documents to enable the **Insurer** to investigate, settle or resist any claim as the **Insurer** may require.

(3) No admission, offer, promise, waiver of rights of recovery, payment or indemnity shall be made or given by or on behalf of the **Insured** without the written consent of the **Insurer** who shall be entitled to take over and conduct in the name of the **Insured** the defence or settlement of any **Claim** or to prosecute in the name of the **Insured** for their own benefit any claim for indemnity or damages or otherwise and shall have full discretion in the conduct of any proceedings and in the settlement of any **Claim** save as hereinafter provided in Conditions (2) and (6).

(4) No expense shall be incurred by or on behalf of the **Insured** without the written consent of the **Insurer** except at the **Insured's** own cost.

(5) Notice to the **Insurer** must be given to the claims notification addresses specified in the **Schedule**, but if this is not possible or practical to the **Insurer** at their registered address.

(6) In connection with any **Claims** against the **Insured** the **Insurer** may at any time pay to the **Insured** the **Limit of Indemnity** (after deduction of any sums already paid) or any less amount for which such **Claims** can be settled and thereupon the **Insurer** shall relinquish the control of such **Claims** and be under no further liability in connection therewith except for **Legal Costs** which the **Insurer** have already agreed to bear in respect of matters prior to the date of such payment.

Except where the **Limit of Indemnity** is stated to be inclusive of all **Legal Costs**, if a payment exceeding the **Limit of Indemnity** has to be made to dispose of a **Claim** the liability of the **Insurer** to pay all **Legal Costs** in

connection therewith shall be limited to such proportion of the said **Legal Costs** as the **Limit of Indemnity** bears to the amount paid to dispose of a **Claim**.

- (7) The **Insured** will at the request and expense of the **Insurer** do and concur in doing and permit to be done all such acts and things as may be necessary or reasonably required by the **Insured** for the purpose of enforcing rights and remedies or of obtaining relief or indemnity from other parties to which the **Insurer** will be or would become entitled or subrogated upon its paying an indemnity under this **Policy**, whether such acts and things will be or become necessary or required before or after their indemnification by the **Insurer**.

In the event of any payment under this insurance, the **Insurer** will act in concert with all other interested persons (including the **Insured**) concerned in the exercise of any rights of recovery.

- (8) The insurance afforded by this **Policy** is excess over and reduced by any other valid and collectable insurance available to the **Insured**. Valid and collectable insurance includes any self insurance plan which would be applicable to the **Occurrence, Claim or Circumstance**.
- (9) If the insured event forms the subject of indemnity under Section A and Section B the **Insureds** maximum liability for the **Deductible** will be the highest applicable **Deductible**.

If settlement of an insured event investigated or defended by the **Insurer** under Sections A and B does not exceed the amount of the applicable **Deductible** the **Insured** will pay, or reimburse the **Insurer** for, as applicable, any **Legal Costs** and paid damages including claimant costs recoverable from the **Insured** and incurred in connection with such insured event.

- (10) The **Policy** and the **Schedule** shall be read together as one contract and any word or expression to which a specific meaning has been attached in any part of this **Policy** or the **Schedule** shall bear such specific meaning wherever it may appear. Furthermore, upon receipt of this **Policy** the **Insured** agrees that it has been issued upon the truth of its declarations and representation made to the **Insurer** or any of its agents relating to this **Policy**.

The interpretation of the terms and exclusions of this **Policy** (and any phrase or word contained therein) shall be interpreted in accordance with the Policy Disputes Law and Jurisdiction stated in the **Schedule**. The **Insured** and the **Insurer** agree to submit to the jurisdiction of any court or competent jurisdiction within the country, state or territory stated as being the Policy Disputes Law and Jurisdiction in the **Schedule** and to comply with all requirements necessary to give such court jurisdiction.

- (11) If any dispute arises between the **Insured** and the **Insurer** as to whether a prosecution should be defended or an appeal made, such dispute will be referred to a solicitor, attorney or similar legal professional (with no less than 10 years experience in the jurisdiction of the prosecution) to be mutually agreed between the parties (or in default of agreement to be nominated by the President of the Law Society (or equivalent body within the jurisdiction of prosecution) whose decision will be final.
- (12) The **Insured** shall give immediate written notice to the **Insurer** (but in any event no later than 30 days) of any fact, event or **Circumstance** which materially changes the information supplied to the **Insurer** at the time when the **Policy** was effected, and the **Insurer** may amend the terms of this **Policy** according to the materiality of such change. Any material alteration or change shall not be binding on the **Insurer** or the terms of this **Policy** until accepted as such by written confirmation from the **Insurer**.
- (13) The **Insured** shall take reasonable precautions at its own expense to prevent any event which may give rise to liability under this **Policy**.

Upon the happening of an insured event and at all times thereafter, the **Insured** shall act as a prudent uninsured and take all reasonable measures as are appropriate to avoid or minimise any claims which may arise from that insured event. Any failure by the **Insured** to take such steps shall mean the **Insurer** may reject or reduce claims and continue the **Policy** on such terms as the **Insurer** may determine.

- (14) The terms of this **Policy** shall not be waived, altered or changed in any way except by written endorsement issued by the **Insurer**.

Furthermore and for the avoidance of doubt, assignment of interest under this **Policy** will not bind the **Insurer** unless and until the **Insurer's** prior written consent is endorsed hereon.

- (15) Where the premium is provisionally based on the **Insured's** estimates, the **Insured** shall keep accurate records and after expiry of the **Period of Insurance** declare as soon as possible (and in any event no later than 30 days from expiry) such details as the **Insurer** require. The premium shall then be adjusted and any difference paid by or allowed to the **Insured** as the case may be subject to any minimum premium that may apply.

It is a condition precedent that all adjustable premiums due to the **Insurer** are paid within ninety (90) days of expiry of each **Period of Insurance**.

- (16) The due observance and fulfilment of the provisions of this **Policy** insofar as they may relate to anything to be done or complied with by the **Insured**, and are not already conditions precedent, will be a condition of this **Policy**. Any waiver by the **Insurer** of any provision will not prevent the **Insurer** from relying on such condition or condition precedent in the future.

In the event of a breach by the **Insured**:

- (a) of any condition in the **Policy**, and without prejudice to any of the **Insurer's** other rights, the **Insurer** may reject or reduce claims connected with the breach providing the **Insurer** can demonstrate prejudice;
- (b) of any condition precedent in the **Policy**, and without prejudice to any of the **Insurer's** other rights, the **Insurer** may reject or reduce claims connected with the breach, and continue the **Policy** on such terms as the **Insurer** may determine. If any payment on account of such claim has already been made the **Insured** will repay forthwith all payments on account to the **Insurer**.

- (17) The **Insurer** may cancel this **Policy** by giving thirty days' notice in writing of such cancellation to the **Insured's** last known address. Such cancellation shall not affect the coverage or premium attributable under this **Policy** to the period prior to cancellation.

Following such notice of cancellation and upon the **Insured's** request the **Insurer** will return to the **Insured** the pro rata premium for the pre-cancelled portion of the **Policy**. In the event of a claim in the pre-cancelled portion of the **Policy**, the return premium shall be calculated at the **Insurer** short period rates.

- (18) The **Insured** maintains full rights of recourse against any person or company with whom the **Insured** has entered into a legal contract for the provision of **Products** (including but not limited to manufacturers, distributors, contract manufacturers, licensees and licensors).
- (19) The **Insurer's** obligations under this **Policy** are several and not joint and are limited solely to the extent of their individual subscriptions. The **Insurers** are not responsible for the subscription of any co-subscribing **Insurer** who for any reason does not satisfy all or part of its obligations.
- (20) If the **Insured** shall make any **Claim** knowing the same to be false or fraudulent, as regards amount or otherwise, such **Claim** shall be void and all cover hereunder shall be forfeited in respect of such **Claim**.



## GENERAL EXTENSIONS

Unless otherwise stated the following Extensions are subject to the overall **Limit of Indemnity** stated in the **Schedule**.

(1) **CROSS LIABILITIES**

Each person or party indemnified is separately indemnified in respect of **Claims** made or losses occurring against any of them by another, subject to the **Insurer's** total liability not exceeding the **Limit of Indemnity** stated in the **Schedule**.

(2) **INDEMNITY TO PRINCIPAL**

As far as is necessary to meet the requirements of any contract or agreement entered into by the **Insured** with any Principal the **Insurer** will at the request of the **Insured** treat the Principal as though he were also the **Insured** but only in respect of liability (as provided for herein) arising out of the performance of such contract by the **Insured** in connection with the **Business** provided that the Principal shall observe fulfil and be subject to the terms of this **Policy** insofar as they apply.

(3) **NORTH AMERICAN JURISDICTION EXTENSION**

In the event of the **Schedule** stating that North American Jurisdiction is "Excluded" this **Policy** shall not apply to any **Claim**, judgement, award or settlement made within any country or territory which operates under the laws of the United States of America or Canada or to any order made anywhere in the world to enforce such **Claim**, judgement award or settlement either in whole or in part.

In the event of the **Schedule** stating that North American Jurisdiction is "Included" this **Policy** shall provide Indemnity within any country or territory which operates under the laws of the United States of America or Canada or to any order made anywhere in the world to enforce such **Claim**, judgement award or settlement either in whole or in part subject to the following conditions, limitations and exclusions applying to such **Claim**:

- (a) This **Policy** does not include as an **Insured** or indemnify any **Insured** domiciled and/or registered in United States of America or Canada unless specifically agreed by the **Insurer** in writing and endorsed to this **Policy**;
- (b) The **Insurer** shall not be liable for fines, penalties, aggravated damages, liquidated damages, multiple damages, punitive damages, or any other increase in damages resulting from multiplication of compensatory damages;
- (c) The **Policy** does not cover any liability for **Injury** or **Property Damage** directly or indirectly caused by **Pollution** or the cost of removing, nullifying or cleaning up **Pollutants**;
- (d) The **Limit of Indemnity** stated in the **Schedule** shall apply including **Legal Costs**;
- (e) A **Deductible** of USD \_\_\_\_\_ each and every **Claim** including **Legal Costs** shall apply;
- (f) A retroactive date of \_\_\_\_\_ shall apply to all **Claims** falling under this extension.

(4) **ADVERTISING LIABILITY**

The **Insurer** will indemnify the **Insured** for all sums which the **Insured** shall become legally liable to pay as compensation (including claimants costs and expenses) in respect of **Advertising Liability** arising out of an **Occurrence** during the **Period of Insurance** in connection with the **Business**, providing that such **Claim** is notified to the **Insurer** (in accordance with General Condition 1b) during the **Period of Insurance**

"**Advertising Liability**" shall mean:

- (a) libel, slander or defamation; or
- (b) any infringement of copyright or passing off of title or of slogan; or

- (c) piracy or unfair competition or idea misappropriation under an implied contract; or
- (d) any invasion of right of privacy.

committed or alleged to have been committed in any advertising, publicity, article, broadcast, or telecast or by the use of any internet website and caused by or arising out of the **Insured's** advertising activities.

The **Insurer** will not indemnify the **Insured** in respect of **Occurrences** arising from:

- (a) failure of performance of contract except **Claims** for unauthorised appropriation of ideas based upon alleged breach of an implied contract;
- (b) infringement of registered trade mark, service mark, or trade name by use thereof as the registered trade mark, service mark, or trade name of goods or services sold, offered for sale or advertised except titles of slogans;
- (c) mistake in advertised price;
- (d) an offence committed by an Insured whose business is principally advertising, broadcast publishing or telecasting;
- (e) any **Advertising Liability** that occurred before the **Insured** created or acquired any company

For the purpose of this extension the term "Property Damage" where used in this **Policy** other than in General Definition (21) shall be deemed to read "Property Damage or Advertising Liability".

The Advertising Liability Extension is subject to a sub-limit of indemnity of USD 1,000,000 any one **Occurrence** and in the annual aggregate.

## GENERAL DEFINITIONS AND INTERPRETATION

The following words will have the same meaning attached each time they appear in this **Policy** in bold type face whether with a capital first letter or not.

Where the context so admits or requires, words importing the singular will include the plural and vice versa and words importing the masculine will include the feminine and the neuter and vice versa. References to 'a person' will be construed so as to include any individual, insurer, partnership, or any other legal entity. References to a statute will be construed to include all its amendments or replacements.

- (1) **"Business"** shall mean the activities of the **Insured** as stated in the **Schedule** and including:
  - (a) ownership, repair, maintenance and decoration of the **Insured's** own property and premises occupied by the **Insured**;
  - (b) provision and management of canteen, social sports, education and welfare organisations for the benefit of any **Employee** and first aid, fire, security and ambulance services;
  - (c) provision of nursery, creche or child care facilities where incidental to the business;
  - (d) the organisation of charitable events or similar fund raising activities;
  - (e) participation in exhibitions, trade fair and conferences;
  - (f) private work undertaken by any **Employee** for any director, partner or **Employee** of the **Insured** with the prior consent of the **Insured**;
  - (g) sponsorship of events, organisations, entities and individuals;
  - (h) employment of subcontractors for performance of work on behalf of the **Insured**.
- (2) **"Circumstance"** means any incident, occurrence, dispute, complaint, fact, matter, act or omission that it is likely to give rise to a **Claim**, including an intention or belief of a request for compensation.
- (3) **"Claim"** shall mean a written demand made against the **Insured** for money or services in respect of **Injury** or **Property Damage**.
- (4) **"Claim Jurisdiction"** shall mean the jurisdiction stipulated in the schedule under which a **Claim** by a third party must be brought for indemnity to be granted by the **Insurer**.
- (5) **"Clinical Trial"** means an investigation (including any healthy volunteer study) in human subjects intended to discover or verify the clinical, pharmacological and / or other pharmacodynamic effects of an **Investigational Product** and / or to identify any adverse reactions to an **Investigational Product** and / or to study absorption, distribution, metabolism and excretion of an **Investigational Product**.
- (6) **"Combined Single Limit"** shall mean the amount stipulated in the **Schedule** which denotes the maximum the **Insurer** will pay by this **Policy** in the event that two sections, to which the combined single limit applies, provide coverage for an insured event.
- (7) **"Deductible"** shall mean the first amount payable by the **Insured** in respect of each and every **Occurrence** or **Claim** as ascertained after the application of all other terms and conditions of this **Policy**. The **Deductible** will be applied to **Legal Costs**.
- (8) **"Employee"** shall mean any:
  - (a) person under a contract of employment or service or apprenticeship with the **Insured**
  - (b) person acting in the capacity of non-executive director of the **Insured**
  - (c) officer, member or voluntary workers of the organisations or services stated in the **Business**

- (d) prospective employees who are being assessed by the **Insured** as to their suitability for employment
- (e) person undertaking study or work experience or supplied under any youth training or similar government scheme
- (f) self employed person
- (g) person hired or borrowed by the **Insured**
- (h) person employed by labour only sub-contractors
- (i) labour master and persons supplied by a labour master
- (j) person on secondment from another **Insurer** that is not an **Insured** under this **Policy**

while working under the control of the **Insured** on behalf of the **Insured** and in connection with the **Business**.

(9) **"Injury"** means

- (a) death, disease, illness, physical or mental injury to a person;
- (b) harm to a person arising out of false arrest, detention, imprisonment, or invasion of privacy
- (c) harm to a person arising out of wrongful entry into or eviction from a room, dwelling or premises that the person occupies

committed in the course of the **Business**.

(10) **"Insured"** shall mean:

- (a) any person or insured named in the **Schedule** and at the request of the **Insured** shall include subsidiary companies of such insured that are in existence at the inception date of the **Policy** and have been declared to the **Insurer** until such time as they may be sold or otherwise disposed.
- (b) subsidiary companies which may hereafter be constituted or acquired provided that any new acquisition:
  - (i) is declared to Underwriters within 30 days of such creation / acquisition
  - (ii) does not represent a material change to the existing Business
  - (iii) does not represent an increase in wages or turnover of more than 10% of the existing declared wages or turnover.

(11) **"Insurer"** means the party specified as Security in the **Schedule** and any other subscribing insurers.

(12) **"Investigational Product"** means any new drug(s), antibiotic drug(s) or biological drug(s), including a biological product(s) used in vitro for diagnostic purposes, that is used in a **Clinical Trial**.

(13) **"Legal Costs"** shall mean

- (a) costs and expenses (other than claimant costs recoverable from the **Insured**) incurred in the investigation, appraisal, adjustment, defence or settlement of an **Occurrence, Claim, or Circumstance** including expert, legal, appeal and defence costs
- (b) costs of legal representation at any coroners inquest or inquiry in respect of any death
- (c) costs of legal representation at proceedings in any court arising out of any alleged breach of statutory duty resulting in an **Occurrence, Claim, or Circumstance**

incurred with the written consent of the **Insurer**.

- (14) "**Limit of Indemnity**" shall mean the amount stipulated in the **Schedule** which is the maximum amount of the **Insurer's** liability under this **Policy**. Any sub-limit of indemnity stated in the **Schedule** shall be deemed to be part of and not in addition to the **Limit of Indemnity**.
- (15) "**Malpractice**" means any negligent act, negligent error, or negligent omission committed by the **Insured** arising out of the rendering of, or failure to render medical services in the conduct of the **Insured's Business**.
- (16) "**Occurrence**" shall mean an accident or event including continuous or repeated injurious exposure to substantially the same general conditions which results in **Injury** or **Property Damage** neither expected nor intended from the standpoint of the **Insured**.
- (17) "**Period of Insurance**" means the period shown as such in the **Schedule**, where the time taken is as per the time zone at the **Insured's** first named address as detailed on the **Schedule** unless otherwise stated.
- (18) "**Policy**" means this document, the **Schedule** (including any **Schedules** issued in substitution), the **Proposal** and any endorsements attaching to this document or the **Schedule** that will be considered part of the legal contract and any word or expression in bold type face on any of these documents will bear the specific meaning stated in these definitions.
- (19) "**Pollutants**" mean any solid, liquid, gaseous or thermal irritant or contaminant including smoke, vapour, soot, fumes, acids, alkalis, chemicals or waste. Waste is deemed to include materials to be recycled, reconditioned or reclaimed.
- (20) "**Pollution**" means the actual, alleged or threatened discharge, seepage, migration, dispersal, release or escape of **Pollutants** at any time.
- (21) "**Product**" means:
- (a) any goods or products after it has left the custody or control of the **Insured** which have been designed, specified, formulated, manufactured, constructed, installed, sold, supplied, distributed, treated, serviced, altered or repaired by or on behalf of the **Insured**, including all containers, packaging, warnings, instructions and other literature furnished in connection with such goods or products, but shall not mean food and drink supplied by or on behalf of the **Insured** primarily to the **Insured's Employees** as a staff benefit ("Food and Drink")
  - (b) licenses, research results and formulae granted to others whether for a fee or not by the **Insured** or on behalf of the **Insured** with the **Insured's** consent.
- (22) "**Property Damage**" means loss of possession or control of or actual damage to tangible property.
- (23) "**Proposal**" means any information supplied by or on behalf of the **Insured**, deemed to be a completed proposal form, application form, submission and medical questionnaire and other relevant or supplementary information that the **Insurer** may have received or require.
- (24) "**Schedule**" means the document titled Schedule that includes the name and address of the **Insured**, the premium and other variables to this standard policy (including endorsement clauses) and is incorporated in this policy and accepted by the **Insured**. Schedules may be re-issued from time to time where each successor overrides the earlier document.
- (25) "**Territorial Limits**" means such countries as stated in the **Schedule** where the **Occurrence** must happen for indemnity to apply under this **Policy**.
- (26) "**Terrorism**" means an act, including the use of force or violence, of any person or group(s) of persons, whether acting alone or on behalf of or in connection with any organisation(s), committed for political, religious or ideological purposes including the intention to influence any government (de jure or de facto) and/or to put the public in fear for such purposes.
- (27) "**War**" means a state of armed conflict between different countries or different groups within a country including but not limited to invasion, acts of foreign enemies, hostilities, or warlike operations (whether war be

declared or not), civil war, mutiny, revolution, rebellion, insurrection, uprising, military or usurped power or confiscation by order of any public authority or government de jure or de facto or martial law but not including **Terrorism**.

## **COMPLAINTS**

If you are dissatisfied with any aspect of the handling of your insurance contact and have a question or complaint about this insurance or the conduct of its intermediary they should contact that intermediary in the first instance.

If you are still not satisfied, your complaint will be sent to the **Insurer**.

If you remain dissatisfied you can contact the Financial Ombudsman Service at:

South Quay Plaza  
183 Marsh Wall  
London  
E14 9SR

### **DETAILS OF OUR REGULATOR**

All subscribing **Insurers** are authorised by the Prudential Regulation Authority (PRA) and regulated by the PRA and the Financial Conduct Authority (FCA).

Medical & Commercial International is a division of Castel Underwriting Agencies who are authorised and regulated by the FCA.

The FCA website, which includes a register of all regulated firms, can be visited at [www.fca.org.uk](http://www.fca.org.uk).

### **FINANCIAL SERVICES COMPENSATION SCHEME**

All subscribing **Insurers** are members of the Financial Services Compensation Scheme. You may be entitled to compensation from the scheme if they are unable to meet their obligation.

Entitlement to compensation under the scheme depends on the type of business and circumstances of the claim. Further information about compensation scheme arrangements is available from:

The Financial Services Compensation Scheme  
Lloyds Chambers  
Portsoken Street  
London  
E1 8BN

or from their website ([www.fscs.org.uk](http://www.fscs.org.uk)).