

Pharmaceutical and Medical Device Business Questionnaire

Public Liability / Products Liability Insurance



QBE Medical Liability Team

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PHARMACEUTICAL AND MEDICAL DEVICE BUSINESS QUESTIONNAIRE

- ❖ PLEASE READ THE IMPORTANT NOTES PRIOR TO COMPLETING THIS PROPOSAL FORM
- ❖ PLEASE ATTACH PRODUCT BROCHURES AND ADDITIONAL COMPANY INFORMATION AS APPROPRIATE

Name:		
Address:	Registered/Trading Address:	
Postcode:	Postcode:	
Telephone no(s):	Subsidiaries:	
Website:	Trade description:	
Is your company involved in Clinical Trials? If 'YES' then please contact us for specific information required		Yes <input type="checkbox"/>
		No <input type="checkbox"/>
Business type (circle as appropriate): Company / Charity / Trustee of a Trust / Individual		
Number of Employees (circle as appropriate): <10 / 10-49 / 50+		
Assets (circle as appropriate): >=£5m / <5m		

1. PUBLIC AND PRODUCTS LIABILITY		
Estimated annual turnover split between:		
i)	Own Manufacture (where you hold the Product Licence)	£
ii)	Where you hold the Product Licence but manufacture is contracted to third party	£
iii)	Where you Contract Manufacture for third parties	£
iv)	Wholesale (unaltered from manufacturers)	£
v)	Parallel Import / Repackaged or relabelled Wholesale Products	£

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

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

1)		
2)		
3)		
4)		
5)		
6)		
7)		
8)		
9)		
10)		

2. EXPORTS

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

Are any exports sent direct to customer from manufacturers outside the UK?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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If 'YES' please advise territory sent from:
 Is there a formal contract in place regarding Quality Control?

3. USA/CANADA		
Please answer this question ONLY if you export to the USA/Canada.		
(a) A full list of all products exported and turnover derived from each		
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.....		
.....		
(b) Are you required to Indemnify any Vendors and/or Distributors in USA/Canada?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If 'YES' please provide names and addresses If 'NO' do they maintain their own insurance for Completed Operations/Products? State limit if known		
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.....		
.....		

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

5. PRODUCTS		
Do products comply with all relevant:-		
(a) British Standard, Industry and Trade Standards or Government Safety Licensing Regulations or equivalent local legislation?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
(b) Official Standard or Government Regulations laid down in countries to which Products are exported?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Are any new products likely to be marketed during the next 12 months?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If 'YES' please advise product name and product type:		
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.....		

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6. QUALITY CONTROL

(a) Do you have a written policy relating to Quality Control?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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If 'YES', how often is it reviewed?

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(b) Do you have a specific Quality Control Team?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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If 'YES':

(i) Who has overall responsibility?

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

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(c) Does Quality Control involve the testing of a sample percentage of product?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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If 'YES', please state:

(i) Percentage of products checked

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(ii) Failure rate.

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(d) Are sampling inspections made on incoming raw materials?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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(e) What is the procedure for dealing with customers complaints?

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(f) Are records of complaints retained?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If 'YES' for how long?		

7. RECALL

(a) Is it possible to trace the ultimate customer of individual products or batches in order to recall the products?
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(b) Is there an formal procedure for emergency product recall?
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(c) Has recall every been necessary or been considered?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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If 'YES', please give details		
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(d) Please give details of Product lines discontinued because of incidence or injury or damage, or where potential hazards have been identified - stating when manufacture or supply ceased

8. MARKETING

(a) Are products labelled and supplied with clear instructions in the language of the country to which they are supplied?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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(b) Are products hazard warnings clearly shown on Products, Packaging and/or Instruction Manuals?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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(c) Do your Legal and/or Design Departments have sight of all advertising material, sales brochures operating manuals etc. To check for misleading statements?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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(d) Are your Representatives warned against overstating usage or effectiveness of Products?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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9. RECORDS

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

10. 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. THESE EXCLUSIONS MAY BE PARTIALLY DELETED SUBJECT TO APPROPRIATE AND SATISFACTORY INFORMATION.			
2,3,7,8 - Tetrachlorodibenzo-p-dioxin (TCDD)		Lincomycin	
2,4 - Dichlorophenoxyacetic acid (2,4-D) and 2,4,5 - Trichlorophenoxyacetic acid (2,4,5-T)		Lindane	
5-Hydroxytryptophan (5-HTP)		LYMERix (Lyme Disease Vaccine Recombinant OspA)	
8 Hydroxy Quinolines		Megestrol Acetate	
Alosetron		Meloxicam	
Amiodarone		Metformin	
Antipsycotics		Methyl Tertiary Butyl Ether (MTBE)	
Any Product that does not have Regulatory Approval		Methylphenidate (MPH)	
Apomorphine		Metronidazole	
Aprotinin (Bovine Pancreatic Trypsin Inhibitor)		Mibefradil	
Astemizole		Minoxidil	
Atomoxetine		Monoclonal Antibodies (mAb)	
Benfluorex		Nabilone	
Benoxaprofen		Naproxen	
Benzbromarone		Nefazodone	
Blood Borne Pathogens		Nicotine	
Bromfenac		Orlistat	
Bromocriptine		Oxandrolone	
Budesonide		Oxcarbazepine	
Bupropion		Oxycodone	
Butorphanol		Pemoline	

Canthaxanthin		Pergolide	
Cerivastatin and/or any other Statins and/or Fibrates		Pertussis Vaccine	
Chromated Copper Arsenate (CCA)		Phenylpropanolamine (PPA)	
Chromium Picolinate		Pimecrolimus	
Cisapride		Polychlorinated Biphenyls (PCB's)	
Clindamycin		Practolol	
Clioquinol		Pramipexole	
Contraceptives (including birth control pills) fertility drugs and products specifically designed and marketed for use during and in connection with pregnancy		Pramlintide	
Cox-2 Inhibitors		Primodos/Amenorone Forte	
Danthron / Dorbanex		Rapacuronium Bromide	
Debendox		Remoxipride	
Dexfenfluramine, Fenfluramine, Phentermine, or any weight control product		Rimonabant	
Dicyclomine		RotaShield Vaccine	
Diethylstilbestrol (DES)		Salbutamol or Albuterol	
Dimeticone		Selective Serotonin Reuptake Inhibitors (SSRI's)	
Dioxins		Serotonin Norepinephrine Reuptake Inhibitors (SNRI's)	
Doxazosin		Sertindole	
Drugs used in Erectile Dysfunction		Silicone	
Ephedrine / Pseudoephedrine		Skin whitening or lightening agents	
Ephedrine Ma Huang Pseudoephedrin Chinese Ephedra Mahuang Extract Ephedra Ephedra Sinica Ephedra Extract Ephedra Herb Powder Epitonin or any derivative thereof		Somatropin	
Erythropoietin (EPO)		Stavudine	
Ethylenediaminetetraacetic Acid (EDTA)		Sumatriptan	
Etretinate		Swine-Flu Vaccine	
Exenatide		Swiss-Flu Vaccine	
Ezetimibe		Tacrolimus	
Fentanyl		Tegaserod	
Fialuridine		Temafloxacin	
Filgrastim		Terbinafine	
Finasteride		Terbutaline	
Flosequinan		Terfenadine	
Formoterol		Thalidomide	

Gabapentin		Theophylline	
Gamma-Hydroxybutyric Acid (GHB)		Thiazolidinediones (Glitazones)	
Genetically Modified Organisms (GMO's) and/or Genetically Engineered Organisms (GEO's)		Thimerosal or Thiomersal	
Germanium		Tiagabine	
Grepafloxacin		TNF Blockers	
Halons		Tobacco or any Tobacco products	
Hormone Replacement Therapies (HRT's)		Tocrolimus	
Hydromorphone Hydrochloride		Tolcapone	
Hydroquinone		Tretinoin (retinoic acid or its salts)	
Indoprofen		Trovafloxacin or Alatrofloxacin	
Itraconazole		Tryptophan	
Kava Kava (Piper Methysticum)		Urea Formaldehyde or any products containing Formaldehyde	
Ketorolac		Valproic Acid	
Latex and/or latex protein and/or latex derivatives and/or latex substances		Varenicline	
Lead		Vigabatrin	
Leflunomide		Xi-melagatran	
Levomethadyl			
Levomethadyl			
Levonorgestrel			

If you have answered YES to any of the products above please provide full details as follows:		
Are products supplied on a Named Patient Basis only or in held accordance with Specials Licence granted?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If 'YES' please provide details of licence		
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.....		

11. PREMISES		
(a) Have all Manufacturing location been inspected by MHRA/FDA or other regulatory body?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If 'YES' what was date of last inspection?		
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.....		

(b) Have you ever had a manufacturing licence withdrawn?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If 'YES' please give details including remedies		
.....		
.....		
.....		

12. GENERAL

(a) Has any Insurer ever:-		
(i) Declined your proposal for Public and/or Products Liability insurance?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
(ii) Refused your renewal for Public and/or Products Liability insurance?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
(iii) Terminated your insurance for Public and/or Products Liability insurance?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

If 'YES' please give full details

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(b) Have any incidents occurred during the last five years resulting, or alleged to have resulted in death, injury or disease to third parties or damage to their property?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If 'YES' please give full details		

Date	Brief Details of Incident whether or not an insurance claim has been made	Paid Amount	Insurers Outstanding Reserve

If possible please supply confirmed claims experience from previous / current Insurers

(c) Are you aware of any circumstances that might give rise to a claim?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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If 'YES' please give full details

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<p>(d) Please state if your existing cover for Products Liability is on a "Claims made" basis or a "Losses occurring" basis.</p> <p>_____</p> <p>_____</p> <p>If on a "Claim made" basis please state retroactive date currently applied to your policy</p> <p>_____</p> <p>_____</p>		
<p>(e) Who are your current Insurer(s)? If currently uninsured please state.</p> <p>_____</p> <p>_____</p> <p>_____</p>		
<p>(f) What is the renewal date of your current Insurance policy covering Public and Products Liability?</p> <p>_____</p> <p>_____</p> <p>_____</p>		
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%;">Please state Limit(s) of Indemnity for which a quotation is required or local currency equivalent</td> <td style="width: 30%; text-align: center;">£</td> </tr> </table>	Please state Limit(s) of Indemnity for which a quotation is required or local currency equivalent	£
Please state Limit(s) of Indemnity for which a quotation is required or local currency equivalent	£	

DECLARATION

I/we declare that to the best of my/our knowledge and belief the answers given on this proposal whether by me/us or on my/our behalf, are complete and true and that I/we have not withheld any material information.

If this proposal has been completed on my/our behalf, I/we agree the person is deemed to be my/our agent and not an agent for QBE Insurance (Europe) Limited and that I/we have read the information provided before signing the form.

I/We confirm that I/we have read and understood the above declaration and the important notes overleaf.

Proposer's Signature _____ Date _____

If in company name, state position held _____

The proposal must be signed by a principal, director or partner of the proposed insured.

IMPORTANT NOTES

Company information

QBE Insurance (Europe) Limited (company number 1761561) is authorised and regulated by the Financial Services Authority (registration number 202842).

QBE Underwriting Limited is the managing agent of QBE Casualty Syndicate 386 at Lloyd's; QBE Syndicate 1886 at Lloyd's and QBE Property Syndicate 200 at Lloyd's.

QBE Underwriting Services (UK) Limited (company number 02262145) is an Appointed Representative of QBE Underwriting Limited (company number 01035198) and is authorised and regulated by the Financial Services Authority (registration number 204858).

The registered address for all the above is: Plantation Place, 30 Fenchurch Street, London EC3M 3BD.

Statement on completion

You must answer all questions correctly and provide all material information. Failure to do so may prejudice you under the policy or the premium that you are requested to pay. Answers such as 'see presentation' or 'see your records' should not be used. If there is insufficient space to answer questions, please use an additional sheet and attach to this form.

If you are unclear as to what is required in response to any question please contact your intermediary.

If there be any material change in, or material addition to, the information given in this proposal form you must notify us writing as soon as practical after you become aware of any such change or addition.

Full details of the policy cover, terms and condition are available on our website at www.qbeurope.com. Alternatively please ask you intermediary for a full copy of the policy.

Choice of contract law

Your policy will be governed by and interpreted in accordance with the laws and jurisdiction stated in the schedule of the policy wording. Both you and us agree to submit to the jurisdiction of any court of competent jurisdiction within the country, state or territory stated as being applicable to comply with all requirements necessary to give such court jurisdiction.

Data Protection

Your information may be disclosed to agents and service providers appointed by us, such as claims handling agents and investigative agents. Your information may also be transferred to any country including countries outside the European Union, for the purpose of administration. Your information may be shared with other members of QBE Insurance Group. We are committed to ensuring that our customers' personal information is protected. All personal information is treated in compliance with the Data Protection Act 1998 and we are registered on the Data Protection Register.

If at any time you wish to contact us with any enquiry relating to our practices governing the use of your personal information or for a copy of our data protection policy, you can do so by writing to:

The Compliance Officer, QBE Insurance (Europe) Limited, Plantation Place, 30 Fenchurch Street, London EC3M 3BD.

Complaints

If You have a question or complaint about this application for insurance or the conduct of its intermediary You should contact that intermediary in the first instance. If You wish to contact the us directly you should write to the address above. Please quote the quote reference or policy number as appropriate in any correspondence.

In the event that you remain dissatisfied and where the insurer is or includes a Lloyd's syndicate it may be possible in certain circumstances to refer the matter to the Policyholder and Market Assistance Department at Lloyd's, One Lime Street, London EC3M 7HA; Tel: 020 7327 5693.

If, after making a complaint you feel that the matter has not been resolved to your satisfaction then if you are an eligible complainant you may contact: The Financial Ombudsman Service, South Quay Plaza 2, 183 Marsh Wall, Docklands, London E14 9SR.

A summary of our complaint handling procedure is available on request and will also be provided to you when acknowledging a complaint.



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