MD29

DEPARTMENT OF HEALTH

MISUSE OF DRUGS ACT 1971
APPLICATION FOR LICENCES FOR THE POSSESSION, SUPPLY, MANUFACTURE AND PRODUCTION OF CONTROLLED DRUGS

DETAILS OF LICENCE APPLICANT

1. Name of Business

2. Registered Business Number

Please provide a copy of the Certificate of Company Registration/Incorporation. If the business is not registered, please provide reasons

3. Registered Business Address

Postcode:

4. Address of Premises for which a Licence is sought (If different from 3. above)

Postcode:

5. Other contact details

Telephone Number:
Email Address
Fax Number
Website

6. Is the Company/Organisation a Registered Charity? Yes/No

If Yes, please specify below your Charity Registration Number and registration date

7. Details of Managing Director/Person in Charge

Name
Title
Telephone Number
Email Address
Fax Number
Address (if different from 3 above)

8. Has the company/organisation ever been refused a licence from a central and/or local government body or Issuing Authority, including the police?
Yes/No

9. If the answer to 8 is YES, please specify details below

10. Does the registered business comprise

(i)	A limited company	Yes/No
(ii)	An individual	Yes/No
(iii)	A group of individuals (i.e. a partnership)	Yes/No
(iv)	A body corporate	Yes/No
(v)	None of the above	Yes

11. If you have answered YES to 10(v), please specify details below

12. What is the business/trading style in regard to your licensing requirement?

(i)	Pharmaceutical Manufacturer/Producer (delete as appropriate)	Yes/No
(ii)	Pharmaceutical Wholesaler	Yes/No
(iii)	Veterinary Wholesaler	Yes/No
(iv)	Healthcare Distributor	Yes/No
(v)	Product Packaging/labelling	Yes/No
(vi)	Importer	Yes/No
(vii)	Exporter	Yes/No
(viii)	Private Hospital/Treatment Centre/Clinic (delete as appropriate)	Yes/No
(ix)	Doctors Deputising Service	Yes/No
(x)	Drugs Research and Development	Yes/No
(xi)	Private forensic/Toxicology Service (delete as appropriate)	Yes/No
(xii)	None of the above	Yes

13. If you have answered YES to 12(xii), please specify details below

14. Please state below the purposes(s) for which a licence/licences is/are being sought

15. If you have answered YES to 12(i), please specify details of all preparations to be produced by virtue of the licence(s) for which application is made.

Drug	**Form**	**Schedule**	**Drug**	**Form**	**Schedule**

16. If you have answered YES to 12(vi) and/or 12(vii), please specify details below:

Drug	**Form**	**Schedule**	**Quantity**	**Import/Export Country**

17. Please specify below the number and type of companies that will comprise your customer base

18. Does the business possess a current Wholesale Dealers Licence or other MHRA licence(s)?

Yes/No

If you have answered YES, please specify details below

Licence No.	**Type of Licence**	**Issue Date**	**Expiry Date**

19. Does the business possess a current RQIA registration? Yes/No

If you have answered YES, please specify details below

Registration No.	**Issue Date**	**Expiry Date**

(You should be prepared to produce, upon request, your MHRA licence(s) and/or your Registration documents.)

DETAILS OF PREMISES TO BE LICENSED

20. Are the premises to be licensed rented, leased or owned (Please tick appropriate box below)?

Rented **Leased** **Owned**

21. If the premises are rented or leased, please state below details regarding owner

Name of Owner:
Address:

Postcode:
Telephone number:

22. What is the total commercial value of controlled drug stock held in (a) Schedule 1 & 2; and (b) Schedule 3 (Buprenorphine, Diethylpropion, Flunitrazepam and Temazepam only) Delete as necessary.

(a) (i) Up to £50,000
(ii) £50,000 - £500,000
(iii) Over £500,000

(b) (i) Up to £50,000
(ii) £50,000 - £500,000
(iii) Over £500,000

23. Do the premises have an electronic alarm system? Yes/No

24. If you answered yes is it (tick box)

NACOSS/SSAIB Registered
Redcare Connected
Police Unique Reference Number (URN)
Centrally Monitored
Annually Serviced
Level 1 or immediate police response
Separate zone alarm for controlled drug safe/store

25. Do the premises have:

(i)	A CCTV system (centrally monitored *)	Yes/No
(ii)	Electronic stock recording system(s)	Yes/No
(iii)	Perimeter fencing	Yes/No
(iv)	Lockable physical security e.g. room, safe, cabinet	Yes/No
(v)	The attendance of site security guards	Yes/No

* Please delete if not applicable

26. Please state below the details of the manager/person responsible for the security of the premises to be licensed.

Name
Title
Telephone Number
Email Address
Fax Number

27. You need to have on site arrangements for the receipt, storage, assembly, picking, distribution, recording and destruction of Controlled Drugs written down as a set of Standard Operating Procedures (SOPs). Do you have these?

28. Please state below the details of the manager/person responsible for legal compliance and regulatory affairs in respect of the premises to be licensed.

Name
Address

Postcode
Telephone Number
Email Address
Fax Number

Please note that the manager/responsible person will be expected to ensure that there is full compliance with the statutory requirements of the Misuse of Drugs Act 1971, the Misuse of Drugs Regulations (Northern Ireland) 2002, the stipulated conditions on any licence that may be issued and that there will be in place written operating procedures that should accompany this application.

29. Is your 'Responsible Person' an employee or a consultant (please delete as appropriate)

30. Do you have the appropriate record keeping system in place? Yes/No

31 Please provide brief details of your record keeping

32. Do you require somebody within your company to be authorised to witness the destruction of controlled drugs? Yes/No

33. Please provide details of the nominated authorised witness:

Name
Title
Telephone number
Email address
Fax number
Address*
line 2
line 3
postcode

SELECTION OF CONTROLLED DRUGS FOR INCLUSION ON LICENCE(S)

34. **Please complete the attached Annex to this Application Form**

DECLARATION UNDER MISUSE OF DRUGS ACT 1971

35. I/We hereby apply for the grant of DOH drugs licence(s) in respect of those activities included in this Application Form.

36. To the best of my/our knowledge and belief all the particulars I/we have declared in this Application Form are correct and complete.

Signature(s):

Name(s) (BLOCK CAPITALS):

Position(s) held:

Date of signature:

APPLICATION FORM – GENERAL NOTES

37. Offences under Section 18(4)(a) of the Misuse of Drugs Act 1971. This Section of the Act provides that a person commits an offence if, for the purposes of obtaining, whether for himself or another, the issue or renewal of a licence under the Misuse of Drugs Act 1971, he makes any statement or gives any information which he knows to be false in a material particular or recklessly gives any information which is false. Being found guilty of this offence is punishable by fine and/or imprisonment of up to 2 years.

38 Confidentiality. Information provided in this Application Form and attached 'Drugs List' will be treated as Commercial-in-Confidence.

39. Signature(s) on Application Form. Applications will not be considered unless they bear the signature of the applicant, a company partner or director, or the company secretary.

RETURN OF APPLICATION FORM/CONTROLLED DRUGS ANNEX

40 These documents should be returned to

Department of Health
Medicines Regulatory Group
Room D4.29
Castle Buildings, Stormont
BT4 3SQ

41. You should take a copy of the completed Application Form and Annex for your retention.

42. Where the Application Form and controlled drugs Annex do not provide sufficient space to include all requested information, please provide typed supplementary sheets as appropriate.

FURTHER LICENSING INFORMATION/CONTACT POINTS

43. For further information and advice about licensing matters, including the completion of this Application Form, you should contact Mr Canice Ward on:

Telephone No.	028 90 523703
Fax No.	028 90 522325
Email	canice.ward@health-ni.gov.uk

Department of Health
Medicines Regulatory Group
Room D4.29
Castle Buildings
Stormont
BT4 3SQ

SELECTION OF CONTROLLED DRUGS AND TYPE OF LICENCES REQUIRED

1. **Please tick appropriately** the boxes in the list below to indicate the controlled drugs (CDs) and the type of licence(s) for which application is being made.

2. The drugs listed below are those most commonly in use and have been divided into their respective Schedules in accordance with the Misuse of Drugs Legislation. Space has been left for the inclusion of drugs not listed.

Names of Controlled Drugs (CDs) in their respective Schedules	**TYPE OF LICENCE**							
	To manufacture Base Drug(s)	**To produce CDs in the Schedules**					**To supply and offer to supply**	**To possess only**
		1	**2**	**3**	**4**	**5**		
Schedule 1								
Cannabis								
Cathinone								
Coca Leaf								
Concentrate of Poppy Straw								
Ecstasy (MDMA)								
Etryptamine								
Lysergide								
Mescaline								
Methcathinone								
Psilocin								
Raw Opium								
others (please specify)								
Schedule 2								
Alfentanil								
Amphetamine								
Cocaine								
Codeine								
Dextromoramide								
Dextropropoxyphene								
Diamorphine								
Dihydrocodeine								
Dihydroetorphine								
Dipipanone								
Ethlymorphine								
Etorphine								
Fentanyl								
Hydromorphone								
Medicinal Opium								
Methadone								

Names of Controlled Drugs (CDs) in their respective Schedules	TYPE OF LICENCE								
	To manufacture Base Drug(s)	To produce CDs in the Schedules					To supply and offer to supply	To possess only
		1	2	3	4	5		
Methylphenidate								
Morphine (inc.papaveretum)								
Oxycodone								
Pethidine								
Phenazocine								
Phenmetrazine								
Pholcodine								
Remifentanil								
Secobarbital								
Others (please specify)								
Schedule 3								
Allobarbital								
Amylobarbitone								
Barbital								
Buprenorphine								
Butobarbital								
Cathine								
Cyclobarbital								
Midazolam								
Meprobamate								
Pentazocine								
Pentobarbital								
Phenobarbitone								
Temazepam								
others (please specify)								
Schedule 4.1								
Alprazolam								
Bromazepam								
Clorazepate								
Chlordiazepoxide								
Clobazam								
Clonazepam								
Diazepam								
Flurazepam								
Loprazolam								
Lorazepam								
Lometazepam								
Nitrazepam								
Oxazepam								
Triazolam								
Zolpidem								
others (please specify)								

Names of Controlled Drugs (CDs) in their respective Schedules	TYPE OF LICENCE								
	To manufacture Base Drug(s)	To produce CDs in the Schedules					To supply and offer to supply	To possess only
		1	2	3	4	5		
Schedule 4.2								
Chorionic gonadotrophin (HCG)								
Clenbuterol								
Gonadtrophin								
Mesterolone								
Non-human chorionic gonadotrophin								
Prasterone								
Somatropin								
Stanozolol								
Testosterone								
Trenbolone								
others (please specify)								
Schedule 5								
Codeine								
Dextropropoxyphene								
Dihydrocodeine								
Diphenoxylate								
Morphine								
Pholcodine								
others (please specify)								

Note:

No licence is required to "possess" Schedule 5 controlled drugs when in the form of a medicinal product.