



Home Office

UNITED KINGDOM CONTROLLED DRUG LICENCE

MISUSE OF DRUGS ACT 1971

The Misuse of Drugs Regulations 2001 (Regulations 5)

UNITED KINGDOM COMPETENT AUTHORITY: HOME OFFICE DRUGS & FIREARMS LICENSING (DFLU) 5TH FLOOR FRY BUILDING 2 MARSHAM STREET LONDON SW1P 4DF	LICENCE HOLDER REF NO.	1547
	LICENCE REF NO	546061
	ISSUE DATE:	9 July 2019
	EXPIRY DATE:	8 July 2020

Licensee-	Licensed Premises:
SIGMA PHARMACEUTICALS PLC Units 1-7 Colonial Way, Watford, WD24 4YR	Unit 7 & A Plant Colonial Way Watford Hertfordshire WD24 4YR

Is hereby granted a licence by the Secretary of State, in pursuance of the Misuse of Drugs Act 1971 (hereinafter called "the 1971 Act), in respect of drugs in the following Schedule(s) to the Misuse of Drugs Regulations 2001 SI 2001/3998 to:

- Schedule 2 possess
- Schedule 2 supply
- Schedule 3 possess
- Schedule 3 supply
- Schedule 4 part 1 possess
- Schedule 4 part 1 supply
- Schedule 4 part 2 possess
- Schedule 4 part 2 supply

The licence is valid in respect of the above drugs, including any stereoisometric forms, and any salts thereof, and any preparation or other product containing any proportion of the drug(s) or its/ their salts (hereinafter called "the drug(s)"), subject to the following conditions:

Security

Stocks of drugs shall, at all times, be in the charge of the licensee or responsible person appointed by him and will be kept securely.

All drugs subject to the 'safe storage' provisions specified in the Misuse of Drugs (Safe Custody) Regulations 1973 (those listed in Schedules 1 and 2 & certain Schedule 3 drugs) shall be securely stored in accordance with those provisions.

Record Keeping

The licensee shall keep records: in accordance with the record keeping requirements set out in the Misuse of Drugs Regulations 2001, unless the provisions set out in regulation 19(3) apply. Those records, which may be in (bound) hard copy or electronic form, must be retained at the premises to which they relate, for a period of at least two years from the date the last entry is made. Where specified by the Regulations, 'registers' must be maintained in accordance with those Regulations. You may be required to produce in paper form pages from your computerised record.

The licence and any stocks of drugs shall be produced for inspection when required by any person duly authorised under section 23 of the 1971 Act.

In the event of the licensee ceasing to require a licence or licence(s) above at the licensed premises, or if the authority of the licence is revoked by the Secretary of State, the licensee shall return the licence immediately to the address below. The licensee must provide full details in respect of the destruction of any residual stocks of controlled drugs.

Authorised Witness

In accordance with the provisions of Regulation 27(1) of the Misuse of Drugs Regulations 2001:

Alison McNichol (hereinafter called "the authorised person") is hereby authorised to supervise the destruction of drugs in the above licensed schedules held at the licensee's premises. In accordance with regulation 27(3), any record that is kept in respect of the obtaining or supplying those drugs that are destroyed under the supervision of the authorised person shall include particulars of the dates of any such destruction, the quantities of the drug destroyed and shall be signed by the authorised person in whose presence the drug must be destroyed.

Thefts and Losses

The licensee must take reasonable precautions to safeguard theft or loss of any drugs in their possession. Thefts or losses should be notified immediately to the Police and the Home Office in writing.

Furnishing of information

The licensee must furnish the Secretary of State such information in relation to this licence as may be required, in accordance with

the requirements set out in Regulation 26(1) to the Misuse of Drugs Regulations 2001.


In addition to the record keeping requirements detailed above, the licensee must provide the following information to the Head of Drug Licensing at the address below and where required, an 'Annual Statistical Return' **by the last day in January each year at the latest of:-**

- The amount of the drug in his possession or coming into his possession
- The amount of the drug supplied; and
- The amount of the drug used

THIS LICENCE IS NOT VALID WITHOUT AN EMBOSSED SEAL IN THIS BOX



SIGNATURE AND NAME OF ISSUING OFFICER

 M. O'SULLIVAN

CONDITIONS

1. This licence is invalid if amended. If amendments are required - including changes of company name or named individuals- this licence should be returned to Drugs & Firearms Licensing Unit (DFLU) for cancellation and a fresh application submitted.
2. This licence is only valid for the Schedule(s) of drugs and activities as specified above.
3. This licence is only valid for the company and premises specified above. It is not transferable to another company or premises.
4. All individuals named on the licence application must obtain refreshed enhanced DBS checks (in accordance with the provisions in SI 2009/1818) at the required frequency.
5. This licence is only valid until the expiry date above, must be retained for inspection and may be revoked at any time by the Secretary of State.
6. Expired licences cannot be extended. Licensees are responsible for submitting a valid application for a further licence, before the expiry date of this licence, in order to preserve the conditions of the licence whilst a decision is pending on a further licence.
7. If this licence is not used it must be returned to DFLU clearly marked for cancellation.