Chapter:	134A	**DANGEROUS DRUGS REGULATIONS**	Gazette Number	Version Date
		Empowering section		30/06/1997

(Cap 134 section 51)

[17 January 1969]

(Originally L.N. 113 of 1968)

Regulation:	1	**Citation**		30/06/1997

These regulations may be cited as the Dangerous Drugs Regulations.

Regulation:	2	**Interpretation**		30/06/1997

In these regulations, unless the context otherwise requires-

"identity card" (身分證) means an identity card issued under the Registration of Persons Ordinance (Cap 177) and includes a permanent identity card; (L.N. 191 of 1996)

"proof of identity" (身分證明文件) means any proof of identity specified in section 17B(1) of the Immigration Ordinance (Cap 115); (L.N. 191 of 1996)

"retail business" (零售業務) means the business of retailing, dispensing or compounding dangerous drugs carried on at a shop;

"retail dealer" (零售商) means a person who carries on a retail business.

(L.N. 191 of 1996)

Regulation:	3	**Requirements with respect to prescriptions**	2 of 2012	17/02/2012

(1) A person by whom a prescription prescribing a dangerous drug is given shall comply with the following requirement that is to say, the prescription shall-

(a) be in writing and signed by the person giving it with his usual signature, and be dated by him;

(b) be in ink or otherwise so as to be indelible;

(c) specify the address of the person giving it;

(d) specify the name, identity card number and address of the person for whose treatment it is given or, if it is given by a registered veterinary surgeon, of the person to whom the article prescribed is to be delivered; (L.N. 191 of 1996; L.N. 556 of 1997)

(e) have written thereon-

(i) if given by a registered dentist, the words "For local dental treatment only" (僅供本地牙治療之用); and

(ii) if given by a registered veterinary surgeon, the words "For animal treatment only" (僅供動物治療之用); (L.N. 556 of 1997)

(f) if the dangerous drug prescribed is a preparation, or if all the dangerous drugs prescribed are preparations,- (L.N. 191 of 1996)

(i) specify the total amount of the preparation or of each preparation, as the case may be; or

(ii) when the preparation is packed in ampoules, either specify as aforesaid or specify the total amount of the preparation or of each preparation, as the case may be, intended to be administered or injected; and

(g) if the dangerous drug is not a preparation, specify the total amount of the drug to be supplied. (L.N. 191 of 1996)

(2) In the case of a prescription given for the treatment of a patient in a prescribed hospital, a health centre maintained by the Government or a health centre of the Hong Kong Garrison, sub-paragraph (d) of paragraph (1) shall be deemed to have been complied with if the prescription is written on the patient's bed card or case sheet, and in such

a case the initials of the person giving the prescription shall be a sufficient signature for the purposes of sub-paragraph (a) of paragraph (1). (2 of 2012 s. 3)

(3) For the purpose of paragraph (1)(d), in the case of a person who is not resident in Hong Kong, the reference number of any proof of identity other than an identity card shall be specified in the prescription. (L.N. 191 of 1996)

[cf. S.I. 1964/1811 reg. 14 U.K.]

Regulation:	4	**Marking of packages and bottles**		30/06/1997

(1) Save as provided in paragraph (2), no person shall-

(a) supply a dangerous drug, other than a preparation, unless the package or bottle in which it is contained is plainly marked with the amount of the dangerous drug contained therein; or

(b) supply a preparation, unless the package or bottle in which it is contained is plainly marked-

(i) in the case of a powder, solution or ointment, with the total amount thereof in the package or bottle and the percentage of the dangerous drug contained in the powder, solution or ointment; or

(ii) in the case of cachets, single dose injections, lozenges, suppositories, pills, tablets or similar articles, with the amount of the dangerous drug in each article and the number of articles in the package or bottle.

(2) Paragraph (1) does not apply-

(a) in a case where a preparation is lawfully supplied by a registered medical practitioner;

(b) in a case where a preparation is lawfully supplied on a prescription lawfully given by a registered medical practitioner; or

(c) in relation to the supply of a dangerous drug specified in Part III of the First Schedule to the Ordinance.

(3) Any person who contravenes paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine of ten thousand dollars and to imprisonment for twelve months.

[cf. S.I. 1964/1811 reg. 16 U.K.]

Regulation:	5	**Keeping of register or other records**	L.N. 556 of 1997; L.N. 3 of 1999	15/01/1999

(1) Every person authorized by or licensed under the Ordinance to supply a dangerous drug, except a sister authorized by section 22 of the Ordinance, shall comply with the following provisions, that is to say-

(a) he shall, in accordance with this regulation and regulation 6, keep a register and enter therein in chronological sequence in the form specified in the First Schedule true particulars with respect to every quantity of a dangerous drug, other than a preparation specified in Part II of the First Schedule to the Ordinance, obtained by him and with respect to every quantity of a dangerous drug, other than a preparation specified in Part II of the First Schedule to the Ordinance, supplied by him, whether to persons within or outside Hong Kong;

(b) he shall use a separate register or separate part of the register for entries made with respect to each of the dangerous drugs specified in paragraph 1 of Part I of the First Schedule to the Ordinance or in paragraph 2, 3, 4, 5, 6 or 7 thereof and for this purpose-

(i) each such drug shall be deemed to comprise its salts and any preparation, admixture, extract or other substance containing any proportion of it or its salts; and

(ii) any isomer of a dangerous drug the existence of which is possible within its specific chemical designation shall be deemed to be identical with that drug;

(c) he shall use a separate page within the register or separate part of the register for entries made with respect to different dangerous drugs and different strengths of preparations comprised within the class of dangerous drugs to which that register or separate part relates. (L.N. 191 of 1996)

(2) (Repealed L.N. 191 of 1996)

(3) Where a registered medical practitioner, a registered dentist, a registered veterinary surgeon or a specified person obtains or supplies any dangerous drug (which, in the case of the specified person, means a specified dangerous drug) packed in ampoules, he shall be deemed to have complied with the requirements- (2 of 1992 s. 13; L.N. 556 of 1997)

(a) of paragraph (1) in regard to entry in the register required to be kept under that paragraph of true particulars with respect to every quantity of every dangerous drug obtained or supplied; or

(b) (Repealed L.N. 191 of 1996)

if he enters as the amount which he has obtained or supplied, as the case may be, true particulars as to either the total quantity of the dangerous drug or the total quantity thereof intended to be administered or injected.

(4)-(5) (Repealed L.N. 191 of 1996)

(6) (a) Subject to sub-paragraph (c), a manufacturer of any preparation specified in Part II of the First Schedule to the Ordinance and a wholesale dealer in any such preparation shall keep every invoice or other like record issued in respect of each quantity of any such preparation obtained by him and in respect of each quantity of any such preparation supplied by him.

(b) A retail dealer in any such preparation shall keep every invoice or other like record issued in respect of each quantity of any such preparation obtained by him.

(c) Sub-paragraph (a) does not apply in the case of a preparation manufactured by a registered medical practitioner, or by a person referred to in subsection (5) of section 22 of the Ordinance, under the authority conferred by sub-section (4) or (5) of the said section 22, as the case may be.

(7) Any person who contravenes any of the provisions of paragraph (1) or (6) shall be guilty of an offence and shall be liable on conviction to a fine of $450000 and to imprisonment for 3 years. (L.N. 191 of 1996; L.N. 201 of 1996)

(8) It is a defence for a person charged with committing an offence under paragraph (7) in relation to paragraph (1) to show that he took all reasonable steps and exercised all due diligence to avoid committing the offence. (L.N. 288 of 1996)

[cf. S.I. 1964/1811 reg. 17 U.K.]

Regulation:	6	**Requirements as to registers**		30/06/1997

The following requirements shall be complied with by any person required to keep a register under regulation 5, that is to say-

(a) there shall be specified at the head of any page of such register-

(i) the class of dangerous drugs; and

(ii) where applicable, the particular dangerous drug and the particular strength of the preparation comprised within such class,

to which the entries on that page relate; (L.N. 191 of 1996)

(b) every entry required to be made under regulation 5 in such register shall be made on the day on which the dangerous drug is received or, as the case may be, on which the transaction with respect to the supply of the dangerous drug by the person required to make the entry takes place, or, if that is not reasonably practicable, on the day next following the said day;

(c) no cancellation, obliteration or alteration of any such entry shall be made, and every correction of such an entry shall be made only by way of a marginal note or footnote which shall specify the date on which the correction is made;

(d) every entry required to be made under regulation 5 in such register, and every correction of such an entry, shall be made in ink or otherwise so as to be indelible;

(e) such a register shall not be used for any purpose other than the purposes of the Ordinance;

(f) such person shall if so required by the Director or any public officer authorized in writing by the Director in that behalf-

(i) furnish such particulars as may be required with respect to the obtaining or supplying by him of any dangerous drug, or with respect to any stock of dangerous drugs in his possession;

(ii) for the purpose of confirming any such particulars, produce any stock of dangerous drugs in his possession; and

(iii) produce such register and such other books or documents in his possession relating to any dealings in dangerous drugs as may be required;

(g) a separate register shall be kept in respect of each set of premises at which the person required to keep the register carries on business, but save as aforesaid not more than one register shall be kept at one time in respect of each class of dangerous drug in respect of which he is required to keep a separate register or part of a register, so, however, that a separate register may, with the approval of the Director, be kept in respect of each department of the business carried on by him;

(h) every such register shall be kept at the premises to which it relates and so as to be at all times available for inspection.

[cf. S.I. 1964/1811 reg. 25 U.K.]

Regulation:	7	**Preservation of documents**		30/06/1997

(1) All registers, records, books, prescriptions and other documents which are kept, issued or made pursuant to the requirements, or for the purposes, of the Ordinance shall be preserved-

(a) in the case of a register, book or other like record, for a period of two years from the date on which the last entry therein is made; and

(b) in the case of any other document, for a period of two years from the date on which it is issued or made.

(2) In the case of any document kept pursuant to paragraph (6) of regulation 5, the keeping of a copy thereof made at any time during the said period of two years shall be treated for the purposes of paragraph (1) as if it were the keeping of the original document.

(3) Any person who contravenes any of the provisions of paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine of ten thousand dollars and to imprisonment for twelve months.

[cf. S.I. 1964/1811 reg. 26 U.K.]

Regulation:	8	**Validity of licence under section 18 and fee therefor**		30/06/1997

(1) A licence issued under section 18 of the Ordinance shall be valid until the 1st day of January next following the day on which it is issued.

(2) The fees specified in the Second Schedule shall be payable on the issue of the licences under section 18 of the Ordinance therein specified.

Regulation:	9	**(Repealed 31 of 1969 s. 7)**		30/06/1997

Schedule:	1	**FORM OF REGISTER**		30/06/1997

[regulation 5]

Date of receipt/ supply	Name and address of person* or firm from whom received/to whom supplied	Patient's identity card number+	Amount		Invoice No.	Balance
			received	supplied		

* Cross reference of the person to whom supplied may be made in which case only the reference number of the person's treatment record needs to be given.

\+ For a patient who is not resident in Hong Kong, the reference number of any proof of identity, other than an identity card, specified in section 17B(1) of the Immigration Ordinance (Cap 115) shall be inserted.

(L.N. 191 of 1966)

Schedule:	2	**LICENCE FEES**	L.N. 77 of 2006	01/07/2006

[regulation 8]

Item	Licence	Fee
1.	Licence to manufacture dangerous drug	$1540

2. Wholesale dealer's licence to supply dangerous drug $860

(L.N. 182 of 1989; L.N. 522 of 1994; L.N. 77 of 2006)

Schedule:	3	**(Repealed 31 of 1969 s. 7)**		30/06/1997