

Regulations 19 and 20

Record-keeping requirements in respect of drugs in Schedules 1 and 2

19. — (1) Subject to paragraph (3) and regulation 21, every person authorised by or under regulation 5 or 8 to supply any drug specified in Schedule 1 or 2 shall comply with the following requirements, that is to say –

(a) he shall, in accordance with the provisions of this regulation and of regulation 20, keep a register and shall enter therein in chronological sequence subject to sub-paragraph (f), using the headings specified in sub-paragraphs (d) and (e), particulars of every quantity of a drug specified in Schedule 1 or 2 obtained by him and of every quantity of such a drug supplied (whether by way of administration or otherwise) by him whether to persons within or outside Northern Ireland;

(b) he shall use a separate register or separate part of the register for entries made in respect of each class of drugs, and each of the drugs specified in paragraphs 1 and 3 of Schedule 1 and paragraphs 1, 3 and 6 of Schedule 2 together with its salts and any preparation or other product containing it or any of its salts shall be treated as a separate class, so however that any stereoisomeric form of a drug or its salts shall be classed with that drug.

(d) The headings in respect of entries made for drugs obtained are. —

- (i) Date supply received;
- (ii) name and address from whom received;
- (iii) Quantity received.

(e) The headings in respect of entries made for drugs supplied are—

- (i) Date supplied;
- (ii) Name/Address of person or firm supplied;
- (iii) Details of authority to possess— prescriber or licence holder's details;
- (iv) Quantity supplied;
- (v) Person collecting Schedule 2 controlled drug (patient/patient's rep/healthcare professional) and if healthcare professional, name and address;
- (vi) Was proof of identity requested of patient/patient's rep (Yes/No);
- (vii) Was proof of identity of person collecting provided (Yes/No).

(f) The headings at sub-paragraph (e)(v) to (vii) apply only in respect of drugs specified in Schedule 2.

(2) Entries made in respect of drugs obtained and drugs supplied may be made on the same page or on separate pages in the register.

(2A) Subject to regulation 20(e), nothing in paragraphs (1) shall prevent the use of a register to record additional information to that required or allowed under those provisions.

- (3) The foregoing provisions of this regulation shall not have effect in relation to –
- (a) in the case of a drug supplied to him for the purpose of destruction in pursuance of regulation 6(2) or (3), a practitioner or pharmacist;
 - (b) a person licensed under regulation 5 to supply any drug, where the licence so directs; or
 - (c) the senior registered nurse or acting senior registered nurse for the time being in charge of a ward, theatre or other department in a hospital or nursing home.

Requirements as to registers

20. Any person required to keep a register under regulation 19 shall comply with the following requirements, that is to say –

- (a) in the separate register or separate part of the register used for each class of drug, a separate page shall be used in respect of each strength and form of that drug and the head of each such page shall specify the class of the drug, its strength and form.
- (b) every entry required to be made under regulation 19 in such a register shall be made on the day on which the drug is obtained or, as the case may be, on which the transaction in respect of the supply of the drug by the person required to make the entry takes place or, if that is not reasonably practicable, on the day next following that day;
- (c) no cancellation, obliteration or alteration of any such entry shall be made, and a correction of such an entry shall be made only by way of marginal note or footnote which shall specify the date on which the correction is made;
- (d) every such entry and every correction of such an entry shall be made in ink or otherwise so as to be indelible or shall be in a computerised form in which every such entry is attributable and capable of being audited and which is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the National Health Service Act 1977;
- (e) such a register shall not be used for any purpose other than the purposes related to these Regulations;
- (f) a separate register shall be kept in respect of each premises at which the person required to keep the register carries on his business or occupation, but subject to that not more than one register shall be kept at one time in respect of each class of drugs in respect of which he is required to keep a separate register, so, however, that a separate register may, with the approval of the Department, be kept in respect of each department of the business carried on by him;
- (g) every such register in which entries are currently being made shall be kept at the premises to which it relates and, where the register is in computerised form, be accessible from those premises.