SCHEDULE 5

OTHER CONTRACTUAL TERMS

PART 3

PRESCRIBING AND DISPENSING

Prescribing

38. The contractor shall ensure that any prescription form for drugs, medicines or appliances issued by a prescriber complies as appropriate with the requirements in paragraphs 39, 40 and 41.

39.—(1) Subject to paragraphs 40 and 41, a prescriber shall order any drugs, medicines or appliances which are needed for the treatment of any patient who is receiving treatment under the contract by issuing to that patient a prescription form and such a prescription form shall not be used in any other circumstances.

(2) In issuing any such prescription form the prescriber shall himself sign the prescription form in ink with his initials, or forenames, and surname in his own handwriting and not by means of a stamp and shall so sign only after particulars of the order have been inserted in the prescription form, and –

(a) the prescription form shall not refer to any previous prescription form; and

(b) a separate prescription form shall be used for each patient.

(3) Where a prescriber orders the drug buprenorphine or a drug specified in Schedule 2 to the Misuse of Drugs Regulations (Northern Ireland) 2002 (controlled drugs to which regulations 14, 15, 16, 18, 19, 20, 21, 23, 26 and 27 of those Regulations apply)(**1**) for supply by instalments for treating addiction to any drug specified in that Schedule, he shall –

(a) specify the number of instalments to be dispensed and the interval between each instalment; and

(b) order only such quantity of the drug as will provide treatment for a period not exceeding 14 days.

(4) In a case of urgency a prescriber may request a chemist to dispense a drug or medicine before a prescription form is issued, only if –

(a) that drug or medicine is not a Scheduled drug;

(b) that drug is not a controlled drug within the meaning of the Misuse of Drugs Act 1971(**2**), other than a drug which is for the time being specified in Schedules 4 or 5 to the Misuse of Drugs Regulations (Northern Ireland) 2002(**3**); and

(c) he undertakes to furnish the chemist, within 72 hours, with a prescription form completed in accordance with sub-paragraph (3).

(5) In a case of urgency a prescriber may request a chemist to dispense an appliance before a prescription form is issued only if –

(a) that appliance does not contain a Scheduled drug or a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 5 to the Misuse of Drugs Regulations (Northern Ireland) 2002;

(**1**) S.R. 2002/1
(**2**) 1971 c. 38
(**3**) Schedule 4 was amended by S.R. 2003/314

(b) in the case of a restricted availability appliance, the patient is a person, or it is for a purpose, specified in the Drug Tariff; and

(c) he undertakes to furnish the chemist, within 72 hours, with a prescription form completed in accordance with sub-paragraph (3).

Restrictions on prescribing by medical practitioners

40.—(1) In the course of treating a patient to whom he is providing treatment under the contract, a medical practitioner shall not order on a prescription form a drug, medicine or other substance specified in any directions given by the Department under Article 57D of the Order(**4**) as being drugs, medicines or other substances which may not be ordered for patients in the provision of medical services under the contract but may, subject to regulation 24(2)(b), prescribe such a drug, medicine or other substance for that patient in the course of that treatment under a private arrangement.

(2) In the course of treating a patient to whom he is providing treatment under the contract, a medical practitioner shall not order on a prescription form a drug, medicine or other substance specified in any directions given by the Department under Article 57D of the Order as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes unless –

(a) that patient is a person of the specified description;

(b) that drug, medicine or other substance is prescribed for that patient only for the specified purpose; and

(c) the practitioner endorses the form with the reference "SL2",

but may, subject to regulation 24(2)(b), prescribe such a drug, medicine or other substance for that patient in the course of that treatment under a private arrangement.

(3) In the course of treating a patient to whom he is providing treatment under the contract, a medical practitioner shall not order on a prescription form a restricted availability appliance unless –

(a) the patient is a person, or it is for a purpose, specified in the Drug Tariff; and

(b) the practitioner endorses the face of the form with the reference "SL2",

but may, subject to regulation 24(2)(b), prescribe such an appliance for that patient in the course of that treatment under a private arrangement.

Restrictions on prescribing by supplementary prescribers

41.—(1) The contractor shall have arrangements in place to secure that a supplementary prescriber will –

(a) give a prescription for a prescription only medicine;

(b) administer a prescription only medicine for parenteral administration; or

(c) give directions for the administration of a prescription only medicine for parenteral administration,

as a supplementary prescriber only under the conditions set out in sub-paragraph (2).

(2) The conditions referred to in sub-paragraph (1) are that –

(a) the person satisfies the applicable conditions set out in Article 3B(3) of the POM Order (prescribing and administration by supplementary prescribers)(**5**), unless those conditions do not apply by virtue of any of the exemptions set out in the subsequent provisions of that Order;

(**4**) Article 57D was inserted into the Order by Article 4 of the 2004 Order
(**5**) Article 3B was inserted into the POM Order by S.I. 2003/696

(b) the medicine is not a controlled drug within the meaning of the Misuse of Drugs Act 1971;

(c) the drug, medicine or other substance is not specified in any directions given by the Department under Article 57D of the Order(**6**) as being a drug, medicine or other substance which may not be ordered for patients in the provision of medical services under the contract;

(d) the drug, medicine or other substance is not specified in any directions given by the Department under Article 57D of the Order as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes unless –

(i) the patient is a person of the specified description,

(ii) the medicine is prescribed for that patient only for the specified purposes, and

(iii) if a supplementary prescriber is giving a prescription, he endorses the face of the form with the reference "SL2".

(3) Where the functions of a supplementary prescriber include prescribing, the contractor shall have arrangements in place to secure that that person will only give a prescription for –

(a) an appliance; or

(b) a medicine which is not a prescription only medicine,

as a supplementary prescriber under the conditions set out in sub-paragraph (4).

(4) The conditions referred to in sub-paragraph (3) are that –

(a) the supplementary prescriber acts in accordance with a clinical management plan which is in effect at the time he acts and which contains the following particulars –

(i) the name of the patient to whom the plan relates,

(ii) the illness or conditions which may be treated by the supplementary prescriber,

(iii) the date on which the plan is to take effect, and when it is to be reviewed by the medical practitioner or dentist who is a party to the plan,

(iv) reference to the class or description of medicines or types of appliances which may be prescribed or administered under the plan,

(v) any restrictions or limitations as to the strength or dose of any medicine which may be prescribed or administered under the plan, and any period of administration or use of any medicine or appliance which may be prescribed or administered under the plan,

(vi) relevant warnings about known sensitivities of the patient to, or known difficulties of the patient with, particular medicines or appliances,

(vii) the arrangements for notification of –

(aa) suspected or known adverse reactions to any medicine which may be prescribed or administered under the plan, and suspected or known adverse reactions to any other medicine taken at the same time as any medicine prescribed or administered under the plan,

(bb) incidents occurring with the appliance which might lead, might have led or has led to the death or serious deterioration of state of health of the patient, and

(viii) the circumstances in which the supplementary prescriber should refer to, or seek the advice of, the medical practitioner or dentist who is a party to the plan;

(b) he has access to the health records of the patient to whom the plan relates which are used by any medical practitioner or dentist who is a party to the plan;

(**6**) Article 57D was inserted into the Order by Article 4 of the 2004 Order

(c) if it is a prescription for a medicine, the medicine is not a controlled drug within the meaning of the Misuse of Drugs Act 1971;

(d) if it is a prescription for a drug, medicine or other substance, that drug, medicine or other substance is not specified in any directions given by the Department under Article 57D of the Order as being a drug, medicine or other substance which may not be ordered for patients in the provision of medical services under the contract;

(e) if it is a prescription for a drug, medicine or other substance, that drug, medicine or other substance is not specified in any directions given by the Department under Article 57D of the Order as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes unless –

(i) the patient is a person of the specified description,

(ii) the medicine is prescribed for that patient only for the specified purposes, and

(iii) when giving the prescription, he endorses the face of the form with the reference "SL2";

(f) if it is a prescription for a medicine –

(i) the medicine is the subject of a product licence, a marketing authorisation or a homeopathic certificate of registration granted by the licensing authority or the European Commission, or

(ii) subject to sub-paragraph (6), the use of the medicine is for the purposes of a clinical trial, and

(aa) that trial is subject of a clinical trial certificate issued in accordance with the Medicines Act 1968(**7**), or

(bb) a clinical trial certificate is not needed in respect of that trial by virtue of any exemption conferred by or under that Act;

(g) if it is a prescription for an appliance, the appliance is listed in Part IX of the Drug Tariff; and

(h) if it is a prescription for a restricted availability appliance –

(i) the patient is a person of a description mentioned in the entry in Part IX of the Drug Tariff in respect of that appliance,

(ii) the appliance is prescribed only for the purposes specified in respect of that person in that entry, and

(iii) when giving the prescription, he endorses the face of the form with the reference "SL2".

(5) In sub-paragraph (4)(a), "clinical management plan" means a written plan (which may be amended from time to time) relating to the treatment of an individual patient agreed by –

(a) the patient to whom the plan relates;

(b) the medical practitioner or dentist who is a party to the plan; and

(c) any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan.

(6) In relation to any time from the coming into operation of any regulations made by the Secretary of State under section 2(2) of the European Communities Act 1972 (general implementation of treaties)(**8**), to implement Directive 2001/83/EC on the Community code relating to medicinal products for human use(**9**), sub-paragraph (f)(ii) shall be read as if it referred to a clinical trial which

(**7**) 1968 c. 67
(**8**) 1972 c. 68
(**9**) O.J. No. L311, 28.11.2001, p. 67

has been authorised, or is treated as having been authorised by licensing authority for the purposes of those Regulations.

Interpretation of paragraphs 38, 39, 40 and 41

42. For the purposes of paragraphs 38, 39, 40 and 41 in their application to a contractor whose contract includes the provision of contraceptive services, drugs includes contraceptive substances and appliances includes contraceptive appliances.

Excessive prescribing

43.—(1) The contractor shall not prescribe drugs, medicines or appliances whose cost or quantity, in relation to any patient, is, by reason of the character of the drug, medicine or appliance in question in excess of that which was reasonably necessary for the proper treatment of that patient.

(2) In considering whether a contractor has breached his obligations under sub-paragraph (1), the Board shall seek the views of the Local Medical Committee (if any) for its area.

Provision of dispensing services

44.—(1) Without prejudice to any separate right a medical practitioner may have under regulation 12 of the Pharmaceutical Regulations (arrangements for provision of pharmaceutical services by doctors)(**10**), a contractor may provide dispensing services to his registered patients under the contract only if he is required to do so by the Board in accordance with the following provisions of this paragraph.

(2) A contractor may provide dispensing services to his registered patients only if he is required to do so by the Board in accordance with the following provisions of this paragraph.

(3) Where the Board, is satisfied that a person, by reason of –

(a) distance;

(b) inadequacy of means of communication; or

(c) other exceptional circumstances,

will have serious difficulty in obtaining from a chemist any drugs, medicines or appliances, other than scheduled drugs, required for that person's treatment, the Board shall require the contractor with whom the person is a registered patient to supply such drugs, medicines and appliances to that person until further notice.

(4) Notwithstanding anything contained in sub-paragraph (3) –

(a) a contractor shall not be required to undertake the supply of drugs, medicines and appliances under sub-paragraph (3) if the contractor satisfies the Board that the contractor does not normally provide dispensing services under the contract;

(b) a contractor shall be entitled to receive reasonable notice from the Board that the contractor is required to undertake the supply of drugs, medicines and appliances under sub-paragraph (2) or that such supply is to be discontinued.

(5) A contractor which is required under this paragraph to provide dispensing services to some or all of his registered patients may provide any necessary dispensing services to a person whom that contractor has accepted as a temporary resident.

(**10**) Regulation 12 was amended by S.R. 2001/222

Terms relating to the provision of dispensing services

45.—(1) A contractor which has been required to secure the provision of dispensing services under paragraph 44 shall ensure that dispensing services are provided in accordance with the following sub-paragraphs.

(2) Subject to sub-paragraphs (3) and (4), a contractor providing dispensing services shall –

(a) record an order for the provision of any drugs, medicines or appliances which are needed for the treatment of the patient on a prescription form completed in accordance with paragraph 39(3);

(b) provide those drugs, medicines or appliances in a suitable container;

(c) provide for the patient a drug or medicine specified in any directions given by the Department under Article 57D of the Order(**11**) as being a drug or medicine which can only be ordered for specified patients and specified purposes only if –

(i) that patient is a person of the specified description, and

(ii) the drug or medicine is supplied for that patient only for the specified purpose; and

(d) provide for the patient a restricted availability appliance only if the patient is a person, or it is for a purpose, specified in the Drug Tariff.

(3) Sub-paragraph (2) does not apply to drugs, medicines or appliances ordered on a prescription form by an independent nurse prescriber.

(4) Where a patient presents an order on a prescription form for drugs, medicines or appliances signed by an independent nurse prescriber, or an order for a restricted availability appliance signed by and endorsed on its face with the reference "SL2" by an independent nurse prescriber, to a contractor who may provide dispensing services, the contractor may provide to the patient such of the drugs, medicines or appliances so ordered as he supplies in the normal course of his practice.

(5) Drugs, medicines or appliances provided under sub-paragraph (4) shall be provided in a suitable container.

(6) A contractor providing dispensing services shall not provide for a patient a drug or medicine specified in any directions given by the Department under Article 57D of the Order as being drugs or medicines which may not be ordered for patients in the provision of medical services under the contract, except that, where it has ordered a drug or medicine which has an appropriate non-proprietary name either by the name or by its formula, it may provide a drug or medicine which has the same specification notwithstanding that it is a drug or medicine specified in such directions (but, in the case of a drug or medicine which combines more than one drug, only if the combination has an appropriate non-proprietary name).

(7) Subject to sub-paragraph (9), nothing in this paragraph shall prevent a contractor providing a Scheduled drug or a restricted availability appliance in the course of treating a patient under a private arrangement.

(8) A contractor providing dispensing services shall comply with paragraph 14A of Schedule 2 to the Pharmaceutical Regulations, as if modified as follows –

(a) for "paragraph 13(a)", substitute "sub-paragraph (3)(a)";

(b) for "paragraph 11A(2)", substitute "sub-paragraph (5)";

(c) for "a doctor who is required by the Board under regulation 12 to provide drugs and appliances to a patient", substitute "a contractor providing dispensing services to a patient"; and

(d) for "doctor", substitute "medical practitioner".

(**11**) Article 57D was inserted into the Order by Article 4 of the 2004 Order

(9) The provisions of regulation 24 (fees and charges) apply in respect of the provision of any drugs, medicines or appliances by a contractor providing dispensing services as they apply in respect of prescriptions for drugs, medicines or appliances.

(10) A contractor who is entitled to provide dispensing services may, with the consent of the patient, order a drug, medicine or appliance for a patient on a prescription form, rather than providing it himself.

Dispensing contractor list

46.—(1) Where the contractor is required by the Board under paragraph 44 to provide dispensing services to his patients and is actually doing so, the Board shall include –

(a) the contractor's name; and

(b) the address of the practice premises from which he is required to dispense,

on a list of such contractors (to be called the dispensing contractors list) which it shall prepare, maintain and publish.

(2) The Board shall remove the name of the contractor from the list referred to in sub-paragraph (1) where the contractor ceases to provide dispensing services to his patients.

Provision of drugs, medicines and appliances for immediate treatment or personal administration

47.—(1) Subject to sub-paragraph (2), a contractor –

(a) shall provide to a patient any drug, medicine or appliance, not being a Scheduled drug, where such provision is needed for the immediate treatment of that patient before a provision can otherwise be obtained; and

(b) may provide to a patient any drug, medicine or appliance, not being a Scheduled drug, which he personally administers or applies to that patient,

but shall, in either case, provide a restricted availability appliance only if it is for a person or a purpose specified in the Drug Tariff.

(2) Nothing in sub-paragraph (1) authorises a person to supply any drug or medicine to a patient otherwise than in accordance with Part 3 of the Medicines Act 1968(**12**) or any regulations or orders made thereunder.

(**12**) 1968 c. 67