SCHEDULE 1

CONTENT OF AGREEMENTS

PART 3

PRESCRIBING AND DISPENSING

Prescribing

10. The provider shall ensure that any prescription form for drugs, medicines or appliances issued by a prescriber complies as appropriate with the requirements in paragraphs 11 to 13.

Prescribing

11.—(1) Subject to paragraphs 13 and 14, a prescriber shall order any drugs, medicines or appliances which are needed for the treatment of any patient who is receiving treatment under the agreement 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 sign the prescription form in ink with the prescriber's initials, or forenames, and surname in the prescriber's 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) In a case of urgency a prescriber may request a pharmacist 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(**1**), other than a drug which is for the time being specified in Schedules 4 or 5 to the Misuse of Drugs Regulations 2001(**2**); and

(c) the prescriber undertakes to furnish the pharmacist, within 72 hours, with a prescription form or repeatable prescription completed in accordance with sub-paragraph (2).

(4) In a case of urgency a prescriber may request a pharmacist 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 2001;

(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) the prescriber undertakes to furnish the pharmacist, within 72 hours, with a prescription form completed in accordance with sub-paragraph (2).

(**1**) 1971 c. 38.
(**2**) S.I.2001/3998. Schedule 4 was amended by S.I. 2003/1432.

Restrictions on prescribing by medical practitioners

12.—(1) In the course of treating a patient to whom a medical practitioner is providing treatment under the agreement, the medical practitioner shall not order on a prescription form a drug, medicine or other substance specified in any directions given by the Scottish Ministers under section 17N(6) of the Act(**3**) as being drugs, medicines or other substances which may not be ordered for patients in the provision of primary medical services under a general medical services contract but may, subject to regulation 22, 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 a medical practitioner is providing treatment under the agreement, the medical practitioner shall not order on a prescription form or repeatable prescription a drug, medicine or other substance specified in any directions given by the Scottish Ministers under section 17N(6) of the Act as being a drug, medicine or other substance which may only be ordered for specified patients and specified purposes in the provision of primary medical services under a general medical services contract 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 "SLS",

but may, subject to regulation 22, 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 a medical practitioner is providing treatment under the agreement, the 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 "SLS",

but may, subject to regulation 22, prescribe such an appliance for that patient in the course of that treatment under a private arrangement.

Restrictions on prescribing by supplementary prescribers

13.—(1) The provider 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 parental administration; or

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

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

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

(a) the supplementary prescriber satisfies the applicable conditions set out in article 3B(3) of the POM Order (prescribing and administration by supplementary prescribers)(**4**), unless those conditions do not apply by virtue of any of the exemptions set out in the subsequent provisions of that Order;

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

(**3**) Section 17N was inserted by the Primary Medical Services (Scotland) Act 2004 (asp 1), section 4.
(**4**) Article 3B was inserted into the POM Order by S.I. 2003/696.

(c) the drug, medicine or other substance is not specified in any directions given by the Scottish Ministers under section 17N(6) of the Act as being a drug, medicine or other substance which may not be ordered for patients in the provision of primary medical services under a general medical services contract;

(d) the drug, medicine or other substance is not specified in any directions given by the Scottish Ministers under section 17N(6) of the Act as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes in the provision of primary medical services under a general medical services contract 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 the supplementary prescriber is giving a prescription, the supplementary prescriber endorses the face of the form with the reference "SLS".

(3) Where the functions of a supplementary prescriber include prescribing, the provider 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 the supplementary prescriber 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; and

(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) the supplementary prescriber 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;

(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 Scottish Ministers under section 17N(6) of the Act as being a drug, medicine or other substance which may not be ordered for patients in the provision of primary medical services under a general medical services 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 Scottish Ministers under section 17N(6) of the Act as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes in the provision or primary medical services under a general medical services contract 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, the supplementary prescriber endorses the face of the form with the reference SLS;

(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 paragraph (6), the use of the medicine is for the purposes of a clinical trial and–

(aa) that trial is the subject of a clinical trial certificate issued in accordance with the Medicines Act 1968(**5**); 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 Parts 2 to 6 or 8 to 10 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 3 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, the supplementary prescriber endorses the face of the form with the reference "SLS".

(5) In sub-paragraph (4)(a), "clinical management plan" means a 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 force of any regulations made by the Secretary of State under section 2(2) of the European Communities Act 1972 (general implementation of

(**5**) 1968 c. 67.

treaties)(**6**) to implement Directive 2001/83/EC on the Community code relating to medicinal products for human use(**7**), sub-paragraph (4)(f)(ii) shall be read as if it referred to a clinical trial which has been authorised, or is treated as having been authorised by the licensing authority for the purposes of those regulations.

Excessive prescribing

14.—(1) The provider 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 provider has breached its obligations under sub-paragraph (1), the Health Board shall seek the views of the area medical committee for its area.

Provision of dispensing services

15.—(1) A provider may secure the provision of dispensing services to its patients under the agreement only if it is authorised or required to do so by the Health Board in accordance with the following provisions of this paragraph.

(2) Where the Health Board is satisfied, after consultation with the area pharmaceutical committee 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 pharmacist any drugs, medicines or appliances, other than Scheduled drugs, required for that person's treatment, the Health Board shall require or authorise the provider with whom the person is a registered patient to supply such drugs, medicines and appliances to that person until further notice.

(3) Notwithstanding anything in sub-paragraph (2)–

(a) a provider shall not be required to undertake the supply of drugs, medicines and appliances under sub-paragraph (2) if the provider satisfies the Health Board that the provider is not in the habit of dispensing drugs, medicines and appliances for the provider's patients;

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

(4) Subject to sub paragraph (6), a provider, who is required by the Health Board to supply drugs, medicines and appliances under sub-paragraph (2) to a patient, in the course of treating that patient under these Regulations–

(a) shall, subject to sub-paragraph (7), record on a prescription form completed in accordance with paragraph 11, an order for supply of any drugs, medicines or appliances which are needed for the treatment of that patient, but shall not be required to issue that form to that patient;

(b) shall supply those drugs, medicines or appliances for that patient under sub paragraph (2) but–

(i) shall not supply under sub paragraph (2) for that patient any Scheduled drug specified as being a drug, medicine or other substance which may not be ordered for patients in the provision of primary medical services under a general medical services contract,

(**6**) 1972 c. 68.
(**7**) O.J. L 311, 28.11.2001, p.67.

except that, where the provider has ordered a drug which has an appropriate non proprietary name either by that name or by its formula, the provider may supply a drug which has the same specification notwithstanding that it is such a Scheduled drug (but, in the case of a drug which combines more than one drug, only if the combination has an appropriate non proprietary name);

(ii) shall supply under sub paragraph (2) for that patient any Scheduled drug specified as being a drug, medicine or other substance which may only be ordered for specific patients and purposes in the provision of primary medical services under a general medical services contract, only where—

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

(bb) that drug, medicine or other substance is supplied to that patient only for the specified purpose;

(iii) shall supply under sub paragraph (2) for that patient a restricted availability appliance only if it is for a patient in a category of person or a purpose specified in the Drug Tariff;

(c) may supply for that patient with the provider's consent, in respect of that treatment but otherwise than under sub paragraph (2), any Scheduled drug.

(5) A provider shall comply with any arrangements made by the Scottish Ministers, or made by the Health Board after consultation with the area medical committee and the area pharmaceutical committee and approved by the Scottish Ministers, under which the provider may obtain and have available any drugs, medicines or appliances which the provider is required or entitled to supply in terms of this paragraph.

(6) Sub paragraph (4) does not apply to drugs, medicines or appliances ordered on a prescription form by a supplementary prescriber or an independent nurse prescriber.

(7) Where a patient presents an order on a prescription form for listed drugs or medicines, or appliances, signed by a supplementary prescriber or an independent nurse prescriber, to a provider who is required under sub paragraph (2) to provide drugs or appliances to that patient, the provider may provide to the patient such drugs, medicines or appliances so ordered as the provider supplies in the normal course of the provider's practice.

(8) A drug supplied by a provider unless administered in person shall be supplied in a suitable container.

(9) Before supplying the drugs, medicines or appliances recorded on a prescription form in accordance with sub paragraph (4) or providing the drugs or medicines or appliances ordered on a prescription form signed by a supplementary prescriber or an independent nurse prescriber in accordance with sub paragraph (7) a provider who is required by the Health Board under sub paragraph (2) to provide drugs, medicines or appliances to a patient shall request any person who makes a declaration on the prescription form claiming either charge exemption under regulation 7 of the National Health Service (Charges for Drugs and Appliances) (Scotland) Regulations 2001(**8**) ("the 2001 Regulations") or charge remission under the National Health Service (Travelling Expenses and Remission of Charges) (Scotland) (No 2) Regulations 2003(**9**) to provide evidence of the patient's entitlement to such exemption or remission.

(10) Sub paragraph (9) shall not apply in respect of claims for exemption under regulation 7(1)(a) to (f) of the 2001 Regulations where the dispensing provider has information in the provider's possession at the time of supplying the item which confirms that the patient is entitled to the exemption claimed.

(**8**) S.S.I. 2001/430, as amended by S.S.I. 2002/100 and 2003/130 and 295.
(**9**) S.S.I. 2003/460.

(11) Where the person presenting the prescription form does not show valid evidence of entitlement and the dispensing provider, in respect of a claim for exemption made under regulation 7(1)(a) to (f) of the 2001 Regulations does not have evidence in the contractor's possession to confirm that the patient is entitled to make that claim, the dispensing provider shall mark the patient's prescription form accordingly before supplying the prescribed item.

(12) The provisions of regulation 22 apply in respect of the provision of any drugs, medicines or appliances by a provider providing dispensing services as they apply in respect of prescriptions for drugs, medicines or appliances.

(13) Nothing in this paragraph shall prevent a provider providing a Scheduled drug or a restricted availability appliance in the course of treating a patient under a private arrangement.

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

16.—(1) Subject to sub-paragraph (2), a provider–

(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 the provider 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(**10**) or any regulations or orders made thereunder.

(**10**) 1968 c. 67.