SCHEDULE 1

CONTENT OF AGREEMENTS

PART 3

PRESCRIBING AND DISPENSING

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)(**1**), 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;

(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:–

(**1**) Article 3B was inserted into the POM Order by S.I.2003/696.

(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(**2**); 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 treaties)(**3**) to implement Directive 2001/83/EC on the Community code relating to medicinal products for human use(**4**), 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.

(**2**) 1968 c. 67.
(**3**) 1972 c. 68.
(**4**) O.J. L 311, 28.11.2001, p.67.